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MARCH 2015

HOW TO SELECT A CMO AND QUALIFY ITS CAPABILITIES

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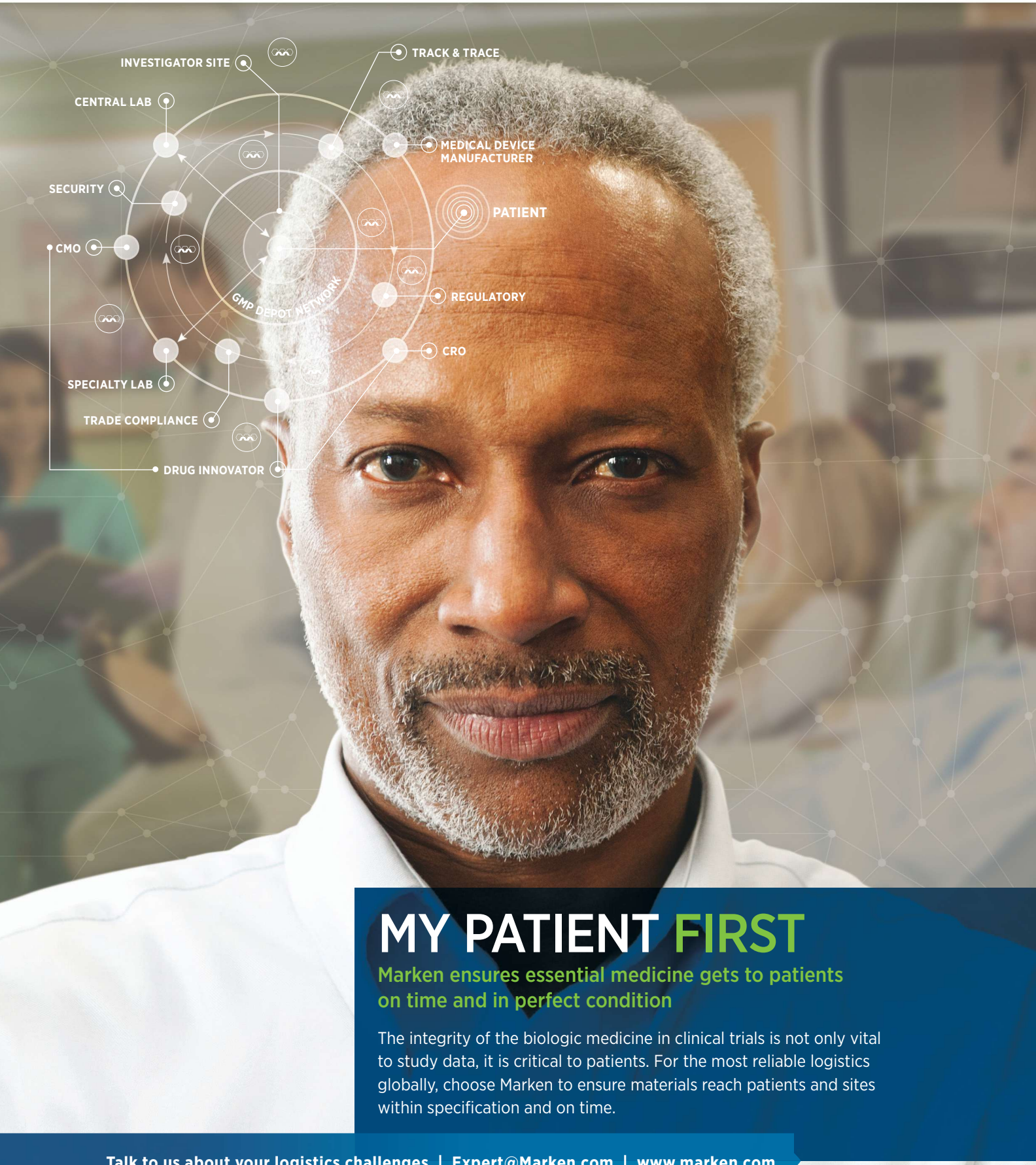

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Enthusiasm Is Good...
But Don't Overdo It

ED MISETA Executive Editor

Right now, enthusiasm in the pharma and biopharma markets seems to be running high. My colleague Rob Wright, chief editor of *Life Science Leader,* recently returned from the JP Morgan Conference in San Francisco. One of his takeaways was the current level of excitement in the industry. Several sources, he says, noted we can expect to see major biotech deals inked in 2015. Biosimilars? Declining revenue? Recession? Patent cliff? Damn the torpedoes! Full speed ahead!

But while enthusiasm is good, we must be careful not to let it cloud our business decisions. One of the best articles I read last year was from the July 2003 *Harvard Business Review,* titled "Delusions of Success: How Optimism Undermines Executives' Decisions." The advice is valuable and timeless. Simply put, overconfidence can often lead to poor decision-making.

This problem is more common than you might think. The authors note that 70 percent of new manufacturing plants in North America close within a decade, and 75 percent of mergers and acquisitions never pay off. Even efforts to enter new markets, a growth strategy for many pharmaceutical firms, end up largely unsuccessful.

A key observation in this article was the role of flawed decision making. In the grip of what the authors call the planning fallacy, managers base decisions on "delusional optimism" — overestimating benefits and underestimating costs. Consequently, they have an attraction to initiatives that are unlikely to satisfy the budget or realize expected returns. For example, the article discusses how a new computer adopted by Oxford Health Plans to better process paperwork ultimately resulted in problems that caused a 63 percent drop in the company's stock price. Another example was Union Pacific Railroad's purchase of Southern Pacific, which resulted in traffic issues, lost cargo, and massive delays.

Of course the life sciences industry is not immune to the concept of delusional optimism. I'm sure most of you can cite your own examples of when this affected a previous project you were working on. And as the amount of outsourcing in the industry increases, so too does the potential for flawed decision making. After executing an outsourcing model for a long period of time, overconfidence could seep into a sponsor company's leadership. Hubris could blind the company, causing it to pay less attention to the quality, reliability, and regulatory knowledge of it partners. The results, of course, could be disastrous.

Helping you avoid any disasters due to overconfidence with outsourcing is one of the purposes of this CMO Supplement. We want to help you make the right decisions by keeping you informed of best practices and giving you access to insights from experienced industry experts. For instance, in the pages that follow, you'll find informative articles giving you advice on choosing a CDMO and finding capital funding.

Beyond this supplement, we're endeavoring to continue to bring you exclusive and impactful outsourcing content via our Outsourced Pharma West Conference & Exhibition. The standing-room only sessions at our 2014 event prompted us to schedule two of these conferences this year, one in San Diego in August and a return engagement in San Francisco in November.

No matter what stage you're at with adopting an outsourcing model, it's always good to occasionally take a step back and reevaluate your status quo. Hopefully, this supplement and our conference can help you with that process.

Life Science Leader

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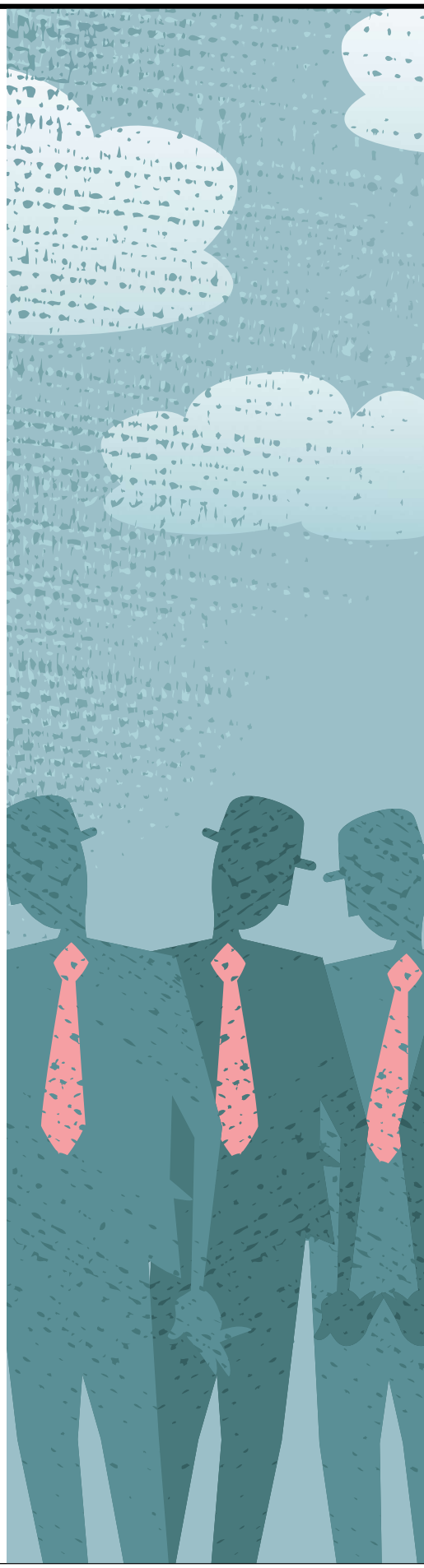
HOW TO QUALIFY A CMO's CAPABILITIES AND BENCHMARK ITS PERFORMANCE

BY ED MISETA



Choose the wrong CMO and your project could easily be derailed, costing your company billions. But how do you avoid making such a mistake? To help answer that question, *Life Science Leader* brought together a panel of outsourcing experts at the inaugural Outsourced Pharma West conference and exhibition in San Francisco last November. Our panelists share some personal experiences and lessons learned on the topic.

The panel participants included:

FIRELLI ALONSO-CAPLEN
Senior director of biotherapeutics & vaccines, Pfizer

JOE GUILES
Director of process chemistry, Medivation

HEIDI HOFFMANN
Senior director of manufacturing, Sutro Biopharma

JUNNING LEE
SVP technical operations, Theravance Biopharma

TERRY NOVAK
COO, Pernix Therapeutics

1

WHAT ARE SOME CHALLENGES TO FINDING A PARTNER THAT ALIGNS WITH YOUR NEEDS?

Terry Novak, Pernix Therapeutics: When you ask that question, you will always hear people saying the same things... capabilities, quality, and regulatory. And all of those factors are important. But I believe sponsors need to take a very detailed approach to these partnerships, much like performing due diligence when acquiring a new product. I like to look at quality, regulatory, and delivery history, but I ask a lot of other questions as well. What is their turnover rate? How long has the management team been in place? Are they able to scale up? If they can't, am I going to have to pay for the capital? These are all questions that should be addressed up front. I was always big on case studies and whether they had worked on a project like mine and were able to deliver. Be as detailed as you possibly can be and

always make your expectations very clear from day one.

Heidi Hoffmann, Sutro Biopharma: I recommend that every sponsor take some time right up front to determine what their business model is and how far they want to take the project. It's important to delve down into the details and understand the strengths of your company. Only then can you try to identify a CMO that complements those capabilities and has expertise that you lack.

This will allow you to prepare a business plan and determine what capabilities you intend to develop over the course of a project versus what you would prefer to outsource and not commit resources to having in-house. Understanding that will make the CMO selection process much easier.

Joe Guiles, Medivation: One point that Terry mentioned really resonates with me: The people involved in the process are critical. If you are the customer, you have to have access to the best people you can get at your CMO.

Turnover is important because you need to have an understanding of their stability. In the end, it's the people working for that CMO who will deliver the product you need. Most service providers have the same technologies in-house. The people who operate those technologies will be the difference makers.

Finally I would just add a short comment about the RFP process. Companies that do not put a lot of time and thought into their RFP will end up in most cases not getting what they want in a response. I think there are different strategies on how to approach it. I believe you need to put enough information in the RFP to get your responders to think and hopefully open a dialogue with you. How CMOs behave in the RFP process is often a mirror of how they will behave under contract. Are they alert, attentive, on-time, thinkers/problem-solvers, during the RFP process?

Firelli Alonso-Caplen, Pfizer: At Pfizer, we do not believe cost should be the major driver when selecting a CMO. That may surprise some people, but what's more important to us in pre-commercial outsourcing is getting the quality and timeliness we desire. The time schedule we have set for getting the drug to the clinic has to be reached, and therefore we need a CMO that can meet our schedule. Cost has to be taken into consideration, but it is never the most important consideration.

In a recent outsourcing decision I was involved in, we started off with a list of five CMOs and then started narrowing it down. One CMO was being taken over by another company. It was eliminated because we didn't know whether it would still be in existence at the end of the project. Another CMO was eliminated because it had no prior experience with the FDA.

Experience was a factor we looked at very closely, and the CMO we ultimately selected was one that had a pre-approval inspection waived by the FDA earlier in the year. That CMO was more expensive than the others, but the FDA decision resulted in a huge savings for us, which made the decision to go with them much easier. That CMO ended up having a waived PAI for our project as well.

"I believe sponsors need to take a very detailed approach to these partnerships, much like performing due diligence when acquiring a new product."

TERRY NOVAK

2

WHAT ARE SOME OF THE PROS AND CONS WHEN ENTERING A RELATIONSHIP THAT IS STRATEGIC VERSUS TACTICAL?

Novak: I have spent 13 years in this industry leading three different CMOs. I have found that a majority of the customers I worked with will often talk strategically then act tactically. Unfortunately you don't find that out until you get to the Master Service Agreement (MSA). They initially talk to you like a partner but then include how they will hammer you with penalties if something goes wrong. That is not strategic.

Customers that truly want a strategic relationship will sit down with you at the start of the process and say, "Here are our expectations. How can we work together as a team to make sure we accomplish these goals?"

I have always felt that if you're working with a CMO, you're in it for the long haul, unless they really mess up because the cost of getting out of a relationship can be tremendous. But it is still important to define that relationship right up front, and to be honest about it. I currently work with 23 CMOs, and I would only classify one of them as being truly strategic.

"When entering into a strategic relationship, keep asking yourself if this company is the long-term partner you had expected."

JOE GUILES

Guiles: Terry makes a good point. When entering into a strategic relationship, keep asking yourself if this company is the long-term partner you had expected.

Alonso-Caplen: I would define a tactical relationship as one where you need additional drug product produced but have run out of available capacity. To me, a true strategic sourcing relationship has to be one where the companies are truly partners. That means you share in the risk, and you share in the success. And you don't start blaming each other when something goes wrong.

3

MANAGING THE OUTSOURCING RELATIONSHIP IS MUCH DIFFERENT FOR A SMALL COMPANY THAN A LARGE ONE. IF YOU ARE NOT A LARGE COMPANY, HOW CAN YOU MAKE SURE YOU ARE STILL GETTING THE MOST OUT OF YOUR CMO?

Junning Lee, Theravance Biopharma: When I first joined Theravance, the company had only one product, but it was a difficult molecule. We had a medicinal chemist who was running all of the CMC (chemistry, manufacturing, and controls). At that time it would have been very difficult to select a CMO. They would have needed a knowledge of chromatography and how to handle an unstable and volatile product. We also had very low yields.

As we moved more product into the pipeline, we gradually built an internal CMC capability. We created several ACE (Analytical Chemist Engineer) Quality Teams that worked together to review processes and activity at various stages. They reviewed assays, ID mapping, studies of different phases, the relevant documents that needed to be submitted, and what experiments had to be run to get the data we needed. We needed a good understanding of the process.

"At Pfizer, we do not believe cost should be the major driver when selecting a CMO."

FIRELLI ALONSO-CAPLEN

The ACE QT developed the process, and eventually we were able to demonstrate it in the laboratory post-Phase 2. Only when we were able to move to late stage did we consider transferring it to a CMO. We have since produced 59 commercial batches without a single deviation and even gotten a pre-approval inspection from the FDA.

So long story short I think you really need to understand your technology before you can even consider working with a CMO. We now have 13 clinical products and one commercial.

Novak: I think there are a lot of smaller companies that feel they are not getting the attention they deserve from their CMO. If you are a small company, here is the best piece of advice I can give you: Develop an internal champion at your CMO, and make sure that person knows your company as well as you do.

If they know your company inside and out, they will be representing you in that CMO. The good ones will do that very, very well, but they need that knowledge from you to know what your company is all about.

Guiles: One of the things that has served me extremely well is former colleagues who are now located around the world, both as customers or in CMOs. These are

folks whose quality of work and technical skill you understand and whose opinions you can trust based on how well you know them. I recommend leveraging social media tools, like LinkedIn, as a means to get in touch and have conversations with them about their experiences with CMOs they may have used or are currently using.

4

ONCE YOU HAVE AN INTERNAL CHAMPION IN PLACE AT THE CMO, HOW DO YOU MANAGE THE RISK OF THAT PERSON LEAVING, BEING REPLACED, OR GETTING OVERBURDENED?

Alonso-Caplen: I believe project management is key to the success or failure of your contract. The folks running the processes are certainly important as well, but having an efficient project manager is critical.

At some point, a project manager you are working with is going to leave, so it's important to look at how deep the bench is. Ask that person if they were to leave, who the likely replacement would be. Get to know that person, too, if you can. One of the parameters I look for in a CMO is that project management capability. One small CMO we looked at years ago asked, "What is project management?" That should definitely send up a red flag.

Hoffmann: I completely agree with those comments. A good project manager is vital. I would add that if you are not happy with a project manager, don't be afraid to ask for a change. Go to the sales department or the person you originally contracted with and tell them it's not working and that you need someone new. If you are an unhappy customer, someone there will want to make you happy.

Alonso-Caplen: I like to compare the CMO/client relationship to a marriage.

"I have seen agreements that will not even let you get a secondary supplier. That is risky, and I have seen companies get burned by it."

JUNNING LEE

The RFP process is the courtship where both companies present their best sides. This will lead to a contract being put in place, which is the marriage. Then you go through the tech transfer process and production, which could lead to many happy anniversaries or an unhappy divorce.

As in other relationships, if there is a break, it usually occurs in the communications process. I cannot overemphasize the importance of communication. It is always better to over-communicate than to under-communicate, and having that project manager be the center of communications between the CMO and the client will help the process.

5

HOW CAN YOU BALANCE THE DESIRE TO PICK A TRUSTED PARTNER VERSUS THE NEED TO SELECT THE BEST CMO FOR YOUR CURRENT STAGE OF DEVELOPMENT?

Lee: Both factors are very important. I think selecting the right CMO is a must in the first phase. Once you have

the right CMO on board, you can start building the relationship. The principles I tend to focus on are capacity, capability, compliance, communication, and creativity.

We had a very good experience with a European CMO. We were working on a product with low yields and impurity issues. We had to scale up and had to move very quickly. It was a challenging project.

We selected the CMO we felt was the best fit and had their chemists work alongside ours. We met the deadline with 99.6 percent purity and a five-fold increase in the yield. It was a great experience, and the relationship and the communication were vital to making it a success.

6

THERE ARE CUSTOMERS WHO STILL PREFER TO WORK WITH CMOs THAT ARE A ONE-STOP SHOP. DO YOU PREFER THAT MODEL OR WORKING WITH CMOs THAT HAVE DIFFERENTIATORS TAILORED TOWARDS A SPECIFIC TYPE OF CHEMISTRY?

Alonso-Caplen: That's a good question, and the answer is, it depends. For example, if I were sourcing for antibody drug conjugates (ADCs), a toxic material, having a supply chain that is fragmented will make it more difficult, especially if the drug substance is in the U.S. and the drug product is in Europe. In that case, I would prefer to go to a one-stop shop.

On the other hand, if I were sourcing for monoclonal antibodies, it really doesn't matter because we would not have the same supply chain concerns. We have CMOs and contract testing labs that are strong in that area. We have established platform methods with several companies, so it makes it much easier to source the testing to one contractor and the production to another. If a CMO were strong in one particular field, say conjugation, then by all means we would prefer to go with that CMO because they have seen a lot of these processes and we can actually learn from them.

Hoffmann: I think this is another situation that can be tied back to the project manager. If you have a one-stop shop that has a single project manager, that individual can follow your project all the way through the process, and there is only one person that you have to talk to at every step. That person will be responsible for managing the logistics of moving your project through the different production stages.

If you have several suppliers, each performing a different stage, you will need the resources to manage the entire process. It's not impossible, but there are more logistics involved, and you have to make sure you have the manpower and resources to handle it.

7

DO YOU HAVE ANY ADVICE ON HOW TO MANAGE THE LONG CYCLE TIMES BETWEEN WHEN A CONTRACT IS SIGNED AND WHEN A PRODUCT MOVES INTO COMMERCIAL PRODUCTION?

Guiles: The best way to handle that is to think ahead and ask a lot of questions during your initial discussions in the RFP phase. Ask the CMO about capacity and any possibility of having to change facilities. If moving from Phase 2b to Phase 3 means moving into another facility, you would want to know that up front.

Novak: That is a good point, and it's a situation that is sometimes unavoidable. Changes will occur when moving from Phase 2b to Phase 3. Suddenly, the project and the commercial capacity that the CMO signed up for have changed for the good of the owner.

But for the CMO, all of a sudden there is a realization that the equipment in-house will not be sufficient to produce the volume the customer is now requesting. In order to do it, there will have to be a large investment. We all know how tough it is on the CMO side to go to the board of directors and say, "Hey, by the way, I need $12 million for another fluid bed dryer." Realizing you suddenly need three times the quantity originally requested is definitely a challenge, but if your relationship is a true strategic partnership, then you should be able to sit down and work things out.

Hoffmann: Here again communication is a key component. There should be a collaborative process in place as your project moves through the different stages. As soon as you know there will be changes, let the CMO know. None of this happens in a vacuum. You have an idea as you move through the different phases of the clinic that your demand might be bigger, and your dose different, than what you originally thought. Always give your CMO as much advance notice as possible. Worst case scenario, if it's not possible for the CMO to accommodate your changes, then go with a second source, which the FDA would prefer anyway.

8

HOW IMPORTANT ARE SITE VISITS?

Hoffmann: Site visits are extremely important. Without them I don't think you can really get a sense of the true capabilities of a CMO. The visits allow you to see firsthand what their labs and other facilities look like. The visits also give you a chance to talk to the technical staff. This will help you to determine how knowledgeable they are and whether or not they are able to answer your questions. Go prepared with specific questions to ask. The business development people are generally very knowledgeable, but the technical staff will be able to tell you how they would approach any problems that arise.

9

WHAT ARE SOME OF THE METRICS YOU USE TO GAUGE THE SUCCESS OF THE RELATIONSHIP?

Alonso-Caplen: My quick answer would be cost and timelines. You will have a schedule, a GANT chart, right from the beginning, which both sides have agreed upon and signed. There are also costs that have been agreed upon. We will typically pay for milestones and deliverables. This illustrates the difference between trying to get something done internally versus externally. Internally, getting something done can be like pulling teeth. But externally, if you don't deliver, we don't pay.

Hoffmann: Those are both important metrics. Once you get past those, I always try to think about how much time my team has to spend managing the project. If the sponsor/CMO relationship is going well, you should find yourself spending less and less time managing the project. It's a very easy and definitive metric. Just keep track of how much time you're spending on it.

Novak: My three favorite metrics are related to quality: on time, in full, and right the first time. I also like to look at deviations and CAPA closures. I recommend building a score card with all of the metrics on it and reviewing it monthly. Then quarterly, I recommend having a face-to-face business meeting with all team members from both sides to review the quarterly business metrics or your timeline.

"Site visits are extremely important. Without them I don't think you can really get a sense of the true capabilities of a CMO."

HEIDI HOFFMANN

10

DO YOU HAVE ANY ADVICE FOR DEALING WITH BAD CONTRACT TERMS THAT YOU INHERIT WHEN JOINING A COMPANY?

Lee: That's a tough one. I have seen agreements that will not even let you get a secondary supplier. That is risky, and I have seen companies get burned by it. When you select a CMO, you need a plan B as well as a backup. Many small pharma companies probably cannot afford to have two CMOs, but you really need to do what you have to in order to have a second supplier.

Novak: When I first joined Pernix, I had six of those contracts. One of the first things I did was to try and redo all of them. I sat down with the CEO of each company and went over our strategy. I told them I needed more flexibility, and if they couldn't provide it, I would move the business. It might take me a year or two, but eventually I would do it. Four of the CMOs worked with me, but two of them refused to budge.

Eventually I did move the business, and those are two companies I will not work with again. As much as you want to retain all of those relationships, in some cases you are just not able to do so.

Finding Investors And Capital To Match Your Goals

BY ED MISETA

It's a nagging uneasy feeling that consumes anyone who's ever developed a new pharmaceutical or launched a new pharma or biopharma company. You need to raise money. You need capital. Otherwise, your company may never get off the ground, or that scientific breakthrough you've been dreaming of will remain just that — a dream. And by the time a molecule is discovered that may hold some potential, putting more money into the company to optimize manufacturing capabilities is not always the first thing on the mind of investors. In fact, landing any type of venture funding, at any time, can be a difficult endeavor.

That's why we asked six venture-funding experts to give their advice on how best to pursue the capital that will help your company grow and manufacture your product the way you want it made.

Our roundtable panel included the following funding experts:

Chris Achar, CEO and founder, Genzum Life Sciences

Tiba Aynechi, principal, Novo Ventures

Kevin Judice, CEO and founder, DiCE Molecules

Julie Papanek, principal, Canaan Partners

Jaisim Shah, CEO and board director, Semnur Pharmaceuticals

Mahendra Shah, venture partner, Vivo Capital


EXIT
ENTER

When a company is looking for capital funding, how should it prepare, and what should executives bring with them to that meeting?

CHRIS ACHAR, Genzum Life Sciences: When talking to outside investors for the first time, I think having a well-vetted business model is the most important part. Given how competitive the start-up world is today, investors have a lot of options to invest in. For yours to stand out, having that solid business model is everything.

TIBA AYNECHI, Novo Ventures: When people come to us with an early stage opportunity, what's important for us is for people to have a good handle on how much they're raising and what meaningful milestones they hope to achieve. You need to have a well-thought-out plan, and you need to make sure your plan is reflective of the data you have in hand. We don't like to invest in speculative data.

It's important for companies to work backwards. Figure out what the exit scenario is going to be, and when it is likely to occur. Your finances need to be able to take you to that point. You have to think very nuanced and detailed about the project, and not in general terms. We want somebody who thinks in detail and not generalized themes.

Do companies generally come in well prepared?

AYNECHI: I think it's 50/50. Most people assume it will be a smooth ride, but it's not, and it inevitably takes longer than you think. You really need to think about contingencies and various scenarios if things don't go according to plan.

We also like to focus on the management team. Is this something the team has done before, or is it their first time? As an investor, we are investing in that team. If we have an experienced team, they can always regroup quickly.

KEVIN JUDICE, DiCE Molecules: I think the idea of starting at the end and working backwards is really important. Think about how much capital you need to get to the point where investors can get a multiple of that capital back.

Take into account that what you're doing is a science-based endeavor. That means there is going to be a lot of back and forth. Always ask yourself if anyone will be willing to pay money for it. At what phase would they buy it? How much money will it take to get this to that phase? This is a for-profit business, and our investors would like to get back a multiple of the money they give you. If you are looking for funding, you need to sit down and think about that.

What happens when someone comes in and they are not prepared? Are you able to help them?

JULIE PAPANEK, Canaan Partners: If someone

seeking investment is not 100 percent prepared in our first meeting, we start thinking of scheduling multiple sets of meetings. At that first meeting, if we believe the product is differentiated and there is potential for it, we will start a conversation about who else the entrepreneur might want on his or her team. We also try to make sure the right individuals, such as executives and consultants, are involved at different stages along the way.

To help those entrepreneurs who are less prepared, we like to ask a lot of questions to better understand the product. If we are meeting with a smart chemist or biologist, we will say, "Help me understand what you want to do. Help me understand how this asset, drug, or pathway will meet an unmet need." You need to start with the science.

JAISIM SHAH, Semnur Pharmaceuticals: When you are at the stage where you are talking to investors, there are several areas that you must be prepared to cover. One is a clear understanding of the unmet need you are trying to address. Not just the scientific or medical need, but also the business need.

You also need to discuss how your idea, concept, technology, or product compares to existing therapies. You should address the potential for superiority, not just one or two, but five years down the road. Having a clear understanding of your development path and what the FDA expectations may be for developing your product are keys.

IP is also a key area that a lot of investors focus on. They want to ensure the product they are investing in will have multiple levels of protection. It basically comes down to summarizing the benefits of investing in your venture versus other ventures.

MAHENDRA SHAH, Vivo Capital: We do late-stage investing, so the companies that come to us have a proof of concept in humans for the target indication they want to develop. The first thing we would do is make sure the IP for the product has been taken care of.

Second, we would look at whether the formulation is there to manufacture a commercial product and if the necessary resources are available, all the way down to the required APIs.

A third thing we look at is the marketing plan and whether the company will be able to market the product on their own. If they can't, we would want to know how they might go about partnering the product, and at what stage of development that should happen.

Finally, we make sure the Phase 3 clinical end points are no different than in Phase 2, to make sure there are no surprises during the study and that the company is not trying to cut corners. At

that stage we do not want to take any chances. We have to make sure the company is fully funded to do a thorough enough trial to get the results they need to sell the company.

What is the due diligence process that takes place from the first meeting until the time a check is issued?

ACHAR: It can run the whole spectrum. On one hand the due diligence process can involve a basic business overview. On the other hand it can include a review of financials and even visits to various facilities. For example, I once had a group of investors that I took to India for two weeks. I took them to the R&D facilities, the clinical trial sites, and even the sites of our manufacturing partners. The investors wanted to have confirmation that the due diligence of the investment has been properly addressed

AYNECHI: I always tell people to create a data room so that all important documents can be housed in one location. You often have to deal with multiple people across multiple locations with differing degrees of expertise. Having all those documents organized and in one central location greatly simplifies the process.

You also want to make sure you have your entire team available for meetings. Not just the CEO, but your CMO, your CSO, and other key members of the management team. They all need to be available for multiple meetings, not just the first one. If everything is well organized and well presented, we can do investments in as short as six weeks.

JUDICE: With a preclinical asset you are asking investors to take a big leap of faith. Being organized and having your presentation reflect a level of scientific rigor is critical. Keep in mind the average VC shop will see thousands of unsolicited business plans every year and will accept maybe 50 or 100 meetings. If you're in a meeting with them, you've already cleared a high bar and want to make the most of it.

I recommend going in and explaining what you're doing and why it's different/better than what the five closest competitors are doing. You've got to get through all of that in the first 5 minutes, because after that you will start to lose them. If you notice everyone looking at their iPhones, you are probably not doing well.

J. SHAH: For preclinical stage products it is important to know how quickly you can get to a go/no-go decision. You can spend a lot of time in preclinical doing early stage work that will not get any specific answers to help you decide in which direction to go. The sooner you can get to that decision point, the stronger your case will be.

M. SHAH: It is absolutely critical that you have a clear understanding of the competitive landscape for existing products with the same indication as the product you are developing. You have to know the landscape well and have key opinion leaders you are working with that have bought into your theory.

If we call a key opinion leader and they say they tried this concept and it doesn't work, the project is dead in the water. Having someone for us to call on will make your life much easier.

Today many different types of funding are available. How do you identify what will be the best source of funding for a given company?

ACHAR: It all depends. I have always felt the best kind of capital comes from the early believers and key opinion leaders. The early investors are the most crucial part in development. They create the first wave and get other potential investors excited.

AYNECHI: There are certainly foundations whose sole purpose is to advance science in a certain area, and it's great to get that kind of money. Companies really need to think about the diligent use of that early stage capital and how to leverage it the best way they can. I would be less concerned about how you raised a million dollars than I would be with what you actually did with it.

We like to think we are advancing science, but at the end of the day these projects still have to make financial sense. But having said that, we don't really look at money as a qualifier. Just because you were able to attract investment from a foundation does not mean that we should be funding the exercise.

I would also caution companies against taking investor money that's too small and too early. That money can become very expensive for you at some level. If there are too many small shareholders, that can make it difficult for us to invest in a company.

PAPANEK: I have seen some capitalization tables come over with 150 names on them. I would worry that some of those people are not qualified investors and that at some point we will have to figure out how to get their capital out of the company. This is why you should think hard about whose money you are taking because it can lead to some very awkward conversations, and we don't want to put people in those situations.

I would still recommend looking at all funding options that are available. I have looked at the Michael J. Fox Foundation and other organizations that have written some sizable checks. But at the same time I don't evaluate a company better or worse if it has money from a foundation.

JUDICE: If you're an entrepreneur, any money is good, especially if you're seeking pre-institutional funding. We have gotten money from the NIH and from small SBIR (small business innovation research) grants, for example. It is truly non-diluted, and it doesn't distract us. There is paperwork that has to be completed, and I have heard people complain about that. But is there anyone else out there willing to give you free money and not make you fill out forms? If it's good money, then you take it.

M. SHAH: If you received money from a foundation, that says a lot to me because it is aware of other studies going on for that indication and still made the decision to invest in your idea. That will give you credibility. Today, many of those groups are growing and now have access to a lot more money. At one time they used to give away free grants. Now they are becoming more sophisticated and will ask for their money back in some form.

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How should representatives go about selling their company?

ACHAR: Keep in mind that you are not just selling a company. You are selling a new medical approach, a new way of doing business, or quite possibly a whole new treatment space. So you have that burden as well.

This actually goes back to some of the earlier comments about having a solid business model and the right key opinion leaders on board. Make the case that you are promoting a viable product, that you have a plan to make it happen, and that you have a portfolio team that believes in the product. Vetting each one of those steps in your pitch is crucial. Be consistent and thorough throughout the entire process.

AYNECHI: I think the sales approach varies based on the stage of investment. If you are looking at a preclinical company, you are very much focused on the fundamentals of the science. The data aspect has to be good, and the management team is also key. We have invested in companies that were literally ideas, but they were brought to us by people who were successful and had a track record in this space. We knew they could actually execute on the idea.

If we are looking at a later stage product that is in the commercial stage, we often will look to have a CEO with significant commercial experience who can handle the launch of the product. We have seen investment opportunities where we liked the science but did not feel confident with the management team. We would not be averse to going back to them and recommending that they enhance the management team. At the very least, we would want them to be open to adding a new executive, a CMO, or someone to fill any gaps we see in the team.

We also like to avoid potential issues before they arise. This is a small community, and reputation does matter.

What are your thoughts on crowd funding from the patient population?

M. SHAH: I just saw a business plan where people from the IT area were setting up a platform on which they could ask the patients to contribute ideas about what they would like to see. The plan called for raising money from patients and their family members to fund the ideas. I think this is a model that will work but not for new drugs. I think old drugs could be repurposed using that kind of a funding model. I think patients will respond to safer and more efficacious versions of drugs they've been struggling with, perhaps for chronic conditions, by repurposing or reformulating drugs.

How big a factor in raising funds is a company's use of third-party suppliers?

ACHAR: I think it's very important, especially if you're a start-up. Being a start-up, you probably don't have the state-of-the-art facilities or infrastructure to do it yourself. That means you need to outsource all aspects of the drug process, including development, clinical trials, and manufacturing.

When we decided to outsource, we picked the number one partners in each of those categories. Those companies had great reputations, and we chose them to convince our partners that we were using the best R&D facility, the best CRO, and the best manufacturing group in the industry. We felt that was very important.

AYNECHI: I agree that if you are an early stage company it is very important. At that point in the process, you do not want to have to invest money in the necessary infrastructure. The quality of your vendors is critical, so you want to go with the right outsourcing options, not just the least expensive. That is something we definitely look at when we are doing investing.

JUDICE: For a preclinical company just starting out, infrastructure and personnel can be very expensive. Much of the science nowadays is commoditized, so the longer you can put off having a lab and hiring people the better off you'll be.

PAPANEK: I work with some virtual companies as well, and we are increasingly trying to find vendors and suppliers that are able to help a start-up company with chemical synthesis, biological assays, and disease-specific expertise.

Increasingly, we are also asking our companies if they know who, exactly, at the CRO they are working with. If the entrepreneur is working with a CRO team, but we get a different project lead and person to contact every time we call, that's something we would be concerned about. We want people who are fully dedicated to our project. We have a good relationship with our contracting groups and recommend them within our portfolio.

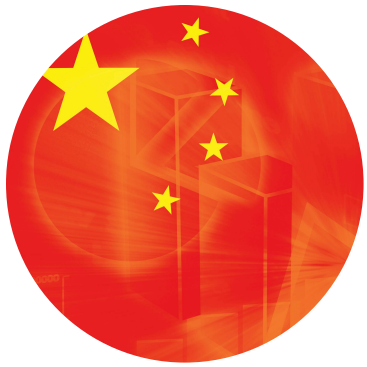
M. SHAH: I would say at least 95 percent of the companies I work with are outsourcing most or all of their development needs. I recommend working with the best companies available. Don't try to save a few dollars because that will come back to haunt you. Even if something looks expensive, just do it. If you don't, you are going to end up having a problem and paying a higher price later on.

Our general rule is to hire the best professionals you can find who are capable of delivering the results you need. Choosing the wrong partner will reduce your value significantly, so always invest your money wisely.

Is China Casting Shadows On Other Opportunities In Asia Pacific?

LOUIS GARGUILO Executive Editor @Louis_Garguilo

Some came looking for a prevailing regional paradigm to hang a hat on, others for specific country advantages and market idiosyncrasies, and maybe most of all, insight into selecting partners and service providers.



It's the final session of the two-day, inaugural Outsourced Pharma West (OPW) conference in San Francisco in November, and it's packed. The aim is an elucidation of the Asia Pacific (APAC) region for biopharma companies of all kinds.

We may have missed the mark. That is, unless all along, the mark really was China.

Two experienced China veterans sit on the four-member panel: one an entrepreneur/consultant, the other an entrepreneur/executive currently at a biotech in San Francisco. The other panelists are from a global analytical services company headquartered in Europe and an India-based outsourcing service provider. The discussion is lively and informative and focused on China. At the conclusion, the buzz among the panel and attendees is that the session was a success.

Still, I'm a bit disappointed. However, the wise moderator, Ken Shultis of Rondaxe Consulting, said to me with a wry smile, "What did you expect?"

In a word, options.

ASIA PACIFIC OPTIONS

For example, I've written about the biopharma outsourcing services industry and healthcare markets in Indonesia, Malaysia, and Singapore, the latter where a well-known pharma executive at OPW told me he runs into more biopharma executives here than at any other location in the world. In Indonesia, there is a growing CMO industry with hopes of moving into drug discovery as well. GlobalData (London) forecasts the Indonesian pharmaceutical market will climb to around $10 billion in the next five years.

There's South Korea, home to "KPharma" companies like Dong-A, Green Cross, Hanmi, LG Life Sciences, and Samsung Biologics, from all reports looking actively for foreign partnerships, in-licensing, and other opportunities. LG and Samsung are following the road map to global relevancy drawn by successful electronics and automobile conglomerates. South Korea is home to pharma service providers, a healthcare system primed for clinical trials, and a growing pharmaceutical market. And by the way, Korean companies have close ties and valuable relationships with their Chinese neighbors.

We can mention Taiwan, with a growing biology sector, the Philippines and Vietnam for emerging drug sales opportunities and service providers.

And there's Japan, always in the mix and for years playing a positive economic role throughout APAC. For much of Big Pharma, Japan remains one of the largest sales markets. If anyone anywhere — from virtual biotech to established players — is not involved in Japan or a Japanese entity of some kind, it isn't for want of trying. China gets most of the publicity nowadays, but Japan remains the second largest pharmaceutical home-market after the U.S. and has its own breed of (increasingly aggressive and global) big and specialty pharma.

Oh, and add Australia, the "Western" APAC country and a growing global model for drug discovery partnerships between academic-led research and industry. Big Pharma in the U.S. and Europe grow more interested in the down under every year. New Zealand has some opportunities as well for those looking for APAC partners or regional launching pads.

And finally, depending on the geographic definition of Asia Pacific, there's India.

Throughout 2014, I wrote many articles on the Indian pharma and services industry (as my publisher reminded me from

time-to-time). But it's that important. India is an undeniable powerhouse in the biopharma outsourcing industry and an accelerating drug home-market. Yes, there was too much negative news out of India in 2014, and serious challenges remain, from compliance to final quality to IP.

Nonetheless, facts are facts: Over 500 Indian facilities are registered with FDA, the highest number for any country outside the U.S. Indian companies accounted for 39 percent of all abbreviated new drug application (ANDA) approvals in 2013 and accounted for 40 percent by volume of U.S. generic drug imports in 2013. Plugging into India could prove valuable.

So there are options for Western researchers and companies in APAC. To be fair, our session at OPW touched on some of these countries and topics, particularly Japan; to have covered them all would have taken a full day. (Hey, that's an idea.)

CHINA, CHINA, CHINA

However, for the most part, our OPW session was focused on China. And, of course, that mirrors what we experience everywhere nowadays.

Perhaps due largely to a growing familiarity with the subject, we often talk about China as a typical capitalist country with an emerging (and potentially huge) healthcare consumer population, open to the global pharma industry and home to competitive biopharma service providers. Opportunities seem limitless. But there's a need to add levity, some would say reality, as a few attendees actually did at the conference.

As I recently wrote in an article for *Outsourced Pharma*, we're reminded of "the lucrative — some say anticompetitive, anticapitalist, and unfair — benefits handed down from Chinese government at various levels, including subsidizing facilities and tax breaks." Strategies at all Western companies, vis-à-vis China, must take into consideration the current government mandate that new drugs for the Chinese market be manufactured domestically. And while some of the best outsourcing service providers on the globe are Chinese, we still recall news stories surrounding some suppliers, with one of the worst historic examples — the heparin contamination tragedy that led to patient deaths globally.

Intellectual property issues can't be swept under a rug like so many CD-ROMs crushed under bulldozers to demonstrate new attitudes. And while China is now one of the world's largest stock markets, it's "largely closed to foreign investors," according to *The Wall Street Journal*.

None of this implies the China juggernaut in the biopharma industry is slowing down precipitously. Hopefully, there

are some different directions taken there. But the above should provide Western companies a measured dose of caution along with the great excitement for China and precipitate a closer look at APAC options, should they make sense.

Countries throughout APAC provide the advantages of outsourcing service prowess and differing cost models. There are university-based research partners (every year standardized measurements put Asian countries at the forefront of educated students in math and science). Discovery and development relationships are possible with a growing list of pharma companies. Many of these options also include established relationships with China.

And this brings us back to our conference.

AN AURA OF INEVITABILITY

For me, the most interesting dialogue at the APAC session at OPW was between two audience members. It started with a quality management professional from a Europe-based pharma company asking the panel a question regarding the biologics market, quality, and IP in China.

Basically, the consensus answer was "Biologics will start to grow as the small molecule sector has, IP is under control, and anyways you [presumably all the biotechs and biopharma in the room] have to be in China." The advice? "Pick your Chinese partners wisely, and monitor them closely. You really can't do this [enter China] alone."

Fair enough, I suppose. But here's the interesting part. A few minutes later, a second person from the audience, from a Chinese biologics company headquartered in a Beijing "free trade zone," then directly questioned the Big Pharma quality management professional. Paraphrasing, the scene went something like this:

"I'm literally just back from China," the audience member said proudly. "I happen to know your company was going to put a major biologics facility in China for a specific drug with a potentially large market, but you decided to build it in Europe. Why would you do that?"

If the Big Pharma rep was surprised by the question, it didn't show. "I wasn't a part of that strategic initiative," came the reply, "but I'm sure there are solid business and other reasons why we felt this is better for global patients and markets."

Our moderator then adroitly used this to move back to the panel for other elaborations.

Why is this particular piece of dialogue important?

To begin with, it demonstrates the value of a conference that brings a wide slice of industry professionals together and facilitates open discussion. Core feelings and attitudes break through, showing sentiments often hard to gain or gauge in any setting.

But the real importance resides in the implications of the panel and the questioner: "You simply have to be in China," seems to be the first. The second is, "How could you then have the audacity not to select China?"

When assumed inevitability becomes a driving business strategy, companies may not make the best decisions. In fact, particularly for Western-based virtual companies, biotechs, or specialty pharmas, this certitude does not exist. If partnering in China or utilizing Chinese service providers is not the right strategy at this time, there are abundant global options, including in APAC.

I last thought about the idea of inevitability. Chinese consumers and businesses grow in their understanding of global markets. If, in the near future, a new drug on global markets is treating or curing patients of a major disease throughout the rest of the world, will the Chinese government be able to exclude its own people because of a home-manufacturing law? Rather, something will have to change, and hopefully well before we get to that scenario.

SUCCESS AFTER ALL

Going back to the European Big Pharma challenged above for not locating a facility in China, I recently learned it is locating a new innovative drug research center ... in Japan. Here's hoping all APAC countries can avoid shadows cast by China to develop their own markets and freely partner, even as that country takes its place as a major player on the global pharmaceutical stage.

"Countries throughout APAC provide the advantages of outsourcing service prowess and differing cost models."

In hindsight, our session at OPW did pierce the notion that APAC has a single premise to which business and scientific strategies can easily be drawn. The real opportunities for scientific and technology partnerships, licensing (in and out), and sales and marketing are revealed within the details of each country. Companies should explore opportunities in China and participate when it makes the most sense. It could very well be the grand prize. But the same should be done for other countries in APAC. They may end up being personal prizes along the way.

OPW set a framework to facilitate open expression from a wide cross-section of industry participants. We got that, and attendees went home with much to reflect upon, maybe particularly from the closing session on APAC. Come to think of it, it was a big success. As for me, I guess I just need to loosen up a bit.

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Innovation In Bayer HealthCare's Quality Management

LOUIS GARGUILO Executive Editor @Louis_Garguilo

"Innovation" and "pharmaceutical quality management" inhabit the same sentence more often these days. Bayer HealthCare's Director of Quality Assurance for Biologic Product Development in Berkeley, Dr. Claudia Lin, takes pride in that.

She's an avowed "innovative research scientist," so what's she doing in quality management? "Now more than ever, quality management requires innovative thinking that comes from the ability to interpret regulations; creatively solve scientific, technical, and business problems; and challenge the status quo. These types of professionals are in demand. I believe this is the onset of a transition, a positive movement in the pharmaceutical quality world."

Lin also believes that if any tenured quality managers haven't already noticed the need for change, their bosses will. "If the top quality leaders in biopharmaceutical companies today don't have these qualities, they should learn from somebody who does. Otherwise, CEOs will realize, 'We are behind the eight ball on this,' and look for options."

Prior to Bayer HealthCare, Lin worked at a number of pharmaceutical and biotechnology companies. She has a Ph.D. from UC Berkeley in cell and molecular biology, two post-docs from UCLA and UC Berkeley, and an undergraduate degree from Fudan University (Shanghai). I met her at the Outsourced Pharma West 2014 conference in San Francisco.

She defines her adopted profession this way: "Quality management is designing manufacturing processes and controlling strategies to arrive at product quality. It's also about continuously improving product quality so that not only do you better serve patients, but also you derive more rewards from your R&D investments."

QUALITY MANAGEMENT AS A CRITICAL BUSINESS FUNCTION

Lin says her desire to further innovation in the quality management field has been growing for years. Personal experience led her to believe there is a major component of innovation in quality, equally as vital as in all other areas of drug research, development, and manufacturing. Moreover, she has a keen view of quality management as a critical business function and as a tool to help drive and solve business solutions.

Her first position, though, was in her first field of study. "As a research scientist specializing in cancer, I always wanted to go into industry to help develop drugs," she says. Throughout her career she became known as a go-to person for difficult projects. She cites an example from a time at a previous company. A leader was needed to identify and implement biomarkers for a new cancer therapy. "This was more than 10 years ago when people just started talking about biomarkers; nobody really knew how to proceed. They looked to me for help. It was all innovation, and very gratifying."

Her next step, she jokes, was when Genentech lured her "to the dark side," and a job in quality. "At the beginning, I thought there was a dichotomy between innovation and quality management," she says. She struggled to find how an innovative scientist could become a valuable quality person, and she even worried she might be on the wrong path. That personal struggle ended up placing her on a career-long path of leadership and advocacy for a new quality management approach.

She says a breakthrough occurred for her when she gained quality management responsibility for a large anti-cancer drug. "At first it was a basic quality job, focused primarily on lot release. I could see why some people think quality is not necessarily innovative," she says. "Granted, in quality you have essential tasks that are repetitive and require methodical checking of details, but I soon realized that is a small portion of what quality management should be doing."

The initial challenge was planning the launch of clinical trials in over 20 countries. While it was tedious strategizing applications and approvals, she says she thought, "Nobody can actually direct us in how to do this. We had to create a way for the first global trial of what became a famous drug."

A smaller victory within that project proved just as educational to Lin. "We had discussed cold chain management. The drug had to be transported through various countries, climates, clinics, and system regulations. It seemed every other day we would get a call saying a package was in customs for five days, or the dry ice

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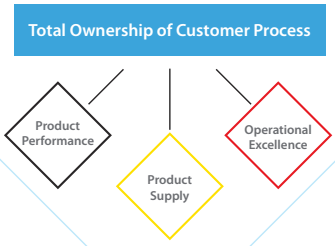

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had melted, or the clinic cold room was not adequately controlled. Product, and thus potentially trials, could be at risk."

Lin threw out the traditional quality approach with the melting ice. "Instead of the usual way of looking at each incidence and rendering a yes or no decision, which would take up vast resources and be ineffective, we sat with experts from different functions, including product stability and shipping validation. Quality management drove a different and more robust solution."

According to Lin, they implemented a process to review all the data, define a time and temperature range for the product, and then build that into the distribution system. The resultant solution reduced inquiries (e.g., those received from shippers, storage facilities, and/or clinical trial managers regarding whether the drug still met specifications and could be used in the clinical trial) and lost product. "It may not seem like a big scientific invention," she says, "but it introduced me to how you can directly apply creative, quality ideas to solve a costly business problem."

"And what is the definition of innovation anyways?" she asks. "It's about finding new ways to do old things. I believe as a result of this applied approach, I was labeled an innovative quality leader. I've had the opportunity to do quality management in a divergent way ever since."

REGULATORS AGREE WITH INNOVATION

ICHQ10, updated guidelines for quality systems issued by the FDA in 2009, reinforced Lin's approach and thinking. In the pharmaceutical quality realm, this was the FDA's official attempt to insert the type of innovation in which Lin believed. The guidelines provided a stimulus for a more holistic thought process for implementing systems for pharmaceutical products.

"When the guidelines were issued, people said, 'This makes sense, but how do we actually do it?'" recalls Lin. Today, regulators and industry seem to be applying the same interpretation. "I was recently on a panel with an associate director at CDER [Center for Drug Evaluation and Research] who is involved with product quality," says Lin. "He shared the same thoughts that I had on this new direction."

That new direction, according to Lin, is determining whether a company understands why it put together particular controls for analytics, particular specifications, but perhaps most important of all, how everything adds up to a strategic and quality manufacturing process. The emphasis is squarely on understanding process and control strategies critical to ensuring product quality. This differs from a more traditional regulatory focus on whether a registered product is following individual procedures for manufacturing and testing.

Drug companies must now demonstrate their forward-looking flexibility and a process to improve as knowledge is gained from more production runs and post-launch market data. "The FDA is looking for integrated thinking regarding how you design your product, as well as the final product itself," she says. "You need this to effectively implement and understand the impact of changes throughout the entire development process. This integrated thinking requires that quality professionals are part of the scientific and business design for drugs and heavily involved with any improvement efforts, issues, and change management."

BAYER (AND OTHERS) GET IT

Lin says the entire Bayer organization benefits from this innovative quality direction. I ask her if she sees signs that other pharmaceutical companies are practicing this quality approach. "Yes, I think many are, and it is becoming the natural way of thinking. And it didn't just start. I remember Genentech started early with a continuous monitoring program, an important element of ICHQ10," she says. "We also worked on quality-by-design when I was there that led to the first submission to FDA and European regulatory agencies utilizing this approach. It was an exciting journey because we got to be innovative for the growing biotech industry."

"Quality management is designing manufacturing processes and controlling strategies to arrive at product quality."

DR. CLAUDIA LIN
Director of Quality Assurance for Biologic Product Development at Bayer HealthCare

Not surprisingly, she sees Amgen also leading this quality philosophy. "Judging from conferences I attend, they consistently embody this way of thinking about quality management. I also hear from many other quality managers at pharmaceutical companies who are passionate about these concepts."

"So, on a company and industrywide basis, this thinking of quality management as an innovative key to enabling better patient and business outcomes is becoming pervasive. It's been gratifying for me to engage in this level of thought leadership," she concludes.


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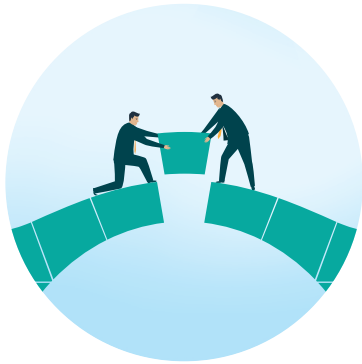
Best Practices For Establishing And Maintaining A Balanced Quality Agreement

ED MISETA Executive Editor @OutsourcedPharm

One of the most important considerations when forging a CMO/client relationship is reaching a consensus on the wording of the quality agreement.



With the FDA cracking down on the responsibilities of both parties in the relationship, it is more important than ever for both sides to be in agreement on the actions that need to be taken when a quality issue comes to light. A panel discussion at the Outsourced Pharma West Conference & Exhibition focused on these agreements, with representatives of both large- and small-sponsor companies sharing insights on the topic.

The agreements are often born of a template that originates with one of the two parties. If anything became clear to me when listening to the exchange between panelists and audience members, it was the importance of reviewing the document, understanding it, and making modifications when necessary. Here are some of the key takeaways from the session.

PREPARING THE QA IS A STRAIGHTFORWARD PROCESS … OR IS IT?

Quality agreements have been around for a long time, and now even the FDA has a guidance regarding them. That would make many think that preparing a QA and putting it in place is a simple and straightforward process. Unfortunately, this is not always the case.

In theory, the document is fairly straightforward. If the templates used by the vendor and the client are well aligned in terms of the requirements of both parties, that makes the process even easier. If, however, there are multiple templates being used by either party, or there are significant differences between them, the process can get much more complicated. There are also issues that can arise if provisions in the agreement can be interpreted differently by either party.

One of the benefits of working with select partners on multiple projects is that both sides get to know each other better. After multiple iterations of the agreement with the same client, the process gets smoother each time. Having the FDA guidance makes the process even smoother.

Still, there are considerations that need to be taken into account. One of the most important is ensuring the agreement contains an appropriate level of detail beyond the normal GMP considerations. That will generally depend on other external factors, such as the criticality of the service being provided and the geographies in which the business will be executed. The right amount of balance, and setting these definitions right up front, will allow both sides to communicate more smoothly and effectively.

AVOID THE LEGALESE AND THE CONTROL

If there is one thing that can make the process of approving a quality agreement more complicated, it's using a template that is full of legal jargon. This can make the agreement very difficult to work through and will require quality personnel to read through every sentence in an attempt to determine who's responsible for what. Anything that can be done to simplify the agreements will lead to better outcomes on both sides.

For example, a couple of panelists remarked on the benefits of a simple template that is both easy to read and understand. One that has a list of responsibilities on the left and an X in a box under columns headed "CMO" and "sponsor" on the right often works well. That type of

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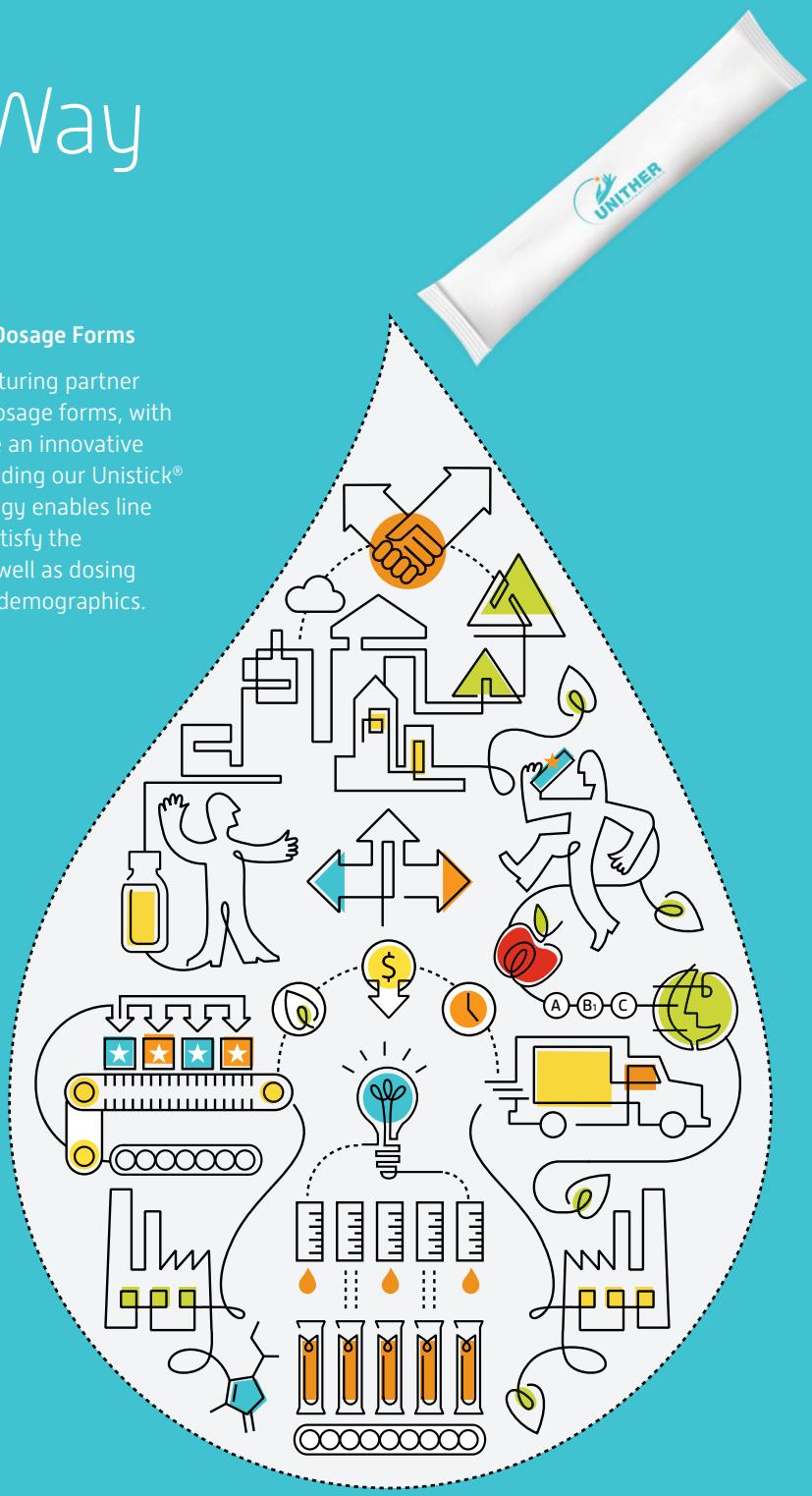

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template is easy to navigate and understand. Vendors and clients can generally get through an agreement like that in less than an hour. However, use caution when using one of these to avoid a lack of specificity. If a task is assigned joint responsibility, it can be easy for both sides to overlook it. For that reason, it may be best to avoid joint responsibility situations or to clarify where one responsibility ends and the next begins.

One of the toughest situations for a CMO is when a client comes in and insists on using their own quality agreement. If a CMO is working with 40 or 50 clients, there could potentially be 40 or 50 different agreements they must work with each year. A sponsor's attorneys might insist that vendors use that specific agreement, but it will take longer for the CMO to figure out what it is agreeing to.

While newer companies (e.g., a small start-up bio firm) might be reluctant to accept a CMO's quality, starting with its quality agreement actually makes a lot of sense. CMOs have signed hundreds, if not thousands, of agreements with sponsor companies. It is unlikely an issue would arise that they have not already considered and made accommodations for.

The bigger issue might be forcing the CMO to abide by different rules for different clients. If that CMO is working with 30 sponsors, and 29 require a deviation notification within 48 hours, then a client requiring a 24-hour notification of that same deviation throws a wrench into the works. There also can be differences in how a client is notified (i.e., by phone or email). Someone in the facility would have to remember or somehow keep track of all these caveats. In that type of situation it is better for the client to look at their agreement and ask if they really need to be notified in 24 hours or if they can abide by the rules the CMO already has in place.

"One of the toughest situations for a CMO is when a client comes in and insists on using their own quality agreement."

WHEN SHOULD WE DISCUSS?

If you are in discussions with a CMO, when is the best time to discuss quality agreements? Should it be when you are vetting the company or after you have made your selection? Perhaps at the same time you submit an RFP? One school of thought is to negotiate the agreement in parallel with any kind of service agreement. However, that may depend on the type of relationship established (transactional versus strategic partnership).

Quality agreements should also reduce subjectivity as much as possible, simply to reduce confusion on both sides. For example, don't try to differentiate between a minor deviation and a major deviation. That is too subjective and will drive people crazy. Simply note that all deviations should be reported within 24 hours.

Unfortunately, sometimes the CMO relationship is managed by someone who is not a part of the quality team. That can add another layer of complexity to the notification process. One panelist recommended that the quality agreement always specify who will notify the client of deviations. It is best for that person to be someone on the quality team and not the project manager. If we have a relationship where CEOs are talking to CEOs and project managers are talking to project managers, then we should have the quality people interacting with each other on issues of quality.

IS IT IN THE REG?

The panel covered two additional points that are worthy of consideration. The first is, don't be afraid to relent on an issue, especially when it involves internal procedures or actions not mandated by regulatory requirements. "We were well into a project when we encountered an issue," notes one panelist. "It was not addressed in the quality agreement, and it wasn't in the Master Service Agreement (MSA). It was an issue where the two sides just had opposing views on it. We ultimately conceded, but a situation like that happens a small percentage of the time."

Another panelist discussed a situation where a CMO pushed back and said, "Show me the reg." Upon looking into it, he discovered the reg didn't actually say what he thought it did. The company had simply been doing it that way for years. "We don't even know who it was, 20 years ago, that said we should do that," he said. "Eventually we relented." The lesson learned? Be willing to work with your CMO on quality disputes, especially if a regulation is not there to back it up.

In closing, I think one final point should be made. A quality agreement, once signed, is not etched in stone. There is nothing that says it can't be changed as needed. Quality personnel from both sides should be open to amending, adding to, or deleting from the agreement as the project, the relationship, or applicable regulations change. Always remember your CMO is your partner, and you need to be able to work together to ensure both sides are successful.

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How To Match A Vendor To Your Stage Of Development

ED MISETA Executive Editor @OutsourcedPharm

One of the most informative sessions from last fall's Outsourced Pharma West Conference & Exhibition in San Francisco discussed matching a vendor to your stage of development.

With a lineup of panelists that included Firelli Alonso-Caplen of Pfizer, Joe Guiles of Medivation, Bob Munday of CMC Biologics, Patrick Murphy of Versartis, David Enloe of Althea, and Jon Crate of FAI Testing Services, attendees were sure to hear from executives with first-hand knowledge of the topic. The speakers did not disappoint.

Finding a CMO that can manufacture your product, meet your requirements, and work closely with your team during bad times and good is not an easy endeavor. Several themes that emerged throughout the session can be culled into best practices to keep in mind throughout the selection process.

THE PROCESS CAN TAKE 6 MONTHS … OR LONGER

If you are conducting your search properly, expect it to take a considerable amount of time. There are agreements that will need to be completed at the outset of the qualification process, including the confidentiality agreement and non-disclosure agreement. One of the critical first steps should also be a site visit. "This is a must," noted one panelist. "You have to see what you are getting into."

Often a supplier will look good on its website, but you don't know how old the facility is or if the photo is even of the facility in question. One Big Pharma executive told me the story of one such visit. The website showed a beautiful building which supposedly housed expertise in analytical testing. "I sent someone with experience in analytical testing to check out the facility," he said. "When he found the laboratory, it was an empty building with the company name on the door."

If the initial site visit goes well, the next step is to send a technical evaluation team to the vendor. That team should be cross-functional and include personnel with expertise in processes, analytical, regulatory, and quality functions. If the CMO passes the technical evaluation, a quality audit will need to be performed. In the case of a drug-product facility, a sterility assurance assessment should also be performed. That can be a two- or three-day visit during which an actual fill activity is observed. The entire process, either an actual or engineering run, should be observed and analyzed.

According to at least one speaker, the entire process can take six months, if you're lucky, perhaps longer if any deviations are noted.

RELATIONSHIPS ARE CRITICAL

Once a relationship is established, it must be properly developed and cultivated. That way, when things are not going so well, you have solid relationships that you can fall back on.

This process should include developing peer-to-peer relationships. These ties should range from the CEOs all the way down to the project managers. This is an organizational alignment where like folks are constantly interacting – finance to finance, lawyer to lawyer, regulatory to regulatory, project manager to project manager. When the relationship is thrown a curve ball, you will not have

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finger-pointing going on. Everyone will talk to their counterparts and get the situation resolved quickly.

This is especially important for smaller bio and pharma companies trying to establish working relationships with CMOs that also happen to be working with Pfizer, Merck, Lilly, and other large pharma companies. Many of those CMOs will have to decide whether or not you are worth their time and effort. In those situations, you will need to sell them on your company and why they should invest their time with you.

Treat these relationships as a marriage. They take time to develop, and they are designed to last a long time. The more time and effort you can put into building those personal relationships with key people in the company, the better it will work out for you in the long run.

WHEN YOU HAVE TO GO WITH ONE PROVIDER, CHOOSE CAREFULLY

Big Pharma companies do not like being put in a situation where they have product coming from a single source. Diversification reduces risk, and in no industry is that more true than life sciences. Unfortunately, for many smaller bio and pharma companies, having multiple suppliers is not a choice. Some may not have the money or resources to seek a secondary supplier, or there is not enough volume to make multiple suppliers cost-effective. Suddenly, the importance of selecting the right CMO is significantly magnified. Make the wrong choice and you may not get a second chance. No one knows which CMO will be the next to receive an FDA Warning Letter. In those situations, how do you go about mitigating risk of having your eggs in one basket?

Panel members stressed the necessity of having a consistent process in place to make the right selection. Identify all of the parameters that will be important to you in a CMO. Then thoroughly investigate and screen all of the candidates on your short list. That investigation should include the aforementioned site visits but also checking with other pharma professionals and consultants in your professional network. Take the time to find out if they are interested in producing your product, and whether they have the bandwidth to do it. Meet the people who will be working on your product and determine their level of expertise.

"While you will always want to have a CMO's A-team working on your project, we all know that will not always be the case."

While you will always want to have a CMO's A-team working on your project, we all know that will not always be the case. There will always be project managers with 30 years of experience and others that have 30 minutes. Do your best to ferret that out and know who will be doing your work. This is also a good time to develop those one-on-one relationships, so ask as many questions as you can.

Regardless of whether you get the best project team at the CMO, you can never waiver on quality. The CMO either has a quality operation or it doesn't. It has a culture of quality or it doesn't. It's the job of your team to understand the company, its people, and its culture and its capabilities. If you cut corners during this selection process, you might be dooming your effort from the start. If you don't like the team at one location, look into the possibility of relocating the project to a different site.

IS A ONE-STOP SHOP THE RIGHT CHOICE?

Finally, a decision always has to be made regarding whether to employ a number of specialty CMOs or select one that can do all of the tasks you might need done. Most CMOs today seem to be moving towards the one-stop shop model. One thing you should ask yourself at this point is whether you have ever found a CMO that is capable of doing everything. Most companies will have an advantage when performing a specific task, such as early clinical or late clinical. Every client will want to select a CMO that is honest about its capabilities. If you need someone to run your cell-based bio assays, do you want a company that specializes in that, or one that says it can do it and will then subcontract it out to a company you have never heard of?

If you ask who will perform the work, most CMOs will give you an honest answer. But even if they tell you they will send the work to another service provider, it is your responsibility to vet that service provider as if it is the CMO you selected.

The panel had one final piece of advice that might help you navigate your vendor relationships: a joint steering committee. Often, an issue might arise that cannot be resolved at the team level. When that happens, a team of decision makers is needed to resolve the issue. Typically, this committee should consist of VP-level executives from both the CMO and the client. They should represent all areas of a project where disputes might arise, including operations, quality, and regulatory. "On the pre-commercial side, we have employed a steering committee for the last 10 years," noted one speaker. "We have found it to be quite successful at managing a number of disputes." L

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You were able to discover a promising molecule, get it manufactured, and obtain approval for clinical trials. You were even able to secure VC funding to get you through to commercialization. But it all may be for naught if you don't properly manage your supply chain.

How do you ensure you have selected the right partners and are doing what is necessary to minimize your supply chain risk? Having a good match between sponsor and vendor is critical to this relationship, so finding partners who are a cultural fit is important. Do the two companies manage communications in a similar way? Does your supplier have the same thoughts on managing risk? Do the two companies share similar views on quality and regulatory issues? These are topics that can make or break a relationship from the outset.

Once you get beyond the selection process, supplier management is critical. Proper supply chain management will minimize quality issues, avoid shortages and regulatory problems, and allow you to sleep at night. A panel at the inaugural Outsourced Pharma West Conference and Exhibition addressed this topic and produced several recommendations to make the process as risk-free as possible.

BOXCARS ARE NOT A STRATEGY

Several speakers noted that the approach many companies take to avoid shortages is what is called "project boxcar." They take a boxcar, fill it with API, and hope that will mitigate their risk of a supply disruption. This does not adequately replace a good second supplier. Unfortunately, with the high cost involved with finding, vetting, and establishing a secondary supplier, the boxcar method seems more cost-effective for many small bio firms. Even when a sponsor claims two sources for a product, it might be a situation where 90 percent of the product is coming from one facility and 10 percent from another. If the former were to go down, it would be almost impossible for the latter to make up the shortfall.

The situation also varies greatly depending on whether you are dealing with a new or existing product. With an existing product that has been around for maybe 15 years, a sponsor might have six months of inventory on hand. A hiccup with one supplier will not matter. With a product just being launched, that inventory doesn't exist, and there has to be zero risk with your suppliers. In these different situations, a one-size-fits-all model is not going to prevail.

EVALUATE EACH FACILITY INDIVIDUALLY

If a supplier has five plants in five different locations, there is no guarantee all five will produce product at the same quality level. A quality mindset, established by management, can go across an entire organization and affect multiple sites. So, if you have three plants, and two of them look to be in poor condition and one looks perfect, don't assume the culture of quality won't be the same at all three. Unless the plants are operating almost as independent operations, a quality issue at one location should make you skeptical of all of the locations.

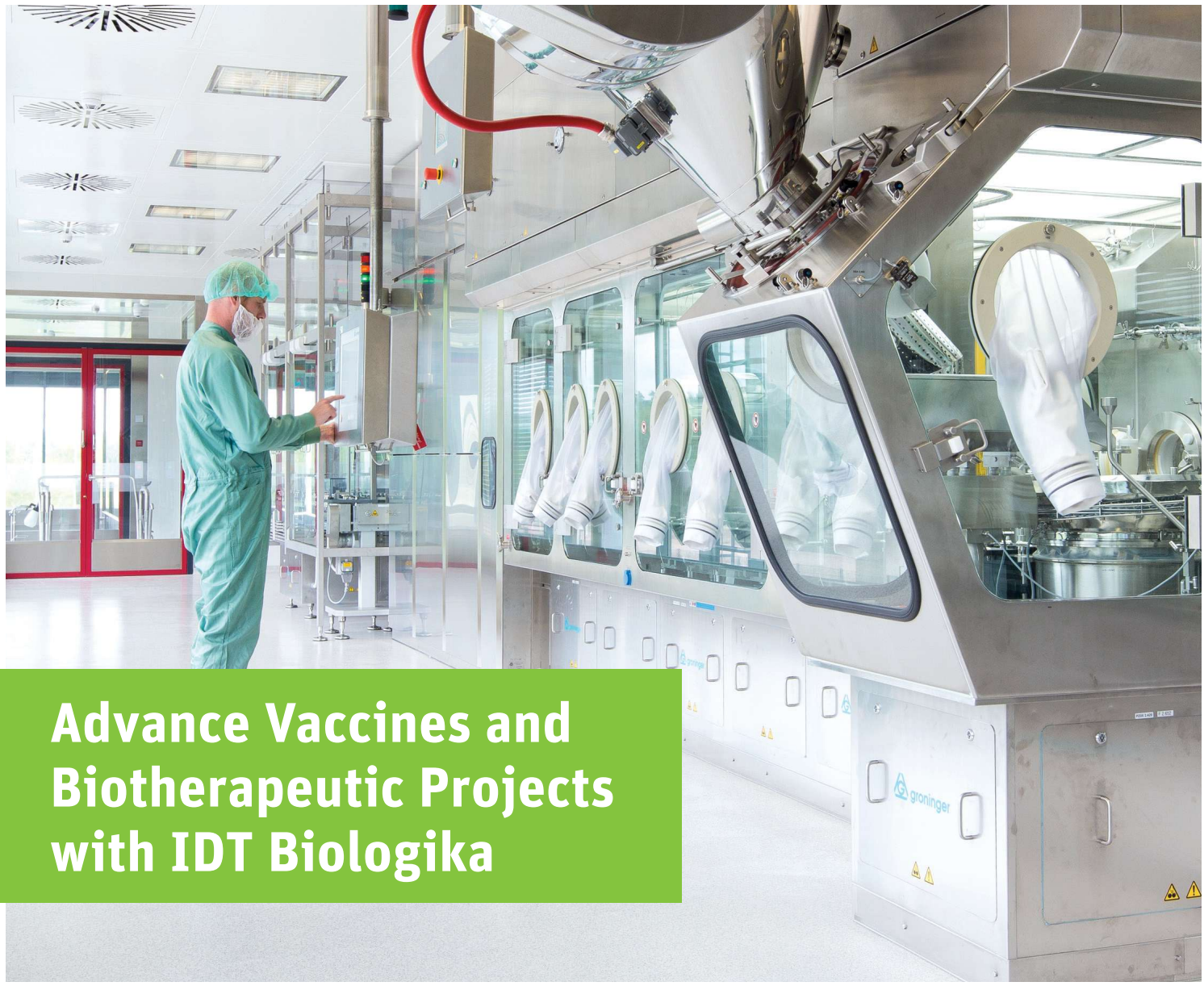
When visiting the different locations, ask questions about issues you perceive to determine what is being done. Then give them time to resolve them. If the issues are at a newly acquired site and the CMO plans to pump $50 million into the facility, that would be an acceptable answer. But if a plant has been in the network for 20 years, is falling apart, and the CMO is moving product out of it, it may be time to keep looking. An FDA warning letter or a bad inspection could easily sink your product.

As one presenter put it, "If you know that plant A and plant B were both shut down in the past, don't be surprised if plant C is soon shut down as well. You would have to be deaf, dumb, and blind to look at that picture and not see that there was a network issue involved and not simply a plant issue."

TRUST YOUR EXPERIENCE

If you have spent enough time evaluating CMOs, at some point you will start to trust your experience and gut instinct when vetting them. There are certain things you will hear or not hear that will give you the confidence to trust or reject a CMO. The level of investment is one metric that seems to give most sponsors a certain level of confidence. If you believe the amount of investment over a number of years has not been sufficient and you are considering moving an important product line there, that should send up a red flag.

While many quality issues might be obvious from touring the plant, our



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panel recommends digging in and asking a lot of hard questions to find out what is the true culture of the organization. Have a good understanding of what you hope to accomplish and what the keys to success for the project will be. Every plant and inspection will be different. Therefore, don't reuse a checklist that was written for another CMO; always start fresh with a new checklist specifically tailored to the plant you are visiting. As one panelist noted, you will often look back and wish you had done a better job on an assessment, but no one has ever said they regret putting too much effort into one.

One metric that should always strike fear into someone performing an assessment is turnover, especially in the areas of quality and analytical. "If a CMO is turning over its quality group every two or three years, there is no consistency that can exist there, and that scares me," said one speaker. This also illustrates the importance of having a relationship with individuals at several levels. If the person you like and work with suddenly leaves the company, it's possible you will be stuck with someone you don't like or who doesn't understand your business. Having other key relationships in the company can help alleviate that problem.

INVESTIGATE YOUR SUPPLIER'S SUPPLIER

It's one thing to manage the risks that you know exist. You determine the risk level, identify possible solutions, evaluate them, and then select the best option. But what about the risks that you don't know exist? Those are the ones that can sneak up on you and sink your project before you even know they exist.

One of the biggest mistakes you can make in auditing a CMO — which can lead to unknown risks — is not digging deep enough into the companies they do business with. One speaker told the story of a project where a sponsor was sourcing a product from three different suppliers. Everything was going great, and the redundancy gave the company peace of mind. Unfortunately, all three suppliers were obtaining product from the same source. Therefore, the company was sole-sourcing the product and did not even know it, nor did they know exactly who was producing it. Eventually they did find out. A fertilizer factory next to the supplier exploded and created a shortage of the product overnight.

It did not occur to anyone at the sponsor company to do a little more digging into the company's suppliers to determine the ultimate source of the product, much less check to see where that supplier was located and who its neighbors were. Many pharma execs have been burned by hidden risks, and only by digging deeper into your

suppliers will you be able to locate them and take appropriate action.

Some panelists and audience members also questioned the level to which risk could be reduced by improving the overall audit function. Asking more in-depth questions would certainly enable auditors to better uncover hidden risks. "I have seen auditors come in and simply go through a checklist," noted one panelist. "But if they had more skills and experience, they would know to ask certain questions that didn't just come off a standard audit checklist. People will ask questions, but they are not the right questions, and they do not get to the right issues that are creating the risk."

Of course, acting on audit results is also important. If audits cite the same issues year after year, but nothing is done about them, an opportunity to reduce or eliminate certain risks is being missed.

FORGET ABOUT THE ONE-STOP-SHOP

No discussion of supply chain issues would be complete without mentioning risk reduction via one-stop-shops. It was on that topic that the panel concluded its discussion. Bringing together an API manufacturer with a drug product manufacturer might be a way to shorten and better secure the supply chain, but the consensus seems to be that the model rarely works as planned.

"I don't think that model is ever going to work," noted one panelist. "My experience is that if you bring together an API and a drug product manufacturer, you will end up with a company that is not as good at either one. In 10 years, I have still not seen it succeed."

The thinking is that by bringing together the two manufacturers, there are more resources, there are synergies that can be derived, and the new company will be bigger and more efficient than the two pieces. But the panelist makes a good point: Will you really end up with a company that is an expert on both sides of the business?

It will be interesting to see, in the next few years, if a lot of the consolidation going on in the industry will result in successful integrations and how valuable they will be to sponsor companies. One factor that may come into question is the scope of these mergers. API and drug manufacturing may work well together. API, drug product, packaging, clinical trials, and toxicology may be a bit much.

"I may be a bit of an optimist," noted another panelist. "I love the idea of a one-stop-shop. It's possible that these companies getting bigger and better resourced will make them more valuable suppliers to the industry. It could be a real win for the industry, and I am encouraged by it."

"Phase-Appropriate" Drug Development

The New "Time And Place"

LOUIS GARGUILO Executive Editor @Louis_Garguilo

Parents today still caution children with the phrase, "Everything in its time and place." For me, it just took "the look" for my parents to convey: This wasn't the right time or place.

In our biopharma industry that axiom gets replaced with, "Everything in its time and *phase*." And "the look" might come from veteran project managers, outsourcing providers, or consultants regarding scale-up strategies.

Four such industry veterans led a free-flowing discussion on "phase appropriate" decisions at the inaugural Outsourced Pharma West (OPW) conference and exhibition in San Francisco last November. They had a common message directed at established pharma: "To find out whether the CDMO has exactly what you're looking for and understands what you're asking at each phase of your project, you need to *forge a good relationship from negotiations*." This requires both sides fully understanding the long-term strategies that will guide step-by-step decisions throughout the business partnership.

Our experts also had a consolidated message for virtual and smaller biopharmaceutical companies. Just as the inexperience of youth makes it hard to judge appropriate actions and timing, you need real-world experience to advance drug development projects from phase to phase. As one of the panelists said: "If there's no one in your organization experienced with CDMOs, you'll definitely want to bring expertise or a consultant in-house. If not, you'll be sending somebody out to build a dam with no engineering background. It's going to leak."

What'll leak is money and time, and at worst the chances your drug makes it to commercial success.

Therefore, experience and the ability to forge relationships with CDMOs form the ground beneath phase-appropriate decision making. Let's meet our "Fab Four" (or maybe that's "Lab Four") to see how to build on that, and then take a closer look at what goes into making scale-up decisions.

THE EXPERTS IN TIME-AND-PHASE

The Outsourced Pharma West discussion was moderated by Bikash Chatterjee, president and CSO, Pharmatech Associates, which provides consulting and services to the regulated and global life sciences industry. In a conversation with Chatterjee just prior to the conference, this comment regarding novice outsourcers stuck with me: "First of all, brace yourself for things taking *longer* than you are used to in your own labs. It's a scientific and business process working with a CDMO, so you must build that into your project timelines."

Ulrich Ernst is senior vice president for manufacturing & quality operations at Amunix, a biotech focused on the design and preclinical development of protein pharmaceuticals with extended serum half-lives. Perhaps his most memorable comment at OPW was a sports analogy.

"If you're coaching a football team, you want your first 10 plays all mapped out to march down the field and score a touchdown. It's no different in drug development. To avoid variability, you want your detailed plan set ahead of time. You really want to get to the goal line."

Patrick Murphy is vice president, manufacturing, at Versartis, Inc., an endocrine-focused biopharmaceutical company developing recombinant human growth hormones for the treatment of growth hormone deficiency. Murphy raised to a higher level the notion of understanding

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"Generally, it should be recognized there's an opportunity cost for a CDMO to accept your business."

JAMES HENSHILWOOD
Senior director, API process development and manufacturing, InterMune

your own business and management strategy when selecting a CMO.

"You need to pick a CDMO appropriate to your company philosophy," he says. "Do you want a potential commercial process put in place right at Phase I, or are you just looking for a quick Phase I acceptable process? These are definitely different. It's a conscious decision for your management team. Based on that you should select a CMO that aligns with that direction."

Last and certainly not least on our panel is James Henshilwood, senior director, API process development and manufacturing for biotech InterMune, now a wholly owned subsidiary of Roche. InterMune is focused on therapies in pulmonology and orphan fibrotic diseases.

Henshilwood is a veteran of the industry since the 1980s and has seen a number of drugs make it from discovery to commercial. He touches on a topic often left out of discussions on provider-sponsor approaches — the provider's pitch.

"Generally, it should be recognized there's an opportunity cost for a CDMO to accept your business," he says. "What are the chances of the molecule you're working on actually making it to the next stage of the market? I've always gone into a CDMO understanding what phase of the project we are in, and with the attitude that I need to pitch my company, to explain why I think it's wise for them to work with us."

We can discern another axiom from all these comments: Know thyself (and thy project). It's incumbent upon the biopharma to understand its own preferred course of advancement, methodology, goals, and overall strategy. And then go out to the outsourcing industry to find a good fit and learn more.

The OPW discussion brought into the open perhaps the biggest tension point between CDMO and project owner: the question of batch size.

TIME, PHASE … AND (BATCH) SIZE

"CMOs tell you their clients think the biggest waste of time is what can be an elaborate discussion during scale up regarding batch size," is how one OPW participant phrased it. "The sponsor says, 'You just made 10 grams, so now make this next one a 10-kilo batch.'"

If only scaling up chemistry or biology were so easy; in most cases it just is not. A small "demonstration batch" for a newly transferred project to show process robustness and control — as well as provide material — rarely becomes a strong enough jumping board to spring to a successful multikilo run at a CDMO (or anywhere). At this juncture, there are still risks and potential unknowns; even should a multikilo batch pass this (one) time, you may miss gathering crucial insight about how the process behaves, starting materials, and what might be the most appropriate equipment for production.

"We'll say, 'Maybe we should make a couple more batches in between,'" explains a representative of a CDMO. "But try discussing with a customer at this stage that we should only scale up to a one-kilo run. All the customer hears is we're somehow trying to get more money to do more batches, and we're wasting time. It's really a back-and-forth, and from this side of the business, hard to negotiate."

Moreover, should a larger scale-up encounter issues, who takes the blame and financial hit? That negotiation is even less pleasant.

On the other side, sponsors (big pharma and virtual biotech alike) may indeed have a well-developed, robust process born from thorough internal investigation (and investment of additional time and money). They naturally look askance upon the need – or logic – in additional "development work," which is what these scale-ups can amount to. "If your internal folks are capable and competent," says one of the experienced attendees, going back to the point above about in-house expertise, "wherever you're transferring a process should be a reasonable fit in the first place because you made the appropriate selection of CDMO.

"To be clear," he continues, "what you want out of this initial scale-up phase is confidence that the process is going to work in the CDMO's hands. You don't want some sideshow where the CDMO is telling you how this or that in-house technology is applicable to your project. You really don't want your process drifting during a tech transfer. I've seen that happen, and it becomes an arm wrestling contest. You really want to avoid that. If you feel confident that what you're bringing in is robust enough, and is a good enough fit, you're going to question additional work or change."

That's quite an admonition of some CDMOs. Perhaps it's not stretching a metaphor to say if the sponsor-provider relationship hasn't "scaled up" to a point of mutual trust, there could be difficulties at this and potentially each new phase that comes along. Our experts say that to a degree it can be expected some further development will enhance a process, and that is a good thing. But more importantly, the appropriate technical counterparts should be talking and helping management map out a realistic strategy for getting to a higher degree of confidence on both sides that the scaling up will work and the best path to the ultimate endpoint is taken.

Before leaving this debate and going back briefly to the specific decision for batch size, sometimes bigger is better. This is particularly true heading toward Phases 2 and 3 when the need and the *cost* for cGMP material both rise. To flip our earlier bias for "smaller is better," a best practice for sponsors is to allow the CDMO to make additional material when that opportunity makes sense.

For example, if a biotech requests a quote for three kilos, but that amount will fill up only half of the equipment train at the CDMO, it might reconsider. One of our panelists put it this way: "A better idea is to also ask for a quote for all the material to fill up the equipment train to its reasonable capacity." Maximizing output can save money on running more batches in the future, and the cost differential for running large batches per se might be pleasantly surprising. That's because most times the biggest contributor to the cost of goods is the labor or equipment time at the plant. Regarding the extra material itself, as somebody at OPW remarked, "Trust me, the additional material will get used. There's always somebody chomping at the bit for material, so they will use it. It's quite a benefit to suddenly have more material at relatively little extra cost."

cGMP AND MORE DECISIONS

Our "batch-sized drama" above has provided a clear example of time-and-phase decisions in drug development. It is one of the most crucial elements for successful project progress for small molecule and perhaps even more for the burgeoning biologics industry. Of course, the wise know there are many more examples, including the timing for production of an initial cGMP batch. Unsuccessful cGMP batches are not only costly from a financial standpoint but also create a batch history for your drug that you'd rather not have documented.

As one participant at OPW said, "The cGMP profile of product development change is dramatic and important as we go from early preclinical GLP [Good Laboratory Practices] through all the phases." Our four experts say this is an area where sponsors, particularly inexperienced companies, need that close relationship and advice with a CMO who has been through the process many times.

"Biotechs particularly should ensure they understand the fact that it is step-by-step going from research to full commercial," advises our panel. "It's key to know when to go from Phase 1 appropriate material to a Phase 2 to a Phase 3 registration. Having an internal understanding, but also with your CDMO advising you up front, is critical. If you haven't got that, then you've got an enormous problem."

At least one decision on the drug development continuum, then, seems straightforward: If you are utilizing outsourcing services, it's *always* the "time and phase" to be actively engaged with your CDMO. L

Maximizing Pharma Partnerships: Dos And Don'ts From Industry Experts

ED MISETA Executive Editor @ OutsourcedPharm

In today's life sciences industry, the most common type of partnership seems to be pharma partnering with pharma. But how do you determine if this model is right for you?

If it is, how should you then identify partners, come to an acceptable agreement, and execute the partnerships? *Life Science Leader* assembled a panel of experts at the Outsourced Pharma West Conference & Exhibition to answer those very questions. The panel consisted of Christopher Haskell, head US Science Hub, Bayer HealthCare; Brian Feth, CEO/founder, Xcell Biosciences, Inc.; Glen Sato, partner, Cooley LLP; Jaisim Shah, CEO and board director, Semnur Pharmaceuticals, Inc.; and Timothy Scott, president, Pharmatek.

PARTNERING WITH BIG PHARMA

The first question posed to the panelists centered on smaller pharma and bio companies partnering with Big Pharma. The consensus opinion seemed to be that the greatest advantage of this relationship is the credibility and validation it brings to the smaller company. "It says a lot for a large pharma company to direct money and resources into any project you might be working on," noted one panelist. In addition to the validation, Big Pharma partnerships also reduce risk for a small company, cutting the R&D burn rate and allowing the company to tap into the resources of a much larger company.

Of course, structuring these deals is all part of the negotiating process. And while Big Pharma has a lot of negotiating experience, many smaller companies may be lacking in this area. That means trust between the two sides is critical to the process, a theme that came up several times during the session. Engaging slowly, then building around the trust you develop along the way, can be an effective way of fostering a partnership.

Still, it is best to have as much knowledge as possible when entering the negotiation process. Do your homework, and talk to companies that have been through the process, especially those with expertise in your area of research. And be prepared to lose some level of control over the product once you enter into a partnership.

Finally, having a shared vision is critical. Both sides need to be ready to share both the pros and cons of the partnership and have one unified development plan moving forward. "I believe 70 to 80 percent of small companies fail because there is not open sharing of information between the companies," noted one panelist. "The pharma company will have one view, and the biotech will have another. The pharma company will present its outlook to the management team and the portfolio management. If the biotech company is looking at it in an entirely different way, that will be a problem. Having both teams call into the same portfolio review will dramatically lessen that situation and increase your chances for success."

THREE SCENARIOS – WHICH WILL YOU PURSUE?

When a small bio company approaches Big Pharma about partnering, they are generally hoping to land one of three types of partnering agreements.

1. WE NEED AN INVESTMENT OF MONEY.
2. WE NEED ACCESS TO YOUR EQUIPMENT AND SOME SPACE.
3. LET'S CODEVELOP THE PRODUCT AND USE YOUR SALES FORCE TO PROMOTE.

The scenario will determine the type of agreement put in place. The most straightforward agreement is one where an asset has been validated and is ready for licensing, and where a Big Pharma partner is needed to help develop it.

The agreements get more complicated when dealing with an earlier stage product, where there might be some potential, but there are a lot of question marks. In this case, a sponsor research agreement might be the best route.

Here again, trust enters the discussion. No one wants to spend six months on an agreement for a project that will maybe last three months. Everyone is looking out for their own self-interest, but it pays to understand both sides. Rather than ask what they can do for you, consider what it is

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that you can offer them. "You are entering into a partnership because you need money, equipment, or other resources," said one panelist. "Your partner has certain things they need. Both sides need to establish goals and make sure those goals align with each other."

BANDWIDTH IS ALWAYS IN SHORT SUPPLY

At start-up, bandwidth is about the only thing that's in shorter supply than cash. That means anyone in that start-up role has to take great care to prioritize their list of tasks. They then need to take on projects only in areas that can help build the company's credibility. Of course, that is easier said than done. The decision is made tougher when someone is giving you money to do something that may not be on your list of priorities.

Some of this talent you may need to hire at some point, but if the skillset is niche and not core to the product itself, then you're best off trying to leverage it from your partner.

MAINTAIN YOUR FREEDOM

Even if you are in a partnership that is working well and giving you the resources and support you need, one issue will still consume you: freedom. Specifically, how much freedom will you have to pursue other partnerships and explore other opportunities outside of what you are doing with your partner?

According to the panel, the answer to that question should be complete freedom. In fact, unless the pharma company is a fiduciary partner with restrictions on what you can and can't do with the technology, you should feel free to pursue any relationships you see fit. In fact, your partner should encourage you to apply your technology and skillsets to other companies as well.

According to one panelist, "From the pharma company perspective, it's even better if [the smaller company grows] but you stay connected to them. If that happens, you are growing your knowledge base as they grow theirs. But you need to recognize that, in the end, you will not own it all."

Another added, "The earlier you are in the stage of development, the more of the ownership that should reside with the innovating company. They are closer to the technology and have more of the expertise. And most Big Pharma companies would admit that their expertise lies in doing larger, Phase 2 and Phase 3, clinical trials."

Keeping more control in the hands of the innovator may also result in more doors opening. If a Big Pharma company takes the lead on a drug, they may not look at other potential uses for that drug the

same way the innovating company might. The innovator will generally know (better than the partner) what other potential uses there are for a product. If that innovating company elects to get into an outlicensing arrangement, it will be very difficult to get the drug back or have much of a say in the entire development process.

TRANSITIONING OUT OF A PARTNERING HORROR STORY

Try as you might, not all partnering agreements will go as planned. Even if you spent a considerable amount of time and effort selecting the right partner, some partnerships are just not meant to be. The session closed with the panelists discussing a deal that did not go as planned. After all, even if a drug has potential, it may simply end up not being a fit for the company you partnered with.

Oftentimes when a deal goes astray, it can be the result of a shift in the priorities of the pharma company. If the science doesn't work out or takes a lot longer than expected, the issue of prioritization will arise. The smaller innovator company can easily find itself moved from a large position in the pharma organization to a secondary position. That type of a move also can result from something as simple as a change in management or the company reshuffling its resources. Those changes can happen overnight, and when they do, the project becomes a nightmare, and getting out can be very difficult.

If that happens, you have to focus on a smooth transition out of the agreement. The last thing you want is for a severing of the partnership to affect you negatively and jeopardize your chances of striking a new partnership with a different company.

Having something in the legal agreement that addresses ownership of the data and the support you will receive during the transition period will make the process go easier. When drawing up the initial agreements, it is easy to make the mistake of looking at it only from the perspective of everything working out as planned. To play it safe, step back and look at the agreements from the perspective of nothing going as originally planned. That will help you identify areas of weakness and risk in the documents.

"Sometimes there is a silver lining there," noted one panelist in closing. "This may be a shiny new car that you invested money into, and which has value, and which has now been given back to you. You now have the ability to do something else with it. With the right partner, you can still bring the technology back and make it a success. The breakdown in one partnership may simply be the start of something new." L

Effective Scaling Strategies In Pharma

ED MISETA Executive Editor @OutsourcedPharm

You have a molecule that appears to hold potential for a disease state. You also have some funding in place, and opportunities for your start-up look promising. But several challenges still lie ahead.

You need to hire the right people to help you move forward. You need to learn how to get along with your investors. And you need to locate new partners and investors to help you develop the product and take it to market. Nothing at this stage in your company's growth is easy or inexpensive, and unfortunately, this stage often determines the success or failure of your business. A panel consisting of an entrepreneur, a consultant, and representatives of pharma met at the Outsourced Pharma West Conference and Exhibition to help attendees navigate through these issues.

Often, the first thing you have to do is decide whom you are going to hire. Whom should you select to help you execute the plan you have in place? If you will be acting as the CEO of the company, our panel recommends that you start off with a knowledgeable chief medical officer and then a qualified CFO to help you manage costs and assist with future fundraising efforts. With a technology- or science-based company, bringing on a technology person would generally be the next step. Of course, identifying the titles that need to be filled is one thing. Finding the right people to fill them is another.

HIRING THE WRONG PERSON CAN SPELL DISASTER

When you are a young and unknown start-up, convincing strangers to buy into your idea and join the company can be a challenge. It also can take a lot of time. For that reason, many CEOs hire people they know simply because they understand the skill and work ethic of people they have worked with in the past. At the same time, you cannot run out and hire every person you know.

"Hiring someone in the start-up phase is like going on one date with someone and proposing marriage," noted one panelist. "This is why it can be so efficient to hire someone you already know. One of the key attributes you are looking for is trust, and you will always have more of that in a personal connection than a total stranger. For example, if I hire a scientist, the only conversation I ever want to have with them is 'Did that work?' All I want is a yes or no answer. I don't want to walk away wondering what they meant by something they said. It erodes the relationship. If I hire someone I trust, I don't have to worry about that scenario."

Another panelist recommended hiring people that you know will work well under pressure. There is always pressure involved in working for a start-up, especially when it is relentless and coming from all sides. A lot of it will originate with your investors who want to hear where things stand and whether the project is still on track. This is another area where trust comes into play.

Always remember this is a tough business, and a lot of things can and will go wrong. All management teams will look good when things are going well. You won't find out how good your team really is until things start to hit the fan.

ALWAYS TRY TO GET ALONG

In this business, relationships are critical, as is getting along with the companies you do business with. If working with a

"It is not uncommon for investors to come up with random suggestions that are meant to be helpful, but which are often quite ridiculous."

CMO, it's important that your scientists see eye-to-eye with theirs.

One attendee noted a situation where a biotech hired a head of outsourcing who did not seem to fully understand the company's chemistry. When it came time to select a partner, instead of speaking to knowledgeable sources in the industry, he opted to hire a broker to help with the search process. "We have been negotiating with them for six months," noted the attendee. "In the meantime, we have already proved the concept and produced the molecule, and are ready to patent our work. How do you avoid these situations?"

While the panelists empathized with the situation, they did not offer much hope. "The chances the CEO will fire the guy he hired are about zero," noted one of them. "It will be left up to you to decide how you want to handle the situation."

The lesson to be learned is that much of what happens in the start-up phase — the funding, hiring, etc. — is all about relationships. If your best scientist for some reason has a falling out with your CMO, the decision to dump the scientist or the CMO is never an easy one.

"This is a small community," noted another speaker. "You never want to throw someone under the bus in order to prove you were right. There is a lot of business out there, and we will walk away from any relationship if it doesn't make sense. There has to be a comfortable fit between the two firms. If we don't have a fit, then it doesn't make sense to be involved."

USE CAUTION WHEN CHOOSING YOUR BOARD

As one panelist noted during this session, if there is money in front of you, you should take it. But if you have the luxury of being able to choose what money to take, you should also perform due diligence on the investors you're considering. Realize going in that there will be VCs who will be good to deal with and those who are not.

For a young CEO starting out in the industry, your investors and board will be important parts of your life. All of your investors and board members will expect you to spend some amount of time interacting with them. The panel recommends you find folks who will support you in the relationship.

"It is not uncommon for investors to come up with random suggestions that are meant to be helpful, but which are often quite ridiculous," noted one panelist. "Someone recently shared their solution to this problem with me, and I found it to be quite ingenious. If you go to a meeting and try to get everyone to agree with you, you will spend a lot of time arguing with them. Instead, try listening to their comments while smiling and nodding. When the person stops talking, move on to the next slide. The barrier to moving on to the next slide are the words "no" or "stop." If you don't hear those words, just let them talk, and then move on. It doesn't matter if you agree with them or not."

"I was once in a similar situation," noted another panelist. "Sometimes you get an investor who can only be described as a wild card. You don't know them, you don't necessarily trust them, and you never know what kind of crazy ideas they will present. With one, I was always wondering how we would be able to move forward with his ideas. People would agree with him because everyone wanted to get along. Afterwards, I would call up the board chair and ask if we were really going to do what was suggested. Generally, we would have a discussion and then fix the situation behind the scenes. These are issues you need to be prepared to deal with."

Preplanning for these meetings is also a big help. For example if there is a data package that you want, talk with the investors ahead of time to understand their concerns and know their perspective going in. Having that knowledge ahead of time will help you to know if you have their support or if it will be a battle. You always want your board meetings to go as smoothly as possible and with as few votes as are necessary.

Another good suggestion: If you are in a situation where you have 20 or 30 angel investors, the best thing to do is put them into an LLC. Then have one representative

"You can paralyze yourself with analysis, but it pays to spend a week doing research to ensure a new technology will work."

from that LLC report back to you. That will keep you from having to deal with all of them individually.

SOMETIMES, THINGS WILL GO WRONG

No matter how much time you put into building relationships, sometimes things will still not go as planned. The panelists were prepared to share some of their personal experiences.

"With one company I was with, we made the decision to purchase portable containment facilities to aid in a manufacturing process," noted one panelist. "We did not have a lot of money at the time, and I believe we paid around $100,000 for them. Unfortunately, they were frames with a plastic bag that just did not do what they were supposed to. Eventually, we threw them in the trash. We also wasted a lot of time and energy trying to make them work. The lesson learned from that was with a new technology, check it out thoroughly ahead of time and make sure it would actually work for the application you have in mind. You can paralyze yourself with analysis, but it pays to spend a week doing research to ensure a new technology will work."

Internal conflicts can also be a problem for CEOs to overcome. These may revolve on how you're going to sell the product, how to properly develop it, or even the technology itself. There may be an ongoing debate between the CEO, the CFO, the CSO, or someone from regulatory affairs about what you can and can't say about a product.

When you are ready to sell the company, you might also face struggles against your own team. One panelist heard stories about these kinds of situations getting so heated that the board had to fire everybody, including the CEO, and start over. Certainly not the situation the founders had in mind.

Issues might also arise when the CEO of the company is too close to the technology. "That can be a problem," added a panelist. "I've worked for CEOs who knew a great deal about the science, and some who knew nothing about it at all. There are certainly pros and cons to it. I have found it is distracting if the CEO acts like a board member who throws out ideas all the time, and then goes out and talks to the junior staff and has them do what he says. It can be a difficult conversation when you go to team members and tell them to stop doing it. On the flip side, they can be well-qualified to make complex scientific arguments about why we should be doing something. If they don't have the experience of being a CEO, they just need to know when to back off."

Finally, the panel recommends keeping in mind that the time to recoup your investment is much different in life sciences than in other industries. In technology you can start a company with a couple million, sell it in two years, and make a large profit. In this industry, the physics of science takes time. There is also an incredible regulatory burden, which one panelist noted is second only to the IRS in terms of intensity and the possibility of capricious decisions.

"This is a process that simply can't be rushed," he notes. "You can make money in biotech, but realize you will have to be patient. I tell scientists and investors that if they want to get rich, they should become an investment banker. But if they want to do something that might change the world, the biotech industry is a great place to be."

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Building Strategic Partnerships With CMOs

There has been an important evolution in the CMO awards this year, which better aligns with some of the Nice Insight research findings that regularly make their way into this column. When it comes to finding the "right" CMO, the qualities that comprise what makes the CMO the "right" one are different among the various buyers of outsourced services. Not only are unbiased peer reviews important, they are more valuable when trying to answer the question, "Does this company work well with a business like mine?"

KATE HAMMEKE
Director of Marketing Intelligence
Nice Insight

To provide better insight and help answer the above question, the CMO awards are now categorized by the five main categories of buyers of outsourced services — Big Pharma, midsize/specialty pharma, emerging, niche or start-up as well as biotechs and emerging biotechs.

The winners of the 2015 CMO Awards are now viewed from a vantage point more similar to the way drug innovators want to compare suppliers — offering which CMOs fit best with companies that have the same types of goals, challenges, preferences, and needs as their own. Interestingly, when reviewing the most important factors that influence CMO selection, there is a considerable amount of overlap among the five categories of buyers. Out of 18 qualities that influence supplier selection, there are four different attributes that continually appear at the top, with some variation in rank and between traditional pharmaceutical companies and biotechnology companies. Interestingly, only one of these traits, which appears in Big Pharma and emerging pharma's top three, is a quantifiable measure: track record/history of success.

One of the main obstacles in developing strategic relationships with suppliers is a lack of measurable traits that strategic partnerships would embody. Rather, CMO selection and the partnerships that form between drug innovators and manufacturers tend to be defined by an assortment of unquantifiable characteristics that impart a feeling rather than checklist facts. Nice Insight has also learned that within an organization, there is seldom a set of benchmark attributes for selecting a contract manufacturer. Thus, for many projects, CMO selection is undertaken tactically, despite a strong desire for a more strategic approach to both the selection process and the relationship that will come from it. Nice Insight's 2015 results show that one-third of biotechs, emerging biotechs, and Big Pharma companies are very interested in a strategic partnership with a CMO, and that one-quarter of midsize and emerging pharma companies are very interested in developing strategic relationships with manufacturing suppliers.

Considering the degree of overlap in preferred traits among the different buyer groups and their strong interest in forming strategic relationships with CMOs, one might think that if these traits are promoted in marketing materials and sales conversations, one should be able to win business from any company that needs a contract manufacturer — and then grow that business into a strategic relationship. But here is the rub: Each of these attributes can be interpreted in a variety of ways. Good communication/transparency means something different to different audiences, even when they are within the same type of organization. To some, it means daily correspondence even when there is no news; to others, good communication/transparency means clear and concise correspondence (with a plan already established and ready to implement) when there is an unforeseen challenge or setback. Which means, as a CMO, it is key to be a good listener and to ask the relevant questions in order to understand not only which attributes carry the most weight in CMO selection, but also to understand how the company you're in conversation with defines those traits. Then, adopt that definition as your own when pitching business to each specific prospect — that is, if you're confident the style of communication can be maintained throughout the relationship when the business is won.

This same approach — learning which attributes matter most to a prospect, and then taking the time to understand how that prospect defines those attributes — can be applied to any soft trait. That is, an attribute that imparts a feeling instead of being a quantifiable set of facts. As for drug innovators looking to develop more strategic relationships, it makes sense to spell it out to prospective partners with regards to exactly what you mean when you're talking about the more ambiguous metrics.

Industry Leaders by Market Segment
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Company Profiles
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CMO LEADERSHIP AWARDS 2015

THE PHILOSOPHY OF THE AWARDS

Life Science Leader's readership of pharmaceutical and biopharmaceutical executives have told us about their struggles in vetting CMO partners. In response, Life Science Leader developed the CMO Leadership Awards based on industry research conducted by Nice Insight. The awards incorporate common filters used by pharma companies to vet CMOs with the added filter of peer feedback. This helps pharma and biopharma companies focus on potential CMO partners who can handle their projects and are considered reputable in the industry.

Nice Insight combines surveying thousands of industry executives with other key analyses to serve both partnering groups, and facilitate better overall outsourcing collaborations. Since there are significant differences in how different types of companies approach outsourcing, research respondents are assigned to one of five categories: big pharma, midsize and specialty pharma, emerging pharma, biotech, and emerging biotech. Scores are assessed by each company type in five perception categories: Innovation, Productivity, Quality, Regulatory, and Reliability. Companies achieving top 10 percentile perception scores are recognized for their achievement with a 2015 CMO Leadership Award.

Unlike other industry awards that are given based on a voting or nomination process, the only votes that count towards the CMO Leadership Awards are those of the pharmaceutical and biopharmaceutical companies using CMO services.

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When Selecting Partners, Survey Respondents Ranked

QUALITY

as their Number One Priority.

RANK OF INDUSTRY DRIVERS (THERE WAS A TIE FOR FOURTH PLACE)

1 Quality
2 Reliability
3 Productivity
4 Innovation
4 Regulatory

WHAT ARE THE AWARDS?

Companies achieving top 10 percentile perception scores in the areas of Innovation, Productivity, Quality, Regulatory, and Reliability are recognized for their achievement. These categories were defined for the research participants as follows:

QUALITY AWARD Business is reputable and compliant

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Pfizer CentreSource
Pharmatek
Recipharm AB
Regis Technologies, Inc.
Rottendorf Pharma
SANDOZ GMBH
Solvias AG
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MID-SIZED/SPECIALTY PHARMA
Althea
AMPAC Fine Chemicals
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CordenPharma International
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IDT Biologika
Lonza
Novasep
Par Pharmaceutical
Pfizer CentreSource

EMERGING BIOTECH
CEPiA Sanofi
CordenPharma International
Glatt Pharmaceutical Services
GlaxoSmithKline Contract Manufacturing
Helsinn Advanced Synthesis SA
Lonza
Neuland Laboratories Limited
Recipharm AB
Rottendorf Pharma
WellSpring Pharma Services
West Pharmaceutical Services, Inc.

RELIABILITY AWARD Business will enhance in-house capabilities through a new idea, method, or device

BIG PHARMA
Avid Bioservices
CordenPharma International
Glatt Pharmaceutical Services
Pharmatek
Piramal Healthcare
Recipharm AB
Regis Technologies, Inc.
Solvias AG
Therapure Biomanufacturing
WuXi AppTec, STA Pharmaceuticals

MID-SIZED/SPECIALTY PHARMA
Capsugel
CEPiA Sanofi
CIMA Labs, Inc.
IDT Biologika
PharmaCore, Inc.
Piramal Healthcare
Recipharm AB
UPM Pharmaceuticals

EMERGING PHARMA
Ash Stevens
CMC Biologics
CPL
FUJIFILM Diosynth Biotechnologies
Helsinn Advanced Synthesis SA
IDT Australia Ltd
SAFC

BIOTECH
BioReliance
CEPiA Sanofi
CIMA Labs, Inc.
Cytovance Biologics, Inc.
DPT Laboratories
Helsinn Advanced Synthesis SA
Pfizer CentreSource
Pharmatek
SAFC
Xcelience

EMERGING BIOTECH
AMPAC Fine Chemicals
Capsugel
CEPiA Sanofi
CoreRx, Inc
Cytovance Biologics, Inc.
Johnson Matthey Pharmaceutical Materials and Services
Lonza
Recipharm AB
Xcelience

2015 Average number of services outsourced by company type (projected)

7.4

2015 Annual Outsourcing Expenditure (projected)

Less than 10 million USD per year	10 to 50 million USD per year	50+ million USD per year
16%	**62%**	**23%**

Average number of methods used to select an outsourcing partner

3

Top 3 methods used to select an outsourcing partner

1. Consultants
2. Referrals
3. Trade Show/Events

PRODUCTIVITY AWARD Business will treat the project as if it was their own

BIG PHARMA
CordenPharma International
Glatt Pharmaceutical Services
GlaxoSmithKline
Contract Manufacturing
Helsinn Advanced Synthesis SA
NextPharma
Pharmatek
SANDOZ GMBH
Siegfried AG
Solvias AG
Therapure Biomanufacturing

MID-SIZED/SPECIALTY PHARMA
Almac Group Ltd
Althea
Capsugel
CordenPharma International
CPL
IDT Biologika
Pfizer CentreSource
Regis Technologies, Inc.
Rottendorf Pharma
SAFC
UPM Pharmaceuticals

EMERGING PHARMA
Aenova
Almac Group Ltd
Althea
Ash Stevens
BioReliance
Glatt Pharmaceutical Services
IDT Australia Ltd
Kemwell Biopharma
Richter-Helm
UPM Pharmaceuticals

BIOTECH
Albemarle Corporation
CEPiA Sanofi
Cobra Biologics
Cytovance Biologics, Inc.
DPT Laboratories
Halo Pharmaceutical
Helsinn Advanced Synthesis SA
IDT Australia Ltd
Kemwell Biopharma
SAI Life Sciences Ltd
Samsung BioLogics, Co. Ltd.
Xcelience

EMERGING BIOTECH
Almac Group Ltd
CEPiA Sanofi
Cook Pharmica, LLC.
Novasep
Recipharm AB
Regis Technologies, Inc.
Samsung BioLogics, Co. Ltd.
SANDOZ GMBH
Siegfried AG
West Pharmaceutical Services, Inc.

INNOVATION AWARD Business will deliver on agreed objectives

BIG PHARMA
CordenPharma International
GlaxoSmithKline
Contract Manufacturing
Metrics Contract Services
NextPharma
Paragon Bioservices, Inc.
Pfizer CentreSource
SAI Life Sciences Ltd
Solvias AG

MID-SIZED/SPECIALTY PHARMA
Ash Stevens
Capsugel
CordenPharma International
IDT Biologika
Metrics Contract Services
Regis Technologies, Inc.
UPM Pharmaceuticals

EMERGING PHARMA
Albemarle Corporation
Althea
Ash Stevens
Avid Bioservices
Baxter BioPharma Solutions
BioReliance
CPL
Fareva
FUJIFILM Diosynth Biotechnologies
Hovione
IDT Australia Ltd
KBI Biopharma, Inc.
Kemwell Biopharma
NextPharma
Patheon
PharmaCore, Inc.
Richter-Helm
Rottendorf Pharma
SANDOZ GMBH
Siegfried AG
Xcelience

BIOTECH
Albemarle Corporation
Althea
Capsugel
CEPiA Sanofi
Cytovance Biologics, Inc.
DPT Laboratories
Helsinn Advanced Synthesis SA
IDT Australia Ltd
Pfizer CentreSource
SANDOZ GMBH
Xcelience

EMERGING BIOTECH
Almac Group Ltd
CordenPharma International
CoreRx, Inc
GlaxoSmithKline
Contract Manufacturing
Hovione
KBI Biopharma, Inc.
Lonza
Norwich Pharma Services
Recipharm AB
Samsung BioLogics, Co. Ltd.
Siegfried AG
West Pharmaceutical Services, Inc.

REGULATORY AWARD Business will meet all project milestones and timelines

BIG PHARMA
Cambrex
CPL
Cytovance Biologics, Inc.
GlaxoSmithKline
Contract Manufacturing
Metrics Contract Services
Paragon Bioservices, Inc.
Recipharm AB
SANDOZ GMBH
Solvias AG
Therapure Biomanufacturing
WellSpring Pharma Services

MID-SIZED/SPECIALTY PHARMA
Capsugel
CIMA Labs, Inc.
Coldstream Laboratories, Inc.
CordenPharma International
CoreRx, Inc
Fareva
Hovione
Metrics Contract Services
Norwich Pharma Services
PCI Synthesis
Pfizer CentreSource
Piramal Healthcare

EMERGING PHARMA
Aenova
Althea
Ash Stevens
BioReliance
CoreRx, Inc
CPL
Glatt Pharmaceutical Services
GlaxoSmithKline
Contract Manufacturing
NextPharma
Novasep
Siegfried AG
UPM Pharmaceuticals

BIOTECH
CPL
Cytovance Biologics, Inc.
Helsinn Advanced Synthesis SA
IDT Australia Ltd
Johnson Matthey Pharmaceutical Materials and Services
Kemwell Biopharma
PCI Synthesis
Pfizer CentreSource
Pharmatek
Samsung BioLogics, Co. Ltd.
SANDOZ GMBH
Xcelience

EMERGING BIOTECH
AbbVie
AMPAC Fine Chemicals
Ash Stevens
KBI Biopharma, Inc.
Kemwell Biopharma
Lonza
Novasep
Recipharm AB
Rottendorf Pharma
Siegfried AG
West Pharmaceutical Services, Inc.

CATEGORIES WON

AbbVie

North Chicago, IL
www.abbviecontractmfg.com

+1 847 938 8524
Michelle Calhoun
michelle.calhoun@abbvie.com
Key locations: Barceloneta, Puerto Rico; Campoverde, Italy; Cork, Ireland; Lake County, IL, U.S.A.; Ludwigshafen, Germany; Sligo, Ireland

DRUG TYPE:
Pharmaceuticals, Biopharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Clinical (Phase 1, Phase 2, Phase 3)
Drug Substance Production: Primary Process Development, Drug Substance Production,
Formulated Drug Production: Dosage Form Development, Dosage Form Production, Packaging, Logistics

SERVICES & CAPABILITIES: aseptic fill/finish, capsules, controlled substances, creams & ointments, cytotoxic & high potency compounds, gels, injectables, liquids, non-sterile, OTC, parenterals (large volume), parenterals (small volume), peptides, powders (non-sterile), powders (sterile), proteins, semisolids, soft gels, solid dose, solutions & suspensions, sterile, sustained release, syringes (prefilled), topicals, vaccines

KEITH KENTALA
vice president, commercial operations

"AbbVie takes great pride in once again being honored by *Life Science Leader* with a CMO Leadership Award. This recognition is a testament of our commitment in making a remarkable impact on patients' lives and to the business partners we serve."

CATEGORIES WON

Albemarle Corporation

Baton Rouge, LA
www.albemarle.com/FCS

+1 225 388 8011
Estela Falla
estela.falla@albemarle.com
Key locations: South Haven, MI; Tyrone, PA; Baton Rouge, LA

DRUG TYPE:
Pharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Preclinical, Clinical (Phase 1, Phase 2, Phase 3)
Drug Substance Production: Primary Process Development, Drug Substance Production

SERVICES & CAPABILITIES: generics, injectables, non-sterile

KURT HOEPRICH
global business manager, pharmaceuticals

"Albemarle Fine Chemistry Services division is pleased to accept these CMO Leadership Awards and honored to be globally recognized for our strong performance and expertise in innovation and productivity. This recognition speaks volumes about the exceptional people at all of our manufacturing sites and our process development and technical capabilities. Albemarle FCS is dedicated to providing high quality products and solutions across global markets to satisfy all of our customers' needs."

CATEGORIES WON

Almac Group Ltd

Craigavon, Co. Armagh, United Kingdom
www.almacgroup.com

+02 838 332 200
Kerry Lyle
kerry.lyle@almacgroup.com
Key locations: Craigavon, Northern Ireland, UK; Durham, NC, and Souderton, PA, U.S.A.; Singapore; Edinburgh, UK

DRUG TYPE:
Pharmaceuticals, Biopharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Discovery, Preclinical, Clinical (Phase 1, Phase 2, Phase 3)
Drug Substance Production: Drug Substance Production
Formulated Drug Production: Dosage Form Development, Dosage Form Production, Packaging, Logistics

SERVICES & CAPABILITIES: aseptic fill/finish, capsules, cytotoxic & high potency compounds, generics, lyophilized products, non-sterile, OTC, peptides, proteins, soft gels, solid dose, sustained release, vaccines

ALAN ARMSTRONG
CEO

"We are delighted to be selected as a winner of this year's CMO Leadership Awards in both the productivity and innovation categories. This is a true reflection of our on-going commitment to deliver a quality service to our global client base through implementing innovative solutions."

ALTHEA
A MEMBER OF THE AJINOMOTO GROUP

CATEGORIES WON

Althea

San Diego, CA
www.AltheaCMO.com

+ 1 858 882 0123
Eric Deneroff
Eric.Deneroff@altheacmo.com
Key locations: San Diego, CA

DRUG TYPE:
Pharmaceuticals, Biopharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Preclinical, Clinical (Phase 1, Phase 2, Phase 3)
Drug Substance Production: Drug Substance Production
Formulated Drug Production: Dosage Form Production, Packaging

SERVICES & CAPABILITIES: aseptic fill/finish, injectables, liquids, lyophilized products, parenterals (large volume) parenterals (small volume), proteins, solutions & suspensions, sterile, syringes (prefilled), vaccines

DAVID ENLOE
president & CEO

"We were very pleased to have again been recognized by those companies we serve as a leader in the CMO space. This award not only acknowledges our strong regulatory track record through commercialization but also for the scientific innovation we provide clients with our Crystalomics® and Corynex® platforms. Althea takes pride in sharing our client's same unwavering tenacity and dedication towards each project - from clinical testing through commercial success. Thank you for this award."

AMPAC™ FINE CHEMICALS

CATEGORIES WON

AMPAC Fine Chemicals

Rancho Cordova, CA
www.ampacfinechemicals.com

+1 916 357 6880
Patrick Park
AFCbusdev@apfc.com
Key locations: La Porte, TX; Rancho Cordova, CA

DRUG TYPE:
Pharmaceuticals, Biopharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Clinical (Phase 1, Phase 2, Phase 3)
Drug Substance Production: Drug Substance Production

SERVICES & CAPABILITIES: controlled substances, cytotoxic & high potency compounds, generics, injectables, liquids, lyophilized products, non-sterile, ophthalmics, parenterals (large volume), parenterals (small volume), peptides, powders (non-sterile), powders (sterile), proteins, semisolids, soft gels, solid dose, solutions & suspensions

ASLAM MALIK
president

"AMPAC Fine Chemicals (AFC) has established a heritage of successful transition from clinical to commercial production, demanding production quantity and highly energetic APIs. AFC is a recognized partner supporting FDA Pre Approval Inspections for complex drug formulations, commercial drug products, controlled substances, high potency, and energetic compounds. AFC has an aggressive growth program focused on medium scale production quickly configured for specific programs as well as large-scale capacity for major batch and continuous operations."

aptuit

CATEGORIES WON

Aptuit LLC

Greenwich, CO
www.aptuit.com

+39 0458 219 333 or +1 855 506 6360
Paul Overton
paul.overton@aptuit.com
Key locations: Oxford, UK; Verona, Italy

DRUG TYPE:
Pharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Discovery, Preclinical, Clinical (Phase 1, Phase 2)
Drug Substance Production: Primary Process Development, Drug Substance Production
Formulated Drug Production: Dosage Form Development, Dosage Form Production, Packaging

SERVICES & CAPABILITIES: capsules, cytotoxic & high potency compounds, generics, liquids, lyophilized products, non-sterile, OTC, peptides, powders (non-sterile), solid dose, solutions & suspensions, sustained release

JONATHAN GOLDMAN
CEO

"Our customers use quality as a comparative element to select and retain their service providers and it differentiates companies on the market place. This award is the result of a company-wide quality improvement initiative that initiated years ago and was further enhanced during 2014. All "quality teams" across the company must work as a seamless organization to address quality best practices and standards on a site-wide model, where KPIs are identified and measured through global metrics."

Ash Stevens

CATEGORIES WON

Ash Stevens

Riverview, MI
www.ashstevens.com

+1 734 282 3370
James Hamby
jhamby@ashstevens.com
Key locations: Detroit and Riverview, MI

DRUG TYPE:
Pharmaceuticals, Biopharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Discovery, Preclinical, Clinical (Phase 1, Phase 2, Phase 3)
Drug Substance Production: Primary Process Development, Drug Substance Production

SERVICES & CAPABILITIES: process development and scale-up; API for toxicology studies, clinical trials, and post-approval manufacturing; cGMP manufacture of Highly Potent Active Pharmaceutical Ingredients (HPAPIs); comprehensive analytical support including methods development and validation; regulatory compliance & quality assurance support: filing support for Investigational New Drug; applications (INDs), New Drug Applications (NDAs) and Drug Master Files (DMF).

STEPHEN MUNK
CEO

"Recognition in all five categories by *Life Science Leader* and Nice Insight is a testament to the Ash Stevens team. It is their steadfast commitment to our customers' unique drug programs that makes being ranked in the top 10% of CMO's worldwide an absolute honor for us all. Acknowledgement by large pharma and emerging biotech alike is an affirmation of our level of engagement with customers and our top quality science."

Avid Bioservices

CATEGORIES WON

Avid Bioservices

Tustin, CA
www.avidbio.com

+1 714 508 6100
Jon Gingrich
jgingrich@avidbio.com
Key locations: Tustin, CA

DRUG TYPE:
Biopharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Clinical (Phase 1, Phase 2, Phase 3)
Drug Substance Production: Primary Process Development, Drug Substance Production

SERVICES & CAPABILITIES: aseptic fill/finish, injectables, liquids, parenterals (small volume), proteins, vaccines, cell line development and optimization, cell culture and feed optimization, analytical methods development and product characterization, clinical and commercial product manufacturing, purification, bulk packaging, final product filling, stability testing and regulatory strategy, submission, support

STEVEN KING
president & CEO

"At Avid, our goal is to be a strategic partner for our clients through every stage of product development. We do this by helping our clients meet tight timelines and providing consistent high quality GMP manufacturing services using our knowledge and expertise, that allows them to advance seamlessly from early clinical development through commercialization. We are dedicated to our clients' success and take great pride helping bring important biologics to the patients who need them."

Baxter

CATEGORIES WON

Baxter BioPharma Solutions

Deerfield, IL
www.baxterbiopharmasolutions.com

+1 800 422 9837 or + 1 224 948 1812
Donna Abear
biopharmasolutions@baxter.com
Key locations: Bloomington, IN, and Round Lake, IL, U.S.A.; Halle (Westfalen), Germany

DRUG TYPE:
Pharmaceuticals, Biopharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Clinical (Phase 1, Phase 2, Phase 3)
Formulated Drug Production: Dosage Form Development, Dosage Form Production, Packaging

SERVICES & CAPABILITIES: ADCs (antibody drug conjugates), aseptic fill/finish, cartridges, cytotoxic & high potency compounds, emulsions, generics, injectables, liquids, liposomes, lyophilized products, nano-suspension, parenterals (large volume) parenterals (small volume), powders (sterile), proteins, solutions & suspensions, sterile, sterile crystalization and ampoules, syringes (prefilled), vaccines

Burkhard Wichert
vice president, manufacturing

"In 2013, Baxter's BioPharma Solutions business announced a third expansion of their contract manufacturing facility in Halle, Germany to meet clients' growing needs for cytotoxic manufacturing. Cancer incidence is on the rise and cytotoxic therapies continue to be at the center of oncology treatment programs. Through this expansion and our advanced technologies, we will continue to support pharmaceutical companies' efforts to address patient needs worldwide. We believe in our customers and the patients they serve."

BioReliance® by SAFC

CATEGORIES WON

BioReliance

Rockland, MD
www.bioreliance.com

+1 301 738 1000
Mike Garrett
mike.garrett@bioreliance.com
Key locations: Glasgow, Scotland; Mumbai, India; Rockville, MD, U.S.A.; Stirling, Scotland; Tokyo, Japan

DRUG TYPE:
Biopharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Discovery, Preclinical, Clinical (Phase 1, Phase 2, Phase 3)

SERVICES & CAPABILITIES: liquids, parenterals (small volume), proteins, sterile, vaccines

ARCHIE CULLEN
president

"Our team is pleased to receive these CMO Leadership Awards. We aim to provide our customers with critical data and solutions that contribute to their success and constantly seek a deeper understanding of their needs for the highest quality, on-time testing services and solutions. It is rewarding to see our scientific and regulatory leadership being recognized by the industry. Thank you for this recognition and for relying on us to help make your medicines safer."

CAMBREX

CATEGORIES WON

Cambrex

East Rutherford, NJ
www.cambrex.com

+1 201 804 3000
Stephan Haitz
stephan.haitz@cambrex.com
Key locations: Charles City, IA, U.S.A.; Karlskoga, Sweden; Paullo (Milan), Italy; Hyderabad, India

DRUG TYPE:
Pharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Clinical (Phase 2, Phase 3), Drug Substance Production
Drug Substance Production: Primary Process Development, Drug Substance Production
Formulated Drug Production: Dosage Form Development, Dosage Form Production, Packaging

SERVICES & CAPABILITIES: controlled substances, contract manufacturing, custom development, cytotoxic & high potency compounds, generics, non-sterile, solid dose, sustained release

STEVEN KLOSK
president & CEO

"Year after year, Cambrex focuses on maintaining superior operational excellence at all our sites worldwide. Our customers continue to tell us that our excellent quality systems and regulatory record are the key reasons they choose to work with us. They know that their project will have long-term success with Cambrex. Our commitment to health, safety, innovation, and continuous improvement ensures that Cambrex will be successful, while providing peace of mind for our customers."

CAPSUGEL®

CATEGORIES WON

Capsugel

Morristown, NJ
www.capsugel.com

+1 862 242 1700
Gary Benedict
gary.benedict@capsugel.com
Key locations: Bend, OR, and Greenwood, SC, U.S.A; Delhi, India; Edinburgh, UK; Ploermel, France; Sagamirhara, Japan

DRUG TYPE:
Pharmaceuticals, Biopharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Preclinical, Clinical (Phase 1, Phase 2, Phase 3)
Drug Substance Production: Primary Process Development
Formulated Drug Production: Dosage Form Development, Dosage Form Production, Packaging, Logistics

SERVICES & CAPABILITIES: abuse deterrence, bioavailability enhancement, capsules, controlled substances, cytotoxic & high potency compounds, delayed and targeted release, generics, inhaled inhalation formulations, liquid-fill hard capsule, OTC, peptides, powders (non-sterile), powders (sterile), proteins, semisolids, soft gels, solid dose, solutions & suspensions, sustained release, vaccines

AMIT PATEL
president

"Each of us at Capsugel Dosage Form Solutions strives to create exceptional value for – and earn the trust of – our customers every day. Based on world class science and engineering, our technology breadth and formulation expertise enables Capsugel product development teams to identify and employ the optimal technology for any problem statement. Our integrated business model allows us to design, develop, scale up, and commercially manufacture innovative dosage forms in any market presentation."

CATEGORIES WON

CEPiA Sanofi

Antony, France
www.cepia-sanofi.com

+ 33 1 55 71 42 82
Pierre Bay
pierre.bay@sanofi.com
Key locations: Agnani, Italy; Ambares, Aramon Tours, and Vertolaye, France; St. Louis, MO, U.S.A.; Ujpest, Hungary

DRUG TYPE:
Pharmaceuticals, Biopharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Clinical (Phase 1, Phase 2, Phase 3)
Drug Substance Production: Primary Process Development, Drug Substance Production
Formulated Drug Production: Dosage Form Development, Dosage Form Production, Packaging, Logistics

SERVICES & CAPABILITIES: an integrated offer from API to DP (one stop shop), analytical method development & validation, API & intermediates catalogue, aseptic fill/finish, capsules, cartridges, chemical/biotech process development & production, controlled substances, creams & ointments, cytotoxic & high potency compounds, gels, generics, injectables, liquids, lyophilized products, non-sterile, ophthalmics, OTC, parenterals (large volume), parenterals (small volume), peptides, powders (non-sterile), powders (sterile), proteins, semisolids, soft gel, solid dose, solutions & suspensions, sterile, sustained release, syringes (prefilled), technical transfer, topicals

JACQUES TAVERNIER
vice president

"We are very proud to be recognized by pharmaceutical and biopharmaceutical leaders throughout the industry as leading CMO. CEPiA-Sanofi is honored to receive CMO Leadership Awards in 4 categories and by different industry sectors. It reflects our wide and complete offer named "ONE-STOP-SHOP". We take this as confirmation that we are committed to continuous improvement to provide our customers a broad range of innovative solutions reinforcing access to healthcare and demonstrating the hard work of our employees."

CATEGORIES WON

CIMA Labs, Inc.

Woodcliff Lake, NJ
www.tapi.com

+1 201 307 6900
Henit Lapid
henit.lapid@tevapharm.com
Key locations: Minneapolis, MN; Salt Lake City, UT

DRUG TYPE:
Pharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Clinical (Phase 1, Phase 2)
Formulated Drug Production: Dosage Form Development, Dosage Form Production, Packaging, Logistics

SERVICES & CAPABILITIES: capsules, soft gels, solid dose

KERRI WOOD
president

"Our partners trust CIMA. We have a successful track record developing and commercializing products. Discovering a new chemical entity (NCE) or creating a new product profile for an existing drug is a huge first step, but it's not the final step. CIMA is a drug delivery partner you can trust to get your products to market quickly and successfully, and once the product is in market, we have the proven ability to meet commercial demand."

CATEGORIES WON

CMC Biologics

Bothell, WA
www.cmcbiologics.com

+1 425 415 5438
Stacie Byars
sbyars@cmcbio.com
Key locations: Berkeley, CA, and Bothell, WA, U.S.A.; Soeborg, Copenhagen, Denmark

DRUG TYPE:
Biopharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Clinical (Phase 1, Phase 2, Phase 3)
Drug Substance Production: Primary Process Development, Drug Substance Production
Formulated Drug Production: Dosage Form Development, Dosage Form Production

SERVICES & CAPABILITIES: lyophilized products, proteins, clinical and commercial GMP development, manufacture of therapeutic proteins

GUSTAVO MAHLER
global chief operations officer

"The CMC Biologics' team is honored to receive this prestigious award as recognition from our customers and the industry as a whole. Our goal is to provide our customers with the highest standards of quality and reliability – the foundation of clinical and commercial success. We are committed to continuous innovation of our facilities and to growing and supporting our most critical asset – our people – to advance biopharmaceutical manufacturing to the next level."

CATEGORIES WON

Cobra Biologics

Keele, Staffordshire, United Kingdom
www.cobrabio.com

+44 1782 714181
Jason Rahal
sales@cobrabio.com
Key locations: Keele, UK; Matfors, Sweden; Sodertalje, Sweden

DRUG TYPE:
Biopharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Discovery, Preclinical, Clinical (Phase 1, Phase 2, Phase 3)
Drug Substance Production: Primary Process Development, Drug Substance Production

SERVICES & CAPABILITIES: aseptic fill/finish, injectables, lyophilized products, non-sterile, peptides, proteins, sterile, syringes (prefilled), vaccines

PETER COLEMAN
CEO

"Cobra has been manufacturing plasmid therapeutics and DNA vaccines for more than 16 years. Our DNA platform process is based on Cobra's pioneering heritage in gene therapy manufacturing and technology development. Cobra's experienced and expert team have a strong track record for producing non-GMP, high quality, and GMP plasmid DNA for preclinical, clinical, and commercial supply, operating efficiently and consistently. Cobra's DNA programs have full regulatory support from a dedicated Quality Assurance (QA) team."

CATEGORIES WON

Coldstream Laboratories, Inc.

Lexington, KY
www.coldstreamlabs.com

+1 859 977 8600
Christopher Verbicky, Ph.D.
customerservice@coldstreamlabs.com
Key locations: Lexington, KY

DRUG TYPE:
Pharmaceuticals, Biopharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Preclinical, Clinical (Phase 1, Phase 2, Phase 3)
Formulated Drug Product: Dosage Form Development, Dosage Form Production

SERVICES & CAPABILITIES: aseptic fill/finish, cytotoxic & high potency compounds, generics, injectables, liquids, lyophilized products, parenterals (small volume), peptides, solutions & suspensions, sterile

ERIC SMART
president & CEO

"Coldstream Laboratories, a Piramal Enterprises business, focuses on quality and innovation to ensure exceptional service for our partners. Delivering creative solutions and skillful manufacturing using mobile isolator technology is central to our business. We are growing the Coldstream facility to include a second filling line to accommodate a wider range of products and larger batch sizes. Our integration with the existing Piramal sites leverages our strength for the formulation/fill/finish of ADCs and commercial sterile injectables."

CATEGORIES WON

Cook Pharmica, LLC.

Bloomington, IN
www.cookpharmica.com

+1 877 312 2665
Cory Lewis
cory.lewis@cookpharmica.com
Key locations: Bloomington, IN

DRUG TYPE:
Pharmaceuticals, Biopharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Preclinical, Clinical (Phase 1, Phase 2, Phase 3)
Drug Substance Production: Primary Process Development, Drug Substance Production
Formulated Drug Production: Dosage Form Development, Dosage Form Production, Packaging

SERVICES & CAPABILITIES: aseptic fill/finish, cartridges, cell culture manufacturing, generics, injectables, liquids, lyophilized products, parenterals (large volume), parenterals (small volume), peptides, proteins, solutions & suspensions, sterile, syringes (prefilled), vaccines

Tedd Green
president

"Cook Pharmica is delighted to once again be recognized by the industry through the CMO Leadership Awards. Our continued focus on delivering quality products in a timely manner is integral to our service offering and very important to our customers and their patients. Our focus on being a flexible and reliable partner has proven to be a differentiator and has helped make us the CMO of choice for the biopharmaceutical clients that we serve."

CATEGORIES WON

CordenPharma International

Plankdstadt, Germany
www.cordenpharma.com

+49 6202 99 2299 or +1 800 868 8208
Michael Quirmbach
sales@cordenpharma.com
Key locations: Caponago, Latina, Italy; Colorado, U.S.A.; Peptisyntha, Belgium; Plankstadt, Germany; Switzerland

DRUG TYPE:
Pharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Clinical (Phase 1, Phase 2, Phase 3)
Drug Substance Production: Primary Process Development, Drug Substance Production
Formulated Drug Production: Dosage Form Development, Dosage Form Production, Packaging, Logistics

SERVICES & CAPABILITIES: aseptic fill/finish, capsules, cartridges, cytotoxic & high potency compounds, generics, injectables, liquids, lyophilized products, parenterals (large volume), parenterals (small volume), peptides, powders (sterile), proteins, solid dose, solutions & suspensions, sterile, sustained release, syringes (prefilled)

ERNESTO PETROSELLI
president

"We are honored to receive this year's Life Science Leader CMO Leadership Awards in nine categories/sectors. Since its establishment in 2006, CordenPharma has been driven by innovation and the highest quality standards to become a full-service CDMO partner to the global pharmaceutical industry. This award from our customers confirms our continuing commitment to expand upon existing capabilities in order to provide reliable, cost-effective, integrated solutions for their complete contract development and manufacturing needs."

CATEGORIES WON

CoreRx, Inc

Clearwater, FL
www.corerxpharma.com

+1 727 259 6950
Jenna Bullard
jenna.bullard@corerxpharma.com
Key locations: Clearwater, FL

DRUG TYPE:
Pharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Discovery, Prelinical, Clinical (Phase 1, Phase 2, Phase 3)
Formulated Drug Product: Dosage Form Development, Dosage Form Production, Packaging

SERVICES & CAPABILITIES: capsules, controlled substances, creams & ointments, gels, generics, injectables, liquids, lyophilized products, non-sterile, powders (non-sterile), solid dose, solutions & suspensions, sustained release, syringes (prefilled), topicals, vaccines

TODD R. DAVIAU, PH.D., MBA
president & CEO

"We at CoreRx are delighted and honored to once again be recognized with top rankings in regulatory, innovation, and reliability by *Life Science Leader*. It's a pleasure to know that CoreRx continues to establish itself as the solution-oriented CDMO of choice for the pharma industry. Our commitment to quality, productivity, and our willingness to focus on the customer are three essential areas of our business, which are fundamental to our clients who trust in CoreRx to meet their formulation and manufacturing needs."

CATEGORIES WON

CPL

Mississauga, ON, Canada
www.cplltd.com

+1 905 821 7600
David Tyler
dtyler@cplltd.com
Key locations: Mississauga, ON, Canada

DRUG TYPE:
Pharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Preclinical, Clinical (Phase 1, Phase 2, Phase 3)
Formulated Drug Production: Dosage Form Development, Dosage Form Production, Packaging

SERVICES & CAPABILITIES: controlled substances, creams & ointments, gels, generics, liquids, non-sterile, OTC, semisolids, solutions & suspensions, topicals

KEN PAIGE
CEO

"CPL is honored to be a multiple CMO Leadership Awards winner. CPL is focused on being the best CDMO and has built a successful company based on our core values of integrity, respect, trust, and fairness. We've created a company where our employees want to do their best, and they deliver outstanding service and results. Our customers trust us to do the right things consistently, and we've formed long-term relationships by delivering on that promise."

CATEGORIES WON

Cytovance Biologics, Inc.

Oklahoma City, OK
www.cytovance.com

+1 405 319 8310
Valerie McDonnell
vmcdonnell@cytovance.com
Key locations: Oklahoma City, OK

DRUG TYPE:
Biopharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Preclinical, Clinical (Phase 1, Phase 2, Phase 3)
Drug Substance Production: Primary Process Development, Drug Substance Production

SERVICES & CAPABILITIES: aseptic fill/finish, injectables, liquids, parenterals (large volume), proteins, sterile, vaccines, specialty suites for processing transgenic, and other specialty processes

DARREN HEAD
CEO

"Cytovance Biologics is proud to be recognized for the CMO Leadership Award. We take pride in being a value-added partner with our clients in providing integral pathways of converting today's novel protein discoveries into future lifesaving therapies. This award is possible thanks to our highly experienced employees who consistently demonstrate commitment to quality, productivity, and innovation. We accept this award as testament to the dedication and hard work of many within our remarkable company."

CATEGORIES WON

DPT Laboratories

San Antonio, TX
www.DPTLabs.com

+1 866 CALL DPT or +1 866 225 5378
Paul Josephs
paul.josephs@dptlabs.com
Key locations: Lakewood, NJ; San Antonio, TX

DRUG TYPE:
Pharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Preclinical, Clinical (Phase 1, Phase 2, Phase 3)
Drug Substance Production: Primary Process Development
Formulated Drug Production: Dosage Form Development, Dosage Form Production

SERVICES & CAPABILITIES: aseptic fill/finish, capsules, controlled substances, creams & ointments, gels, generics, injectables, liquids, non-sterile, ophthalmics, OTC, parenterals (small volume), semisolids, soft gels, solid dose, solutions & suspensions, sterile, topicals

PAUL JOHNSON
president & CEO

CATEGORIES WON

Dr. Reddy's Custom Pharmaceutical Services (CPS)

Princeton, NJ
www.drreddys-cps.com

+1 609 375 9900
Jerry Whelan
gwhelan@drreddys.com
Key locations: India, Mexico, UK, U.S.A.

DRUG TYPE:
Pharmaceuticals, Biopharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Preclinical, Clinical (Phase 1, Phase 2, Phase 3)
Drug Substance Production: Primary Process Development, Drug Substance Production
Formulated Drug Production: Dosage Form Development, Dosage Form Production

SERVICES & CAPABILITIES: capsules, controlled substances, cytotoxic & high potency compounds, generics, injectables, lyophilized products, parenterals (large volume), parenterals (small volume), peptides, solid dose, sustained release, syringes (prefilled)

ANURAG ROY
global business head, CPS

"We are proud to be selected by our customers for our outstanding quality. The award already describes why we were ranked in this category: We treat each customer project as if it were our own. It rewards the team of Dr. Reddy's CPS for its consistent work on building strong partnerships with our customers by delivering rapid, innovative, and cost-efficient results across the entire product life cycle from APIs to final dosage forms."

CATEGORIES WON

FUJIFILM Diosynth Biotechnologies

Morrisville, NC
www.fujifilmdiosynth.com

+ 1 919 337 4400
Jozef Orpiszewski
jozef.orpiszewski@fujifilmdb.com
Key locations: Billingham, UK; College Station, TX, U.S.A.

DRUG TYPE:
Biopharmaceuticals

DRUG LIFE CYCLE STAGES:
Research and Development: Preclinical, Clinical, (Phase1, Phase 2, Phase 3)
Drug Substance Production: Primary Process Development, Drug Substance Production

SERVICES & CAPABILITIES: non-sterile, proteins, vaccines

STEVE BAGSHAW
CEO

"We are once again honored to be recognized by the industry in the CMO Leadership Awards. Innovation is at the heart of our organization in the quest to help our clients bring their medicines to market efficiently and reliably. To receive this acknowledgment by the CMO Leadership Awards is a testament to the hard work of not just our scientists but everyone across the organization."

CATEGORIES WON

GlaxoSmithKline Contract Manufacturing

Brentford, Middlesex, UK
www.gsk.com

Russell Harris
russell.b.harris@gsk.com
Key locations: Australia, China, Europe, Japan, Middle East, North America, South America

DRUG TYPE:
Pharmaceuticals, Biopharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Clinical (Phase 2, Phase 3)
Drug Substance Production: Primary Process Development, Drug Substance Production
Formulated Drug Product: Dosage Form Development, Dosage Form Production, Packaging, Logistics

SERVICES & CAPABILITIES: aseptic fill/finish, capsules, controlled substances, creams & ointments, cytotoxic & high potency compounds, foams, gels, generics, injectables, liquids, lyophilized products, non-sterile, ophthalmics, OTC, parenterals (large volume), parenterals (small volume), peptides, powders (sterile), proteins, semisolids, solid dose, solutions & suspensions, sterile, sustained release, syringes (prefilled), topicals

RUSSELL HARRIS
director, business development and third party sales

"Once again, we are thrilled to be recognized as a company that offers a sustainable, robust value proposition in the field of contract manufacturing. But more importantly, we are delighted to be offering patients access to our best-in-class integrated supply chains and development capabilities. We look forward to another successful year."

CATEGORIES WON

Halo Pharmaceutical

Whippany, NJ
www.halopharma.com

+1 973 428 4000
Sally Langa
services@halopharma.com
Key locations: Mirabel, Quebec, Canada; Whippany, NJ, U.S.A.

DRUG TYPE:
Pharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Preclinical, Clinical (Phase 1, Phase 2, Phase 3)
Formulated Drug Production: Dosage Form Development, Dosage Form Production, Packaging

SERVICES & CAPABILITIES: capsules, controlled substances, creams & ointments, gels, liquids, non-sterile, ophthalmics, semisolids, solutions & suspensions, sustained release, topicals

HELSINN
Building quality cancer care together

CATEGORIES WON

Helsinn Advanced Synthesis SA

Biasca, Switzerland
www.helsinn.com

+41 91 873 94 00
Sandra Moro
Sandra.Moro@Helsinn.com
Key locations: Biasca, Switzerland

DRUG TYPE:
Pharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Clinical (Phase 1, Phase 2, Phase 3)
Drug Substance Production: Primary Process Development, Drug Substance Production

WALDO MOSSI
general manager

"Helsinn is honored to receive this award covering eight important client-partnering categories. We believe this is a reflection of our continued efforts in quality management and our ability to deliver high quality products and services together with our partners. This award represents a crowning achievement for Helsinn Manufacturing and our 30-year history in pharmaceutical bulk drug manufacturing."

Hovione

CATEGORIES WON

Hovione

Loures, Portugal
www.hovione.com

+351 21 9829362
Antonio Dinis
adinis@hovione.com
Key locations: Cork, Ireland; Loures, Portugal; New Jersey, U.S.A.; Taipa, Macau

DRUG TYPE:
Pharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Clinical (Phase 1, Phase 2, Phase 3)
Drug Substance Production: Primary Process Development, Drug Substance Production
Formulated Drug Production: Dosage Form Development

SERVICES & CAPABILITIES: cytotoxic & high potency compounds, dry powder inhalers devices, generics, hot melt extrusion, inhalation formulation, particle engineering, powders (non-sterile), spray drying

GUY VILLAX
CEO

"We have a quality culture that puts patient safety first. This shapes our behaviors and motivates us to improve and innovate. Our values read: *We are Principled Think Differently and Deliver.* Everything we do is about aligning ourselves with our customers' goals, and we passionately turn any challenge into a solution by working as a team. These awards reward a great team effort. Hovione people are amazing, and we're *In It For Life!*"

idt australia limited

CATEGORIES WON

IDT Australia Ltd

Boronia, Victoria, Australia
www.idtaus.com.au

+61398018888
Mark Rowlands
mrowlands@idtaus.com.au
Key locations: Adelaide, Australia; Melbourne, Australia

DRUG TYPE:
Pharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Preclinical, Clinical (Phase 1, Phase 2, Phase 3)
Drug Substance Production: Primary Process Development, Drug Substance Production
Formulated Drug Production: Dosage Form Development, Dosage Form Production

SERVICES & CAPABILITIES: aseptic fill/finish, capsules, controlled substances, cytotoxic & high potency compounds, generics, injectables, liquids, lyophilized products, non-sterile, solid dose, solutions & suspensions, sterile, sustained release, dedicated beta-lactam antibiotic API R&D and commercial manufacturing facility

PAUL MACLEMAN
managing director

"IDT helps companies fast-track products from early API synthesis and dosage form development & manufacture through to clinical trials. By accessing the Australian R&D Tax Incentive and Clinical Trial Notification programs, our customers can speed their product into clinical trials faster and access up to a 43.5% cash rebate on their R&D spend. We help our customers to reach their milestones quicker and to achieve more with their development funding."

CATEGORIES WON

IDT Biologika

Dessau, Germany
www.idt-biologika.com

+49 34901 885 0
Gregor Kawaletz
gregor.kawaletz@idt-biologika.de
Key locations: Dessau, Riems-Greifswald, Germany

DRUG TYPE:
Pharmaceuticals, Biopharmaceuticals

DRUG LIFE CYCLE STAGES:
Drug Substance Production: Drug Substance Production
Formulated Drug Production: Dosage Form Development, Dosage Form Production, Packaging, Logistics

SERVICES & CAPABILITIES: aseptic fill/finish, liquids, lyophilized products, sterile, vaccines

RALF PFIRMANN
CEO

"Everyone at IDT Biologika anticipates the changing requirements of the biopharmaceutical industry. Working with our principal owner, the Klocke Group, IDT Biologika reinvested in technical talent, infrastructure, and the management system to better serve our partners. We appreciate that *Life Science Leader* has recognized our recent advances in innovation, reliability, productivity, and quality. Speaking on behalf IDT Biologika, we look forward to producing the highest quality products for all our partners around the globe."

CATEGORIES WON

Johnson Matthey Pharmaceutical Materials and Services

Devens, MA
www.jmpharmaservices.com

+1 978 784 5000
Garrett Dilley
garrett.dilley@jmusa.com
Key locations: Annan, Scotland; Conshohoken, PA, Devens, MA, North Andover, MA, West Deptford, NJ, U.S.A.; Yantai, China

DRUG TYPE:
Pharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Preclinical, Clinical (Phase 1, Phase 2, Phase 3)
Drug Substance Production: Primary Process Development, Drug Substance Production

SERVICES & CAPABILITIES: controlled substances, cytotoxic & high potency compounds, generics, non-sterile, parenterals (large volume), parenterals (small volume), peptides, powders (non-sterile)

BERNHARD PAUL
general manager

"We are honored to be recognized with the CMO Leadership Awards for reliability and regulatory track record. This is a testament to our culture of continuous improvement, customer focus, and our commitment to quality. Our team at Johnson Matthey Pharmaceutical Materials and Services focuses on creating value for our customers and providing them with the highest quality products and services."

CATEGORIES WON

KBI Biopharma, Inc.

Durham, NC
www.kbibiopharma.com

+1 919 479 9898
Prathima Acharya
pacharya@kbibiopharma.com
Key locations:Boulder, CO; Durham, NC; Research Triangle Park, NC

DRUG TYPE:
Pharmaceuticals, Biopharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Discovery, Preclinical, Clinical (Phase 1, Phase 2, Phase 3)
Drug Substance Production: Primary Process Development, Drug Substance Production
Formulated Drug Production: Dosage Form Development

SERVICES & CAPABILITIES: bulk drug substance manufacturing, formulation development, particle characterization, analytical development and characterization, stability studies

JOE MCMAHON
president & CEO

"KBI Biopharma's mission is to partner with our clients to improve the quality of human life through the accelerated development of their innovative drug programs. We have the privilege of serving these clients in bringing medicines to the sick, and in so doing, bringing hope to these patients and their families. We are honored to be recognized for our leadership in innovation as well as our ability to consistently maintain our outstanding regulatory track record."

KEMWELL
Keeping You Competitive

CATEGORIES WON

Kemwell Biopharma

Bangalore, India
www.kemwellbiopharma.com

+918039285450
Karan Bagaria
karan.bagaria@kemwellpharma.com
Key locations: India, Sweden, U.S.A.

DRUG TYPE:
Pharmaceuticals, Biopharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Preclinical, Clinical (Phase 1, Phase 2, Phase 3)
Drug Substance Production: Primary Process Development, Drug Substance Production
Formulated Drug Production: Dosage Form Development, Dosage Form Production, Packaging

SERVICES & CAPABILITIES: aseptic fill/finish, capsules, controlled substances, creams & ointments, gels, generics, injectables, liquids, lyophilized products, non-sterile, ophthalmics, OTC, parenterals (small volume), peptides, powders (non-sterile), proteins, semisolids, solid dose, solutions & suspensions, sterile, sustained release, syringes (prefilled), topicals

ANURAG BAGARIA
chairman & managing director

"Kemwell definitely stands to be a first-choice strategic partner for any pharma/biopharma company looking to outsource their development and manufacturing activities Our strong compliance history proves highest quality standards and our 100% service-oriented nature has convinced companies to maintain long-lasting relationships, often spanning decades. Our strong and diverse senior management team brings 100+ years of collective experience. This scientific and technical depth creates the perfect platform for innovative problem solving."

Lonza

CATEGORIES WON

Lonza

Basel, Switzerland
www.lonza.com

+41 61 316 81 11
Colleen Floreck
colleen.floreck@lonza.com
Key locations: Maryland, New Hampshire, Texas, U.S.A.; Nansha, China; Porrinno, Spain; Slough, UK; Tuas, Singapore; Visp, Switzerland

DRUG TYPE:
Pharmaceuticals, Biopharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Discovery, Preclinical, Clinical (Phase 1, Phase 2, Phase 3)
Drug Substance Production: Primary Process Development, Drug Substance Production

SERVICES & CAPABILITIES: active pharmaceutical ingredients (APIs), advanced intermediates, antibody drug conjugates, biologics, cell therapy, creams & ointments, cytotoxic & high potency compounds, fine chemicals, functional ingredients, generics, peptides, proteins, vaccines, viral therapy

MARC FUNCK
chief operating officer

"Lonza's recognition in the areas of quality, reliability, and regulatory excellence supports our successful inspections and customer audits at our cGMP sites in 2014 and secures our position as a reliable manufacturing partner. We strive continuously to reach the next level of excellence in commercial and innovation activities to support our customers' value chains. We are dedicated to being a customer-focused and market-driven organization and our high ranking reflects the outcome of these recent initiatives."

metrics contract services

CATEGORIES WON

Metrics Contract Services

Greenville, NC
www.metricsinc.com

+1 252 752 3800
Tom Salus
thomas.salus@maynepharma.com
Key locations: Greenville, NC

DRUG TYPE:
Pharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Preclinical, Clinical (Phase 1, Phase 2, Phase 3)
Formulated Drug Production: Dosage Form Development, Dosage Form Production, Packaging

SERVICES & CAPABILITIES: analytical testing, capsules, controlled substances, cytotoxic & high potency compounds, liquids, non-sterile, powders (non-sterile), solid dose, solutions & suspensions, sustained release

JOHN ROSS
executive vice president

"On behalf of our employees who routinely make our clients' projects successful, we at Metrics Contract Services are honored to be recognized as a recipient of the CMO Leadership Awards for 2015. We truly enjoy our CDMO role in this dynamic industry which gives us the distinct pleasure of working with many innovative sponsor companies to solve complex analytical and formulation challenges."

CATEGORIES WON

Neuland Laboratories Limited

Hyderabad, Telangana, India
www.neulandlabs.com

+91 040 3021 1600
Shashank Mahashabde
shashankm@neulandlabs.com
Key locations: Bonthpally Village, Medak District, India; Isnapur Village, Patancheru, Medak District, India

DRUG TYPE:
Pharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Clinical (Phase 1, Phase 2)
Drug Substance Production: Primary Process Development, Drug Substance Production

SERVICES & CAPABILITIES: APIs, custom manufacturing solutions, peptides

SUCHETH RAO DAVULURI
CEO

"Achieving the highest standards of quality and regulatory excellence, which we view as deeply intertwined, are core values at Neuland Laboratories. It is fitting that Neuland, with more than 90 percent of our business in highly regulated markets in the U.S., Europe, and Japan, has won CMO Leadership Awards in quality and regulatory. As one of the first FDA-inspected CMOs in India, we are proud of our record and committed to excellence for our customers."

CATEGORIES WON

NextPharma

Send, Surrey, United Kingdom
www.nextpharma.com

+1 617 816 9551
Craig LaMarca
craig.lamarca@nextpharma.com
Key locations: France, Germany

DRUG TYPE:
Pharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Preclinical, Clinical (Phase 1, Phase 2, Phase 3)
Formulated Drug Production: Dosage Form Development, Dosage Form Production, Packaging, Logistics

SERVICES & CAPABILITIES: beta-lactams, capsules, controlled substances, creams & ointments, gels, generics, hormones, liquids, non-sterile, OTC, powders (non-sterile), semisolids, soft gels, solid dose, solutions & suspensions, sustained release, topicals

PETER BUREMA
CEO

"NextPharma is proud to be consistently recognized amongst industry leaders as a CMO Leadership Award recipient. With a dynamic offering from development through commercial production and packaging on a wide range of dosage forms and niche services including hormones, beta-lactams, and pellets, we work diligently to maintain high quality and regulatory standards. We are honored that our hard work is recognized by our clients and this CMO award is a true testament to those efforts."

CATEGORIES WON

Norwich Pharma Services

Norwich, NY
www.norwichpharma.com

+1 888 674 7979
John Bender
info@norwichpharma.com
Key locations: Norwich, NY

DRUG TYPE:
Pharmaceuticals

DRUG LIFE CYCLE STAGES:
Formulated Drug Production: Dosage Form Production, Packaging

SERVICES & CAPABILITIES: capsules, controlled substances, generics, OTC, solid dose, sustained release

JOHN BENDER
vice president, commercial operations

"Norwich has been manufacturing commercial pharmaceutical products for 127 years and counting. We have built our business around our legacy of quality and regulatory compliance. We are focused on maintaining our high quality standards and providing dependable product supply to our customers."

CATEGORIES WON

Novasep

Lyon, France
www.novasep.com

+33 437 282 030
Andrew Brennan
andrew.brennan@novasep.com
Key locations: Chasse-sur-Rhône, France; Gosselies, Belgium; Le Mans, France; Leverkusen, Germany; Mourenx, France; Pompey, France

DRUG TYPE:
Pharmaceuticals, Biopharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Clinical (Phase 1, Phase 2, Phase 3)
Drug Substance Production: Drug Substance Production

SERVICES & CAPABILITIES: API and advanced intermediate custom synthesis, BSL3 pathogen production, controlled substances, custom purification, cytotoxic & high potency compounds, generics, lyophilized products, non-sterile, peptides, powders (sterile), process development, proteins, sterile, vaccines

THIERY VAN NIEUWENHOVE
president,
synthesis business unit

"We are delighted to receive these four awards in 2015 following the two we received last year. The categories reflect particularly well our day-to-day focus in serving our customers: quality, regulatory compliance, and productivity. It is an honor since these awards recognize the efforts of the Novasep team throughout this past year."

CATEGORIES WON

Par Pharmaceutical

Rochester, MI
www.parpharm.com

+1 800 828 9393
Jeff Siterlet
CMO@parpharm.com
Key locations: Rochester, MI

DRUG TYPE:
Pharmaceuticals, Biopharmaceuticals

DRUG LIFE CYCLE STAGES:
Formulated Drug Production: Dosage Form Production

SERVICES & CAPABILITIES: aseptic fill/finish, injectables, lyophilized products, parenterals (small volume), sterile

MIKE RUTKOWSKI
senior vice president,
general manager

"Par Sterile Products is thrilled to receive the CMO Leadership Award in quality! This is truly a testament to the diligence and passion of our entire workforce and our commitment to flawless execution and operational effectiveness. We are focused on a continuous and compliant supply of products; delivering to our customers and patients products when they need them and with a quality that will continue to benefit our life-saving industry as a whole."

CATEGORIES WON

Paragon Bioservices, Inc.

Baltimore, MD
www.paragonbioservices.com

+1 410 975 4050
Philip Wills, Ph.D.
pwills@paragonbioservices.com
Key locations: Baltimore, MD

DRUG TYPE:
Biopharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Discovery, Preclinical, Clinical (Phase 1, Phase 2)
Drug Substance Production: Primary Process Development, Drug Substance Production
Formulated Drug Production: Dosage Form Production, Packaging

SERVICES & CAPABILITIES: aseptic fill/finish, injectables, liquids, parenterals (small volume), proteins, sterile, vaccines

DR. MARCO CHACÓN
president & CEO

"Valuable recognition from our clients reflects the level of commitment and dedication on the part of Paragon's scientists and engineers. They are a highly trained group of professionals that are guided by very high principles in their pursuit of science and biopharmaceutical development. With more than 20 years in the business, Paragon has become a key partner for innovation and a center of excellence for proteins, vaccines and GMP manufacturing."

Patheon
Performance the World Over®

CATEGORIES WON

Patheon

Durham, NC
www.Patheon.com

+1 919 226 3200
Gayle Grandinetti
doingbusiness@patheon.com
Key locations: Cincinnati, OH, Greenville, NC, St. Louis, MO, U.S.A.; Linz, Austria; Monza, Italy; Swindon, UK

DRUG TYPE:
Pharmaceuticals, Biopharmaceuticals

DRUG LIFE CYCLE STAGES:
Drug Substance Production: Primary Process Development, Drug Substance Production
Formulated Drug Production: Dosage Form Development, Dosage Form Production, Packaging

SERVICES & CAPABILITIES: aseptic fill/finish, capsules, cartridges, controlled substances, cytotoxic & high potency compounds, generics, injectables, lyophilized products, non-sterile, OTC, parenterals (large volume), parenterals (small volume), peptides, powders (non-sterile), powders (sterile), proteins, semisolids, soft gels, solid dose, solutions & suspensions, sterile, sustained release, syringes (prefilled)

JAMES MULLEN
CEO

"We are honored that our customers continue to recognize Patheon as a leader through the CMO Leadership Awards. We continue to focus on delivering a combination of unrivaled quality, reliability, and compliance, with a reputation for scientific and technical excellence to customers in the pharmaceutical and biopharmaceutical sectors. We have a comprehensive set of solutions to help customers of all sizes satisfy complex development and manufacturing needs at all stages of the development cycle."

PCI

CATEGORIES WON

PCI Synthesis

Newburyport, MA
www.pcisynthesis.com

+1 978 462 5555
Ed Price
ed.price@pcisynthesis.com
Key locations: Devens, MA; Newburyport, MA

DRUG TYPE:
Pharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Preclinical, Clinical (Phase 1, Phase 2, Phase 3)
Drug Substance Production: Primary Process Development, Drug Substance Production

SERVICES & CAPABILITIES: generics, injectables, non-sterile, ophthalmics, solid dose

ED PRICE
president

"As the largest drug substance manufacturer in New England, PCI is always looking for ways to continuously improve its operations. Our CMO Awards would not be possible without our engaged employees who treat our customers' projects as if they were their own. This ethos of ownership not only allows us to perform at the highest level but to also look critically at how we run our business and continuously seek to make it better."

Pfizer CENTRESOURCE
Partnering with our Customers for a Healthier World

CATEGORIES WON

Pfizer CentreSource

Kalamazoo, MI
www.pfizercentresource.com

+1 269 833 5844
Kyle Chisholm
kyle.w.chisholm@pfizer.com
Key locations: Andover, MA, Kalamazoo, MI, Pearl River, NY, U.S.A; Ascoli, Italy; Freiburg, Germany; Newbridge, Ireland

DRUG TYPE:
Pharmaceuticals, Biopharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Clinical (Phase 2, Phase 3)
Drug Substance Prodcution: Primary Process Development, Drug Substance Production
Formulated Drug Production: Dosage Form Production, Packaging, Logistics

SERVICES & CAPABILITIES: aseptic fill/finish, capsules, controlled substances, creams & ointments, cytotoxic & high potency compounds, injectables, liquids, lyophilized products, non-sterile, parenterals (large volume), parenterals (small volume), powders (non-sterile), semisolids, solid dose, solutions & suspensions, sterile, sustained release, syringes (prefilled), topicals, Primary focus – steroid intermediates, APIs, biologic drug substance and drug product including ADCs and high containment solid oral dose (high potency molecules)

CRISTIN GROVE
director,
contract manufacturing

"We believe our specialty focus (biologics, high containment solid oral dose, and steroid API), technical expertise, and customer-centric culture drives significant value for our partners. We are humbled and truly appreciate being recognized for this award the past four years."

CATEGORIES WON

PharmaCore, Inc.

High Point, NC
www.pharmacore.com

+1 336 841 5250
Cheryl Garr
cgarr@pharmacore.com
Key locations: High Point, NC

DRUG TYPE:
Pharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Discovery, Preclinical, Clinical (Phase 1, Phase 2, Phase 3)

SERVICES & CAPABILITIES: API manufacture, chemistry services, controlled substances

ROB MADDOX
president

"At PharmaCore, we pride ourselves on providing outstanding client service while maintaining the highest standards obtainable. As a leading, U.S.-based chemistry services company, providing chemistry R&D, API manufacture, and analytical services, we closely interact with our clients to ensure our deliverables meet or exceed expectations. Therefore, to be recognized as a 3-category recipient of the CMO Leadership Awards is a testament to the chemistry and manufacturing team that sets PharmaCore apart."

CATEGORIES WON

Pharmatek

San Diego, CA
www.pharmatek.com

+1 858 805 6383
Elizabeth Hickman
ehickman@pharmatek.com
Key locations: San Diego, CA

DRUG TYPE:
Pharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Preclinical, Clinical (Phase 1, Phase 2, Phase 3)
Formulated Drug Production: Dosage Form Development, Dosage Form Production, Packaging, Logistics

SERVICES & CAPABILITIES: capsules, creams & ointments, cytotoxic & high potency compounds, injectables, liquids, lyophilized products, non-sterile, peptides, powders (non-sterile), semisolids, solid dose, solutions & suspensions, sustained release, topicals

TIMOTHY SCOTT
president

"Pharmatek is honored to again be recognized by our peers with a 2015 Leadership Award. While the business of pharma is ever-changing, the focus on quality is the undeniable core of our success. Pharmatek's culture of accountability and emphasis on smart science empowers our employees to achieve quality results. From the data we generate to the products we manufacture, we are focused on what makes each formulation and manufacturing production a success."

CATEGORIES WON

Piramal Healthcare

Mumbai, Maharshatra, India
www.piramalpharmasolutions.com

+912230956666
Brian Shaughnessy
Brian.Shaughnessy@piramal.com
Key locations: Andhra Pradesh, India; Aurora, ON, Canada; Scotland, UK; Madhya Pradesh, India; Morpeth, Northumberland, UK; Tamil Nadu, India

DRUG TYPE:
Pharmaceuticals, Biophamaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Discovery, Preclinical, Clinical (Phase 1, Phase 2, Phase 3)
Drug Substance Production: Primary Process Development, Drug Substance Production
Formulated Drug Production: Dosage Form Development, Dosage Form Production, Packaging

SERVICES & CAPABILITIES: capsules, generics, injectables, lyophilized products, ophthalmics, solid dose

VIVEK SHARMA
CEO

"The award serves as a validation of our efforts to keep the customer as the focal point, while emphasizing on project ownership, time delivery, and commitment toward quality. This recognition from our clients will further motivate our team as we drive toward becoming the 'partner of choice.' Receiving these awards also showcase our company values of entrepreneurship, expertise, and trusteeship."

CATEGORIES WON

Recipharm AB

Honey Brook, PA
www.recipharm.com

+1 484 467 2664
Aaron Small
aaron.small@recipharm.com
Key locations: France, Germany, Italy, Portugal, Spain, Sweden, UK

DRUG TYPE:
Pharmaceuticals, Biopharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Preclinical, Clinical (Phase 1, Phase 2, Phase 3)
Drug Substance Production: Primary Process Development, Drug Substance Production
Formulated Drug Production: Dosage Form Development, Dosage Form Production, Packaging

SERVICES & CAPABILITIES: aseptic fill/finish, capsules, cartridges, controlled substances, creams & ointments, gels, generics, injectables, liquids, lyophilized products, non-sterile, ophthalmics, OTC, parenterals (small volume), powders (non-sterile), semisolids, solid dose, solutions & suspensions, sterile, sustained release, topicals, vaccines

AARON SMALL
U.S. sales manager

"I am happy to see that Recipharm has once again been voted in the CMO Leadership Awards. Our commitment to our customers and shareholders is unsurpassed in the industry, and I think that these awards reflect that. Our peers have recognized us as being a leader in contract manufacturing and development, and we will continue to provide that same commitment for years to come."

CATEGORIES WON

Regis Technologies, Inc.

Morton Grove, IL
www.registech.com

+1 847 967 6000
Wayne Nowicki
wnowicki@registech.com
Key locations: Morton Grove, IL

DRUG TYPE:
Pharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Preclinical, Clinical (Phase 1, Phase 2, Phase 3)
Drug Substance Production: Primary Process Development, Drug Substance Production

SERVICES & CAPABILITIES: controlled substances, cytotoxic & high potency compounds, generics, non-sterile, ophthalmics

LOUIS GLUNZ, IV
president & CEO

"Team Regis is proud to be recognized with five CMO Leadership Awards. We see these awards as a byproduct of Regis' continued commitment to solving complex chemistry problems and delivering quality products for our customers. The FDA has recognized our quality and compliance in the last two FDA audits, which resulted in no form '483 observations. Regis looks forward to serving more customers in 2015 wishing to partner with a top tier, domestic CMO."

CATEGORIES WON

Richter-Helm

Hamburg, Germany
www.richter-helm.eu

+49 40 55290 435
Tamara Rupp
t.rupp@richter-helm-biotec.eu
Key locations: Bovenau, Hamburg, and Hannover, Germany

DRUG TYPE:
Biopharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Preclinical, Clinical (Phase 1, Phase 2, and Phase 3)
Drug Substance Production: Primary Process Development, Drug Substance Production
Formulated Drug Production: Dosage Form Development, Dosage Form Production, Packaging

SERVICES & CAPABILITIES: aseptic fill/finish, cartridges, generics, injectables, liquids, lyophilized products, non-sterile, peptides, plasmid DNA, proteins, syringes (prefilled), vaccines

CATEGORIES WON

Rottendorf Pharma

Chicago, IL
www.RottendorfUS.com

+1 312 794 7836
Gordon Haines
inquires@RottendorfUS.com
Key locations: Chicago, IL, U.S.A.; Ennigerloh, Germany; Valenciennes, France

DRUG TYPE:
Pharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Preclinical, Clinical, (Phase 1, Phase 2)
Drug Substance Production: Primary Process Development, Drug Substance Production
Formulated Drug Production: Dosage Form Development, Dosage Form Production, Packaging, Logistics

SERVICES & CAPABILITIES: capsules, controlled substances, generics, hot melt extrusion, hot melt granulation, non-sterile, powders (non-sterile), solid dose, solutions & suspensions, sterile

STEPHAN FLECK
CEO

"We are delighted to be recognized with five CMO Leadership Awards across all industry audiences and four of the perception categories. We attribute this success to what is foundational to Rottendorf: scientific and technological competence, ownership stability, and total process ownership – our approach to reducing customer oversight, complexity, and cost. We are also committed to delivering on our promises. These awards demonstrate the value that clients place in our efforts to exceed their expectations."

CATEGORIES WON

SAFC

St. Louis, MO
www.sigmaaldrich.com/safc.html

+1 314 534 4900
Patrick Duffy
safcglobal@sial.com
Key locations: Arklow, Ireland; Buchs, Switzerland; Missouri and Wisonsin, U.S.A.

DRUG TYPE:
Pharmaceuticals, Biopharmceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Discovery, Preclinical, Clinical (Phase I, Phase 2, Phase 3)

SERVICES & CAPABILITIES: controlled substances, sytotoxic & high potency compounds, generic, liquids, lyophilized products, non-sterile, ophthalmics, peptides, powders (sterile), proteins, solutions & suspensions, sterile, vaccines

GILLES COTTIER
president

"Thank you to the customers and partners who voted for us to receive multiple CMO Leadership Awards. Our mission is to develop and manufacture difficult to replicate, high quality commercial products, and provide critical service solutions for our customers. We continue to strategically invest in this mission and appreciate seeing our approach resonate within the industry through these awards. They further our drive to be a choice supplier that customers want to recognize for excellence."

CATEGORIES WON

SAI Life Sciences Ltd

Hyderabad, TG, India
www.sailife.com

+91 (0)4066777555
Marcel Velterop
marcel.v@sailife.com
Key locations: Bidar, Karnataka; Bollaram and Shamirpet, Hyderabad; Hinjewadi, Pune

DRUG TYPE:
Pharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Discovery, Preclinical, Clinical (Phase 1, Phase 2, Phase 3)
Drug Substance Production: Primary Process Development, Drug Substance Production
Formulated Drug Production: Dosage Form Development

SERVICES & CAPABILITIES: controlled substances, sytotoxic & high potency compounds, generic, liquids, lyophilized products, non-sterile, ophthalmics, peptides, powders (sterile), proteins, solutions & suspensions, sterile, vaccines

KRISHNA KANUMURI
CEO

"SAI continuously strives to get better and improve every aspect of our service offerings to our customers, who are the main reason for our existence."

SAMSUNG BIOLOGICS

CATEGORIES WON

Samsung BioLogics, Co. Ltd.

Incheon, South Korea
www.samsungbiologics.com

+82 32 455 3114
Jenifer Wheat
jenifer.wheat@samsung.com
Key locations: Songdo, IFEZ (Incheon Free Economic Zone), South Korea

DRUG TYPE:
Pharmaceuticals, Biopharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Preclinical, Clinical (Phase 1, Phase 2, Phase 3)
Drug Substance Production: Primary Process Development, Drug Substance Production
Formulated Drug Production: Dosage Form Production, Packaging

SERVICES & CAPABILITIES: aseptic fill/finish, injectables, liquids, lyophilized products, peptides, proteins, sterile, vaccines

TH KIM, PH.D.
president & CEO

"Samsung BioLogics' innovation in unique facility design and construction methods have demonstrated the world's most rapid construction and commissioning of large scale cGMP facilities. Our legacy of continuous processing enabled us to achieve the fastest, high-yield technology transfers in biopharmaceuticals as well as high capacity, high productivity, cost-effective, and highest quality manufacturing. Together with our strategic partners, leading biopharma clients, we will have progressed from groundbreaking through PAI in less than five years."

SANDOZ Biopharmaceuticals

CATEGORIES WON

SANDOZ GMBH

Kundl, Tirol, Austria
www.sandoz.com

+43(0)53382002609
Johannes Reiter
biotech.cooperations@sandoz.com
Key locations: Kundl and Schaftenau, Austria

DRUG TYPE:
Biopharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Clinical (Phase 1, Phase 2, Phase 3)
Drug Substance Production: Primary Process Development, Drug Substance Production

SERVICES & CAPABILITIES: cytotoxic & high potency compounds, peptides, proteins

JOHANNES REITER
head biotech cooperations

"The opinion of our customers is critical to us. We are happy to be recognized as a well-established and reliable partner in this field, receiving the CMO Leadership Awards now the third year in a row. We are proud of our long history in manufacturing partnerships, certainly based on excellent technology transfer experience, flexibility of production capabilities, and fully integrated services, but finally it's all about experience and dedication of our people and the good relation to the teams of our partners which is the foundation of long-term success in this business."

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CATEGORIES WON

Siegfried AG

Zofingen, Argau, Switzerland
www.siegfried.ch

+41 62 7461520
Marianne Spaene
marianne.spaene@siegfried.ch
Key locations: Switzerland, China, Germany, Malta; Pennsville, NJ (U.S.A.) and Irvine, CA (U.S.A.)

DRUG TYPE:
Pharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Clinical (Phase 1, Phase 2, Phase 3)
Drug Substance Production: Primary Process Development, Drug Substance Production
Formulated Drug Production: Dosage Form Development, Dosage Form Production, Packaging, Logistics

SERVICES & CAPABILITIES: aseptic fill/finish, capsules, cartridges, controlled substances, gels, high potency compounds, injectables, non-sterile, ophthalmics, parenterals (large volume), parenterals (small volume), semisolids, solid dose, solutions & suspensions, sterile, sustained release

DR. RUDOLF HANKO
CEO

"Siegfried is privileged to receive the CMO Leadership award for a third time, and honored to be recognized in 4 categories (productivity, quality, regulatory, and innovation). Offering integrated drug substance and drug product services, Siegfried provides products and tailor-made services that seamlessly support your value chain. Whether it's customer development services producing APIs and drug products (oral or sterile), or controlled substances and higher potency you desire, I am convinced you can expect more with Siegfried as your preferred integrated partner."

CATEGORIES WON

Solvias AG

Kaiseraugst, Switzerland
www.solvias.com

+41 61 845 60 00
Ronald Yarger
ronald.yarger@solvias.com
Key locations: Basel and Kaiseraugst, Switzerland; Hombourg, France

DRUG TYPE:
Pharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Preclinical, Clinical (Phase 1, Phase 2, Phase 3)
Drug Substance Production: Primary Process Development, Drug Substance Production

SERVICES & CAPABILITIES: controlled substances, cytotoxic & high potency compounds, generics, injectables, liquids, opthalmics, parenterals (small volume), peptides, proteins, topicals, vaccines

KAREN HUEBSCHER
CEO

"Solvias AG supports the development of drug substances, drug products, and manufacturing processes for pharma, biotech, medtech, and cosmetic companies. Located in Switzerland and France, Solvias offers profound know-how for process chemistry, chiral ligand development, and analytical chemistry. Our proven track record and a team of 400 highly qualified employees ensure the success of small and large molecule development projects. We provide the confidence that projects will be expertly performed and delivered on time."

CATEGORIES WON

Therapure Biomanufacturing

Mississauga, ON, Canada
www.therapurebio.com/CDMO

+1 905 286 2670
Rajan Puri
busdev@therapurebio.com
Key locations: Mississauga, ON, Canada

DRUG TYPE:
Biopharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Preclinical, Clinical (Phase 1, Phase 2, Phase 3)
Drug Substance Production: Primary Process Development, Drug Substance Production
Formulated Drug Production: Dosage Form Production

SERVICES & CAPABILITIES: aseptic fill/finish, cartridges, injectables, liquids, lyophilized products, parenterals (large volume), parenterals (small volume), proteins, solutions & suspensions, sterile, syringes (prefilled), vaccines

NICK GREEN
president & CEO

"For the fourth consecutive year, Therapure is honored to be recognized with a CMO Leadership Award and this year in the categories of quality, reliability, productivity, and regulatory. This recognition is only possible through the continued diligence of our employees who are passionate about developing and manufacturing the highest quality biotherapeutics for our clients. Our employees are committed to a common goal with our clients – producing therapeutics that help improve the lives of patients."

CATEGORIES WON

UPM Pharmaceuticals

Bristol, TN
www.upm-inc.com

+1 423 989 8000
Mary Lee Schiesz
mschiesz@upm-inc.com
Key locations: Bristol, TN

DRUG TYPE:
Pharmaceuticals, Biopharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Preclinical, Clinical (Phase 1, Phase 2, Phase 3)
Formulated Drug Production: Dosage Form Development, Dosage Form Production, Packaging

SERVICES & CAPABILITIES: capsules, controlled substances, creams & ointments, cytoxic & high potency compounds, gels, generics, liquids, non-sterile, OTC, peptides, powders (non-sterile), semisolids, solid dose, solutions & suspensions, sustained release, topicals

JAMES E. GREGORY
president

"UPM Pharmaceuticals works hard to continue the legacy of intellectual distinction and uncompromising performance with every new project. The talent and experience of our team, our dedication to science-based formulation design, and our commitment to timely communications have enabled us to offer the highest level of customized drug development services, from concept through commercialization. This is all done while adhering to a strict sense of quality, timeliness, and affordability for all our clients."

CATEGORIES WON

WellSpring Pharma Services

Oakville, ON, Canada
www.wellspringcmo.com

+1 844 879 7427
Sam Ricchezza
sricchezza@wellspringpharm.com
Key locations: Oakville, ON, Canada

DRUG TYPE:
Pharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Clincal (Phase 2, Phase 3)
Formulated Drug Production: Dosage Form Production, Packaging

SERVICES & CAPABILITIES: capsules, controlled substances, creams & ointments, cytotoxic & high potency compounds, gels, generics, liquids, non-sterile, OTC, powders (non-sterile), semisolids, solid dose, solutions & suspensions, sustained release, topicals

DAVID MAYERS
president,
pharma services

"We are honored to have been recognized once again as a 2015 CMO Leadership Award winner by the pharmaceutical industry, this year in the categories of excellence in quality and of excellence in regulatory. Since 2001, WellSpring's mandate has been to establish itself as a leader in providing contract pharmaceutical manufacturing and packaging services. At the heart of our success is our commitment to exceeding the pharmaceutical industry's quality and regulatory standards."

CATEGORIES WON

WuXi AppTec, STA Pharmaceuticals

Shanghai, China
www.wuxiapptec.com

+1 86 21 5017 8852
Yu Lu
yu.lu@wuxiapptec.com
Key locations: Shanghai WaiGaoQiao Free Trade Zone; Jinshan, Shanghai; Changzhou, Jiangsu, China

DRUG TYPE:
Pharmaceuticals, Biopharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Discovery, Preclinical, Clinical (Phase 1, Phase 2, Phase 3)
Drug Substance Production: Primary Process Development, Drug Substance Production
Formulated Drug Production: Dosage Form Development, Dosage Form Production, Packaging, Logistics

SERVICES & CAPABILITIES: aseptic fill/finish, capsules, creams & ointments, cytotoxic & high potency compounds, injectables, lyophilized products, non-sterile, peptides, powders (non-sterile), powders (sterile), solid dose, sterile, sustained release

MINZHANG CHEN
sr. VP of WuXi PharmaTech,
general manager of STA

"On behalf of 1,500 highly dedicated employees at STA, I am very pleased to accept this award. Every day we at STA strive to provide our customers with the highest quality of services across our integrated small-molecule API development and manufacturing platform from process chemistry to research and commercial manufacturing."

CATEGORIES WON

Xcelience

Tampa, FL
www.xcelience.com

+1 813 286 0404
Sharon Burgess
info@xcelience.com
Key locations: Tampa, FL

DRUG TYPE:
Pharmaceuticals, Biopharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Discovery, Preclinical, Clinical (Phase 1, Phase 2, Phase 3)
Drug Substance Production: Primary Process Development, Drug Substance Production
Formulated Drug Production: Dosage Form Development, Dosage Form Production, Packaging, Logistics

SERVICES & CAPABILITIES: capsules, controlled substances, creams & ointments, cytotoxic & high potency compounds, gels, liquids, lyophilized products, non-sterile, powders (non-sterile), semisolids, solid dose, solutions & suspensions, sustained release, topicals

DEREK HENECKE
president & CEO

"Of the six awards Xcelience earned this year, I am especially proud of the innovation award. These awards cement Xcelience's reputation as first-rate problem solvers. We put the industry's best minds to work creating new solutions to maximize speed, efficiency, and success rates. The reliability, regulatory, and productivity awards establish the baseline which our clients expect of us. But innovation is the skill that enables us to exceed client expectations and rise above the competition."

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CMO LEADERSHIP AWARDS 2015 INNOVATION

CMO LEADERSHIP AWARDS 2015 PRODUCTIVITY

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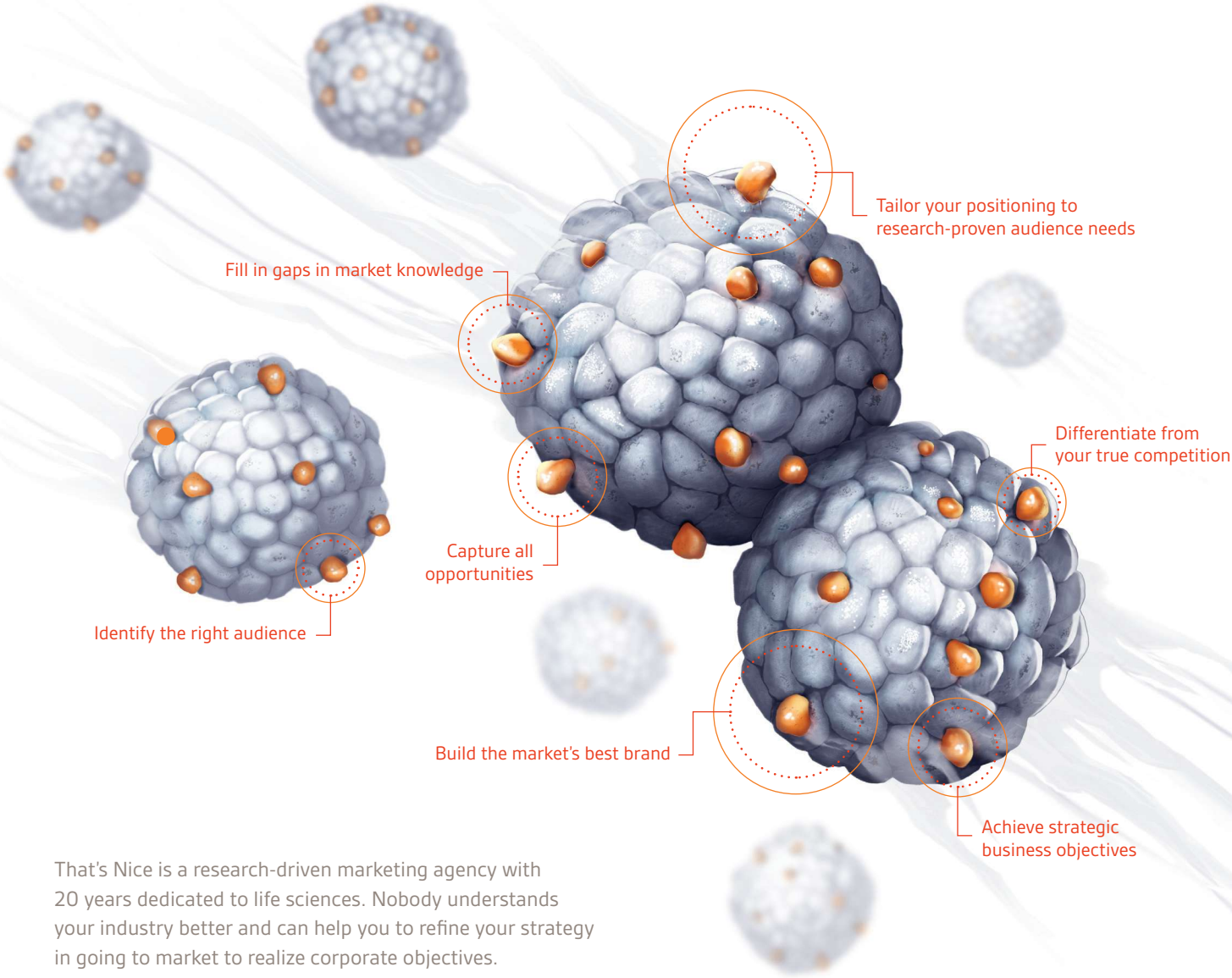

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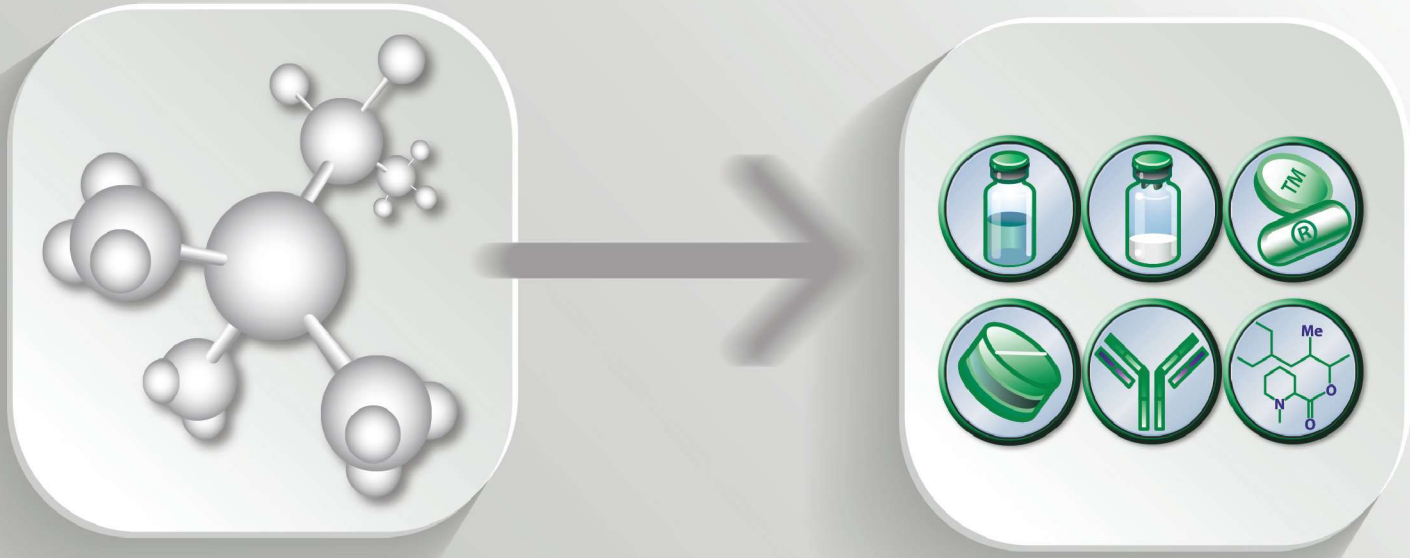

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