A Supplement to
Life Science Leader
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MARCH 2017

Some Straight Talk To CMOs

p. 8

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VP of Technical Operations, Achaogen

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p. 38

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Contents

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We Told You We're Different (And The Best)

LOUIS GARGUILO
Chief Editor, Outsourced Pharma

Most service companies regard themselves as different from their competitors. As a result of those differences, they'll insist they are the best at exceeding their customers' expectations. In the biotech and pharma industry, our annual *CMO Leadership Awards* are a way to verify that customers actually share those self-estimations of prowess. Additionally, the *Awards* serve global drug sponsors that more than any time in our history are constantly seeking the best prospective partners for drug development and manufacturing. You might say we've got both sides of outsourcing covered for our readers.

But there's more. Today, sponsors and service providers are seeking advice on best practices and advanced methods for working together, improving productivity and project outcomes, and raising profitability while lowering costs for patients. That's why, along with our listings of *Award* winners, this year's supplement includes a select group of experienced industry veterans providing best practices and advice related to outsourcing and managing supply chains. Whether you're new to working with contract development and manufacturing organizations, or somebody who's been at this for years, I'm certain you'll derive value in learning, or being reminded of, the strategies and tactics involved in the "artful" activity of outsourcing.

Regarding the "art" of surveying the outsourcing industry, this is our second year teaming up with Industry Standard Research (ISR). To obtain the most accurate survey results, ISR focuses on the attributes biopharma companies say are essential in deciding which CMOs best serve their clients: Quality, Reliability, Capabilities, Expertise, Compatibility — and our newest category — Development (i.e., development-related services).

Yet, even when using these common key attributes, we know that the strategic approaches to outsourcing vary significantly thanks to today's widening categories of "sponsor" — from virtuals and startups, to more traditional biotechs and all-sized pharma companies. Thus, our challenge was to figure out how to capture this aspect without becoming too granular and ending up obscuring competitive results. Participants in our survey have told us the two additional sponsor categories we initiated last year — big pharma and small pharma — were helpful, so we're sticking with these this year, too. However, we're always open to new ideas regarding ways to more accurately measure performance.

And also here, on behalf of my colleagues at *Life Science Leader*, I'd like to say thank you to all of our readers who participated in the *Awards* survey for 2017. Likewise, my personal thank you to Tina Larson of Achaogen, for "opening up" on the state of our small and large molecule industries, and particularly the need for all of us to understand what really drives business decisions at drug sponsors. As important as the attributes that make up a winning CMO are, none will reach full potential benefit if not applied to the areas most important to sponsors. By the way, Larson, a member of the Outsourced Pharma Advisory Board, as well as the authors within these pages, will continue to provide us with unique content and insight throughout the rest of the year at OutsourcedPharma.com.

Finally, on behalf of everyone at *Life Science Leader*, a heartfelt congratulations to all our *CMO Leadership Award* winners!

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MARCH 2017 CMO SUPPLEMENT

LIFE SCIENCE LEADER
5340 Fryling Rd., Suite 300
Erie, PA 16510-4672
Telephone: 814 897 7700
Fax: 814 899 5587
WWW.LIFESCIENCELEADER.COM

SVP OF PUBLISHING/PRODUCT DEVELOPMENT
Jon Howland / Ext. 203
jon.howland@lifescienceconnect.com

EDITORIAL DIRECTOR
Dan Schell / Ext. 284
dan.schell@lifescienceleader.com

CHIEF EDITOR
Rob Wright / Ext. 140
rob.wright@lifescienceconnect.com

EXECUTIVE EDITOR
Wayne Koberstein
wayne.koberstein@lifescienceleader.com

EDITORS
Louis Garguilo
louis.garguilo@lifescienceconnect.com

Bob Marshall
bob.marshall@lifescienceconnect.com

Ed Miseta
ed.miseta@lifescienceconnect.com

Anna Rose Welch
anna.welch@lifescienceconnect.com

VP OF AUDIENCE DEVELOPMENT
Michael Bennett
michael.bennett@lifescienceconnect.com

DIRECTORS OF STRATEGIC PARTNERSHIPS
Tim Bretz / 724-940-7555 / Ext. 123
tim.bretz@lifescienceconnect.com

Cory Coleman / Ext. 108
cory.coleman@lifescienceconnect.com

Tracy Tasker / Ext. 297
tracy.tasker@lifescienceconnect.com

Perry Rearick / Ext. 263
perry.rearick@lifescienceconnect.com

Derek Van Slyke / Ext. 217
derek.vanslyke@lifescienceconnect.com

PUBLISHER/BIOPHARM & LAB
Shannon Primavere / Ext. 279
shannon.primavere@lifescienceconnect.com

GROUP PUBLISHER/OUTSOURCING
Ray Sherman / Ext. 335
ray.sherman@lifescienceconnect.com

BUSINESS DEVELOPMENT MANAGER
Mike Barbalaci / Ext. 218
mike.barbalaci@lifescienceconnect.com

SR. ACCOUNT EXECUTIVE
Scott Moren / Ext. 118
scott.moren@lifescienceconnect.com

DIRECTOR OF DATA ANALYTICS
Kevin Morey
kevin.morey@lifescienceconnect.com

PRODUCTION DIRECTOR
Lynn Netkowicz / Ext. 205
lynn.netkowicz@jamesonpublishing.com

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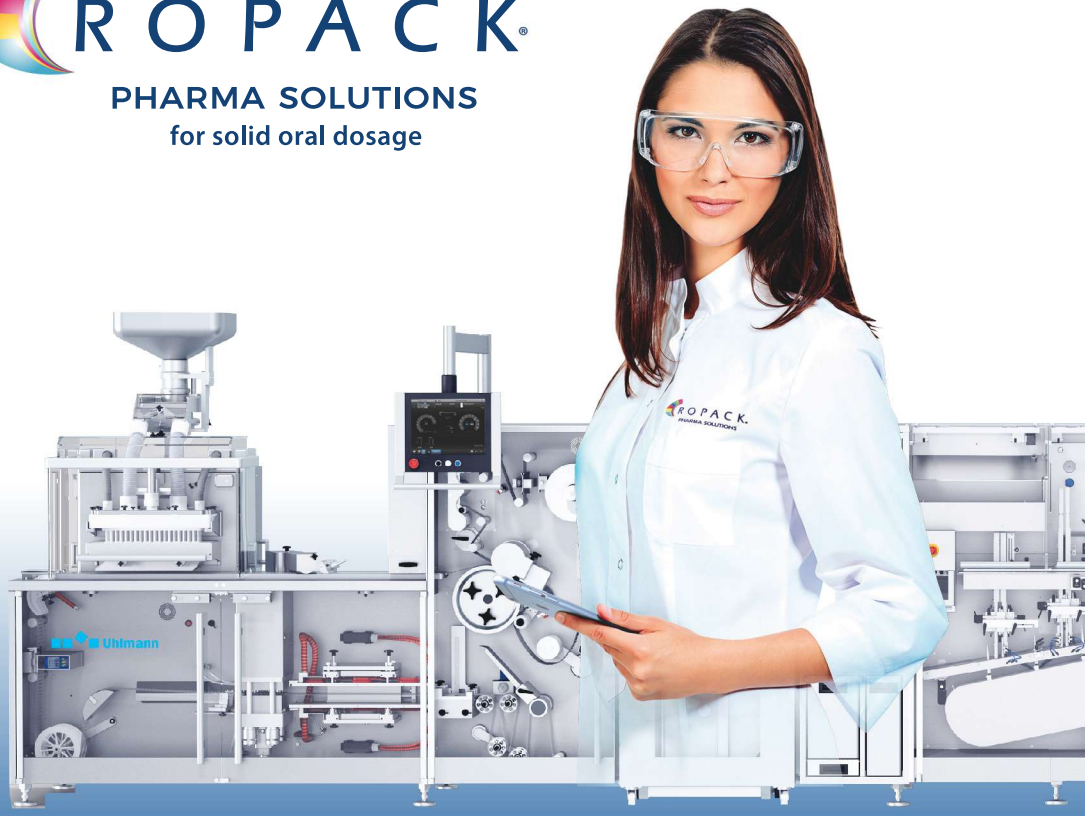

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TINA LARSON
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Achaogen

Achaogen's Tina Larson opens up on the real business needs of sponsors

SOME STRAIGHT TALK TO CMOs

LOUIS GARGUILO Chief Editor, Outsourced Pharma
@Louis_Garguilo

> "I spent much of my career as an introverted engineer, only comfortable speaking to close colleagues and avoiding crowds."
>
> TINA LARSON
> VP of Technical Operations
> Achaogen

Larson may be indulging in a bit of introversion inflation. After all, her career included a successful climb through Genentech, starting as that shy associate engineer and then progressing to leadership roles, including global head of technical development in business operations (Roche), before she moved to Achaogen last year. (And does that look like an introvert on our cover?) In one of my recent conversations with Larson she says: "I used to be so cautious. Now it's time to be more open and provocative."

Fortunately, we get both sides of Larson as she explores the real needs of drug sponsors today. She offers up thoughts like this: "It's interesting to think about why the small molecule industry, including CDMOs and CMOs, hasn't learned or revolutionized in the way the biologics industry has, even in places where we have common technology." And this: "If you can get 200 percent more out of a biologics manufacturing process from a CMO, who cares? That's not what's driving our business decisions."

A *large* step back, a *small* step forward

At Achaogen, Larson is working on the global push for a repioneering of the antibiotics space. "By 2050," she says, "antimicrobial resistance is projected to kill more people than cancer unless we do something. Our industry needs to revitalize its ability to bring novel antibiotics to market. And we need to do it now."

She's got her challenges. "Although I went from driving innovation in biologics manufacturing facilities to this cutting-edge work on next-generation antibiotics, still for me it's like a journey back in time a few decades," says Larson. That journey requires recalibrating herself to older, small molecule manufacturing facilities, after spending a career inside their younger biologic cousins. "I've recently seen technologies like something out of the early 1980s, for example in chromatography steps, which should be more in common to both facilities," she says. "Biologics plants are just not that old."

> "I've had great experiences collaborating on process analytical technology [PAT] via cross-industry groups."

Nonetheless, Larson says it's instructive to have this "back-in-time experience," and enjoys the challenge of partnering with CMOs in her new space. "Engaging a small molecule service provider feels different from engaging a biologics CMO," she explains. "I have to admit, my first questions were: 'What motivation do small molecule CMOs have to modernize? Is this segment of our industry actually interested in modernizing drug manufacturing?'"

Larson isn't impugning past models or motivations. Rather, she's encouraged that with the renewed, worldwide, and urgent focus on antibiotics today, positive change is on the way. In fact, her experience, and that of others like her, may be just the medicine needed for advancement.

"I can see our future within those biologics plants I was used to previously," she explains. "I bet a decade from now, we'll visit today's small molecule facilities, and perhaps with the help of professionals from cell-based therapy companies and others, they'll be the ones driving innovation and the next generation of transformative technology. Small molecule manufacturing has the potential to be so much more elegant, because the chemistry is so well characterized compared to biologics. Manufacturers have just lacked the business drivers to modernize. I can see this changing."

But there's also a twist in her narrative, because she feels that the biologics facilities are starting to seem dated; it won't be long before we are talking about how old these plants are. So where to look next? "The new kids on the block are smaller organizations using, for example, technologies for single-use solutions, enabling more potent, niche, and cell-based therapies," she replies. "To enable new antibiotics, we need both small molecule and biologics manufacturers that are cost-effective, but most importantly, focused on speed to market."

But more on the business needs of speed to market later. First, let's quickly review the drug development and manufacturing environment where that speed must take place.

Depending on disruption?

A lack of innovation speaks directly to institutionalized industry barriers. They include an elongated product-development cycle for new drugs, extended on-the-market timelines, and regulatory roadblocks. This list provides a partial answer to Larson's question above of motivation: Both sponsors and service providers (perhaps particularly on the small molecule side) can, to a degree, get away without innovating and still achieve relative success.

A most obvious challenge to innovation lies with the filing of an NDA (new drug application) or BLA (biologic license application), setting off what's become a regulatory process with immense impact on markets for drug owners. Says Larson, "The global nature of managing a supply chain and making postmarket or even premarket changes is so daunting and expensive you need an incredibly good reason to implement any innovations to process or manufacturing technologies."

She notes that most plants are still designed to run drug substance and product processes without variation, and often for decades. Furthermore, when the next development drug is introduced into a facility — external or internal — the temptation is to try to fit even that poten-

tially modernized process, in which you could implement innovation, into the existing equipment and technology in the plant. So not only do we have a problem innovating on products that are already commercially available, we have one innovating on products throughout the entire pipeline. "It becomes self-sustaining," Larson laments. "The only way this gets altered is when you have something truly disruptive — like cell-based therapies — where you are forced to do things completely different."

Waiting for these innovation disruptions can mean patients, pricing, and products are slow to benefit from any modernization. Nevertheless, Larson believes there are still incremental ways to modernize and innovate in the supply chain. "For example, I've had great experiences collaborating on process analytical technology [PAT] via cross-industry groups. I've also worked with these groups on technology-development road maps for biologics manufacturing. Cross-industry technical experts will come together for a mutual goal, and I witnessed the collaboration among users of emerging single-use technologies. There's a big benefit to standardizing single-use equipment options, similar to the benefit we all get in our daily lives from using standard USB connectors for our communication devices. The fundamental question always has been: How can we together advance meaningful innovation into our industry, and learn to help the suppliers help us in the effort?"

A good place to start might be ensuring service providers understand the meaning of "meaningful" to their customers, which brings us back to speed to market and understanding real business drivers.

Change for the good or no change at all

Unfortunately, says Larson, there can be a disconnect between drug developers and their external partners about what is truly beneficial in an overall business sense. "I have this great opportunity at Achaogen to build an antibody development function basically from zero," she says. "I was mostly on the side pushing for innovations when I was at Genentech, and I can see that the equation doesn't change that much. You have to understand what the positive impact of innovations are to the sponsor's business."

Her prime example is a first assumption by large molecule

CMOs: Improvement in titers drives down the cost of goods. "This isn't unlike other industries with supply chains and strong competition between service providers," she says. "In the chemical industries, if you figure out how to get a 10 percent improvement in your distillation column, you can practically retire on that. However, a CMO's idea to double the titer for one of my processes isn't necessarily going to drive down the cost of my goods, and it certainly won't induce us to make a business decision. Actually, in some situations, you could be offered 200 percent more material out of a biologics manufacturing process, but who cares? Honestly, I hate to say that, but that's not the real target."

So what is?

Fundamentally, throughout the entire pipeline, this business is all about speed to market. "That's the business driver. It's not about manufacturing," says Larson emphatically. "It is about being the first one to get a product to market and as fast as we can. Our process is essentially locked at market application for this purpose. This is the context for that 200-percent improvement in output. Any post-filing innovation of that sort will be offset by the cost of new filings, potentially even redoing a clinical trial, and specifically our speed to market. It simply is not worth it."

She adds that, even premarket, you need to decide if you are talking about improving a process that in any way could slow you down from getting to your filings. "If so, it's probably not worth it. I mean, I see an underestimation of speed to market as being the key driver of this industry for most products. CDMOs, CMOs, and our own process-development folks need to take this to heart."

Larson provides an example where a service provider was pushing for an improved titer, but that increase consequently resulted in a different quality profile and more variants; the material would end up harder to purify with less consistent production. "We've seen companies push levels up to multiple grams per liter, but they actually never ran that at commercial scale," she explains. "There's this tendency to become obsessed with cell-culture yield because it's an easy metric. But if you lose one or two runs in manufacturing, the cost completely wipes out your titer improvement."

"For years we've focused on the drug substance, but increasingly the differentiation is in other areas, for example on device and delivery," she continues. "So you are focusing on getting your drug substance down to $10 a dose from the antibody production, but then you put that in a device that brings your dose closer to $50. You're focusing on the wrong place. You might want to be looking at things like the likelihood of delivery by sterile, prefilled syringes, and simply the best quality and consistency from your CMO."

Larson makes clear that sponsors like Achaogen are looking for continued modernization — implementation of up-to-date equipment and technologies — to produce material reliably and consistently. However, she says the disconnect is when CMOs bring ideas and the sponsor has to respond: "Yes, we want better titer output, and higher purification, but that's not the key drivers of our business. We'd need more foundational innovation to make a real business difference."

> "Small molecule manufacturing has the potential to be so much more elegant. Manufacturers have just lacked the business drivers to modernize."

So what would a foundational innovation be? One example, says Larson, is dramatically rethinking how to work with cell lines. "Maybe it's cell-expression systems, or something like cell-free synthesis that Jim Swartz [Stanford University's James H. Clark professor at the School of Engineering, and professor of chemical engineering and bioengineering] has been working on for years. Others have looked at E. coli expression systems, although here the purification is still quite challenging. I think that the foremost opportunity for game-changing innovation today is basically cleaning up the expression systems, although that's obviously not going to be easy."

She believes that the bottom line is that high-yield manufacturing gets completely disconnected with the overall business. "Look at the wider industry today, particularly as we move to more personalized medicine, high-potency products, and advanced delivery systems, all meaning less volume," she explains. "I have worked on products where all the material needed for a decade could be produced by just doing the qualification batches. More than ever, sponsors and their service providers have to keep an eye on the evolving business

strategies and global markets. The real value is in understanding how our businesses actually operate."

WHAT'S A CMO TO DO?

That understanding starts with knowing yourself; understand what you are good at. Second, know your customers; learn their real business drivers and needs.

Consider the needs in some therapeutic areas for massive amounts of drug substance and product. For example, a customer developing drugs for Alzheimer's disease or diabetes will potentially be dosing chronically for decades. Larson says, "There's probably not enough manufacturing capacity in the world to make some of the needed antibodies." The questions to ask yourself include:

- Are you a CMO geared for this type of large-scale need?
- How can you continue to modernize to serve these customers?
- Or, are you better suited for clients with ADCs (antibody-drug conjugates), with little need for antibodies?

"We have this kind of bifurcation of volume in the industry," Larson says. "There are CMOs that recognize and are taking advantage of the opportunity by understanding precisely who they are and what services and innovation their clients need to drive their business decisions in that realm."

In summary, Larson reiterates the need for small molecule-focused CMOs to modernize their facilities, and she again cautions that the biologics-focused folks not get complacent. Both sides need to continue to implement the newest technologies and equipment with the goal being to achieve the best quality, consistency, and reliability, all leading to enhancing speed to market for customers.

Perhaps the best outcome will be a convergence of technology and understanding of both sides (small and large molecule). That may actually be led by the new kids on the block: the single-use or continuous-manufacturing innovators, and for example, those working on niche cell-based therapies. So who knows? Perhaps after all, innovation — the meaningful kind — will soon drive Larson and others in their business decisions. She certainly won't be shy about letting partners know when that happens.

An Outsourcing Challenge: Creating A Knowledge Base With Legacy Value

SUE WOLLOWITZ

At risk of speaking about an overdiscussed topic, knowledge management continues to be a challenge at the interface between sponsors and CDMOs. We know that regulatory agencies see knowledge management as a major component of quality risk assessment, and understanding of the design space, as quoted in ICH Q10:

> *Product and process knowledge should be managed from development through the commercial life of the product up to and including product discontinuation. For example, development activities using scientific approaches provide knowledge for product and process understanding. Knowledge management is a systematic approach to acquiring, analyzing, storing, and disseminating information related to products, manufacturing processes, and components. Sources of knowledge include, but are not limited to, prior knowledge (public domain or internally documented); pharmaceutical development studies; technology transfer activities; process validation studies over the product life cycle; manufacturing experience; innovation; continual improvement; and change management activities.*

However, when outsourcing development activities, documentation of the development history can become particularly challenging because the sponsor does not have 100 percent access to the primary data or the environment in which it was gathered. In addition, changing dynamics at the sponsor company can place additional demands on the documentation of development activities. Here is an example of the complications that can arise particularly for the small companies that depend on CDMOs for a majority of their development activities:

> *A small startup with limited funds identifies a development candidate and a possible synthesis route in-house. It contracts a CDMO to initially provide GLP and Phase 1 material, and to do early analytical development and stability. Subsequently with some new funding sources, the startup then hires additional CMC (chemistry, manufacturing, and controls) professionals internally. These new members must quickly catch up to learn what has been done at the CDMO and identify new service providers to do preformulation work, solid state characterization, and/or Phase 1 drug product manufacture. After a year of activity, with funds again running low, the startup tightens its belt, the project is put on hold, and these recently hired CMC experts move on to other companies.*
>
> *Another year later, the project is reactivated, or being reviewed for outlicensing/partnering. The internal people who oversaw the development work are gone. Contracts with the CDMOs have expired, and workers there have changed positions. What remains is a pile of development reports from multiple sources, gathering e-dust. New employees must decide how long it will take to be Phase 2 or 3 ready, whether the formulation or test method is truly robust, if they can support a process change without more work, why the yields are so variable, etc.*

Or how about this one?

> *A CDMO is asked to quote on a project that has already been in a Phase 1 study. It is given summaries of the process, formulation, test methods, etc. in a technical package, perhaps taken right out of the IND (investigational new drug) application. After taking on the project, the CDMO finds that the test method has insufficient resolution or the process cannot be replicated, and has to invest more time (and money) in the project than in its quotation, frustrating both service provider and client. When they finally do complete their work, their reports are subject to numerous rewrites by the client. Two years later, when they are no longer working with the client, the CDMO is asked to provide additional supporting data that has long been archived.*

If you have been in our business for a while, you may have found yourself in situations like these, frustrated by the way development activities have been docu-

mented at the CDMO and with the sponsor interface. Clearly, a database of poor-quality documents is not knowledge management. We know a legacy perspective on the documentation of development activities is essential. Information and the assessment of that information must be captured in a manner that recognizes how people may use the information in the future, particularly in the absence of its creators.

This is not just a minor issue of convenience and efficiency, avoiding the need to repeat studies. Miscommunication of results can have strategic consequences as well as tactical ones. For example, misunderstanding of stability results or processing conditions used in a study may lead to erroneous decisions on candidate viability, the need for a specific process or presentation, or acceptability of a clinical formulation. It may lead to misjudging the value of an asset, the uniqueness of a formulation, or the probability of success.

CONSIDER ALL USERS

To create legacy-value reports, both sponsors and providers need to keep in mind all the potential users of the documents. As shown in Table 1, the accessibility of usable information impacts the company and the program over many years.

The tertiary, or "forensic," reader is particularly challenged by poor knowledge management. Even in an electronic world, we still assume that the connectivity between points of data will be made by the project guru, if you will. But project gurus disappear, and the value of the knowledge database is only measured by what can be retrieved — and understood — in their absence.

Development documents that should meet the criteria discussed here include: process and product development reports (summaries of the work that is captured in notebooks and batch records), design-of-experiment studies, method-development reports, stability reports, and campaign reports. Documentation such as data analysis and modeling — which use data from other reports to create new results, draw new conclusions, or communicate technical progress and positions to a broader audience — should also be included.

To ensure that documents have the quality to add legacy value to the knowledge database, they should be assessed against the above needs. Basic questions you should ask include:

- Can anyone look at this document and know what project it is for, why it was done, and what the key conclusions were?

- Can a person skilled in the art, but not familiar with the project, repeat the work based on this document and any referenced materials (that are also in the knowledge base)?
- Are the results sufficiently traceable to primary documents and data that can be used to support regulatory and quality positions?
- Are key conclusions fully supported by the evidence provided in the document (and if not, should they be key conclusions)?

Still, documentation doesn't have to be complicated or take a lot of time. In some cases, CDMOs already have systematized their reports to a certain level, and introduction of a "context" page by the sponsor before completion or filing is all that is needed. In other cases, CDMO documentation practices may require an upgrade, but I have found that, in the long run, CDMOs end up happy they made the requested changes.

Sometimes a simple checklist is helpful for the review process. For example, are the types of test equipment, raw materials, and excipients adequately defined? Is there CDMO-specific jargon that needs clarification? Are referenced documents also on file with the sponsor? Is sufficient (and clear) raw data and spectra provided to allow the sponsor to reanalyze the results a year from now? As part of good communication, it is helpful for the sponsor to provide such a checklist or the parties to agree on expectations upfront to minimize review cycles, close out reports more quickly, and reduce later requests for archived or unfindable results.

Including specific expectations as part of contractual agreements will allow the CDMO to make sure the proposals are adequately structured and that the data is being collected most effectively to create requisite reports. Of course the format may be proposed as well for editing by the sponsor. In either case, the internal reviewers at the CDMO can subsequently use such "documentation agreements" as their own review criteria for the most efficient closure.

Knowledge management of non-GMP documentation may not fall under the purview of the current data integrity discussions. However, good documentation practices in R&D labs, combined with the translation of primary data into high-quality reports, will render the results and findings useful to all readers during the project and product life cycle and ensure legacy value to the knowledge database. L

SUE WOLLOWITZ is president of Wollowitz Associates, LLC.

TABLE 1

Document Users	What The Information Is Used For	What They Need To Get From The Document
Primary readers worked with the technical expert(s) at the CDMO, i.e., knowledge creators, to carry out the activities. Typically, they are technical experts themselves, though not always.	▸ Making decisions about next technical steps ▸ Making quality decisions ▸ Providing support for regulatory submissions	They need results from the experiments, analysis, and evaluations to help them understand and document a preferred (or failed) process, formulation, method, model, etc., or to make a decision on steps forward.
Secondary readers were not involved in the creation of the information, but they have some ability to pull knowledge history from others.	▸ Effectively becoming team members or taking over projects ▸ Understanding key decisions made previously ▸ Identification of missing knowledge that needs completion	They need all of the above, plus context for what problems were being addressed and how the document fits into the overall library of information on the project, e.g., references to prior work, dates, etc.
Tertiary readers review documents without contact with the authors or those that hold knowledge history. They are forensic readers, trying to find details or understand whole projects based on the documents available.	▸ Intellectual property ▸ Manufacturing change control support ▸ Due diligence for in-licensing or investing ▸ Reactivation of a dormant program ▸ Regulatory document support in multicycled programs	They need all of the above, plus information on where the work was done, where to find original data, who did the work, and who may have reviewed or approved the reports. Information on alternate names or identifiers that may have been used across companies is useful when mapping out project histories and re-creating files.

Congratulations

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For Outsourcing, Make Sure Your Risk Management Is Redundant

PETER BIGELOW

Many biotechnology and pharmaceutical companies are struggling with what I call the "sourcing dilemma": How do I achieve redundancy in my supply chain while keeping costs down and incentivizing my primary suppliers — whether internal or external? Redundancy is expensive, it consumes precious time and resources, and it distracts your team from driving all-important development milestones.

But the potential points of failure in a supply chain represent risks that investors and other stakeholders cannot stomach. Too many vital medicines do not get to patients and too many development programs are crippled because of a breakdown of the "weakest link" and the absence of viable backup plans.

Therefore, drug development organizations need to be deliberate in decision making regarding building redundancy and managing supply chain risks. The following key questions and initial answers can serve as a guide to those deliberations.

1. WHERE EXACTLY ARE THE RISKS?

I suggest drug sponsors undertake a formal supplier risk-assessment process with the specific goal of identifying potential failure points. This list should include quantifying risks associated with capacity, the ability to react to market changes, compliance, and technical capabilities, among other items. There are a number of effective techniques used to perform supply chain risk assessments. As an example, the ISPE Drug Shortage Gap Assessment Tool, available to ISPE members, is an excellent methodology to identify and understand the vulnerabilities in your supply chain. Additionally, some consultants who work in this field have created templates to guide assessments and identify potential points of failure.

In all cases, a common-sense approach — something that makes sense for your organization and product(s) — is essential. Members of your team or outside technical and business specialists with deep knowledge of facilities and processes — and that may include a trusted CDMO or CMO partner — should systematically review all aspects of the supply chain, from raw materials to final product. Initially, your professionals can provide an objective rating you've decided on for all areas of operation, particularly for those activities that you may already know from experience or product characteristics could potentially lead to supply problems.

2. HOW BIG ARE THOSE RISKS REALLY, AND CAN I RECOVER QUICKLY FROM A FAILURE?

Next, it's imperative you understand the potential impact of any supply chain failures. To decide where risk mitigation tools should be employed, determine the resiliency of suppliers and try to assess the time to recover. For example, the time to recover from a problem at a contract packager may be much shorter than at an API manufacturer, so you may prioritize the API manufacturer for further analysis and attention. Many factors can come into play here, starting with, as I'm sure we all recognize, adding a second (or third) manufacturer to your network will require at least changes to filings/dossiers, and additional stability or bioavailability studies. Despite these hardships, I'd put it this way: You have to come to grips with the implications of any supply interruption, and even more importantly, your ability to recover quickly from such a disruption.

"What if" analyses may be quite useful to understand the various scenarios that could impact product supply: What if a key supplier had a compliance issue? If a natural disaster (e.g., hurricane) occurred, how long could production be curtailed? What if a key ingredient was not available for three months or six months? Again, your current and potential outsourcing partners are good sources to consult, particularly since any disruption will affect them as well. Finally, another important consideration is the accuracy — or uncertainty — of your product forecasts. Has adequate capacity been reserved if the product meets or exceeds upside forecasts? We've all heard of issues with incorrect forecasts, and because of the difficulty in understanding future needs and markets, the best policy is to be ready when the forecast is off. Chances are, it will be.

3. CAN THE PRODUCT BE SUPPORTED WITH REDUNDANCY?

It isn't always easy – or even possible – to qualify a backup supplier. For example, as products are launched, looking to simply divide launch volumes between multiple suppliers may be problematic. That's because real-world timing, availability, costs, etc., make this more difficult than it may seem at first. Nowadays, with newer and narrower therapy targets, you may have too small quantities to interest a new supplier to make the investment to prepare to manufacture your material. In other cases, it may be difficult to identify a backup supplier with enough available capacity and the appropriate equipment to manufacture or package the product. Of course, cost — to the suppliers and you, the drug owner — is almost always a — if not the — key contributing factor. The risk-cost analysis you perform has to make sense to your entire organization.

4. WHAT TYPE OF REDUNDANCY SHOULD BE CONSIDERED?

While redundancy overall is a vital risk-mitigation tool, all redundancy is not created equal. For example, qualifying two equipment/manufacturing trains within a single facility may be one tactic, and this occurs probably more than you might think. However, qualifying manufacturing trains in two separate facilities often provides a higher level of comfort and risk mitigation. But do you want those two facilities to be owned by the same CMO? That's another thought process. Moreover, consider that redundant suppliers can be set up for a "cold start" (requiring new procedural activities and longer time) or a "warm start" (where product may already be in smaller production at a provider but needs to be ramped up). These have to be recognized as quite different strategies.

It's also important to point out redundancy considerations can occur at different production and management levels. Consideration and analysis should reach down to individual systems within a plant, and even to specific product components. Should you install a complete secondary high-purity water loop within a manufacturing plant, in case the first one requires maintenance? Could you even approach your CMO with the idea? Should you qualify a second supplier of rubber stoppers for an aseptic vial product, in case the primary supplier has a problem? Does your CMO already have this covered? There are no pat answers, but these types of questions should be addressed so you arrive at the responses best for you and your development and manufacturing partners.

> *"You have to come to grips with the implications of any supply interruption, and even more importantly, your ability to recover quickly from such a disruption."*

There are many strategies that may not be immediately obvious, such as, for example, building strategic inventory, including work in progress (WIP) at key points in the supply chain to provide a buffer in case of a short-term interruption. In some cases — and we are starting to see this with Big Pharma — it may make sense to reserve capacity at a supplier even if the current forecast does not warrant it (as we touched on above). Of course, options like these will come with a cost. Don't forget about effective lean manufacturing/Six Sigma programs: These programs have proved to improve performance, reduce cycle times, and allow a faster recovery period on a product-by-product basis. As most of us know, at times our products themselves come with inherent risks, but those can be reduced by improving the formula or manufacturing process.

5. WHAT IS THE RIGHT BALANCE?

Understanding all the trade-offs involved in your redundancy-related decisions allows you to more clearly understand individual decisions and your entire supply chain. We might expect a company with a single new product in development to have a much lower tolerance for risk than a generic firm or a company with many products. Trade-offs are decided in large part by setting priorities, both on a corporate and project level. We might like to believe that risks with the potential for highest impact get addressed first. Yet some mitigation activities are inexpensive and easy to accomplish and can immediately impact the risk scenario positively. Qualifying multiple packaging component suppliers could be an example of this. A thoughtful balance between risks, time, and costs will go a long way in guiding your decisions.

Actually, all the questions above in one way or another address your balancing risk and reward. Once these have been asked, hearty discussions by the right technical and business experts have taken place, and honest assessments and analyses have been made, I suggest establishing (yet another) formal plan. This one would be a multi-year look to clearly outline priorities, identify constraints, and mention mitigation strategies, that is brought to the organization's senior executive level for approval. With that, full internal socialization of the plan is critical.

Two more points here: First, your best estimates of all costs should be built into all budgets being formulated for your development and manufacturing of a product. Second, don't forget your partners. Consult with them, and at the same time agree to put metrics in place that effectively measure performance and provide leading indicators of possible issues. This should be viewed as something that helps guide both you and your development and manufacturing service providers. The best policy is to develop a culture of collaboration with your suppliers. When that happens, those metrics more than measure; they drive the right behavior in the first place. This also means that issues are anticipated or recognized early, and performance improvement is the continued expectation.

EXPECT RISK ASSESSMENT REVIEWS

The intense focus on reducing drug shortages throughout the drug industry has created a fuller awareness of the impact of supply chain failures — and has created the expectation that bio/pharmaceutical companies must have robust programs to prevent shortages in the first place. Around the world, regulators are asking to review risk assessments and mitigation strategies, and you can expect this to become the norm. Having transparent and understandable risk-management plans and activities in place will go a long way in helping your organization get your products to patients.

PETER BIGELOW is president of xCell Strategic Consulting.

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Harmonizing Quality Management Systems In Early Drug Development

BIKASH CHATTERJEE

Today, most biopharma development programs include the support of a contract service provider (CSP) for everything from early development contract research to commercial manufacturing and analytical support. The factors that drive the decision to engage a CSP for commercial manufacturing are many, and there are multiple collaboration elements that impact organizations' ability to work together effectively. Let's explore one of the most important considerations when establishing a relationship with a CSP for early development programs.

A LOOK AT DIVERGENT PRIORITIES

The challenges that face the sponsor company and CSP are often divergent. For example, a CSP must balance the unique requirements for a new program with the commitments and systems it has already in place for existing commercial clients and products. The compliance tolerance and philosophy of a sponsor, on the other hand, can be moving targets, complicated by evolving regulatory standards and industry best practices, and to a great extent, innovation and technology. The CSP's ability to juggle and accommodate these customer variances will often define its suitability as a long-term and fully aligned partner.

In a recent industry survey, 315 respondents cited no less than 18 criteria for evaluating a CMO. But while every outsourcing decision has program-specific elements integral to the selection criteria, there are common elements to be considered that help avoid unexpected surprises – on both parties' behalf.

HARMONIZING QUALITY MANAGEMENT SYSTEMS

A core challenge to a successful engagement with a CSP is aligning the quality management system (QMS) for both the sponsor and the provider. For virtual organizations, there may be very little to harmonize, and partners are often selected in large part based on the maturity of their QMS. However, as programs move through development, and the sponsor establishes its own internal expertise and oversight, the potential for divergent processes and practices increases. Here are several elements of a QMS that can become points of contention between a sponsor and CSP and should be considered when evaluating a partner.

CHANGE CONTROL

Change control processes are notorious for their ability to impede a program. Poorly designed change control programs are known to suffer from a myriad of weaknesses, including a poorly defined or missing risk component, poorly defined structure and content, and a propensity for subjectivity. Each of these weaknesses is magnified when engaging a CSP.

An initial due diligence audit is an excellent opportunity for determining how change control is administered at the development site, and how and when the sponsor will be involved in its evaluation. Often, it's stated that "any change that could impact the sponsor's product will include an evaluation by the sponsor." But as always, the devil is in the details. For example, does a one-for-one replacement, typically described as a "like and kind" replacement, include a sponsor sign-off? When evaluating the change control process, consider the following four questions:

1. Does the procedure clearly articulate what constitutes a minor, major, or critical change?
2. Does the change control procedure clearly define under what circumstances and to what extent a sponsor can be involved in a change control process and decision?

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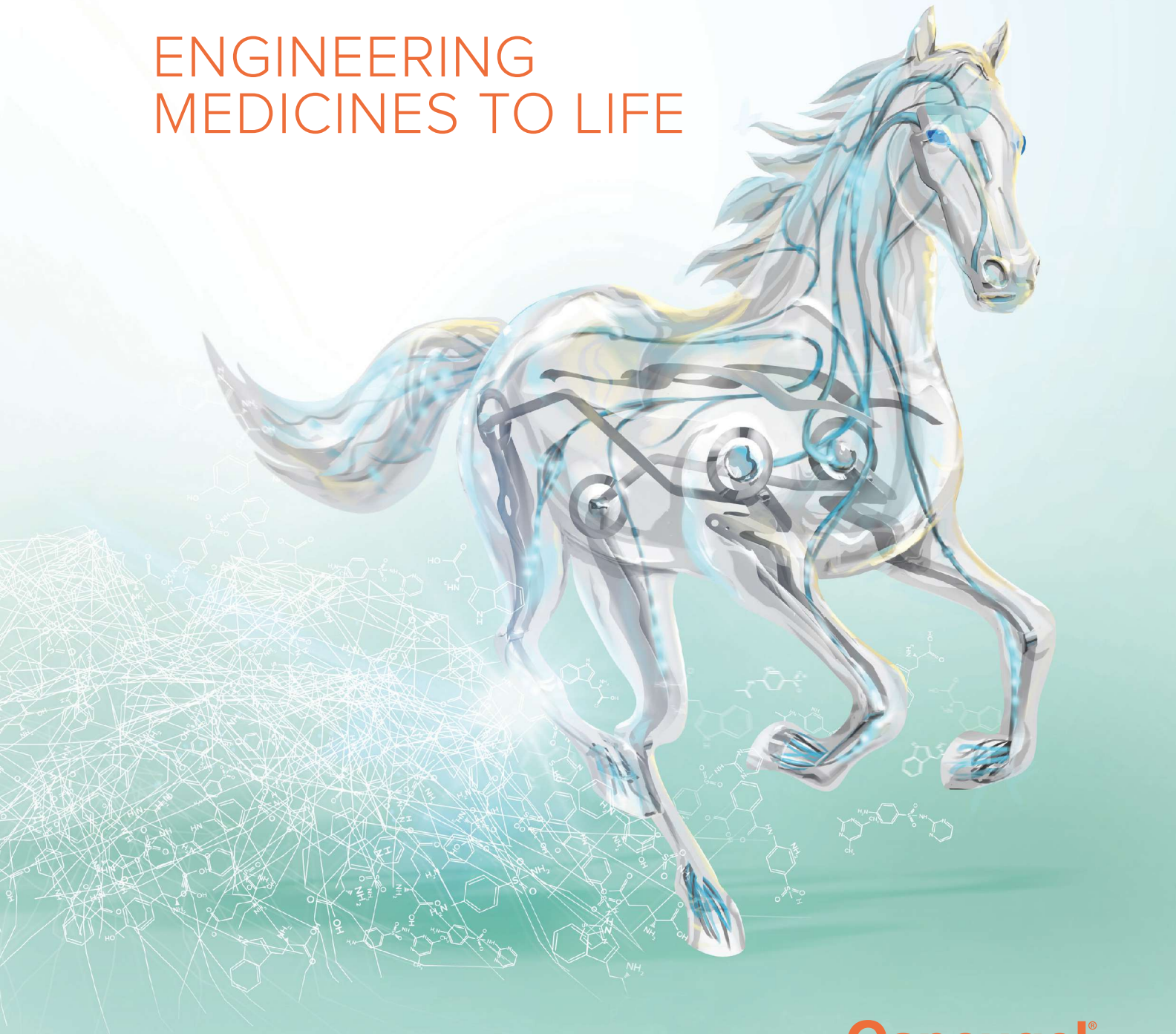

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3. Does the sponsor have a clear process for capturing changes in the CDMO's process within its own QMS?
4. Is that process compatible with the CSP's current process?

This last point particularly is often overlooked and can be a major point of friction for sponsors with their own well-developed QMS. Moreover, this can be especially critical for sponsors with products that utilize a device component, which could entail a cross-reference between the design history file, if changes are required.

INVESTIGATING DEVIATIONS/NONCONFORMANCES

Deviations require both the CSP and sponsor to understand the root cause and implications of a process or QMS excursion. Unfortunately, the thoroughness of the root cause investigation can also become a point of contention, particularly because it can impact both material supply and financial responsibility. Understanding whether a sponsor can be involved in an investigation — and to what extent — is critical to conducting and documenting an effective root cause investigation. For early development programs, where the technical insight is fluid, it is not unusual to have the sponsor intimately involved. In later stage programs, the sponsor may have only review and approve authorization. In fact, some CSPs will only allow review and approve authorization. This, though, can place a great deal of responsibility back on the sponsor in its assessment of the provider's ability to effectively execute a thorough root cause analysis.

> *"One of the most challenging elements of any development program is the transfer and implementation of laboratory testing."*

Most CSPs are, in fact, reluctant to modify their typical deviation template, because they would constantly be revising the document for each new customer engaged. In addition, deviations will reside in the provider's QMS, and so the sponsor needs to decide if it is important to have corresponding references within its own system.

Another element of complexity, depending on the severity of the excursion, occurs when the CSP can choose to limit an observation to the sponsor's specific lot, but the sponsor determines that the excursion is part of a larger, fundamental issue. It's vital to have a clearly articulated process for handling this type of discussion.

LABORATORY SERVICES

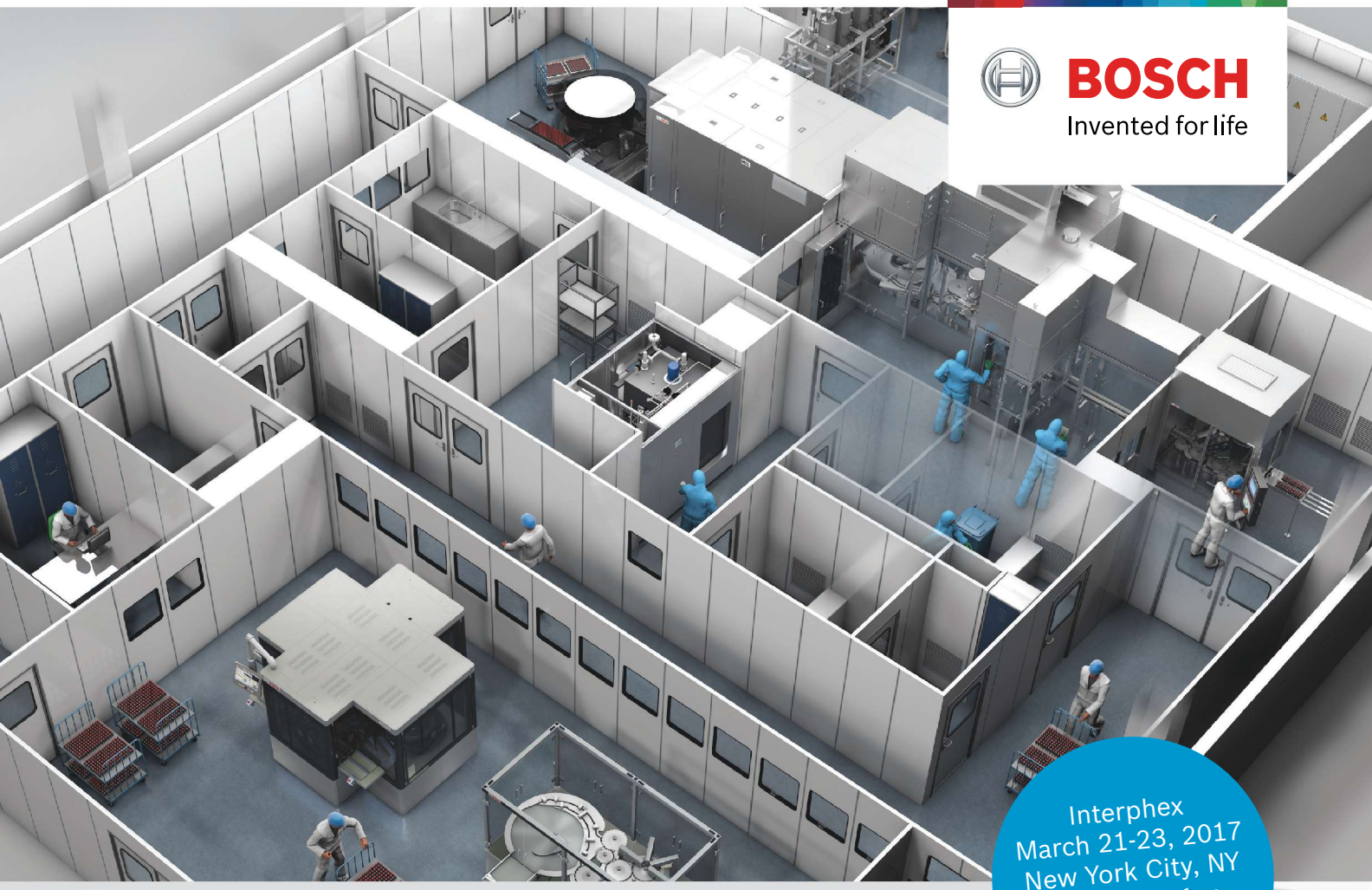
One of the most challenging elements of any development program is the transfer and implementation of laboratory testing. Of course it is essential to have confidence in the tools being used to measure your product and process performance, and again, a thorough audit can uncover small differences – those that could have a meaningful impact on product testing. For example, how is the sample treated when placed in the sample log-in area? Can it sit for a day waiting to be logged in and placed in the appropriate storage unit? The ability to infuse technical considerations into the assessment is a typical way to prompt a dialogue regarding product-specific requirements.

Method transfer is another area where it is important to have clarity regarding what information will be provided to the sponsor. Since methods are not validated early in the development program, it is important to have access to all of the raw data associated with the testing performed. Some CSPs will only provide a summary report, so if raw data is required, a discussion regarding the prerequisites to release this information to the sponsor is a good place to start. Questions to ask include: Is all of the data QA reviewed and released? Will the CSP release data that has not been QA reviewed?

Out-of-specification (OOS) test results are another area where it is crucial to be explicit, especially in early development programs. If a method constantly has Phase 1 laboratory investigation reports (LIRs), then perhaps the method needs some adjustment. Understanding the level of partnership in the successful deployment of the method is important to establish early on in the relationship.

Engaging a contract service provider requires much more than evaluating the technicality, quality, and robustness of the organization. Understanding the roles, responsibilities, and expectations between sponsor and provider early in the engagement process will ensure a smoother and more effective relationship, and one of the keys in early development is harmonizing quality management systems.

BIKASH CHATTERJEE is president and chief science officer of Pharmatech Associates.



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Timeline And Developmental Activities When Resources Are Limited

DAVE CASEBIER

It is increasingly rare that early-stage compounds or platform technologies are acquired without demonstration of clinical effect. Many years ago you could get funding for an idea, a piece of data, or a novel platform. With little exaggeration, funding could be generally raised as long as there was promise and the ability to tell a story, or until the concept was fully disproven. A new enzyme-based target, or even a quasi-crystalline idea, was sufficient for seed funding, and Phase 1 compounds were thought to be solid investments or acquisition targets.

Today, with translational/personalized/biomarker-driven medicine, we are in a much different environment. Nowadays, typical funding and investments are made in tranches and based on milestone events, so small biopharmaceuticals, with nominal funding for proof of concept and less chance of asset monetization (e.g., IPO, acquisition, large pharma partnership/licensing), find themselves with minimal budgets to get to IND (investigational new drug)-enabling studies or IND filing and possibly beyond a Phase 1 clinical trial. At the same time, given the pressures to be first to market, time is more a factor than ever in the making of critical decisions.

Outsourcing partners play an increasingly key role, but biotechs and other small companies may only have the resources to assign one or two people to work with the CDMO or manage the CDMO. Many of the activities that must be outsourced are nonnegotiable, meaning required for compound development, yet the implementation and administration can vary widely. Below I'd like to offer some reminders and a bit of advice to startups — or any drug developer — about what to expect and how to plan for what's not expected in the process of advancing new drugs.

LIMITED RESOURCES IN A DEMANDING BUSINESS

We'll start with the often-used saying of "fast, cheap, or good: you can only pick two." Perhaps this is especially true for smaller companies. In other words, the intersection of fast and cheap precludes a good product. Obtaining a high-quality product on a reasonable budget is generally time-consuming, but for a resource-limited company, time is money. On the other hand, creating a quality product quickly generally requires, shall we say, pallets of cash.

> *"The life sciences industry is far from cheap, but there are activities that are at least flexible."*

First, here are a couple of comments on "cheap." With limited resources (e.g., money and headcount), trying to advance as inexpensively as possible is a given. The life sciences industry is far from cheap, but there are activities that are at least flexible. The best descriptor of this might be the concept of phase-appropriate development, and spending only as the program progresses, throttling immediate spend, but achieving milestones that trigger subsequent funding.

Second, let's look at "fast." Time is money, especially in the sense that a small company generally has fixed costs that mount on a month-by-month basis; the fast-

er you can get to first-in-human experience, the better. However, this requires spending a great deal of that preclinical cash very rapidly, generally in a six-to-10-month time frame. A balance needs to be struck between an exhaustive comprehensive study and one that is more minimalistic, or even skeletal.

Finally, there is "good." In the biopharmaceutical industry, good is of course not optional, but it does have varying degrees. So how do we define good? While a vague term in general, it can be parsed into several components and addressed individually. I'll describe them here briefly as safety, manufacturing controls (quality), and clinical (and projected commercial) efficacy. Safety of course is nonnegotiable. In vitro and in vivo profiling are required by the FDA and other regulatory agencies. The holistic design of IND-enabling trials, with alternative plans for using feedback from early in-life experience, will generally save money and be faster overall than walking through the menu of initial studies sequentially.

cGMPs, while they may vary by product, process, and aspect of supply chain, have sufficient components in common as to be understandable to even the nonexpert receiving adequate training in standard operating procedures. However, quality — the result of cGMP implementation and controls — can elevate what might appear to be a straightforward production of a relatively inexpensive material into an unexpectedly costly budget section. The third component, clinical efficacy, may be indicated by preclinical studies, but is really definitively proven in Phase 3 trials. The end result is very difficult to anticipate or accommodate in almost any environment, let alone the resource-limited one we are focusing on.

DIVIDE (TASKS) AND CONQUER?

Henry Ford famously said that nothing is particularly hard if you divide it into small jobs. Investors and senior management at startups might agree, and they will add that they like to see a sense of urgency to get projects moving. However, I know from experience that a holistic plan will better assist both the operational and administrative stakeholders.

I'd advise creating the entire list of activities — as far as you can identify them — from in vitro testing and solubility profiling to canine/primate repeat dosing, even nationalization of patents. Since many or all of these activities are outsourced, the complete landscape can allow for coordinating, scheduling, and budgeting more efficiently. Particularly, (1) create each study, or

set of common-purpose studies, as an individual unit (e.g., Ames, micronucleus, and caco-2; receptor binding/inhibition panels; physico-chemical studies and preformulation), then build these out with dependencies and timing, with best estimates for expense; and (2) place more flexible activities in gaps that typically occur in development (repeat dosing studies or report generation from service providers). Once these are interlocked, the budgeting becomes significantly easier to project. I like to clearly identify activities that are flexible but still must be completed by certain filing, publication, presentation, or commercialization target dates. These hard-target dates need to be monitored in order to prevent a seemingly small developmental activity from delaying the advancement of an entire program.

A major advantage of an integrated plan is the coordination of internal and external studies and activities. If external study plans are synthesized with internal activities, the resulting plan can eliminate material shortages and at the same time help avoid redundant activities and expenses (not to mention maximizing safety and data acquisition). These plans may also help project needs for subsequent manufacturing and supply demands, something every contract manufacturing organization and sponsor knows is difficult to anticipate at best.

> *"I typically advocate starting to work with potential commercial API, drug substance, and drug product CMO partners as soon as possible."*

I typically advocate starting to work with potential commercial API, drug substance, and drug product CMO partners as soon as possible. Late-stage technology transfer is much more challenging, and often more expensive overall, than selecting a partner that can provide services for process optimization into clinical trial supply and through to commercialization. Generally, if a company has helped commercialize a compound, it is also able to contribute that experience to your advancement.

MANAGING EXPECTATIONS AND MAKING CHOICES

Finally, I'd like to address the concept and great challenge of designing, performing, and particularly accepting the results of the "killer experiments." These are the critical experiments that companies undertake and which will determine "in black and white" the viability of a program. Unfortunately, and perhaps too often, when negative results are indeed received, attempts to salvage the asset begin, thus seriously compromising the entire premise of the experiments. Everyone should be aware that while early failure of a drug saves money for the company and investors – and is, in a way, planned for – those running the business have a vested interest in keeping the program (and their positions) alive. Therefore, setting expectations, adhering to principles, and maintaining original targets are tough. It takes a good deal of discipline to face the failure of a program and shut it down rather than continue in the hope of finding a lifeline.

Even short of results that could end development, virtuals, startups, and biotechs particularly should prepare the members of their organization for the unexpected. Material can suddenly fail on stability, prompting a reformulation, limiting storage or packaging conditions, and shortening expiry. Issues may arise in scale-up that change the impurity profile enough to require a bridging safety study. A good policy is to list the potential ways that things could go wrong and provide guidance to executive management regarding their cost should those contingencies arise. Working with your partners — CROs, CDMOs, consultants — can help ameliorate negative impacts. Exact costs are almost impossible to project, but even "greater than 'X' and smaller than 'Y'" can help to get folks' attention as to the magnitude of any risk.

All stakeholders participating in a small biotech need to be in agreement as to plans, activities, timing, possible risks and remediation, and all known and potential costs. With everyone on board, have confidence in your plan and stick with it. Very few organizations have the challenge of wondering what to do with all the cash and free days on their hands. Smaller drug developers especially need to make the best of all their resources.

DAVE CASEBIER is principal at DSC Consulting LLC.

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Strategy For Early-Phase API Development

SRIRAM NAGANATHAN

Most often, the delay in initiating human clinical trials is caused by the unavailability of suitable drug. Therefore, there is great pressure on the chemical development group to not be the limiting factor and ensure sufficient drug is available in a timely manner. As the drug development advances into later phases, drug supply is usually less of a constraint, because the physicochemical properties of the drug are better understood, and a reliable supply chain begins to take shape.

There are multiple best practices for rapid filing of an investigational new drug (IND) application and initiating clinical trials. But there are only a few trusted principles that ensure the chemical development group is not a barrier to the drug supply.

"PERFECT IS THE ENEMY OF THE GOOD"

When planning for the initial delivery of clinical trial material (both drug substance and drug product), the focus should be on the delivery of enough material to cover the Phase 1 trial and also initiate Phase 2 trials if needed. Along the way, material needs for formulations development may be fulfilled through judicious planning of batch size and production schedule. If the clinical program is successful, there will be sufficient time and resources to develop an elegant and cost-effective commercial process. At this stage, a process that can be scaled to produce a consistent and predictable quality of the drug substance is entirely adequate.

ONE BATCH VS. TWO BATCHES

Initially, the drug substance requirements are generally small and limited to conducting nonclinical toxicological studies, which enable the initiation of Phase 1 human trials. Drug substance needs for Phase 1 trials tend to be a few kilograms to a few tens of kilograms and usually consist of the entire quantity of the available world's supply of the drug! Thus, the debate over whether the chemical development group makes one batch of the drug substance for use in both the nonclinical toxicology studies and Phase 1 trials, or adopts the two-batch strategy by making a smaller batch for the toxicology studies followed by a batch manufactured under cGMP for Phase 1 trials. Obviously, each approach has its advantage and associated risk.

> *"In our experience, the two-batch strategy has been employed successfully in over 20 programs."*

The one-batch strategy is a linear process, and once manufactured, the materials can be engaged in the development activities without any risk or interruption. However, all chemical development and manufacturing have to be completed prior to the start of any dosing, human or animal, and could last about six to 12 months for a typical small molecule. Adding the customary six months it takes to obtain reports from IND-enabling toxicology studies, time for first-in-human dosing could be 12 to 18 months from nomination of a clinical candidate.

Employing a two-batch strategy is likely to be considerably faster because several activities happen in parallel. First, a smaller batch of drug substance is prepared and used to initiate the toxicology studies,

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typically three to six months from nomination of the candidate. In the six months it takes to conduct the toxicology studies, the process is refined sufficiently to enable the cGMP manufacture of the batch to be used in Phase 1 trials (commonly referred to as GMP-1), just in time for the IND application to become effective. In this approach, the clinical trials start nine to 12 months from candidate nomination.

In our experience, the two-batch strategy has been employed successfully in over 20 programs, resulting in a median time of 11 months from candidate nomination to being ready to dose humans.

THE CHALLENGES

The cornerstone of chemical development is ensuring that results obtained in clinical and nonclinical studies using every batch of drug substance can be connected to a past and a future batch — it is not as important to have the highest purity levels from the outset as it is to have progressively lower levels of the same set of impurities in every successive batch, or to have eliminated most of them altogether. Every impurity above a certain level must be qualified in toxicological studies. The appearance of a yet-unseen impurity would be a significant problem, and potentially cause delays to clinical studies.

The majority of challenges during early process development and synthesis fall into the following areas:

IMPURITY CONTROL

It is difficult to manage the impurities resulting from starting materials early in development, especially when the route of synthesis is still under development. In fact, the starting materials may themselves be under development, let alone the process for their manufacture. The most common way to ensure that starting materials do not contribute to different impurity profiles in the two-batch strategy is to employ the same batch of key starting materials for the toxicology and the clinical batches.

Better yet, if a route of synthesis can be established early, the manufacture of advanced intermediates can be undertaken at a CDMO while process development is ongoing. In some cases, we have utilized the synthesis of an advanced intermediate by a CDMO to evaluate its suitability for the manufacture of the drug substance, especially if it possesses capability to operate under cGMP.

Ultimately, avoiding impurities cropping up unexpectedly depends on the quality of the analytical method (see below). As the chemical process gets refined and the side reactions brought under control, once-insignificant, or even once-invisible, impurities become prominent.

SALT SELECTION AND POLYMORPHISM

A form (polymorph) screen should be embarked upon as early as the drug candidate is identified. As most drug candidates have basic or acidic functions, a salt is appropriate for control of both a robust solid-state form and also as a control point for achieving impurity rejection. Having said that, one should not dismiss proceeding with a freebase (or free-acid) as the final form being developed. There have been many instances where a salt really does not add much to the bioavailability or stability compared to the freebase. However, the formation and breaking of the salt provide an important stage for purification. Quite often there may be more than one viable salt or polymorph, and the final form for development may not reveal itself well into the development process. So, the toxicological studies will have to be initiated with one salt (form) and then a different salt (form) may be preferred for human trials. This switch requires a bridging toxicology/pharmacokinetic study.

STABILITY & ANALYTICAL METHOD DEVELOPMENT

Development of analytical methods and controls to assess impurities, forms, and stability (degradation) of the drug substance must be undertaken early in the development. This is especially true for the development of stability-indicating methods and obtaining early indication of the stability of the selected form of the drug substance. This is one aspect of development that cannot be mitigated by throwing more resources at it! A six-month stability study takes six months no matter how hard one tries to shorten that duration.

CDMO SELECTION

Working with a compressed timeline means that several activities are happening simultaneously, and judicious selection of a CDMO becomes very important — including one-stop vs. several specialty experts. While a one-stop provider may understand the contexts and timelines better, it may not have the insight and expertise into specialized problems (e.g. polymorph-related issues). The most important characteristics are adaptability to rapidly changing conditions, technical expertise, and ability to communicate clearly in a timely manner.

SRIRAM NAGANATHAN is senior director of chemical development at Dermira, a biopharmaceutical company focused on bringing innovative and differentiated products to dermatologists and their patients.

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Pharma Industry Lacks Consensus On Key Attribute Of A Sponsor-CMO Relationship

KATE HAMMEKE

Over the past several decades, the practice of outsourcing has evolved from transactional, client-vendor relationships where cost savings were the primary focus, to preferred provider relationships with pre-vetted companies to start up projects quickly and then to relationships more strategic in nature to gain access to technologies, skills, or expertise not possessed in-house. Regardless of your level of outsourcing experience and approach, it is important to know there are tools available to make this time-consuming and complex process of selecting and vetting a manufacturer simpler and more effective in meeting your needs for a qualified supplier.

Life Science Leader's annual CMO Leadership Awards is one of these tools. The data — collected by Industry Standard Research, a full-service market research provider to the pharma and pharma services industries — that serves as the foundation for the awards is experience-based and brings an important component into the CMO selection process: how the CMO performed for its current and recent customers relative to their expectations. While the adoption and implementation of outsourcing strategies is diverse, feedback from peers on their experiences when working with specific manufacturers is inherently valuable for guiding your own CMO selections.

The 2017 CMO Leadership Awards result from the feedback of 339 industry peers and reflect 1,755 service encounters with more than 80 CMOs' offerings, including drug substance (small molecule and biologic) and drug product manufacturing activities. ISR screens for involvement with outsourced manufacturing and/or decision-making influence on contract manufacturer selection to ensure the respondent group is relevant for providing feedback on outsourced manufacturing activities. This year, the respondent group includes 44 percent of participants from large biopharma (R&D $1B+) companies and 56 percent from small and midsize biopharma companies. The majority of respondents work for companies headquartered out of North America (71 percent) and Western Europe (27 percent); a small proportion are based out of the Middle East and Japan (2 percent). Interestingly, four out of five respondents mentioned the company they work for has a large molecule offering; in fact, most respondents work at companies that currently have both marketed biologics and biologics in development (57 percent). All this is to say, the data that identifies the CMO Leadership Award winners comes from a well-qualified group.

To help *Life Science Leader's* readers understand more about these industry peers, ISR asked participants in the research to prioritize a list of metrics as "Top 5" and the "Most Important" when it comes to selecting a contract manufacturer. This information will help new outsourcers know which attributes have contributed to successful outsourcing relationships in the past, and it will help experienced outsourcers identify CMOs based on information from peers who share their same outsourcing priorities. This can be especially important when there is a lack of consensus around the most important attribute for a CMO to possess.

For the second year in a row, *A Strong Regulatory Track Record* topped the list as the most important attribute influencing CMO selection according to 12 percent of respondents and was in the top 5 selection criteria for one-third of respondents. *The Proven Ability To Manufacture API/The Dosage Forms We Require* placed second with 11 percent of respondents indicating this is the most important selection criterion and one-quarter of respondents including the attribute in their top 5. With 10 percent of the vote, *Reliable, On-Time Delivery* netted third position for the most important selection attribute and captured 37 percent of respondent votes as a top 5 selection attribute. Following closely at 9 percent and in fourth place for the most important selection attribute is a *Track Record For Meeting Quality Performance Metrics.* This attribute was among the top 5 for 28 percent of respondents.

After these first four attributes, which were each deemed the most important criterion by ~1 in 10 respon-

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dents, there is a drop-off, and the next three attributes are perceived most important by ~1 in 20 respondents; the next drop-off is more substantial, and the following 18 attributes were ranked as most important by anywhere from 1 in 33 to 1 in 100 respondents. This pattern shows how some metrics carry a substantial amount of influence for different parties in the outsourced services buying audience; this lack of consensus leads to a cloudy decision-making process because no specific criterion dominates the CMO selection decision. Unfortunately, ISR's research suggests this trend toward greater diversity in selection criteria is going to continue to grow rather than to consolidate around specific metrics.

These same attributes are used as evaluation criteria for each contract manufacturer included in the study. Figure 1 displays how the performance metrics are classified by buyers of outsourced services and the performance metrics that correspond to the award categories. Respondents who have worked with a company within the past 18 months or are currently engaged with the CMO can rate the contract manufacturer on its performance relative to expectations.

Using insight from industry peers on the CMO attributes that contribute to a successful outsourcing relationship along with performance ratings can help your outsourcing decision-making unit streamline the shortlisting process. Match your own priorities and project needs with companies that have proven to excel in those areas — and feel confident because the process is guided by data based on recent customer feedback and insight from experienced outsourcers. The 2017 CMO Leadership Awards winners represent the CMOs that have performed the best on these metrics for their customers. A variety of contract manufacturers in terms of size and offering are winners this year. So, whether your company's preference is for a one-stop shop with an end-to-end offering, or your projects have unique requirements only available at niche providers, know that these companies come with the "seal of approval" from your industry peers. L

Survey Methodology: Industry Standard Research's Contract Manufacturing Quality Benchmarking research is conducted annually via an online survey. For the 2017 CMO Awards data, more than 80 contract manufacturers were evaluated on 27 different performance metrics. Research participants were recruited from biopharmaceutical companies of all sizes and screened for decision-making influence and authority when it comes to working with contract manufacturing suppliers. **Respondents only evaluate companies with which they have worked on an outsourced project within the past 18 months.** This level of qualification ensures that quality ratings come from actual involvement with a business and that companies identified as leaders are backed by experiential data.

Figure 1
Source: Industry Standard Research, CMO Quality Benchmarking Report Suite (2017)

AWARD CATEGORY: QUALITY	RELIABILITY	CAPABILITIES	EXPERTISE	COMPATIBILITY	DEVELOPMENT	PERFORMANCE METRICS	PRIORITY: TOP 5	MOST IMPORTANT
●			●			Strong regulatory track record	34%	12%
		●				Proven ability to manufacture API/dosage forms we require	27%	11%
	●					Reliable on-time delivery	37%	10%
●						Track record for meeting quality performance metrics	28%	9%
			●			Scientific knowledge	31%	7%
	●	●				Has capacity to meet our demands	32%	7%
						Low cost	31%	6%
			●			Ability to smoothly scale up manufacturing and transfer technology	21%	4%
		●		●		Stability testing capabilities	16%	3%
				●		Well-regarded within the industry	20%	3%
			●			Experience level of staff	27%	3%
●						Right first-time measurements	27%	3%
		●				Facility has most up-to-date manufacturing technologies	15%	2%
	●					Flexibility to adjust schedule for special requests	16%	2%
		●	●			Offers innovative solutions	11%	2%
		●		●		Complementary core competencies to in-house or other manufacturing contractors	9%	2%
	●					Metrics for meeting overall project timelines	12%	2%
	●			●		Timely project communications	16%	2%
				●		Access to desired markets	8%	2%
		●	●			Provides regulatory support for filing	14%	2%
				●		Cultural fit	12%	2%
●	●					Up-front contingency planning, risk management	11%	2%
				●		Accessible senior management	8%	1%
	●			●		Financial strength/stability	14%	1%
	●	●				All facilities fully owned (i.e., not subcontracted)	7%	1%
		●				Storage capabilities	10%	0%
					●	Process development capabilities	N/A	N/A
					●	Analytical method development, qualification, and validation	N/A	N/A
					●	Regulatory support for filing IND or NDA	N/A	N/A

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List Of Winners
Page 40-47
Company Profiles
Page 48-60

CMO LEADERSHIP AWARDS 2017

Life Science Leader's readership of pharmaceutical and biopharmaceutical executives has told us about their struggles in efficiently vetting potential CMO partners. In response to this input, *Life Science Leader* developed the CMO Leadership Awards.

Based on Industry Standard Research's Contract Manufacturing Quality Benchmarking annual online survey, more than 80 contract manufacturers were evaluated on 30 different performance metrics. Research participants were recruited from biopharmaceutical companies of all sizes and were screened for decision-making influence and authority when it comes to working with contract manufacturing suppliers. Respondents only evaluate companies with which they have worked on an outsourced project within the past 18 months. This level of qualification ensures that quality ratings come from actual involvement with a business and that companies identified as leaders are backed by experiential data. CMOs have an opportunity to win these awards in up to three groups of outsourcing respondents — Big Pharma, Small Pharma, and Overall (combined Big and Small Pharma).

WHAT ARE THE AWARDS?

ISR survey participants were asked to provide an expectation rating for each CMO they have worked with in the past 18 months. Respondents answered over 45 questions per outsourcing category (small molecule, biologic, finished dose) and rated CMOs across 30 performance attributes. Points were then totaled for a combined score for each attribute, and a composite score for each core category was determined. Winning CMOs were determined when comparing their overall score vs. the competitive set.

To learn more about ISR's industry reports, customized research, or to be included in future CMO Leadership Awards annual surveys, visit isrreports.com or contact ISR at (919) 301-0106.

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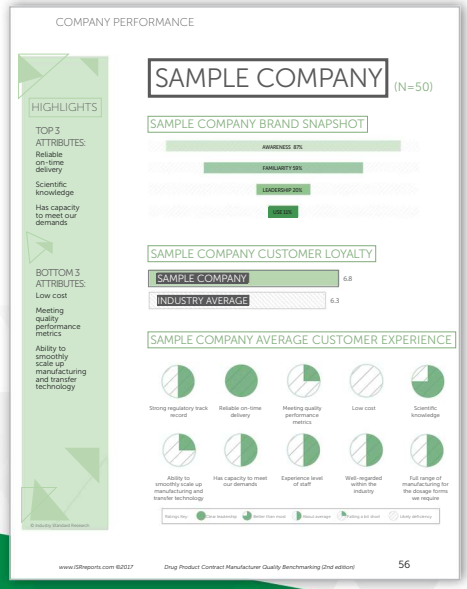
Smarter questions ∴ Smarter answers



Biologic, small molecule and drug product CMO quality evaluations—updated for 2017

CMO LEADERSHIP AWARDS2017

DISCOVER THE DATA BEHIND THE AWARDS

- *Consumer Reports*-style analysis of CMO performance
- A benchmark of contract manufacturers on their performance specific to small molecule API, biologic API, and drug product related services
- Performance ratings from hundreds of CMO users

THE LATEST IN MANUFACTURING REPORTS

- Contract Development and Manufacturing Outsourcing Models
- Bioprocessing Market Trends & Outsourcing Dynamics
- Biosimilars Manufacturing: Key Considerations & Expected Outsourcing Practices

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CMO LEADERSHIP AWARDS 2017 CAPABILITIES

- All facilities fully owned
- Complementary core competencies to in-house or other manufacturing contractors
- Facility has most up-to-date manufacturing technologies
- Full range of manufacturing for the dosage forms we require
- Has capacity to meet our demands
- Offers innovative solutions
- Proven ability to manufacture API
- Provides regulatory support for filing
- Stability testing capabilities; storage capabilities

CAPABILITIES

TOP PERFORMERS

OVERALL

PCI Synthesis
PharmaZell
Albemarle Corporation
Pfizer CentreOne
FLAMMA

EXCEEDED CUSTOMER EXPECTATIONS

OVERALL

Helsinn Advanced Synthesis SA
Sai Life Sciences
Ash Stevens, LLC (A Division of Piramal Pharma Solutions)
IDT Biologika
Wockhardt
Paragon Bioservices
Cobra Biologics
GSK Contract Manufacturing
Halo Pharmaceuticals
CEPiA Sanofi
Hetero
AbbVie
Fareva
Evonik
Kemwell
AMPAC Fine Chemicals
Siegfried
KBI Biopharma
Cambrex
Samsung BioLogics
3M Drug Delivery Systems
CordenPharma
NOVASEP
Sandoz
Boehringer Ingelheim Biopharmaceuticals GmbH
AMRI
Dalton Pharma
Dr. Reddy's
Avid Bioservices

BIG PHARMA

Pfizer CentreOne
PharmaZell
Halo Pharmaceuticals
Sai Life Sciences
GSK Contract Manufacturing
CEPiA Sanofi
Cambrex
Samsung BioLogics
Sandoz
Capsugel
Wockhardt
Evonik
Fareva
Recipharm
Boehringer Ingelheim Biopharmaceuticals GmbH
Almac
CordenPharma
AbbVie
Siegfried

SMALL PHARMA

Wockhardt
AbbVie
NOVASEP
Pfizer CentreOne
Ajinomoto Althea
Siegfried
Fareva
Halo Pharmaceuticals
Evonik
Dr. Reddy's
CordenPharma
GSK Contract Manufacturing
AMRI
Cambrex
STA
Dalton Pharma Services
Aesica

MET CUSTOMER EXPECTATIONS

OVERALL

Aesica
Famar
Aptuit
STA
CMC Biologics
Celltrion
Richter-Helm
SAFC
Baxter BioPharma Solutions
PCI Pharma Services
Therapure Biopharma
Almac
Lonza
Recipharm
Capsugel
Piramal Pharma Solutions
WuXi AppTec
Cook Pharmica
Patheon
Vetter
Ajinomoto Althea
Catalent
Cytovance Biologics
FUJIFILM Diosynth Biotechnologies
Alcami

BIG PHARMA

PCI Pharma Services
AMRI
Aptuit
Dr. Reddy's
SAFC
Aesica
WuXi AppTec
Baxter BioPharma Solutions
Piramal Pharma Solutions
Lonza
NOVASEP
STA
Patheon
Catalent
KBI Biopharma
Famar

SMALL PHARMA

Boehringer Ingelheim Biopharmaceuticals GmbH
Lonza
SAFC
Richter-Helm
Cytovance Biologics
CEPiA Sanofi
Aptuit
Baxter BioPharma Solutions
Sandoz
Piramal Pharma Solutions
Patheon
Almac
Samsung BioLogics
WuXi AppTec
Recipharm
Catalent

The terms "Small Pharma" and "Big Pharma" pertain to the outsourcing respondents, not the winners. "Overall" is a combination of Big and Small Pharma.

CMO LEADERSHIP AWARDS 2017
COMPATIBILITY

- Access to desired markets
- Accessible senior management
- Complementary core competencies to in-house or other manufacturing contractors
- Cultural fit
- Financial strength/stability
- Timely project communications
- Well-regarded within the industry

COMPATIBILITY

TOP PERFORMERS

OVERALL

Albemarle Corporation
FLAMMA
PCI Synthesis
Helsinn Advanced Synthesis SA
PharmaZell
Cobra Biologics
Pfizer CentreOne

BIG PHARMA

Pfizer CentreOne

EXCEEDED CUSTOMER EXPECTATIONS

OVERALL

IDT Biologika
Ash Stevens, LLC (A Division of Piramal Pharma Solutions)
Sai Life Sciences
Paragon Bioservices
AMPAC Fine Chemicals
Fareva
Halo Pharmaceuticals
CEPiA Sanofi
Siegfried
3M Drug Delivery Systems
Hetero
GSK Contract Manufacturing
Wockhardt
Cambrex
Evonik
Famar
KBI Biopharma
Avid Bioservices
AbbVie
Samsung BioLogics
NOVASEP
CordenPharma
Boehringer Ingelheim Biopharmaceuticals GmbH
Sandoz
Dr. Reddy's
Dalton Pharma

BIG PHARMA

Halo Pharmaceuticals
Sai Life Sciences
PharmaZell
Cambrex
CEPiA Sanofi
GSK Contract Manufacturing
Samsung BioLogics
Recipharm
Evonik
Fareva
Wockhardt
Sandoz
Boehringer Ingelheim Biopharmaceuticals GmbH
Capsugel
Almac
Aptuit

SMALL PHARMA

Fareva
Siegfried
NOVASEP
Ajinomoto Althea
AbbVie
Halo Pharmaceuticals
CordenPharma
Pfizer CentreOne
Evonik
Wockhardt
Cytovance Biologics
Cambrex
Dr. Reddy's
AMRI
STA
Baxter BioPharma Solutions
GSK Contract Manufacturing

MET CUSTOMER EXPECTATIONS

OVERALL

AMRI
Therapure Biopharma
Aptuit
Celltrion
Kemwell
Recipharm
Aesica
Almac
SAFC
Baxter BioPharma Solutions
CMC Biologics
Cook Pharmica
PCI Pharma Services
Capsugel
Piramal Pharma Solutions
Lonza
Cytovance Biologics
Ajinomoto Althea
STA
Patheon
Alcami
Richter-Helm
Vetter
WuXi AppTec
Catalent
Jubilant HollisterStier
FUJIFILM Diosynth Biotechnologies
Hovione

BIG PHARMA

AbbVie
CordenPharma
Famar
Siegfried
Dr. Reddy's
AMRI
Aesica
PCI Pharma Services
KBI Biopharma
SAFC
NOVASEP
Baxter BioPharma Solutions
Lonza
WuXi AppTec
Piramal Pharma Solutions
Patheon
Catalent
STA
CMC Biologics
FUJIFILM Diosynth Biotechnologies
Celltrion
Cook Pharmica

SMALL PHARMA

SAFC
Piramal Pharma Solutions
Dalton Pharma Services
Aptuit
CEPiA Sanofi
Aesica
Boehringer Ingelheim Biopharmaceuticals GmbH
Sandoz
Lonza
Richter-Helm
Patheon
Almac
Therapure Biopharma
Recipharm
Samsung BioLogics
Catalent
WuXi AppTec
Alcami

CMO LEADERSHIP AWARDS 2017 DEVELOPMENT

- Process development capabilities
- Analytical method development, qualification, and validation
- Regulatory support for filing IND or NDA

DEVELOPMENT

TOP PERFORMERS

OVERALL

Helsinn Advanced Synthesis SA
PharmaZell
Wockhardt
PCI Synthesis

EXCEEDED CUSTOMER EXPECTATIONS

OVERALL

Albemarle Corporation
Pfizer CentreOne
Ash Stevens, LLC (A Division of Piramal Pharma Solutions)
FLAMMA
Paragon Bioservices
AMPAC Fine Chemicals
Sai Life Sciences
CordenPharma
Cambrex
GSK Contract Manufacturing
NOVASEP
Siegfried
KBI Biopharma
Evonik
Cook Pharmica
Celltrion
CEPiA Sanofi
Fareva
Dr. Reddy's
AbbVie
IDT Biologika
Boehringer Ingelheim Biopharmaceuticals GmbH
Halo Pharmaceuticals
Samsung BioLogics
Sandoz
Dalton Pharma
FUJIFILM Diosynth Biotechnologies
Hetero

MET CUSTOMER EXPECTATIONS

OVERALL

Vetter
AMRI
Therapure Biopharma
Almac
STA
Aptuit
Alcami
Lonza
Piramal Pharma Solutions
SAFC
PCI Pharma Services
Aesica
Baxter BioPharma Solutions
WuXi AppTec
CMC Biologics
Patheon
Recipharm
Ajinomoto Althea
Catalent
Richter-Helm
Cytovance Biologics

The terms "Small Pharma" and "Big Pharma" pertain to the outsourcing respondents, not the winners. "Overall" is a combination of Big and Small Pharma.

CMO LEADERSHIP AWARDS 2017
EXPERTISE

- Ability to smoothly scale up manufacturing and transfer technology
- Experience level of staff
- Offers innovative solutions
- Provides regulatory support for filing
- Scientific knowledge
- Strong regulatory track record

EXPERTISE

TOP PERFORMERS

OVERALL

PCI Synthesis
FLAMMA
Albemarle Corporation
PharmaZell
Pfizer CentreOne

BIG PHARMA

Pfizer CentreOne

SMALL PHARMA

Wockhardt

EXCEEDED CUSTOMER EXPECTATIONS

OVERALL

Cobra Biologics
Paragon Bioservices
Wockhardt
Sai Life Sciences
GSK Contract Manufacturing
Helsinn Advanced Synthesis SA
CEPiA Sanofi
Halo Pharmaceuticals
Evonik
Dalton Pharma
KBI Biopharma
CordenPharma
AMPAC Fine Chemicals
Siegfried
Ash Stevens, LLC (A Division of Piramal Pharma Solutions)
AbbVie
3M Drug Delivery Systems
IDT Biologika
Fareva
Cambrex
Sandoz
Hetero
Avid Bioservices
Boehringer Ingelheim Biopharmaceuticals GmbH
Aptuit
NOVASEP
Samsung BioLogics

BIG PHARMA

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PharmaZell
GSK Contract Manufacturing
CEPiA Sanofi
Sai Life Sciences
Cambrex
Evonik
Sandoz
Aptuit
Capsugel
Wockhardt
CordenPharma
Samsung BioLogics
Fareva
Boehringer Ingelheim Biopharmaceuticals GmbH
AMRI
Recipharm
AbbVie
Siegfried

SMALL PHARMA

AbbVie
Pfizer CentreOne
Siegfried
NOVASEP
CordenPharma
Evonik
GSK Contract Manufacturing
Halo Pharmaceuticals
Fareva
Cambrex
Ajinomoto Althea
Dr. Reddy's
Dalton Pharma Services
STA
SAFC
Aesica
AMRI

MET CUSTOMER EXPECTATIONS

OVERALL

AMRI
Dr. Reddy's
Kemwell
PCI Pharma Services
Richter-Helm
SAFC
Therapure Biopharma
Lonza
Aesica
Celltrion
CMC Biologics
Almac
Capsugel
Recipharm
Baxter BioPharma Solutions
WuXi AppTec
Cook Pharmica
Patheon
Famar
Piramal Pharma Solutions
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Cytovance Biologics
Ajinomoto Althea
Catalent
Alcami

BIG PHARMA

Almac
PCI Pharma Services
WuXi AppTec
Dr. Reddy's
Lonza
SAFC
Baxter BioPharma Solutions
Aesica
NOVASEP
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FUJIFILM Diosynth Biotechnologies
Piramal Pharma Solutions
KBI Biopharma
Famar
Catalent
CMC Biologics
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Cook Pharmica

SMALL PHARMA

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CEPiA Sanofi
Sandoz
Cytovance Biologics
Aptuit
Baxter BioPharma Solutions
Richter-Helm
Piramal Pharma Solutions
Patheon
Almac
Samsung BioLogics
Recipharm
Catalent
Therapure Biopharma
WuXi AppTec

CMO LEADERSHIP AWARDS 2017 QUALITY

- Right first-time measurements
- Strong regulatory track record
- Track record for meeting quality performance metrics
- Up-front contingency planning, risk management

QUALITY

TOP PERFORMERS

OVERALL

PCI Synthesis
FLAMMA
PharmaZell
Albemarle Corporation
Pfizer CentreOne

SMALL PHARMA

Siegfried

EXCEEDED CUSTOMER EXPECTATIONS

OVERALL

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AMRI
Aptuit
Boehringer Ingelheim Biopharmaceuticals GmbH

SMALL PHARMA

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Ajinomoto Althea
NOVASEP
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Cambrex
Evonik
Wockhardt
Cytovance Biologics
STA
GSK Contract Manufacturing
Baxter BioPharma Solutions
Aesica

MET CUSTOMER EXPECTATIONS

OVERALL

Boehringer Ingelheim Biopharmaceuticals GmbH
Baxter BioPharma Solutions
NOVASEP
Kemwell
AMRI
Aptuit
Aesica
Dalton Pharma
Almac
Dr. Reddy's
Cytovance Biologics
CMC Biologics
Celltrion
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Piramal Pharma Solutions
Recipharm
SAFC
Ajinomoto Althea
Alcami
Richter-Helm
Patheon
FUJIFILM Diosynth Biotechnologies
Vetter
Cook Pharmica
Capsugel
Catalent
Glatt Pharmaceutical Services
Jubilant HollisterStier

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Aesica
Capsugel
Dr. Reddy's
WuXi AppTec
Siegfried
SAFC
Lonza
Piramal Pharma Solutions
KBI Biopharma
Patheon
FUJIFILM Diosynth Biotechnologies
STA
NOVASEP
Catalent
CMC Biologics
Celltrion

SMALL PHARMA

Sandoz
AMRI
Piramal Pharma Solutions
Dr. Reddy's
Lonza
SAFC
Aptuit
Dalton Pharma Services
Almac
CEPiA Sanofi
Samsung BioLogics
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Recipharm
Alcami

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CMO LEADERSHIP AWARDS 2017 RELIABILITY

- All facilities fully owned
- Financial strength/stability
- Flexibility to adjust schedule for special requests
- Has capacity to meet our demands
- Reliable on-time delivery
- Timely project management
- Up-front contingency planning, risk management

RELIABILITY

TOP PERFORMERS

OVERALL

PCI Synthesis
FLAMMA
Albemarle Corporation
PharmaZell
Pfizer CentreOne
Helsinn Advanced Synthesis SA

BIG PHARMA

Pfizer CentreOne

EXCEEDED CUSTOMER EXPECTATIONS

OVERALL

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CordenPharma
AMPAC Fine Chemicals
CEPiA Sanofi
Paragon Bioservices
3M Drug Delivery Systems
GSK Contract Manufacturing
Fareva
Hetero
Cobra Biologics
Siegfried
Evonik
KBI Biopharma
AbbVie
Samsung BioLogics
Cambrex
Wockhardt
Avid Bioservices
Famar
Dalton Pharma
Sandoz
Boehringer Ingelheim Biopharmaceuticals GmbH
AMRI

BIG PHARMA

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Cambrex
CEPiA Sanofi
Sai Life Sciences
GSK Contract Manufacturing
Samsung BioLogics
Recipharm
Evonik
CordenPharma
Fareva
Sandoz
Almac
Capsugel
Boehringer Ingelheim Biopharmaceuticals GmbH
Wockhardt
Siegfried
AbbVie

SMALL PHARMA

Ajinomoto Althea
CordenPharma
Siegfried
AbbVie
Fareva
Halo Pharmaceuticals
Pfizer CentreOne
Evonik
NOVASEP
STA
Cytovance Biologics
Wockhardt
Baxter BioPharma Solutions
Dr. Reddy's
GSK Contract Manufacturing
AMRI
Cambrex

MET CUSTOMER EXPECTATIONS

OVERALL

NOVASEP
Dr. Reddy's
Baxter BioPharma Solutions
Kemwell
Celltrion
Almac
PCI Pharma Services
CMC Biologics
STA
Aptuit
Piramal Pharma Solutions
Ajinomoto Althea
Recipharm
Aesica
Lonza
Capsugel
Cytovance Biologics
WuXi AppTec
SAFC
Patheon
Cook Pharmica
Alcami
Richter-Helm
FUJIFILM Diosynth Biotechnologies
Catalent
Vetter
Jubilant HollisterStier

BIG PHARMA

AMRI
PCI Pharma Services
Dr. Reddy's
Aesica
Famar
Aptuit
Baxter BioPharma Solutions
WuXi AppTec
Piramal Pharma Solutions
KBI Biopharma
Lonza
SAFC
Catalent Patheon
NOVASEP
STA
FUJIFILM Diosynth Biotechnologies
Celltrion
CMC Biologics

SMALL PHARMA

Dalton Pharma Services
Piramal Pharma Solutions
Lonza
SAFC
CEPiA Sanofi
Sandoz
Richter-Helm
Aesica
Aptuit
Almac
Patheon
Boehringer Ingelheim Biopharmaceuticals GmbH
WuXi AppTec
Samsung BioLogics
Catalent
Recipharm
Alcami

CMO LEADERSHIP AWARDS

INDIVIDUAL ATTRIBUTE AWARDS

The Individual Attribute Awards were developed as a result of many conversations we have had with the readers of *Life Science Leader* and the attendees at our Outsourced Pharma Events. These conversations uncovered common attributes that sponsor companies identified as being imperative when choosing a supplier and deciding to continue doing business with a supplier. They were often referred to as the ever-important "intangibles" a supplier brings to the table. Outside of the cover metrics of capabilities, compatibility, development, expertise, quality, and reliability, these attributes were what our readers identified as being the most important, and as such, we felt it was important to share the data with other sponsor companies.

ACCESSIBLE SENIOR MANAGEMENT

TOP PERFORMERS

FLAMMA
Helsinn Advanced Synthesis SA
PCI Synthesis
Ash Stevens, LLC (A Division of Piramal Pharma Solutions)
Albemarle Corporation
Cobra Biologics

EXCEEDED CUSTOMER EXPECTATIONS

AMPAC Fine Chemicals
Sai Life Sciences
Halo Pharmaceuticals
Famar
Paragon Bioservices
Fareva
Cambrex
Pfizer CentreOne
IDT Biologika
PharmaZell
KBI Biopharma
Therapure Biopharma
Cytovance Biologics
Siegfried
3M Drug Delivery Systems
Hetero
Evonik
Sandoz
Samsung BioLogics
Aptuit
NOVASEP
CordenPharma
Recipharm
Cook Pharmica
CMC Biologics
Capsugel
GSK Contract Manufacturing
Avid Bioservices
Dr. Reddy's
Boehringer Ingelheim Biopharmaceuticals GmbH
Hovione
Vetter

CULTURAL FIT

TOP PERFORMERS

Helsinn Advanced Synthesis SA
Albemarle Corporation
Cobra Biologics
PCI Synthesis
FLAMMA
Fareva

EXCEEDED CUSTOMER EXPECTATIONS

Pfizer CentreOne
KBI Biopharma
Therapure Biopharma
Sai Life Sciences
NOVASEP
Siegfried
Cambrex
Halo Pharmaceuticals
SAFC
Famar
CEPiA Sanofi
Sandoz
CMC Biologics
Samsung BioLogics
Cytovance Biologics
GSK Contract Manufacturing
AbbVie
Aptuit
Evonik
CordenPharma
PharmaZell
AMRI
Hetero
AMPAC Fine Chemicals
Dr. Reddy's
3M Drug Delivery Systems
Kemwell

INNOVATION

TOP PERFORMERS

PCI Synthesis
Paragon Bioservices
Pfizer CentreOne
Albemarle Corporation
PharmaZell
Wockhardt

EXCEEDED CUSTOMER EXPECTATIONS

KBI Biopharma
GSK Contract Manufacturing
CEPiA Sanofi
FLAMMA
Kemwell
Cobra Biologics
Evonik
Sandoz
IDT Biologika
Richter-Helm
AMPAC Fine Chemicals
Celltrion
Aptuit
AbbVie
Fareva
Samsung BioLogics
Halo Pharmaceuticals
Avid Bioservices
Dalton Pharma
NOVASEP
Siegfried
Cambrex
CordenPharma
Boehringer Ingelheim Biopharmaceuticals GmbH
Helsinn Advanced Synthesis SA

ON-TIME DELIVERY

TOP PERFORMERS

Helsinn Advanced Synthesis SA
FLAMMA
PCI Synthesis

EXCEEDED CUSTOMER EXPECTATIONS

Pfizer CentreOne
AMPAC Fine Chemicals
Sai Life Sciences
Dalton Pharma
Fareva
PharmaZell
KBI Biopharma
CordenPharma
Hetero
Albemarle Corporation
Famar
Ash Steven, LLC (A Division of Piramal Pharma Solutions)
Cambrex
Cobra Biologics
Paragon Bioservices
CEPiA Sanofi
AbbVie
Halo Pharmaceuticals
Siegfried
Samsung BioLogics
GSK Contract Manufacturing
Kemwell
CMC Biologics
Avid Bioservices
3M Drug Delivery Systems
Evonik
Aptuit
AMRI
Baxter Biopharma Solutions
Capsugel
Wockhardt
NOVASEP

CMO LEADERSHIP AWARDS

INDIVIDUAL ATTRIBUTE AWARDS

RIGHT FIRST TIME

TOP PERFORMERS

FLAMMA
Famar
Helsinn Advanced Synthesis SA
Pfizer CentreOne
PCI Synthesis

EXCEEDED CUSTOMER EXPECTATIONS

PharmaZell
KBI Biopharma
CordenPharma
Sai Life Sciences
Ash Stevens, LLC (A Division of Piramal Pharma Solutions)
Wockhardt
AMPAC Fine Chemicals
Fareva
Albemarle Corporation
Avid Bioservices
Evonik
Siegfried
Hetero
Halo Pharmaceuticals
AbbVie
GSK Contract Manufacturing
CEPiA Sanofi
Cambrex
3M Drug Delivery Systems
PCI Pharma Services
IDT Biologika
Kemwell
Cobra Biologics
Aesica
Richter-Helm
Samsung BioLogics

STATE-OF-THE-ART

TOP PERFORMERS

PharmaZell
PCI Synthesis
Albemarle Corporation
Pfizer CentreOne
Helsinn Advanced Synthesis SA

EXCEEDED CUSTOMER EXPECTATIONS

Cobra Biologics
IDT Biologika
CEPiA Sanofi
Samsung BioLogics
Halo Pharmaceuticals
Siegfried
Wockhardt
FLAMMA
GSK Contract Manufacturing
Evonik
Ash Stevens, LLC (A Division of Piramal Pharma Solutions)
Sai Life Sciences
PCI Pharma Services
AbbVie
Boehringer Ingelheim Biopharmaceuticals GmbH
Cambrex
AMPAC Fine Chemicals
Richter-Helm
Therapure Biopharma
CordenPharma
Sandoz
NOVASEP
Avid Bioservices
Hetero
Dr. Reddy's
3M Drug Delivery Systems
Kemwell

STRENGTH OF SCIENCE

TOP PERFORMERS

PharmaZell
Albemarle Corporation
FLAMMA
PCI Synthesis
Wockhardt

EXCEEDED CUSTOMER EXPECTATIONS

Pfizer CentreOne
KBI Biopharma
Evonik
Cobra Biologics
Helsinn Advanced Synthesis SA
AMPAC Fine Chemicals
IDT Biologika
GSK Contract Manufacturing
Dalton Pharma
Hetero
Ash Stevens, LLC (A Division of Piramal Pharma Solutions)
Paragon Bioservices
Avid Bioservices
CEPiA Sanofi
Halo Pharmaceuticals
Sai Life Sciences
Siegfried
Boehringer Ingelheim Biopharmaceuticals GmbH
Aptuit
CordenPharma
AbbVie
3M Drug Delivery Systems
Samsung BioLogics
NOVASEP
Dr. Reddy's
Cambrex
AMRI
Kemwell
Therapure Biopharma
Lonza

REPUTATION

TOP PERFORMERS

Albemarle Corporation
FLAMMA
PCI Synthesis
PharmaZell
Helsinn Advanced Synthesis SA

EXCEEDED CUSTOMER EXPECTATIONS

Pfizer CentreOne
AMPAC Fine Chemicals
Paragon Bioservices
Cobra Biologics
Avid Bioservices
IDT Biologika
Halo Pharmaceuticals
Ash Stevens, LLC (A Division of Piramal Pharma Solutions)
AbbVie
Evonik
GSK Contract Manufacturing
Sai Life Sciences
Cambrex
Fareva
Dalton Pharma
CEPiA Sanofi
CordenPharma
Sandoz
Almac
Wockhardt
Celltrion
Siegfried
3M Drug Delivery Systems
Boehringer Ingelheim Biopharmaceuticals GmbH
Samsung BioLogics
NOVASEP
Hetero

CATEGORIES WON:

AbbVie

North Chicago, IL
www.abbviecontractmfg.com

Phone: +1 847 938 8524
Contact: Michelle Calhoun
Email: michelle.calhoun@abbvie.com
Key locations: Ludwigshafen, Germany; Sligo & Cork, Ireland; Campoverde, Italy; Barceloneta, Puerto Rico; Worcester, MA and Lake County, IL, USA

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

SERVICES & CAPABILITIES: aseptic fill/finish, capsules, controlled substances, creams & ointments, cytotoxic & high potency compounds, gels, injectables, liquids, non-sterile, OTC, parenterals (large & small volume), proteins, semisolids, soft gels, solid dose, sustained release, syringes: prefilled, hot melt extrusion, bioavailability enhancement techs, modified & targeted release, bi-layer tablets, liquid-fill hard capsule techs, controlled substances, proteins, mammalian cell culture syringes (prefilled)

INDIVIDUAL ATTRIBUTE AWARDS: cultural fit, innovation, on-time, reputation, right first time, state-of-the-art, strength of science

AZITA SALEKI-GERHARDT, PH.D.
SVP Operations

"Our team is committed to producing the highest quality support and services for our partners, and this award demonstrates the consistency necessary for great customer service in the areas of capabilities, compatibility, expertise, quality, reliability and discovery. We are extremely proud of this accomplishment and the remarkable impact we help make for patients around the world."

CATEGORIES WON:

Aesica Pharmaceuticals

Newcastle Upon Tyne, UK
www.aesica-pharma.com

Phone: +44 (0)191 293 1460
Contact: Mark Hammond
Email: mark.hammond@aesica-pharma.com
Key locations: Cramlington, UK; Queenborough, UK; Monheim, UK; Zwickau, Germany; Pianezza, Italy

DRUG TYPE:
Pharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Discovery, Pre-Clinical, 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, creams & ointments, cytotoxic & high potency compounds, gels, generics, injectables, liquids, non-sterile, powders: non-sterile, solid dose, sustained release, topicals, continuous manufacturing, serialization & aggregation

INDIVIDUAL ATTRIBUTE AWARDS:
right first time

IAN MUIR, PH.D.
Managing Director

"As a leading CDMO for APIs and finished dosage forms, we take pride in our ability to partner with our pharmaceutical customers to provide a quality and reliable service that is backed by a team of world-class scientific experts. Being recognized in these CMO Leadership Awards for our quality, capabilities, and expertise is a true testament to our people, culture and service/abilities."

CATEGORIES WON:

Albemarle Corporation

Charlotte, NC
www.albemarle.com/FCS

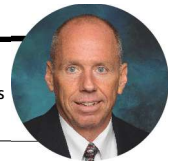
Phone: +1 980 299 5700
Contact: Julie Risdon
Email: julie.risdon@albemarle.com
Key locations: South Haven, MI; Tyrone, PA; Pasadena, TX

DRUG TYPE:
Pharmaceuticals

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

SERVICES & CAPABILITIES: creams & ointments, generics, injectables, liquids, non-sterile, ophthalmics, OTC, parenterals: large volume, powders: non-sterile, proteins, semisolids, soft gels, solid dose, solutions & suspensions, topicals, vaccines

INDIVIDUAL ATTRIBUTE AWARDS: accessible senior management, cultural fit, innovation, on-time, reputation, right first time, state-of-the-art, strength of science



SCOTT MARTIN
President - Fine Chemistry Services

"Albemarle Corporation's Fine Chemistry Services business is excited and honored to receive the CMO Leadership Awards. These awards are validation of over thirty years of tireless efforts, dedicated to custom manufacturing. Through teamwork and a customer focus, we have established world-class facilities where we can support bench to commercial processing at one site and enable customers to take Registered Starting Materials to final Active Pharmaceutical Ingredients with one US manufacturer."

ALMAC
Partnering to Advance Human Health

CATEGORIES WON:

Almac

Craigavon, Co. Armagh, UK
www.almacgroup.com

Phone: +44 (0) 28 3833 2200
Contact: Ruth Fowler
Email: ruth.fowler@almacgroup.com
Key locations: Craigavon, UK; Audubon; Charnwood

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, Logistics

SERVICES & CAPABILITIES: capsules, cytotoxic & high potency compounds, parenterals: small volume, solid dose, solutions & suspensions, sustained release

INDIVIDUAL ATTRIBUTE AWARDS: reputation

ALAN ARMSTRONG
Chairman & CEO

"We pride ourselves on our ability to not only meet, but exceed expectations to our global clients by ensuring that we provide exceptional and reliable quality in all aspects of our work. Eclipsing that quality determines the extent of our commitment and success."

ALTHEA

CATEGORIES WON:

Ajinomoto Althea

San Diego, CA
AltheaCMO.com

Phone: +1 858 882 0123
Contact: Anish Parikh
Email: anish.parikh@altheaCMO.com
Key locations: San Diego, CA

DRUG TYPE:
Pharmaceuticals, Biopharmaceuticals

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

SERVICES & CAPABILITIES: aseptic fill/finish, injectables, liquids, lyophilized products, parenterals: large volume, parenterals: small volume, peptides, proteins, solutions & suspensions, sterile, sustained release, syringes: pre-filled, vaccines

DAVID ENLOE
President & CEO

"Althea's business has grown – a lot – in the past several years. The number of commercial products and countries from which we have received regulatory approval continues to rapidly increase. We are very proud of the growth we have achieved while strengthening our stellar regulatory track record. Our technical teams demonstrate a relentless dedication to our clients, each other, and to the patients we all serve. Thank you for validating all of our efforts."

AMPAC™ FINE CHEMICALS

CATEGORIES WON:

AMPAC Fine Chemicals

Rancho Cordova, CA
www.ampacfinechemicals.com

Phone: +1 888 330 2232
Contact: Patrick Park
Email: afcbusdev@apfc.com
Key locations: Rancho Cordova, CA; La Porte, TX; Petersburg, VA

DRUG TYPE:
Pharmaceuticals

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

SERVICES & CAPABILITIES: analytical testing, APIs and HPAPIs, controlled substances, cytotoxic & high potency compounds, drug substance, fine chemicals, generics, peptides, product stability & release, registered intermediates

INDIVIDUAL ATTRIBUTE AWARDS: accessible senior management, cultural fit, innovation, on-time, reputation, right first time, state-of-the-art, strength of science

ASLAM MALIK
President & CEO

"AMPAC Fine Chemicals is experiencing dynamic growth in business and facilities expansion as we continue to maintain a leadership position in large scale commercial production. As we expand, our heritage of successfully transitioning drugs from development to commercial success remains our core strength. AFC takes pride in being recognized by the pharmaceutical industry as a leader in six categories and believes this reflects our commitment to enabling the success of our customers, large and small."

CATEGORIES WON:

AMRI

Albany, NY
www.amriglobal.com

Phone: +1 518 512 2000
Contact: Teresa Pallotta
Email: teresa.pallotta@amriglobal.com
Key locations: United States; Glasgow, UK; France; Italy; Spain; Aurangabad, India

DRUG TYPE:
Pharmaceuticals, Biopharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Discovery, Pre-Clinical, 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, 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, semi-solids, solid dose, solutions & suspensions, sterile, sustained release, syringes: pre-filled, topicals

INDIVIDUAL ATTRIBUTE AWARDS: cultural fit, on-time, strength of science

WILLIAM S. MARTH
President & CEO

"Our recent growth, coupled with a focus on complex science and technology, solidly positions us to continue to deliver on all of these key qualities as a CDMO of choice for the biopharmaceutical industry. We remain grateful to our customers and peers for recognizing us once again, and would like to congratulate the rest of the CMO award recipients."

CATEGORIES WON:

Aptuit

Greenwich, CT
www.aptuit.com

Phone: +1 855 427 8848
Contact: Dan Conlon
Email: dan.conlon@aptuit.com
Key locations: Verona, Italy; Oxford, UK

DRUG TYPE:
Pharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Discovery, Pre-Clinical, Clinical (Phase 1)
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, non-sterile, powders: non-sterile, powders: sterile, solid dose, solutions & suspensions

INDIVIDUAL ATTRIBUTE AWARDS: accessible senior management, cultural fit, innovation, on-time, strength-of-science

JONATHAN GOLDMAN
CEO

"Aptuit is proud to have been announced a winner in the quality, expertise, and compatibility categories of the 2017 CMO awards. This achievement demonstrates that our customers have once again recognized our unique capabilities in integrated discovery, CMC, and preclinical development. We are focused on helping our customers discover, develop, and produce drugs of very high quality, whilst minimizing operational risks. We remain best in class for scientific quality, speed, and cost."

CATEGORIES WON:

Ash Stevens, LLC

A Division of Piramal Pharma Solutions

Riverview, MI
www.ashstevens.com

Phone: +1 734 282 3370
Contact: James Hamby
Email: james.hamby@piramal.com
Key locations: Riverview, Michigan

DRUG TYPE:
Pharmaceuticals

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

SERVICES & CAPABILITIES: cytotoxic & high potency compounds

INDIVIDUAL ATTRIBUTE AWARDS: accessible senior managemnt, on-time, reputation, right first time, state-of-the-art, strength of science

STEPHEN MUNK
President

"We are very honored to be receiving this year our fourth consecutive CMO Leadership Award. As a customer-focused API service provider, this award is very important to us since it is determined by feedback from sponsor companies who outsource manufacturing services or, in other words, our customer base. Ash Stevens, LLC is proud to be part of the Piramal Pharma Solutions (PPS) family that share the same commitment to quality and customer satisfaction."

CATEGORIES WON:

Avid Bioservices

Tustin, CA
www.avidbio.com

Phone: +1 714 508 6100
Contact: Jon S. Gingrich
Email: jgingrich@avidbio.com
Key locations: Tustin, California

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: injectables, liquids, parenterals: large volume, parenterals: small volume, proteins, sterile, vaccines, monoclonal antibodies, enzymes, biosimilars

INDIVIDUAL ATTRIBUTE AWARDS: accessible senior management, innovation, on-time, reputation, right first time, state-of-the-art, strength of science

STEVEN KING
President & CEO

"At Avid Bioservices, we are uniquely positioned to provide a comprehensive range of services to our biotechnology and biopharmaceutical clients ranging from process development through commercial cGMP manufacturing. We have established innovative processes for generating and characterizing a broad range of biopharmaceutical products including monoclonal antibodies, highly glycosylated recombinant proteins, enzymes, vaccines, and biosimilars. Our top priority is serving our clients and we are proud of our reputation for delivering quality products."

CATEGORIES WON:

Baxter BioPharma Solutions

Deerfield, IL
www.baxterbiopharmasolutions.com

Phone: +1 800 422 9837
Email: biopharmasolutions@baxter.com
Key locations: Bloomington, IN, USA; Halle (Westfalen), Germany; Round Lake, IL, USA

DRUG TYPE:
Pharmaceuticals, Biopharmaceuticals

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

SERVICES & CAPABILITIES: aseptic fill/finish, cartridges, cytotoxic & high potency compounds, injectables, lyophilized products, parenterals: large volume, parenterals: small volume, sterile, syringes: pre-filled, vaccines

INDIVIDUAL ATTRIBUTE AWARDS: on-time

MARIE KEELEY
Vice President

"Baxter BioPharma Solutions (BPS) is honored to be recognized for a 2017 CMO Leadership Award in multiple categories. Baxter's heritage is built on 80+ years of parenteral expertise, including over 30 years of CMO experience, which provides a firm foundation for the BPS contract manufacturing business. By leveraging expertise in every functional area within our international manufacturing network, BPS can serve customers globally and provide vital therapies to their patients."

CATEGORIES WON:

Boehringer Ingelheim Biopharmaceuticals GmbH

Ingelheim am Rhein, Germany
www.bioxcellence.com

Phone: +49 6132770
Contact: Pauline Bronzel
Email: bioxcellence@boerhinger-ingelheim.com
Key locations: Biberach, Germany; Vienna, Austria; Fremont, USA; Shanghai, China

DRUG TYPE:
Biopharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Pre-Clinical, Clinical
Drug Substance Production: Primary Process Development, Drug Substance Production
Formulated Drug Production: Dosage Form Development, Dosage Form Production

SERVICES & CAPABILITIES: aseptic fill/finish, cartridges, liquids, lyophilized products, peptides, proteins, syringes: pre-filled

INDIVIDUAL ATTRIBUTE AWARDS: accessible senior managment, innovation, reputation, state-of-the-art, strength of science

BARBARA ESCH
Head of Strategic Marketing, Contract Manufacturing Biopharmaceuticals

"This award is a further and important recognition for our contract manufacturing organization and a great confirmation for continued drive to put our customers first. We thank our customers and *Life Science Leader* for honoring us in these 6 categories."

Cambrex

CATEGORIES WON:

Cambrex

East Rutherford, NJ
www.cambrex.com

Phone: +1 201 804 3000
Contact: Alex Maw
Email: alex.maw@cambrex.com
Key locations: Charles City, IA, USA; High Point, NC, USA; Karlskoga, Sweden; Paullo, Milan, Italy; Tallinn, Estonia; Wiesbaden, Germany

DRUG TYPE:
Pharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Pre-Clinical, 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, branded APIs, custom development & manufacture

INDIVIDUAL ATTRIBUTE AWARDS: accessible senior management, cultural fit, innovation, on-time, reputation, right first time, state-of-the-art, strength of science

STEVEN M. KLOSK
President & CEO

"I am extremely proud that Cambrex has for the third consecutive year been selected as a winner of the CMO Leadership Awards. Cambrex has a strong customer focus and a commitment to world class quality. Receiving the awards in the key categories demonstrates our continued commitment to our customers and recognition by the pharmaceutical industry."

Capsugel

CATEGORIES WON:

Capsugel

Morristown, NJ
www.capsugel.com

Phone: +1 862 242 1700
Email: dfsinquiry@capsugel.com
Key locations: USA, Mexico, Scotland, France, Belgium, India, China, Japan, Indonesia

DRUG TYPE:
Pharmaceuticals, Biopharmaceuticals

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

SERVICES & CAPABILITIES: capsules, controlled substances, cytotoxic & high potency compounds, generics, liquids, OTC, peptides, powders: non-sterile, proteins, semisolids, soft gels, solid dose, solutions & suspensions, sustained release, vaccines

INDIVIDUAL ATTRIBUTE AWARDS: accessible senior management, on-time

GUIDO DRIESEN
President & CEO

"Capsugel is greatly appreciative of this recognition by our customers. Our colleagues throughout the organization strive to provide integrated solutions to advance products from design and development through to commercial manufacture. Our focus is on creating novel, high-quality and customized solutions that align with our customers' evolving needs. We believe our unique combination of science, engineering, formulation, and capsule expertise is what sets us apart."

CEPiA Sanofi

CATEGORIES WON:

CEPiA Sanofi

Antony, France
www.cepia-sanofi.com

Phone: + 33 1 41 24 55 39
Contact: Christina Da Cunha
Email: christina.da-cunha@sanofi.com
Key locations: Elbeuf, Sisteron, Frankfurt, Ujpest, Vertolaye, Aramon

DRUG TYPE:
Pharmaceuticals, Biopharmaceuticals

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

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

INDIVIDUAL ATTRIBUTE AWARDS: cultural fit, innovation, on-time, reputation, right first time, state-of-the-art, strength of science

JACQUES TAVERNIER
Vice President

"For the fourth year in a row, *Life Science Leader* magazine has awarded CEPiA-Sanofi as a worldwide CMO Leader. CEPiA with its industrial European culture has strong assets: 11 chemical sites, manufacturing 200+ API, for more than 60 years. CEPiA serves all pharmaceutical companies, including commercial capacities and specific molecules with exclusive agreements, promoting its Quality and Regulatory worldwide expertise."

CATEGORIES WON:

Cobra Biologics

Keele Science Park, Newcastle under Lyme, UK
www.cobrabio.com

Phone: +44 (0)1782 714181
Contact: Jason Rahal
Email: jason.rahal@cobrabio.com
Key locations: Newcastle under Lyme, UK; Sodertalje, Sweden; Matfors, Sweden

DRUG TYPE:
Biopharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Pre-Clinical, 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, generics, injectables, liquids, lyophilized products, non-sterile, parenterals: large volume, parenterals: small volume, proteins, solutions & suspensions, sterile, syringes: pre-filled, vaccines, DNA, viruses, microbiota, fill finish, cell line development, cell banking, stability testing, protein characterization, bioassays, analytical services, sterile drug product fill & finish

INDIVIDUAL ATTRIBUTE AWARDS: accessible senior management, cultural fit, innovation, on-time, reputation, right first time, state-of-the-art, strength of science

PETER COLEMAN
CEO

"I am delighted that Cobra has been selected for a CMO Leadership Award. I believe our global reputation in the market for excellent science and GMP manufacture, along with a close rapport with our growing customer base, are the reasons behind our rapid growth over the last 5 years as we aim to become a global leader in biologics contract manufacturing."

CATEGORIES WON:

Cook Pharmica

Bloomington, IN
www.cookpharmica.com

Phone: +1 877 312 2665
Contact: Cory Lewis
Email: busdev@cookpharmica.com
Key locations: Bloomington, IN

DRUG TYPE:
Pharmaceuticals, Biopharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Discovery, Pre-Clinical, 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, cartridges, injectables, liquids, lyophilized products, parenterals: large volume, parenterals: small volume, peptides, proteins, solutions & suspensions, sterile, syringes: pre-filled, vaccines, development, bulk drug substance, parenteral drug product, secondary packaging

INDIVIDUAL ATTRIBUTE AWARDS: accessible senior management

TEDD GREEN
President

"At Cook Pharmica, we take pride in helping develop and deliver life-enhancing biopharmaceuticals to patients around the world. Through time, our team has had the pleasure of assisting our clients in developing and manufacturing truly amazing products. We are humbled that our clients continue to value the work we perform. And, we appreciate the favorable acknowledgement by these clients, as recognized via the CMO Leadership Awards."

CATEGORIES WON:

CordenPharma

Plankstadt Germany
www.cordenpharma.com/contact-us/

Phone: +1 800 868 8208
Email: sales@cordenpharma.com
Key locations: Colorado, USA; Caponago, IT; Latina, IT; Plankstadt, DE; Bergamo, IT; Brussels, BE; Switzerland; Chenôve, FR

DRUG TYPE:
Pharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Pre-Clinical, 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, cytotoxic & high potency compounds, generics, injectables, liquids, lyophilized products, non-sterile, parenterals: large volume, parenterals: small volume, peptides, powders: non-sterile, powders: sterile, proteins, solid dose, solutions & suspensions, sterile, syringes: pre-filled

INDIVIDUAL ATTRIBUTE AWARDS: accessible senior management, cultural fit, innovation, on-time, reputation, right first time, state-of-the-art, strength of science

ERNESTO PETROSELLI
President

"We are honored to receive the *Life Science Leader* 2017 CMO Leadership Awards across all six core categories, recognized by small and large pharma customers. Organized under five technology platforms, CordenPharma experts are committed to full-service supply as a CDMO partner to the global pharmaceutical industry. These awards from our customers reflect our continuing drive to expand upon existing capabilities in order to provide cost-effective, integrated solutions for their complete contract development and manufacturing needs."

CATEGORIES WON:

Cytovance Biologics Inc.,
a Hepalink Company

Oklahoma City, OK
www.cytovance.com

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

DRUG TYPE:
Biopharmaceuticals

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

SERVICES & CAPABILITIES: aseptic fill/finish, injectables, liquids, proteins, vaccines, cell line development using Freedom® CHO-S®, microbial strain development using GeneGPS Codon Optimization Technology (DNA2.0), & Cytovance® Biologics' Keystone Expression System™, research cell bank production, process development, process optimization using statistical Design-of-Experiments (DoE), technology transfer, scaled-down model development & process characterization using a QbD framework.

INDIVIDUAL ATTRIBUTE AWARDS: accessible senior management, cultural fit

DARREN HEAD
President & CEO

"We are ecstatic to be recognized as a CMO Award winner. This honor is a reflection of our dedication to providing quality and reliability and maintaining our core competency for all of our clients. These awards would not be possible if it weren't for our highly experienced employees who give effortlessly in meeting our clients' daily needs. We accept these awards on behalf of the dedication and hard work of many within our remarkable company."

CATEGORIES WON:

Dalton Pharma Services

Toronto, ON, Canada
www.dalton.com

Phone: +1 416 661 2102
Contact: Kavvita Santilli
Email: ksantilli@dalton.com
Key locations: Toronto, ON, Canada

DRUG TYPE:
Pharmaceuticals, Biopharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Discovery, Pre-Clinical, 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, creams & ointments, 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 gels, solid dose, solutions & suspensions, sterile, sustained release, topicals, vaccines

INDIVIDUAL ATTRIBUTE AWARDS: innovation, on-time, reputation, strength of science

PETER PEKOS
President & CEO

"We are very honored to have been recognized for the second consecutive year in five major categories. The 2017 award validates Dalton's management team's goals to continuing to build a culture of excellence, and demonstrates our ongoing commitment to providing high quality, reliable, cost-effective integrated solutions for our clients' drug development and manufacturing projects."

CATEGORIES WON:

Fareva

Tournon sur Rhône, France
www.fareva.com

Phone: +1 919 768 6858
Contact: George Hlass
Email: ghlass.usa@fareva.com
Key locations: France, Germany, Italy, United States

DRUG TYPE:
Pharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Clinical (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, cytotoxic & high potency compounds, gels, generics, injectables, liquids, lyophilized products, non-sterile, ophthalmics, OTC, parenterals: large volume, parenterals: small volume, powders: non-sterile, powders: sterile, semisolids, solid dose, solutions & suspensions, sterile, sustained release, syringes: prefilled, topicals

INDIVIDUAL ATTRIBUTE AWARDS: accessible senior management, cultural fit, innovation, on-time, reputation, right first time

BERNARD FRAISSE
President & CEO

"Fareva's success in contract manufacturing for our API and Pharma customers is based on the experience and the creativity of our teams in development, manufacturing, and regulatory affairs and they allow us to consistently provide innovative solutions. Besides flawless and reliable supply, Fareva has established a position as a long-term preferred supplier by building relationships based on clear and open communications, vital to continuously meeting the wide-ranging needs of our customers."

CATEGORIES WON:

FLAMMA

Chignolo d'Isola, Bergamo, Italy
www.flammagroup.com

Phone: 011 39 035 4991811
Contact: Kenneth Drew, Ph.D.
Email: ken.drew@flammagroup.com
Key locations: Chignolo, Italy; Isso, Italy; Dalian Honkai, China

DRUG TYPE:
Pharmaceuticals

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

SERVICES & CAPABILITIES: generics, peptides, powders: non-sterile, powders: sterile, APIs, NCEs, RSMs, high value chiral intermediates, high value amino acids, key intermediates, building blocks, starting materials, process R&D, stability studies, analytical method development & validations

INDIVIDUAL ATTRIBUTE AWARDS: accessible senior management, cultural fit, innovation, on-time, reputation, right first time, state-of-the-art, strength of science

GIAN PAOLO NEGRISOLI
President & CEO

"FLAMMA is family owned and run since 1950. Long term management stability helps to differentiate FLAMMA from other CMOs. Our two cGMP facilities in Italy and our new cGMP facility in China give FLAMMA the ability to have a full control of the supply chain and to provide optimal service to customers. When it matters most, pharmaceutical companies continue to turn to FLAMMA! Thanks to those who recognized FLAMMA for these 2017 CMO Leadership Awards."

CATEGORIES WON:

GlaxoSmithKline

Contract Manufacturing

Brentford, Middlesex, UK
www.gsk.com

Contact: Janice Graff
Email: janice.l.graff@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 Production: Dosage Form Development, Dosage Form Production, Packaging, Logistics

SERVICES & CAPABILITIES: API's (phase I-III), cephalosporins, cytotoxic & high pot. cpds, lyophilised prod., non-sterile, OTC, parenterals, peptides, proteins, aseptic fill/finish, capsules, injectables, liquids, powders: sterile, solid dose, semisolids, suspensions, sust. release, syringes: prefilled, tablets: bi- & tri-layer, process & analyt. dev., fermentation: bacteria & yeast, multiple harvest, downstream capture, purification & bulk fill, sterile liquids, & freeze-dried drug prod.

INDIVIDUAL ATTRIBUTE AWARDS: accessible senior management, cultural fit, innovation, on-time, reputation, right first time, state-of-the-art, strength of science

JANICE L. GRAFF
Director of Finished Product Sales & Business Development

"We are delighted to receive six awards this year, particularly as they are based on feedback from our clients. Our extensive expertise helps companies deliver products for their patients and customers. We offer the Pharma/Biopharma industry a fully integrated supply chain solution with FDA and EMA approved multi-product facilities providing multiple services. GSK works closely with our customers, matching their specific needs with our capabilities and facilities, from development through commercial production. We look forward to more successful collaborations in the future."

CATEGORIES WON:

Halo Pharmaceuticals

Whippany, NJ
www.halopharma.com

Phone: +1 973 428 4000
Contact: Louis Weber
Email: lweber@halopharma.com
Key locations: Whippany, NJ, USA; Montreal, Quebec, Canada

DRUG TYPE:
Pharmaceuticals, Biopharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Pre-Clinical, 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, generics, liquids, non-sterile, ophthalmics, OTC, peptides, powders: non-sterile, semisolids, solid dose, solutions & suspensions, sterile, sustained release, topicals

INDIVIDUAL ATTRIBUTE AWARDS: accessible senior management, cultural fit, innovation, on-time, reputation, right first time, state-of-the-art, strength of science

LEE KARRAS
Chief Executive Officer

"We see pharmaceutical outsourcing as a partnership and not just as the more traditional "supplier-customer" relationship. This view differentiates us from our competitors in our customers' eyes as they witness first hand our flexibility, expertise, and commitment to quality. In today's highly competitive and challenging healthcare environment, having a partner who understands the challenges our customers face is critical in ensuring a mutually successful outcome."

HELSINN
Building quality cancer care together

CATEGORIES WON:

Helsinn Advanced Synthesis SA

Biasca, Switzerland
www.helsinn.com/state-of-the-art-manufacturing

Phone: +41918739400
Contact: Allison Vavala
Email: allison.vavala@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

SERVICES & CAPABILITIES: controlled substances, cytotoxic & high potency compounds

INDIVIDUAL ATTRIBUTE AWARDS: accessible senior management, cultural fit, innovation, on-time, reputation, right first time, state-of-the-art, strength of science

WALDO MOSSI
General Manager

"We are delighted to have won across categories at this prestigious awards ceremony. The CMO Leadership Awards recognize the highest manufacturing quality globally and are respected amongst industry peers making this even more pleasing."

HETERO

CATEGORIES WON:

Hetero

Hyderabad, Telangana, India
www.heteroworld.com

Phone: +91 40 23704923 24 25
Contact: William Chelak
Email: wchelak@heterousa.com
Key locations: Hyderabad & Vizag

DRUG TYPE:
Pharmaceuticals

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

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

INDIVIDUAL ATTRIBUTE AWARDS: accessible senior management, cultural fit, on-time, reputation, right first time, state-of-the-art, strength of science

DR. PARTHASARADHI REDDY BANDI
CEO

"Helping our partners achieve their strategic objectives is the ultimate goal of Hetero's Custom Pharmaceutical Services (CPS) offerings. The breadth of our expertise spans across APIs, Formulations and Biosimilars and is strongly backed by state-of-the-art manufacturing facilities, advanced research systems, best-in-class technologies, adherence & practicing of global standard quality systems, extensive global delivery network outstanding track record of success helps us to offer 'quality, reliable, capable & value driven services.' Our experienced R&D team is capable of offering customized solutions to meet individual needs even for the most niche products."

IDT

CATEGORIES WON:

IDT Biologika

Dessau, Germany
www.idt-biologika.com

Phone: +49 34901 885 0
Contact: Gregor Kawaletz
Email: gregor.kawaletz@idt-biologika.de
Key locations: Dessau, Germany; Riems-Greifwald, Germany; Rockville, MD, USA

DRUG TYPE:
Pharmaceuticals, Biopharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Pre-Clinical, 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, cytotoxic & high potency compounds, injectables, liquids, lyophilized products, parenterals: large volume, parenterals: small volume, vaccines

INDIVIDUAL ATTRIBUTE AWARDS: accessible senior management, innovation, reputation, right first time, state-of-the-art, strength of science

RALF PFIRMANN
CEO

"With our competence and wide range of capabilities in industrial development and manufacture, IDT is the most helpful partner for all organizations working on new solutions with the mission of bringing new vaccines or biological drugs to patients. Our increasing worldwide recognition is based on our dedication to serving these needs. The success of our customers is highlighted by the multiple categories of the CMO award we are decorated with this year."

CATEGORIES WON:

KBI Biopharma

Durham, NC
www.kbibiopharma.com

Phone: +1 919 479 9898
Contact: Stewart McNaull
Email: smcnaull@kbibiopharma.com
Key locations: Durham, NC; Boulder, CO, The Woodlands, TX

DRUG TYPE:
Biopharmaceuticals

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

SERVICES & CAPABILITIES: injectables, liquids, lyophilized products, peptides, proteins, vaccines, analytical development, protein characterization, formulation development, cell line development, microbial process development, mammalian process development, particle characterization, mass spectrometry

INDIVIDUAL ATTRIBUTE AWARDS: accessible senior management, cultural fit, innovation, on-time, right first time, strength of science

TIM KELLY
President

"KBI Biopharma's mission is to accelerate the development of innovative discoveries into life-changing biological products. We are honored to be recognized for our leadership in all six categories, as they directly reflect KBI's core values. These values are also shared by the most talented and dedicated professionals in our industry, and I feel very grateful to work alongside many of them, as colleagues and clients, to rapidly advance therapeutic programs for patients."

CATEGORIES WON:

NOVASEP

Lyon, France
www.novasep.com

Phone: +33 437 282 030
Contact: Jean-Baptiste Agnus
Email: jean-baptiste@novasep.com
Key locations: Le Mans, France; Chasse-sur-Rhône, France; Mourenx, France; Pompey, France; Leverkusen, Germany; Gosselies, Belgium

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

SERVICES & CAPABILITIES: aseptic fill/finish, cytotoxic & high potency compounds, generics, vaccines

INDIVIDUAL ATTRIBUTE AWARDS: accessible senior management, cultural fit, innovation, on-time, reputation, state-of-the-art, strength of science

JEAN BLÉHAUT
President, Synthesis Business Unit

"Our sincere thanks to our customers for rewarding Novasep in so many categories and for your loyal support. Customer service remains at the core of our day-to-day activities, and we thank our dedicated Project Management team for their key role in developing customer relationships based on teamwork, transparency and mutual trust. Finally we recognize the outstanding contribution of our Quality Assurance team with 3 successful FDA site inspections in 2016."

CATEGORIES WON:

Paragon Bioservices

Baltimore, MD
paragonbioservices.com

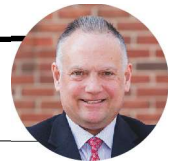
Phone: +1 410 975 4050
Contact: Philip Wills
Email: pwills@paragonbioservices.com
Key locations: Baltimore, MD

DRUG TYPE:
Biopharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Discovery, Pre-Clinical, 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: aseptic fill/finish, cytotoxic & high potency compounds, injectables, liquids, non-sterile, parenterals: small volume, peptides, proteins, solutions & suspensions, sterile, vaccines, process development, cell & virus banking, fermentation, cell culture, purification, formulation

INDIVIDUAL ATTRIBUTE AWARDS: accessible senior management, innovation, on-time, reputation, strength of science



PETER BUZY
President & CEO

"Credit for this recognition goes, first and foremost, to all of our hard-working scientists, engineers, quality systems personnel, and project managers. This acknowledgement from our peers is a great honor and we believe that it reflects our dedication and passion for the science. At Paragon, we are committed to building a world class GMP organization to support growth initiatives in vaccine and gene-therapy viral vector manufacturing."

PCI Pharma Services

CATEGORIES WON:

Philadelphia, PA
www.pciservices.com

Phone: +1 215 613 3600
Contact: Justin Schroeder
Email: justin.schroeder@pciservices.com
Key locations: Philadelphia, PA, USA; Rockford, IL, USA; Woodstock, IL, USA; Tredegar, UK; Bridgend, UK; Hay-on-Wye, UK

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: drug development & manufacturing services for oral solid dose, liquids, powders, gels & semisolids, with specialization of contained manufacture of potent compounds. Packaging & distribution services for all delivery forms including oral solid dose, liquids & powders, as well as parenteral delivery forms including ampoules, vials, syringes & injectable devices.

INDIVIDUAL ATTRIBUTE AWARDS:
right first time, state-of-the-art

BILL MITCHELL
President & CEO

"At PCI Pharma Services, our #1 commitment is to provide the industry's leading customer experience. We hold ourselves to the highest standards and focus on demonstrating a true partnership model with our customers, striving to be a seamless extension of their supply chains. We are very grateful to be recognized for such a prestigious award and further trusted to be the supplier of choice to the leading pharmaceutical and biotech companies around the world."

PCI Synthesis

CATEGORIES WON:

Newburyport, MA
www.pcisynthesis.com

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

DRUG TYPE:
Pharmaceuticals

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

SERVICES & CAPABILITIES:
controlled substances, generics, non-sterile, ophthalmics, solid dose, topicals

INDIVIDUAL ATTRIBUTE AWARDS: accessible senior management, cultural fit, innovation, on-time, reputation, right first time, state-of-the-art, strength of science

ED PRICE
President

"After nearly 20 years, PCI Synthesis has developed a strong sense of where the industry is headed. We recruit great people and continuously train them. We also spend a lot of time delivering what our clients want:

1. Transparency: Communicating so sponsors always know the status of their projects, and with no surprises.
2. Collaboration: Working together keeps projects on a successful trajectory.
3. Expertise: Adding expertise that's complementary to sponsors' in-house capabilities."

Pfizer CentreOne

CATEGORIES WON:

New York, NY
www.pfizercentreone.com

Phone: +1 269 833 2297
Contact: Olivier Roux
Email: pfizercentreone@pfizer.com
Key locations: Kalamazoo, MI, USA; McPherson, KS, USA; Rocky Mount, NC, USA; Ringaskiddy/Little Island, Ireland; Newbridge, Ireland; Melbourne, Australia

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 Production: Dosage Form Development, Dosage Form Production, Packaging, Logistics

SERVICES & CAPABILITIES: aseptic fill/finish, cartridges, controlled substances, cytotoxic & high potency compounds, injectables, lyophilized products, parenterals: small volume, peptides, solid dose, solutions & suspensions, sterile, syringes: pre-filled, highly potent solid oral dose, custom small-molecule API synthesis, small-molecule steroid, hormone intermediates, APIs

INDIVIDUAL ATTRIBUTE AWARDS: accessible senior management, cultural fit, innovation, on-time, reputation, right first time, state-of-the-art, strength of science

PETER STEVENSON
Vice President & General Manager

"We're honored to be recognized by pharmaceutical companies big and small. In fact, up to 70 percent of our biopharma partners start out with us as small to mid-sized companies. As a global contract manufacturer embedded within Pfizer, we leverage Pfizer's experience with 600 medicines in more than 160 markets on behalf of our biopharmaceutical partners, regardless of their size, while focusing on their individual technical, cultural, and business needs."

Recipharm
good for business

CATEGORIES WON:

Recipharm AB

Stockholm, Sweden
www.recipharm.com

Phone: +46 8 602 52 00
Contact: Aaron Smalls
Email: info@recipharm.com
Key locations: Sweden, France, Italy, Spain, Germany, UK, Portugal

DRUG TYPE:
Pharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Pre-Clincial, 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, creams & ointments, gels, generics, injectables, liquids, lyophilized products, non-sterile, ophthalmics, OTC, parenterals: large volume, parenterals: small volume, powders: non-sterile, powders: sterile, semisolids, solid dose, solutions & suspensions, sterile, sustained release, topicals

INDIVIDUAL ATTRIBUTE AWARDS:
accessible senior management

THOMAS ELDERED
CEO

"I am very pleased that Recipharm has once again been recognized for a CMO Leadership Award. We work extremely hard with our processes to ensure that our customers benefit from the reliability, pharmaceutical expertise, and ability to manage complexity which we offer."

Sai
make it better together

CATEGORIES WON:

Sai Life Sciences

Hyderabad, Telangana, India
www.sailife.com

Phone: +91 (0)40 331 56000
Contact: Marcel Velterop
Email: marcel.v@sailife.com
Key locations: Hyderabad, India; Karnataka, India

DRUG TYPE:
Pharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Discovery, Pre-Clincial, 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, generics, liquids, lyophilized products, parenterals: small volume, solid dose, sustained release

INDIVIDUAL ATTRIBUTE AWARDS: accessible senior management, cultural fit, on-time, reputation, right first time, state-of-the-art, strength of science

KRISHNA KANUMURI
CEO

"This is the first time ever Sai has been recognized in all six categories, which has both surprised and delighted us. Over the past 12-18 months we have spend tremendous effort in improving our business processes, and added required infrastructure. Sai is all about making it better together and we believe the main reason for receiving these awards is our willingness and openness to listen to our customers always and then act on it."

SAMSUNG
BIOLOGICS

CATEGORIES WON:

Samsung BioLogics

Songdo-dong, Yeonsu-gu, South Korea
www.samsungbiologics.com

Phone: +82 32 455 9334
Contact: Jungyeon Lee
Email: jung-y.lee@samsung.com
Key locations: Incheon, Songdo, South Korea

DRUG TYPE:
Biopharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Pre-Clinical, 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, injectables, liquids, lyophilized products, proteins

INDIVIDUAL ATTRIBUTE AWARDS: accessible senior management, cultural fit, innovation, on-time, reputation, right first time, state-of-the-art, strength of science

TH KIM
President & CEO

"Samsung BioLogics is honored to once again be recognized as winner of the CMO Leadership Awards. Meeting all core criteria – development, quality, expertise, reliability, capabilities, and compatability – we are a full service provider for mammalian biopharmaceutical products from clinical development to commercial manufacturing in our state-of-the-art facilities. From recent successful IPO we'll continue to provide quality-driven cGMP manufacturing for flexible and cost-effective services that ensure dedicated support for our clients and their patients."

Siegfried

CATEGORIES WON:

Siegfried

Pennsville, NJ
www.siegfried.ch

Contact: Sandra Cernick
Email: sales@siegfried.ch
Key locations: Switzerland; Pennsville, NJ, USA; Irvine, CA, USA; China; France; Germany; Malta

DRUG TYPE:
Pharmaceuticals

DRUG LIFE CYCLE STAGES:
Research & Development: Discovery, Pre-Clinical, 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, cytotoxic & high potency compounds, gels, injectables, liquids, ophthalmics, parenterals: large volume, parenterals: small volume, semisolids, solid dose, solutions & suspensions, sterile, syringes: pre-filled, spray drying, micronization, milling, azide chemistry, phosgenation, controlled substances

INDIVIDUAL ATTRIBUTE AWARDS: accessible senior management, cultural fit, innovation, on-time, reputation, right first time, state-of-the-art, strength of science

RUDOLF HANKO
CEO

"I'm delighted to receive the CMO Leadership award for Siegfried with recognition in all core categories. Siegfried transformed over the past five years into a global network having nine sites worldwide, offering fully integrated drug substance and drug product services. We provide customers superior products and tailor-made services to support their entire value chains. Whether it's custom development, producing APIs, controlled substances, or drug products (solid or sterile liquids), you can expect more with Siegfried."

STA Pharmaceuticals / WuXi AppTec

CATEGORIES WON:

STA Pharmaceuticals
A WuXi AppTec Company

Shanghai, China
www.wuxiapptec.com

Phone: 86 (21) 2066-3734
Contact: Yu Lu
Email: yu.lu@wuxiapptec.com
Key locations: Shanghai, China; Changzhou, China; Wuxi City, China; San Diego, CA, USA

DRUG TYPE:
Pharmaceuticals

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

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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: non-sterile, proteins, vaccines

STEVE BAGSHAW
CEO

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Guidance & Predictions From New Outsourcing Advisory Board Members

LOUIS GARGUILO Chief Editor, Outsourced Pharma @Louis_Garguilo

(As Previously Seen On OutsourcedPharma.com)

The following are new leaders on the Outsourced Pharma Editorial Advisory Board, and they're not hesitant to provide bold analysis on outsourcing drug development and manufacturing:

CHARLENE BANARD, Senior VP, Global Quality, Shire

BERNIE HUYGHE, Senior Director, Pfizer

TINA LARSON, VP Technical Operations, Achaogen

SESHA NEERVANNAN, SVP Pharmaceutical Development, Allergan

CAROL SHERAKO, Director Program Management, Genzyme

Here are some of their recent thoughts, and a few grams of guidance, taken from OutsourcedPharma.com, the pages of *Life Science Leader*, and Outsourced Pharma thought-leadership conferences.

FOCUSED FLEXIBILITY YOU CAN MEASURE

Banard and colleagues from Shire hosted a discussion at an Outsourced Pharma conference in Boston, documented in the articles *The Creation Of Shire's Outsourcing Model* and *For M&A, Shire Stays Three Dimensional With CMOs*. Shire applies a dynamic and flexible approach to managing its widespread supply chain. This approach, applied to individual supplier relationships, necessitates articulating the value proposition of each one "internally to your company," Banard says. "There's no way you can just do this out of the goodness of your heart. That's not what we're suggesting. But we have learned putting the relationship into strategic terms and managing for some type of win-win brings a combined competitive advantage to the marketplace."

That clear articulation is backed by rigorous measurement. Banard elicited audible gasps at the Boston conference when she presented a detailed CMO-evaluation dashboard. "I'm always hesitant to put up some of our dashboards," she said, "for fear they might make people's heads spin at first. But they're designed to show, at a glance, how our suppliers are performing and where we need to focus our efforts."

Her advice to drug sponsors who may not have the human and financial resources available to Shire? "You can't afford to not be involved as much as you possibly can," she replies. "[Sponsors are] accountable for the performance of each supplier and that shared relationship. We use tools to measure CMO quality performance, but in fact, these are tools to understand how we are doing as the provider of that contract. Often, when a supplier is not performing as expected, we find we can do something to help improve that performance."

A BOARD FULL OF QUESTIONS

The most valuable Board members might be those best at posing insight-inducing questions. We learned in *Pfizer's Key Questions For CMO Innovation* that nobody poses better questions to CMOs than Huyghe of Pfizer.

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When it comes to outsourcing focused on commercial success, you need a CMO that has been there many times through deep scientific expertise and world-class facilities.

Here are some of those questions, specific to driving innovation and new technologies throughout the external supply chain:

- Would having internal funding for innovation in your budget help you get customers?
- How many of you have lost a customer because your company couldn't innovate?
- How many CMOs believe some clients may have not approached you at all because you've made it clear you don't partner for innovation or codevelopment?
- If Big Pharma approaches you with an opportunity, you also have to entice the customer, show you have some skin in the game. What are you [the CMO] bringing to the table to help us [pharma]?

Regarding this last topic, Huyghe adds: "Today, Big Pharma does pay CMOs to innovate and learn. And CMOs will most likely be able to utilize that new technology — potentially even with our competitors. So what are we really getting out of the relationship? From the CMO perspective, yes, the challenge is very much to justify the cost. But for us, we're not always looking at the best price, but we are always looking for the best deal."

SO YOU WANT TO BE A PROJECT MANAGER?

In the OutsourcedPharma.com articles *Required Skills For Project Management At Genzyme* and *Sanofi Genzyme — And CMOs — Serious About Training Project Managers*, Sherako of Genzyme stipulates that any presumptive candidate for project manager should have an inherent desire to understand what makes a project tick. "Unfortunately," she concludes, "this concept can get lost nowadays. Some project managers don't have the awareness — or that drive — to translate research and development strategy into detailed activities and plans that can be supported by a cross-functional team. Yet they want the title of project manager. It concerns me."

First, to call yourself a project manager, you need the basic skills to understand how to take strategy and translate it into a detailed 'work-breakdown' structure of all project activities. Planning activities, sequencing them, resourcing them, coming up with a schedule, and then managing to a critical path — that is an absolute. Openly sharing the overall project plan with your outsourcing provider so everyone understands where they fit into the scheme is enlightening and engaging for both sides."

A second prerequisite for project managers, according to Sherako, is to have industry-specific knowledge. "I don't care if it's the defense industry or environmental remediation. This has to do with a deep understanding of the strategic stage-gates and specific requirements to drive a project forward, from discovery to commercialization, within a highly regulated industry. If you're discovering and developing drugs, then you need to know the entire industry framework you're working within."

DON'T OVERTHINK THE PATH FORWARD

In *Can Pharma Build An Innovation Business Model For CMOs?*, featured in *Life Science Leader's* 2017 Industry Outlook issue, Neervannan of Allergan agrees that moving from a traditional model of fee-for-service to one of partnerships is key to the industry's future. He also makes clear you don't need to overthink this concept.

"Shared innovation can be approached initially from a strict business sense," he says. "You can ask if a quid-pro-quo approach works … where the innovators are rewarded with payments for specific innovations. This can then evolve into an ongoing milestone approach, not unlike licensing deals we are familiar with. It does require, though, evolved thinking from both the sponsors and providers — specifically on how to estimate valuation — and coming to a mutually acceptable business agreement."

Has Allergan put this into practice? "Yes, we've worked effectively with several vendors and partners on novel technologies," Neervannan replies. He says while innovation isn't "a routine selection criteria for CMOs, we are increasingly selective in looking for innovative partners." Examples include for "difficult-to-synthesize molecules or unique formulation technologies."

Are the CMOs ready to help with innovation? "I believe most large CMOs today are looking for big manufacturing contracts and not so interested in R&D work where more innovation is called for," he says. "At the same time, we are seeing more boutique companies — mostly in the U.S. and Western Europe — that thrive on this innovation model, and we increasingly seek them out."

These relationships, he explains, "are dependent on mutual trust and respect. That starts with a big company like mine realizing we want the help from the outsourcing innovator community, and taking responsibility for providing the appropriate incentives." Most important is for sponsors to provide "clear rewards in exchange for solutions to problems. Ultimately," he concludes, "it comes down to recognition and reward."

WHAT REALLY HELPS DRUG SPONSORS

Larson of Achaogen (who is on the cover of this issue) says, "It's interesting to think about why the small molecule industry — including CDMOs and CMOs — hasn't learned or revolutionized in the way the biologics industry has, even in places where we have common technology. If you can get 200 percent more out of a biologics manufacturing process from a CMO, who cares? That's not what's driving our cost."

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Are CMOs Sufficiently **Serving Biotechs?**

LOUIS GARGUILO Chief Editor, Outsourced Pharma @Louis_Garguilo

(As Previously Seen On OutsourcedPharma.com)

In the summer of 2016, Louis Demers (pronounced "Louie" in the French of his native Quebec City) brought his outsourcing experience — including at a J&J company and Genentech — to the newly created role of director of development and manufacturing outsourcing at XOMA, a drug discovery and development company with a portfolio of innovative therapeutic antibodies. His mission: Turn this historically self-reliant biotech into a reliable outsourcer.

Demers knows what he'd like to see in contract development and manufacturing organizations to accomplish this. For example, they should be networked with other service providers and in mission-critical alignment with XOMA.

Can he get what he wants? Can any outsourcing leader at a biotech today?

A TRIANGLE OF STRATEGIC PARTNERSHIPS

We've witnessed biotechs become uber-successful over the years, and today there's a proliferation of virtual and startup drug development models. Without service-provider assistance, little of this would be happening. At the same time, we're increasingly hearing from biotechs about CMOs being much less than enabling. Demers' thought process — and CMO search parameters — can help us in understanding both of these scenarios and the real challenges of finding the right service partners.

We can start here: Demers isn't into complexity. He'll do whatever he can to keep it out of his supply chain, even as his company continues to outsource more.

"In terms of having networks that are less complex, I'd like to see CMOs that have created strategic partnerships between themselves," says Demers. Although XOMA is not in the business of ADCs (antibody-drug conjugates), he cites that sector as a good example. "There, an antibody manufacturer and a drug-substance manufacturer will partner with a conjugation specialist and also have a cytotoxic-fill facility that they work with."

Demers describes these organizations as forming "a triangle of strategic partnerships," providing a more seamless offering to their ADC clients. "In my mAb [monoclonal antibody], noncytotoxic world, I'd like to see either a single CMO that has all the elements or CMOs that have these strategic partners across service areas," he says. With either of these scenarios comes the advantage of streamlined tech and information transfer. "We don't have to create needless tech transfers and new protocols between the different stages of development and manufacturing."

Regarding the one-stop-shop ideal he mentions first, Demers knows — as so many biotechs do — it's a limited if not nonexistent subset. Even those providers claiming they've captured the universe of specialties often require outside expertise.

There's also a size issue, which can start to impact a CMO's business model. In other words, CMOs have to grow substantially — and serve many masters — if they are attempting to envelop the long chain of drug development and manufacturing services. Bigger providers may have more services, but are they built to serve smaller clients? (We'll get back to this in a moment.)

Despite these questions and challenges, Demers says his key search parameter to simplify even a relatively small supply chain of a biotech remains in place.

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He explains: "While I'll draw from our own internal technical expertise, for practical purposes, I'm the outsourcing department. I need to ensure our network stays streamlined and manageable. However, this has to be accomplished without compromising deliveries, timelines, or of course, quality. It can't lead to a lack of price leverage or to cost disadvantages. The goal is to keep the work complexity at that optimal minimum."

"I'm trying to do this by setting up strategic relationships that fit our operation and business philosophy," he adds.

DO THEY ACTUALLY EXIST?

But are the opportunities for these strategic relationships available to today's biotechs? "CMOs and we biotechs may operate in the same space, but we're not in the same business," Demers says. "I mean this in the sense that the service provider's first goal can be, for example, capacity utilization. Ours is more speed to the clinic. We are based on different business models. Somehow, we've got to diagram that right spot intersecting mutual needs."

That intersection may be hard to find. A recently published article on more mutuality in sponsor-provider relationships received this reader rebuke:

> *"I have been reading your exuberant articles about partnering Pharma and Biotech sponsors with CMOs. … Our experience has been diametrically opposed to the picture you've painted. … As a small biotech with a viable biologic product, we signed a deal with a top-tier CMO to manufacture our bulk drug substance in the U.S. in 2011. … We gained approval of our BLA [biologic license application] in 2016 and then were informed by our CMO they were closing our manufacturing area, and we had up to five years to transfer our process to one of their international sites or somewhere else. … That's a $30 million, three-year project we never expected to undertake. On top of this, larger sponsors with deeper pockets appear to have locked up the capacity out to 2020, so we also face a manufacturing shortage."*

This is a critical report from the front lines. First, bigger ("deeper pocket") sponsors competing with biotechs for capacity have always presented a challenge, but a lack of capacity — or the right capacity — seems exacerbated today. Add that it appears biotechs are being squeezed by consolidation in the CMO industry, forming "Big CMOs" with operating models built less around the smaller customer. Big, it appears, is the enemy of biotech.

"I'd like to see CMOs that have created strategic partnerships between themselves."

LOUIS DEMERS
Director of Development & Manufacturing Outsourcing, XOMA

SIZE MIGHT BE DISPOSABLE

Demers, too, has experienced "Big CMOs" focusing more on filling their large-scale production capacity with larger clients and big-volume material needs. "They're geared more toward a larger pharma, or maybe a smaller pharma or biotech if there is a highly predictable commercial operation upcoming."

Yet Demers insists there are service providers out there that are flexible, can operate at different demand levels, and with smaller clients. "I wouldn't say it's necessarily size that's always the concern," he says. "If a CMO has the vision to meet the needs of the emerging biotech — and for example, in our case serving the orphan drug industry — then it is a viable option no matter the size."

One specific attribute Demers looks for today in a service provider — big or small — is disposable technology. "We need flexibility for speed," explains Demers. "To that extent, we're fully committed to disposables versus stainless steel. We're elated this technology is now well-accepted across the industry, and we look for a CMO that's adopted this equipment platform."

Disposal equipment is a key advancement. But it won't dispose of the increasing tensions between today's virtual and other biotech models, and the consolidation at CMOs. Even more, the natural evolution of pharmaceutical markets will continue to have an impact. Demers mentions the orphan drug industry above — a growing market target that revolves around smaller volumes, less capacity needs, and greater flexibility.

For decades, the advancement of smaller-sized drug developers has been fueled by the growth of service-provider models. XOMA itself is a biotech with a living history of this parallel trajectory. In part two (found on OutsourcedPharma.com) of our discussion with Demers, we take a closer look at the course of those lines and whether they can form today's needed biotech-provider intersections.

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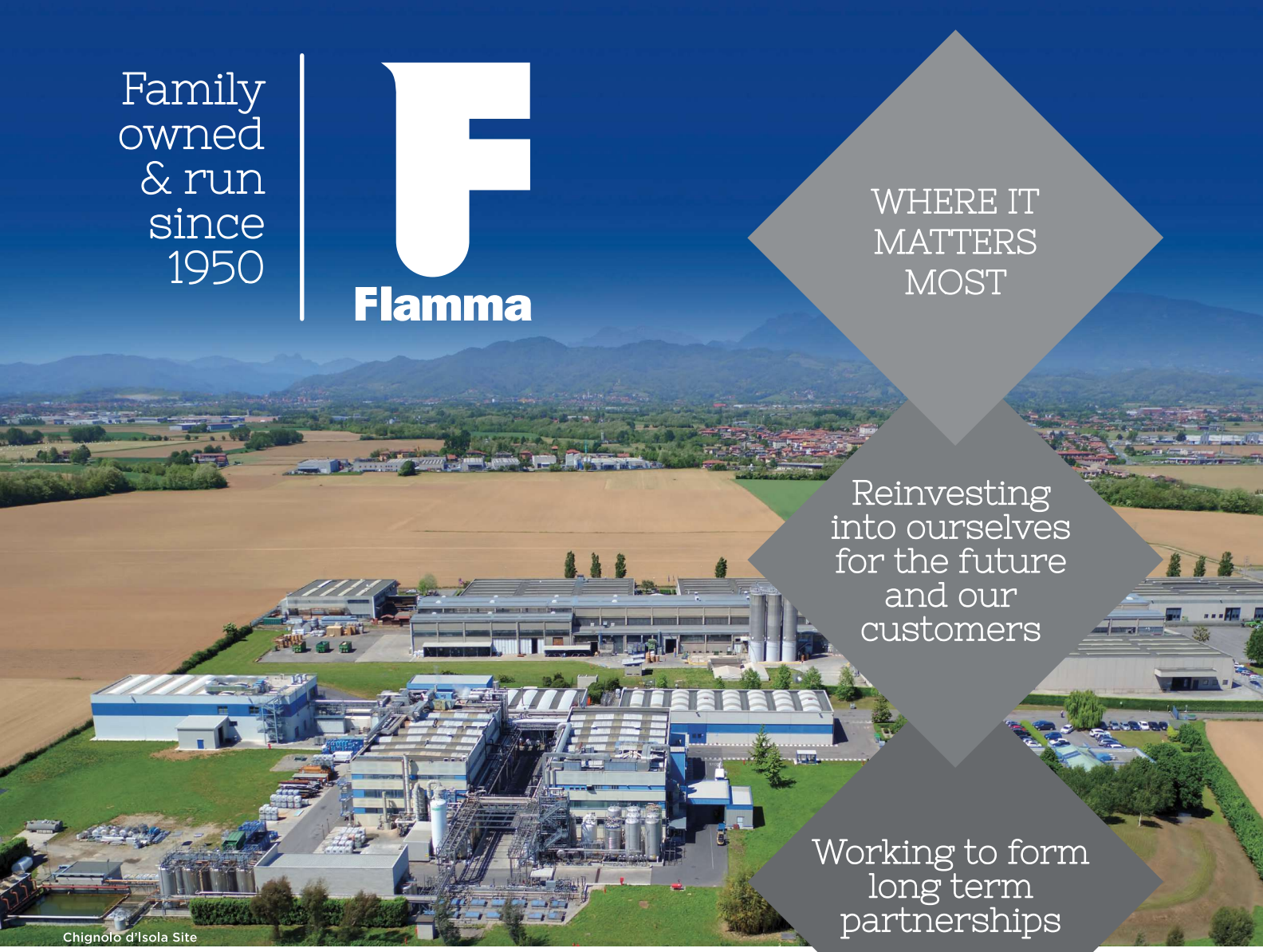

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Emerging Biopharma & Their CMOs – Crazy Like A Fox

LOUIS GARGUILO Chief Editor, Outsourced Pharma @Louis_Garguilo

(As Previously Seen On OutsourcedPharma.com)

> *"Most of the CMOs we spoke to, frankly, just thought we were crazy."*
> – Comment from a biopharma executive at Outsourced Pharma Boston 2016

Crazy, that is, like a fox. And this sponsor found an equally crafty CDMO willing to join its pursuit in developing a new class of medicines. Today, that sponsor-provider relationship exemplifies a new model of alliance between emerging biopharma and CMOs.

ARE YOU SURE YOU WANT TO DO THIS?

The biopharma of this chronicle believes it leads the world in developing a new class of therapeutics, those that include the daunting challenges of producing nonsterile, live bacterial for oral-dose drugs. The company spoke to over 60 CMOs worldwide. Only a handful responded affirmatively. To be clear, this wasn't a quotidian request for an outsourcing relationship. These CMOs were, in effect, being asked to think about altering what they do, what they may become, and who they may be able to serve in the future.

That a partner emerged points to the existence of a different breed of CMO, one willing to take a larger bet on a single-sponsor relationship. This organization had some background in the scientific field. However, to the emerging sponsor, the more important consideration was the CMO's fit to strategic purpose. It was relatively small and owned a strategy not necessarily of large growth and client diversity.

YOUNG AND EXPERIENCED

The subsequent business agreements and tech transfer between sponsor and provider were successful for at least two reasons, both of which place the sponsor in a group of emerging biopharma separate from the currently popularized virtual biotechs. One of those reasons is the biopharma's stance vis-à-vis CROs. We'll save this explanation for last.

We'll start with the attitude that "although we're a new biotech, it doesn't mean we can't have a mature and experienced CMC (chemistry, manufacturing, and controls) infrastructure and strategy," as one sponsor at Outsourced Pharma Boston 2016 put it. With such companies, "from the very beginning, CMC is a core capability, vitally important to our business strategy and approach to partnership with external partners."

In-house, CMC expertise facilitated the quick and comprehensive tech transfer we're describing here. A testament to that success, and the progress of the program and relationship, is how quickly others in the industry started to take notice. "A lot of people stopped thinking we were crazy when we moved through Phase 1 to a Phase 2 study and had clinical supplies manufactured in a relatively short time period."

For those CMOs asking how they might get involved in these tighter integrations with sponsors (i.e., become this new breed of service provider), the answer we heard is "it starts by being identified as an organization fully willing to leap into the emerging field, take on that new knowledge and training, and have the sponsor on the premises 24 hours a day."

SUCCESS FOR THE CMO?

No one is suggesting, though, that a CMO leap before looking. The CMO in this type of business relationship, to a large degree, takes on the risk profile of the sponsor. Accordingly, potential rewards should be hashed out in equal measure. Getting this balance right will ultimately determine if these partnerships flourish or new models develop yet again.

Here's what the sponsor provides the CMO: specialized scientific knowledge and unique processing experience. The CMO gets to design a whole new capability in an advancing technology and drug type, and if the product is successful, long-term business is created.

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Here are the questions raised:

- How does that tech transfer take place, practically and contractually?
- How is IP — transferred and newly generated — dealt with?

From the outset, there also must be some long-term strategy for success and a future left for the CMO should the sponsor's project fail in the clinic.

Besides the willingness of the CMO to engage, these issues can be resolved only because of the makeup of this young and experienced biopharma sponsor.

The second defining attribute of the new biopharma is that it kept early research at home and, for the most part, out of the hands of CROs. Perhaps this is the most intriguing component we are documenting. "[This model of strong CMC and in-house research] has been vitally important to our business strategy and approach to partnership with external partners." Let's finish with this final point on CROs.

NOT THE BEST MODEL FOR CROS?

This class of emerging biopharma sponsors doesn't engage as intimately with CROs as we might see in the more traditional virtual biotech model, where the trend has been to outsource as much as possible throughout the product life cycle.

That virtual paradigm calls for venture capital-funded biotechs to outsource to CROs for the testing and developing of ideas, new science, and technology. Upon proof-of-concept, programs are transferred to a later-stage development (and manufacturing) organization. VCs get to stay away from funding fixed assets and incurring up-front, often nonreturnable costs. (CROs themselves have tried to elongate their services so that transfer stays internal, the "one-stop-shop CRO/CMO model.")

But what we heard at the conference was a strategy of increased internal investments from the sponsor, to better nurture the emerging science and technology. Some believe there's more flexibility in this model of outfitting labs and even beyond, and that more VC firms, "even with very early-stage startups," will start to think the same. These proponents say they'd be surprised "if the future has a lot of CRO-to-CMO transfers, particularly for unique, nonstandard, nonplatform products."

This article is based on panel discussions at the Outsourced Pharma Boston conference, Westin Copley Place, April 20-21, 2016.

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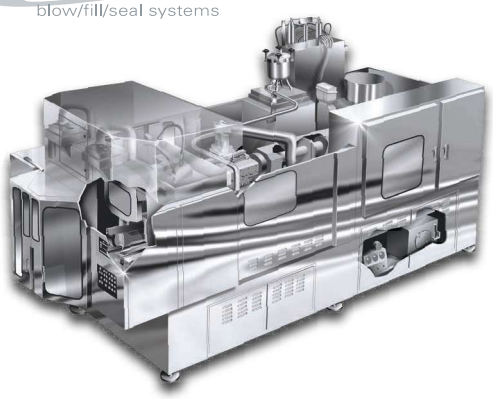

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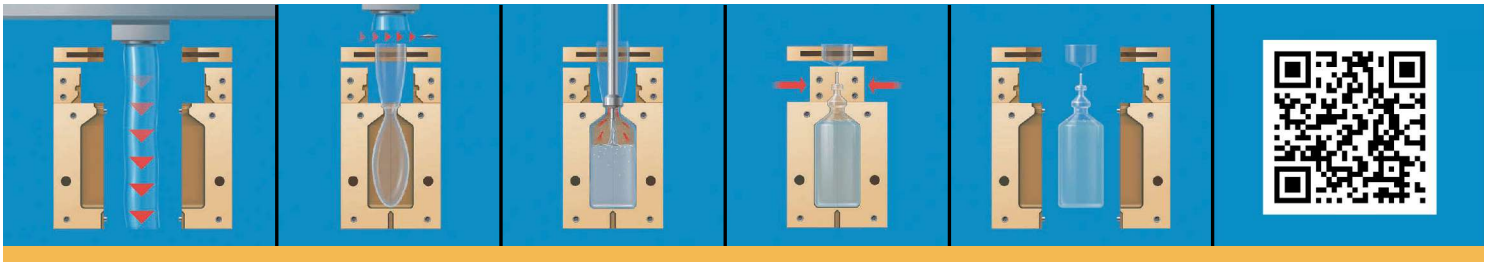

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Outsourcing 2017: Countries, Costs, & Some Concerns

LOUIS GARGUILO Chief Editor, Outsourced Pharma @Louis_Garguilo

(As Previously Seen On OutsourcedPharma.com)

A renewed crossing into Asia or U-turn back to Europe and the U.S.? Thoughts of capacity and costs running over filling your head these days? Perhaps some of the following comments from Outsourced Pharma editorial board members will help answer some of the questions you have regarding outsourcing in 2017.

COUNTRIES TO COUNT ON

There was a time not too long ago when few Big Pharma or Big Biotech based in Europe or the U.S. would consider outsourcing important drug discovery or development work to Asia. Then came a new dawn, when it seemed everything was in the process of being sailed overseas to service providers in India, China, even South Korea and other distant destinations. Today, we hear it's coming back. There's been a backtracking to the days of keeping projects closer to the vest.

Well, people like Nils Olsson, VP chemistry, manufacturing and controls at Retrophin Inc., doesn't quite agree.

For the foreseeable future, he says, "I suspect we'll see much more API manufacturing done in China. Also, as the market there matures, many of the perceptions of questionable confidentiality and looser protection of trade secrets will diminish. Some organizations in China are taking remarkable steps to protect a customer's IP, and those efforts become models for others there."

Olsson is responsible for outsourcing his company's entire discovery, development, and manufacturing, including for three commercial products. "Retrophin is 100 percent virtual," he says. It's also focused on orphan diseases. Readers of OutsourcedPharma.com know of concerns that consolidation and the growth of "Big CMOs" might not fit the needs of companies such as Retrophin, focused as they are on smaller target markets.

Olsson predicts that the improvements in reputation and reliability in China and India may provide more options for virtual and smaller companies like his. Now that will be something to follow in the coming months and surely beyond.

And there's another related challenge, according to Olsson. It has to do with the growing distances between CMOs themselves. "Coordination of activities between CMOs, for example API manufacturers and fill-finish providers, or external analytical services, has become a key to moving forward," he says. "For a company operating under a virtual business model of outsourcing everything, [the existence of this distance] can be challenging."

Specifically, he sees two immediate options. "Go with a lead CMO [or a consulting group as middleman] to basically work as your general contractor. However, while this may seem convenient, it can also mean giving up another degree of control."

The other option? "Immerse yourself in the management of each company involved in your supply chain," he says. "I think it's a matter of personal preference. But no matter where you outsource, quality and reliability of your products remain your responsibility."

COSTS AND CMO CONSOLIDATION

"A definite theme for us has been the need to drive toward lower costs," says Peter Bigelow, president, xCell Strategic Consulting, and former Pfizer and Patheon executive. But he's not talking about tougher negotiating between drug owners and service providers. He's focused on improved partnering for better productivity and overall financial outcomes.

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Bigelow restates a mantra of 2016, "Together, drug owners, service providers, consultants, and regulatory bodies need to identify ways to bring drugs to market as efficiently as possible." He believes innovative companies now fully understand that product pricing will incur intensifying visibility and public pressures moving forward. Unfortunately, says Bigelow, "Many of the new products under development require expensive ingredients and complicated manufacturing processes. Creative ways to incentivize CDMOs to improve processes and drive for lower cost of goods is a top priority for many companies."

Bigelow says that, as the CDMO industry consolidates and matures, pharmaceutical companies will have greater expectations for partnering. He believes that out of necessity, they'll establish fully integrated relationships with solutions providers.

"I expect 2017 to be a breakout year in terms of the types of contracts that are signed," he says. "Traditional pharmaceutical companies continue to increase their strategic interactions with partners and look for ways to effectively manage risks by integrating with CDMOs."

From this integrating, an important consequence arises: It will ensure that less capacity will be built internally by Big Pharma, and more CDMO capacity will need to be leveraged. This will put more stress on specialty capacity, such as biologicals, but will also create efficiency opportunities for more traditional capacity.

Hold that thought.

CONCERNS CASCADING FROM YEAR TO YEAR

When I asked about outsourcing in 2017, I expected Carol Sherako, director program management at Sanofi Genzyme, to focus on project management. After all, articles we worked together on in 2016 on this subject became some of the most widely read on OutsourcedPharma.com.

She didn't let us down: Both internal and external project management, she says, continue to grow in importance to her and her company and, she believes, most of the outsourcing arena.

Sherako agrees with Olsson's comments that in 2017 it'll be important to look at utilizing more global CDMOs. She feels this may play a key role "in helping us learn how to form better partnerships, those needed in all our sponsor-provider relationships."

As she takes a wider survey of the business environment and competitive landscape, Sherako also sees a growing need for services directed at more focused and specific science and technologies. "People won't just need capacity; they'll need specific capacity," she says. She uses her own field as an example: "Will there be capacity in the area of gene therapy?"

She too wonders about new or expanded CMO facilities — and the expertise to operate them. "Are we in a buyer's or seller's market? What is the business environment? Are CMOs at capacity in certain areas of technology? Will those of us who wish to outsource more have to negotiate differently to come to terms for IP, expenses, and scheduling? If CMOs are indeed at capacity, will this cause companies to invest internally in cGMP facilities capable of manufacturing clinical trial material and commercial supply?"

"Creative ways to incentivize CDMOs to improve processes and drive for lower cost of goods is a top priority for many companies."

PETER BIGELOW
President, xCell Strategic Consulting

INTERNAL VERSUS EXTERNAL CAPACITY

I told you we'd get back to this topic of future internal versus external capacity buildout. And we get a very straight reply on this from another Outsourced Pharma board member, Darren Dasburg, VP BioVentures — Biologics at MedImmune/AstraZeneca. "Topic one for me during 2016 was the rather sudden realization that CMOs will not be able to carry us forward in the near term, and if we continued to push it, could cost a commitment to batches in future years," Dasburg explains. "This caused us to look deeply at what we could do ourselves, as well as got us in the acquisition game on the bio-drug substance side."

He continues: "Additionally, like many others we have a reliance on drug-product filling; we're learning that not everyone approaches quality and regulatory quite like we do. Our near-decade focus internally has us visiting the idea that we are paired with a certain external group of providers, but there's a growing demand for our time and attention."

Clearly, some countervailing winds in the seas of outsourcing are certain to blow in 2017. Happy sailing.

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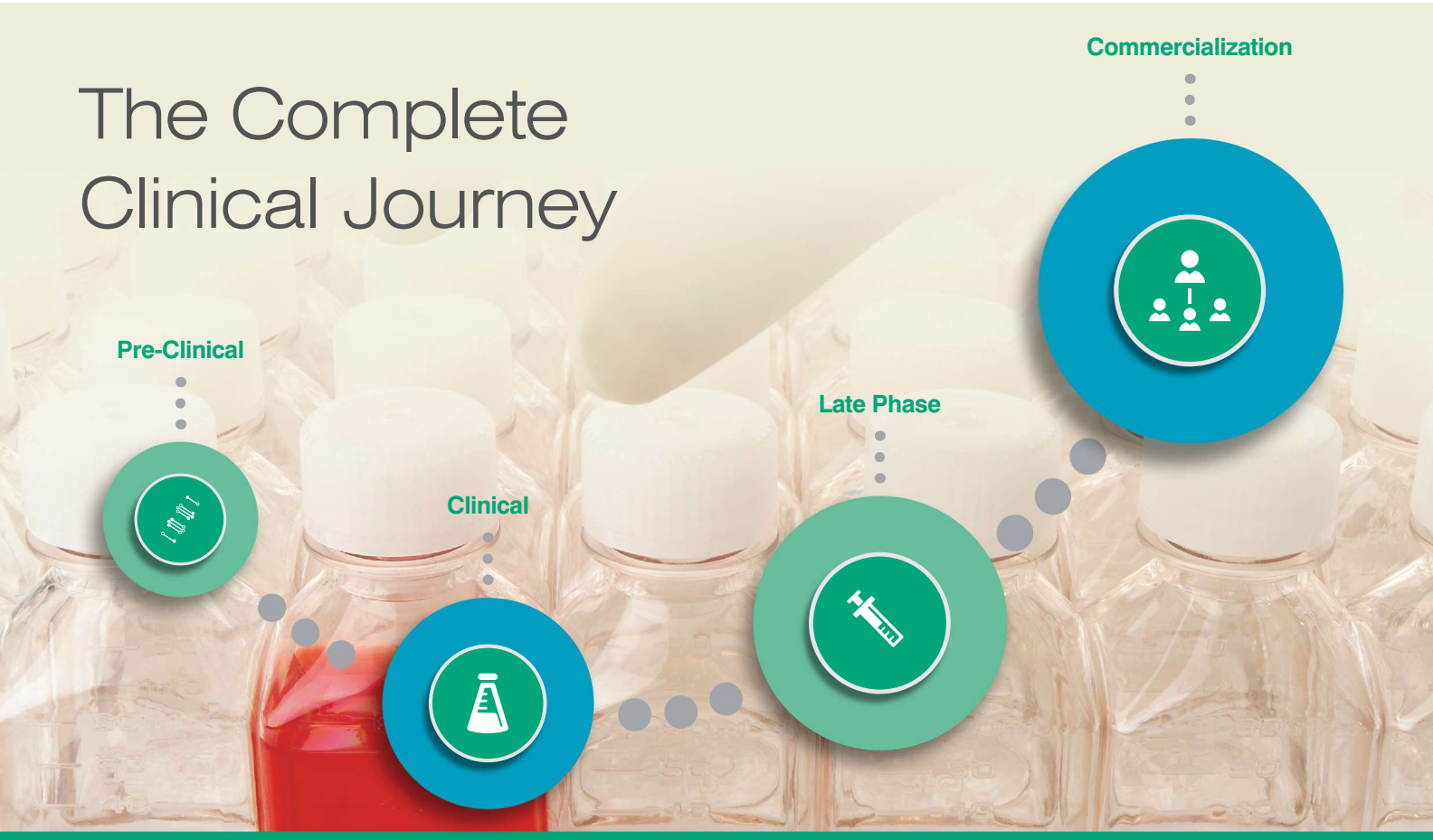

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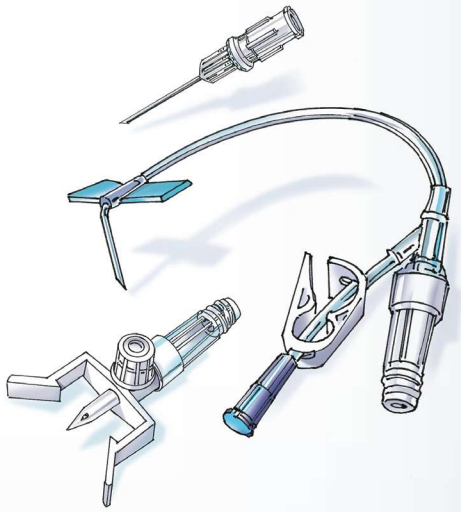

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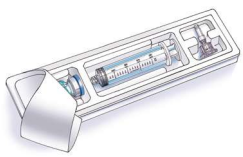

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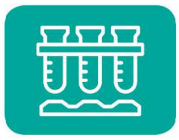

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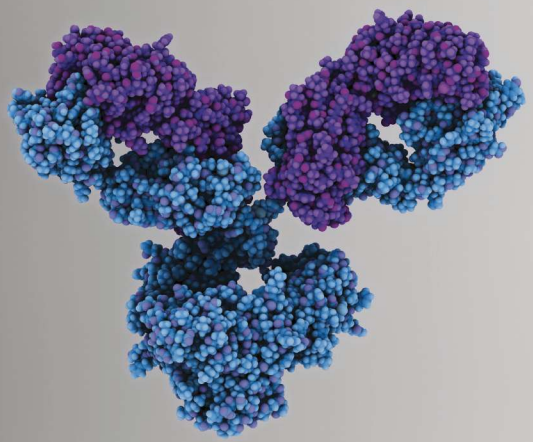

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