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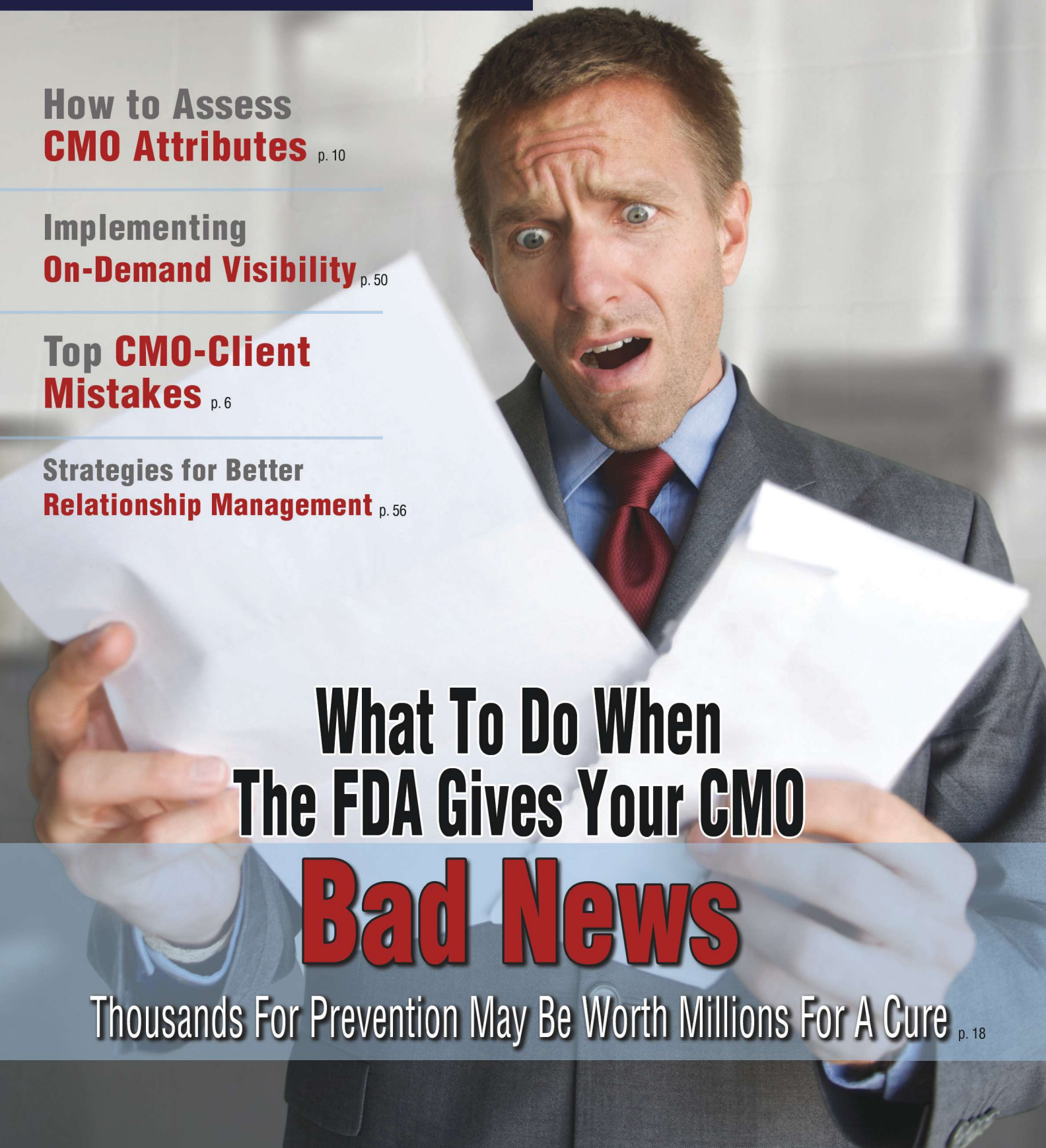
SPECIAL ISSUE:
THE CMO LEADERSHIP AWARDS



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Does Your CMO Have A Contingency Plan?

In August, I flew to New Orleans for personal reasons and soon found myself unable to leave as a result of Hurricane Isaac. As the storm approached the city, many of the area businesses and residents began preparing for the storm — shutting down early, boarding up windows, purchasing fuel for generators, bottled water, canned goods, and so on. When a hurricane is coming, residents even fill up the bathtub with water in case it is needed for flushing toilets. In essence, the hurricane reminded me of the importance of contingency planning, an important practice in the pharmaceutical and biotech industries. What if your primary CMO is unable to provide a reliable supply of product as a result of a natural disaster, terrorist event, or FDA-mandated shutdown? What do you do?

If you are a pharmaceutical or biotech company, having a well thought out contingency plan can mean the difference between life and death. Did you know that 50% of all companies which are reliant on computer services that experience a disaster, and do not recover within 10 business days, never recover financially or file Chapter 11?

So whose responsibility is it to create an effective contingency plan, yours, or your CMO's? You might think that most quality driven organizations will have contingency plans and a contingency planning process. But do they? Have you checked? Does your CMO have a plan in place that if one of its sites has to shut down, it could quickly ramp up production at another location? Better yet, are they willing to create an agreement with one of their competitors that should they drop the ball and not be able to produce your product, a competitor could quickly step in to save the day? You may think this sounds crazy, but to me it sounds like excellent customer service and the kind of company with which I would want to do business. If your company has never considered developing a contingency plan, or perhaps it needs to be dusted off and updated, but you are unsure of where to start, a basic disaster recovery and contingency plan can be found by going to www.adminservice.org/templates.

If I were the CEO of a company which outsourced its manufacturing capabilities, I would certainly be inclined to thoroughly vet any partner company on its contingency plan for being able to deliver my product. You should too.

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BIO DATA POINTS

Top Mistakes Made By CMOs And Their Clients

By Eric Langer, president and managing partner, BioPlan Associates, Inc.

Outsourcing in the biopharmaceutical industry continues to evolve and become more sophisticated, and both biotherapeutic developers (clients) and their CMOs recognize the need for efficient and hassle-free relationships. But year after year, our annual study shows that critical elements of this relationship have not improved. Our 9th Annual Report and Survey of Biopharmaceutical Manufacturers examines, among other critical industry issues, the CMO-client relationship from both perspectives. We evaluate and quantify the issues so outsourcing partners can address chronic weaknesses and strengthen their relationships.

We identified 19 factors affecting client selection of CMOs, asking clients to rate factors as either "important" or "very important." Our study shows that "establishing a good working relationship" remains the top factor considered by biotherapeutic developers when considering a CMO, with a leading 96.8% of respondents considering this either "important" or "very important."

Beyond operational proficiencies, clients are demanding their CMOs develop softer skills. For example, some contributing relationship factors such as "sticking to a schedule" remain a major concern. But this issue shows a steady decline during recent years. As a "very important" problem it declined from nearly 60% five years ago to 44% this year, suggesting fewer mistakes and problems in scheduling are occurring.

Interestingly, the "good working relationship" factor remains ahead of other major issues such as "comply with my company's quality standards" and "effectively handle cross-contamination issues." Complying with the client's quality standards may be non-negotiable, so these latter operational factors are minimum performance issues if a CMO is even to be considered. Thus, as CMOs become increasingly proficient, it will become more difficult to differentiate themselves on scientific attributes. Soft factors such as relationship development and showing cost-effectiveness may become increasingly important selection criteria.

CMOs looking at strategic ways to differentiate themselves might look beyond these prerequisites to the next tier of critical issues. The trends suggest that communication and management skills are increasingly becoming top-of-mind factors for clients when selecting the ideal CMO.

During the last seven years the most critical attribute rankings have shifted to some extent. However, the "establish a good working relationship" factor is always a top contender. The factor moved from the number four spot in 2006 to the number two spot in 2010, and to the number three spot this year. As the industry matures, customer service and establishing good client-vendor relationships should become more important attributes. Maintaining good client-vendor relationships is important to clients, and it is likely that poor communications between clients and vendors is a major factor in the persistent "working relationship" issues.

COMMUNICATION PROBLEMS EXIST ON THE CLIENT SIDE, TOO

When we looked at the relationship from the CMO perspective, we also found communication issues to be prevalent. CMOs identified 11 of the most common mistakes clients make in the contractual relationship and rated as either "very" or "somewhat" common. We discovered that 86% of CMOs believe clients don't communicate with them effectively. This was tied with two other common mistakes for the top spot: "clients don't build in sufficient time for the project" and "clients want to contain cost by doing limited developing runs, but still expect successful full scale manufacturing." Both of those problems can be traced to unrealistic expectations — expectations that can presumably be managed at the outset of the relationship through more effective communication.

Interestingly, of the top five most common mistakes made by clients, all of those mistakes declined in percentage of respondents from last year, except one: clients not communicating effectively. This year's 86.1% of CMOs indicating this to be a "very" or "somewhat" common problem is a step up from both 2011 (84%) and 2010 (80.4%), and indicates that communication issues are only becoming more important over time.

As outsourcing continues to become more widespread, clients will expect CMOs to improve their service offerings — not only from a technical standpoint, but also from a communications and relationship management perspective. Ensuring good communication will continue to be critical, as deficiency in this area not only translates to the "working relationship" issues on the client side, but also to the unrealistic expectations problems from the CMO perspective.

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Figure 1: Selected Critical Issues When Selecting A CMO

Percent Responding "Very Important" and "Important"

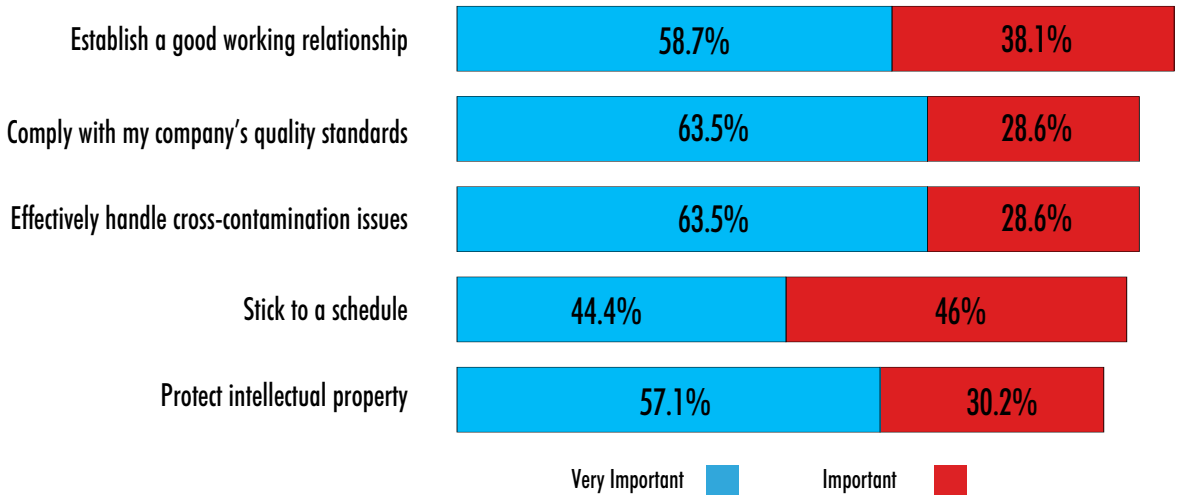
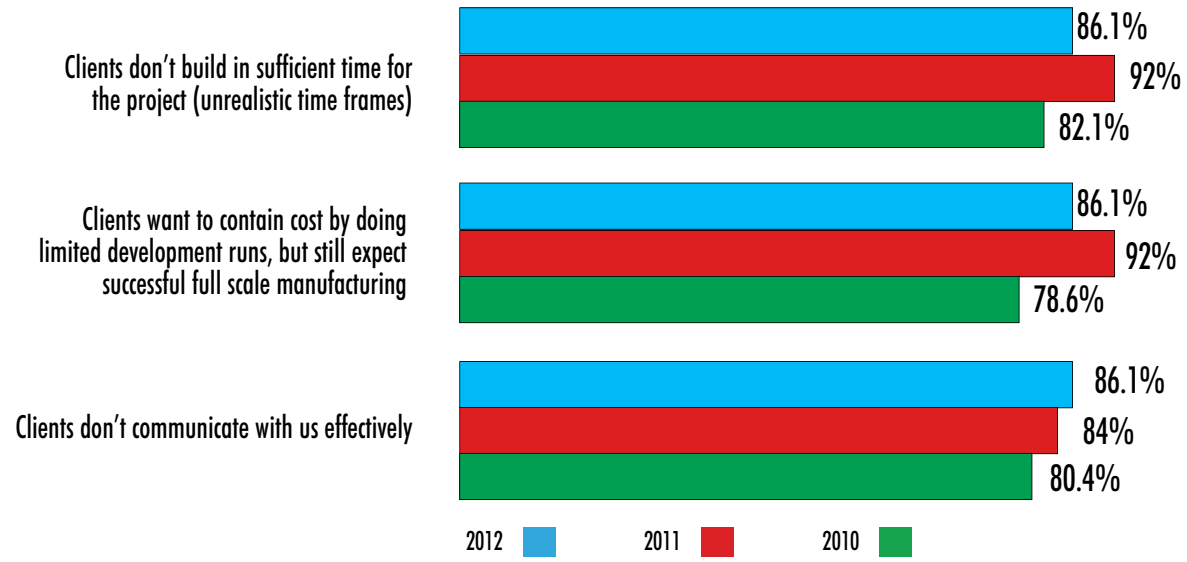


Figure 2: Selected Common Mistakes Biopharmaceutical Sponsors Make With Their CMOs (2010-2012)

Percent Responding "Very common" and "Somewhat Common Problem"



Survey Methodology: The 2012 Ninth Annual Report and Survey of Biopharmaceutical Manufacturing Capacity and Production in the series of annual evaluations by BioPlan Associates, Inc., yields a composite view and trend analysis from 302 responsible individuals at biopharmaceutical manufacturers and contract manufacturing organizations (CMOs) in 29 countries. The methodology also included 185 direct suppliers of materials, services, and equipment to this industry. This year's survey covers such issues as: new product needs, facility budget changes, current capacity, future capacity constraints, expansions, use of disposables, trends and budgets in disposables, trends in downstream purification, quality management and control, hiring issues, and employment. The quantitative trend analysis provides details and comparisons of production by biotherapeutic developers and CMOs. It also evaluates trends over time and assesses differences in the world's major markets in the U.S. and Europe.

If you want to learn more about the report, please go to bioplanassociates.com.

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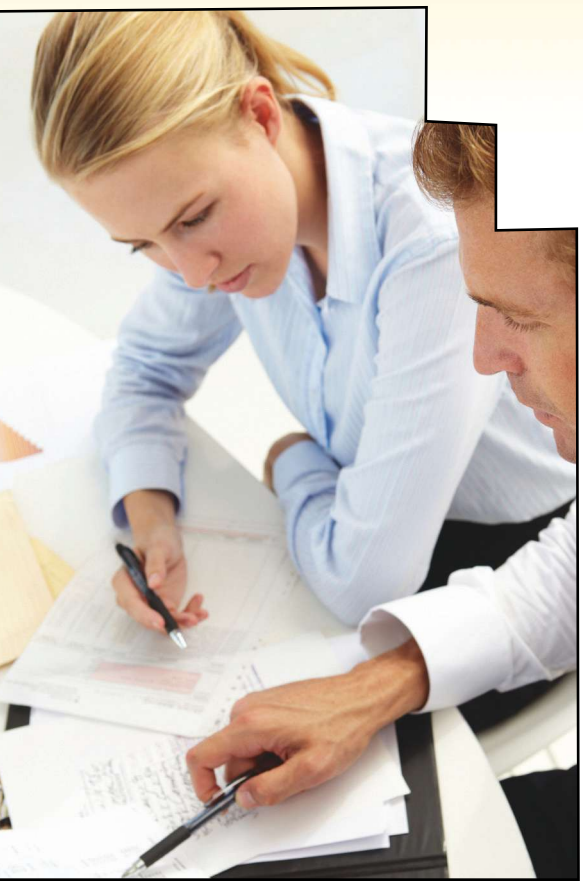

How The Experts Assess CMO Attributes

By Rob Wright

The global CMO market was valued at $26 billion in 2010 — growing from 2008 at a CAGR of 10.7%. The main factor driving this market is the increase in sourcing of biologics and generics. Forecasts anticipate the market reaching revenues around $60 billion by 2018 – CAGR of 11%. The trend of pharmaceutical and biotech companies outsourcing their product manufacturing has no end in sight, even though many recent and very public recalls have involved CMOs. As this trend continues, so too must the trend of both parties to be vigilant during the process of developing strategic partnerships. In a recent article, Jeffrey Baker, Ph.D., deputy director, office of biotechnology products at the FDA's Center for Drug Evaluation and Research (CDER), stressed the importance of differentiating between outsourcing and strategic partnerships saying, "In strategic partnering, there is shared pain and shared gain. You can contract out activities, but you cannot contract out responsibilities." With this in mind, *Life Science Leader* magazine posed a series of questions to industry experts in order to gain their insights on how they assess CMO attributes, as well as to uncover potential growth opportunities in the CMO space.

Firelli Alonso-Caplen, Ph.D., is the senior director of Pfizer's biotherapeutics and vaccines outsourcing group within the BioTherapeutics Pharmaceutical Sciences organization of worldwide R&D. Dr. Alonso-Caplen has 27+ years of combined experience in research, development, and cGMP production of biological products and vaccines, with more than 7 years specific to outsourcing, project/contract management, and technology transfer to qualified third parties. Barry Rosenblatt, Ph.D., is a subject matter expert in chemistry and manufacturing controls (CMC) of biotherapeutics. Dr. Rosenblatt is the president of SME Biotech Consulting. He has 27+ years of experience in the biopharmaceutical and contracting industry, which include previously held positions with Centocor, J&J, and Charles River Laboratories.

RANK THE FOLLOWING CMO ATTRIBUTES: INNOVATION, PRODUCTIVITY, QUALITY, REGULATORY, AND RELIABILITY

Firelli Alonso-Caplen of Pfizer: Quality is always number one, followed by regulatory, reliability, productivity, and innovation. For my group — biotherapeutics and vaccines outsourcing — quality refers to the quality of the deliverables (e.g. clinical trial materials) made in compliance with cGMP (regulatory), ahead or on schedule (reliability), at reasonable costs and meeting success criteria (productivity). Innovation is important when generating better or more effective processes, products, or services, as in an R&D environment.

Barry Rosenblatt of SME Biotech Consulting: In my estimation, reliability should be ranked the highest because in order for a CMO to be reliable, it must have elements of all of the other attributes. A CMO that is not productive has questionable quality, does not maintain adherence to the regulatory requirements, cannot demonstrate innovation when required, and cannot be reliable. Solid quality and quality systems would be next on my list, especially in light of the current emphasis by both the FDA and EMA (European Medicines Agency) on CMO

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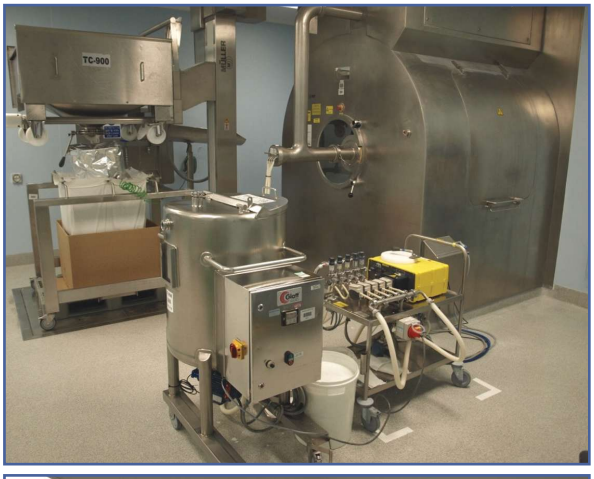

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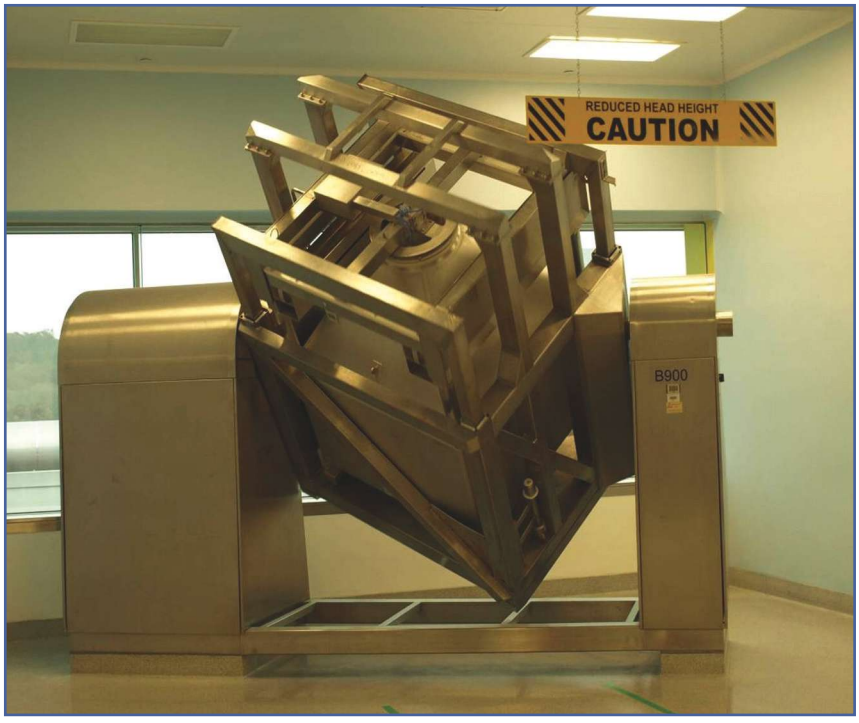

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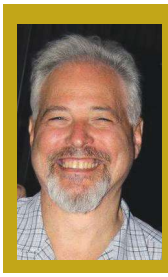
compliance. Following close behind would be regulatory adherence, for the same reason. Productivity is easier to attain, assuming the CMO has all of its other systems in place. Innovation can be a double-edged sword in a CMO. If applied to improved operational systems and problem solving, innovation is a positive attribute. If the CMO tries to innovate on a client's process, however, it can lead to delays and unforeseen changes in a transferred process.

HOW DO YOU ASSESS A CMO AS POSSESSING THE ATTRIBUTE OF INNOVATION?

Alonso-Caplen: A CDMO (contract development and manufacturing organization) would score high on innovation when the organization can offer practical solutions to improve processes, products, technologies, or services needed by their client, on top of continuing to meet quality, regulatory, reliability, and productivity attributes.

Rosenblatt: A CMO that has the ability to adapt its internal procedures to meet the sponsor's needs (i.e. introduction of a novel technology or piece of equipment into its facility) is one good indicator of innovation. Companies that can offer suggestions on operational practices to increase efficiency/decrease costs of goods (i.e. use of bar coding for tracking raw materials/samples/products) demonstrate innovative thinking.



"Many sponsors place a great deal of emphasis on the experience of the [CMO's] senior most staff, without assessing the experience of the technical staff." Barry Rosenblatt, Ph.D., SME Biotech Consulting

DESCRIBE A SITUATION OF A CMO DEMONSTRATING THE ABILITY TO BE INNOVATIVE?

Alonso-Caplen: A CMO that is able to significantly decrease the number of purification steps of a product, with concomitant increase in overall yields, is an example of innovation.

Rosenblatt: In one project, the process required the use of multiple bioreactors feeding into a common capture step in a semicontinuous process. The CMO room design was originally set up for contiguous USP/DSP suites using dedicated feed lines between the rooms. The CMO used an innovative modification of the feed lines to redirect the feed stock from two rooms into a single DSP suite, bypassing the intermediary rooms.

WHAT IS THE BEST WAY TO MEASURE A CMO's PRODUCTIVITY?

Alonso-Caplen: Typically, when drafting a service agreement for a late-stage product, a list of success criteria is included. Delivery of the required number of engineering and GMP runs on time, within budget, and meeting all of the success criteria, exemplifies a CMO's excellence in productivity.

Rosenblatt: Productivity is linked to capacity, quality systems, adherence to regulatory requirements (no citations or 483 notices), and delivery of product on schedule with minimal or no deviations. Examination of deviation history, regulatory inspections, and plant utilization, measured against the total number of past projects, will result in a reasonable estimation of the productivity of the operation.

HOW DO YOU ASSESS A CMO's QUALITY?

Alonso-Caplen: The CMO has to undergo a two-to-three day audit by our QA auditors, depending on the complexity of the project that will be outsourced. A team of two to three auditors, including an outsourcing SME (small to medium enterprise), will assess the CMO's quality systems. A typical starting point for an audit is the warehouse, where raw materials and components are received, go through the production and testing process flow and associated quality systems and facilities, and end with storage areas for either bulk drug substance or for drug product.

Rosenblatt: Assessment of the quality of a CMO is focused on the quality systems in place. Reviewing the SOP structure during an audit (i.e. policies, SOPs, batch records), as well as the content of each is essential for establishing trust in the CMO's understanding of quality. Other essential pieces include a change-control system, OOS (out of specification)/deviation system, sample tracking system, external vendor audits, process/equipment/people flow procedures, and personnel training. Every audit should contain a spot check of documentation to determine whether SOPs are being followed. Inspection records from regulatory agencies (observation and/or 483 letters) should also be examined. Lastly, philosophy of the quality group and CMO management should be compared to the philosophy of the sponsoring company, with any disconnects covered in a quality agreement.

WHAT IS THE BEST PREDICTOR OF A CMO's RELIABILITY?

Alonso-Caplen: Reliable CMOs will meet all project milestones

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and deliverables. A CMO that has a project management group separate from its science and technology lines reflects a CMO that is well experienced in contract work. The project manager oversees the daily coordination and execution of all activities, as well as the key performance indicators for each project. Monitoring and tracking functions are crucial for keeping projects on time, within budget, and meeting the highest quality standards. Those functions also offer the opportunity to routinely evaluate risks or identify gaps.

"A CMO that can produce drug substance and drug product, and be able to perform release and stability testing of antibody-drug conjugates, is a specific example of a desired CMO."

Firelli Alonso-Caplen, Ph.D., Pfizer

Rosenblatt: Reliability of a CMO can be measured in its consistency of on-time delivery of the promised amount of product with a minimum of deviations. Warning signs of less reliability include a large number of deviations, unusually long lead times, and a lack of milestones presented in project plans.

WHAT IS A COMMONLY USED CMO ASSESSMENT TOOL THAT BRINGS LITTLE OR NO VALUE TO THE SELECTION PROCESS, AND WHY DOES IT CONTINUE TO BE UTILIZED?

Alonso-Caplen: All the tools we currently use for the assessment of a CMO are currently utilized, otherwise these would be eliminated. However, the selection criteria are weighted, and CMOs are scored and ranked on predetermined weighted criteria based on their responses to RFPs and after their successful completion of a technical evaluation, a quality/compliance audit, and an environmental health and safety audit. Cost competitiveness is not a weighted criterion. However, it can become the tiebreaker when faced with choosing between CMOs that are equal in all other weighted criteria.

Rosenblatt: Many sponsors place a great deal of emphasis on the experience of the senior most staff, without assessing the experience of the technical staff. Since quality in any organization should come from all segments of the organization, not just from the top, this tends to overestimate the quality of the CMO. It is commonly utilized as a selling point for the CMO, embedded in their sales presentations.

WHERE DO YOU SEE GROWTH OPPORTUNITIES FOR THE CMO MARKET?

Alonso-Caplen: More CMOs that can offer "soup-to-nuts" capabilities (i.e. an integrated service model) for various technologies are areas for growth opportunities. A CMO that can produce drug substance and drug product, and be able to perform release and stability testing of antibody-drug conjugates, is a specific example of a desired CMO. This simplifies the supply chain and reduces the occurrence of a technology transfer with oversight by a single team.

Rosenblatt: There are several potential growth areas for CMOs in the current economy.

- Service offerings: With Big Pharma often reducing or shutting down its research and early-stage development groups, CMOs with the ability to develop early-stage production and purification processes, as well as GMP production, will likely see an uptick in business as these companies increase outsourcing. In addition, many pharmas are looking for "one-stop-shops" to meet their outsourcing needs. Partnering or implementing CRO offerings, especially as package deals, will shift some business away from stand-alone CROs.
- Cost of goods reduction: CMOs partnering with technology companies (disposables, high-throughput purification systems, etc.) to reduce the cost of goods will be attractive to both the innovator companies and biosimilar companies.
- International markets: As markets grow in areas outside of the U.S. and Europe, and as pressures increase to reduce costs, expansion into "developing" areas will be attractive for the next few years.

WHAT TOOLS DO YOU USE TO ASSESS A CMO IN THE AREA OF REGULATORY COMPLIANCE?

Alonso-Caplen: We typically ask a CMO to fill out a technical site previsit information questionnaire a couple of weeks prior to a scheduled technical evaluation. This template includes questions on regulatory submissions history, if any. Depending on the phase of the project to be outsourced, lack of experience with preap-

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proval inspections could be a deal breaker.

Rosenblatt: Assessment of the quality systems for adherence to regulatory guidelines is a common tool. Looking for references in documentation concerning adherence to U.S. (21CFR, points to consider, and USP), EU (CPMP [committee for proprietary medicinal products] documents, EP [European Pharmacopoeia]) and, most notably international (ICH [International Conference on Harmonization]) regulatory compliance documents, coupled with a cross examination of the procedures and the regulatory documents are good indicators of compliance. Inspection history (e.g. warning letters, 483 history), is also a key indicator of company compliance.

WHAT IMPORTANT CMO ATTRIBUTE NOT PREVIOUSLY DISCUSSED OFTEN GETS OVERLOOKED AND WHY?

Alonso-Caplen: Flexibility of a CMO is an important attribute that typically gets overlooked, perhaps because it is difficult to measure. Timelines are quite dynamic, particularly in the precommercial landscape, where processes and control methods are not quite fully established. Typically the timing of clinical trials drives the needs for clinical trial materials and other associated supplies. In R&D, the faster you get to the clinic the better, without sacrificing quality, and at the lowest cost. Balancing these three parameters can become a "mission impossible," but a flexible CMO can definitely help.

Rosenblatt: There are two attributes that are commonly overlooked by companies. The first is the ability to retain personnel. The turnover rate of employees is often overlooked in favor of the overall industrial experience of the technical staff. It is a common misconception that overall experience is more important than experience in the current position or company. This can be problematic, especially in cases where extensive technology transfer is required. There is nothing that cuts into productivity more than having to train new personnel.

The second attribute is the CMO's analytic capability. This is usually overlooked as it is frequently considered a lesser concern than production capabilities. Without sufficient analytic capability, in-process and lot-release testing can suffer delays and lapses in quality, resulting in potential loss of product.

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WHAT SHOULD YOU DO WHEN YOUR CMO GETS BAD NEWS FROM THE FDA?

THOUSANDS FOR PREVENTION MAY BE WORTH MILLIONS FOR A CURE IF A CHAIN OF 483s LEADS TO WARNING LETTERS AND EVEN SHUTDOWN OF A VITAL PRODUCT SUPPLIER.

BY WAYNE KOBERSTEIN, CONTRIBUTING EDITOR

Sometimes the tip of the iceberg symbolizes the doomed ship itself — vast danger below, misjudged from above. A procession of seemingly small problems in the engine room belies overlooked structural faults that suddenly overwhelm the ship's integrity and send it to the bottom. Until the last moment, the captain on the bridge sails on at full steam, unaware of any danger large or small. Whose fault is it then? The engineer's for not informing the captain, or the captain's for not demanding to be informed?

Likewise, when your CMO is suddenly overwhelmed by a severe FDA warning letter, and it decides the problems are too expensive to fix and closes the only plant making your product, which one of you caused the situation? In a strict regulatory sense, you did. "The drug sponsor will always be and should be held more responsible than the CMO. Ultimately, the sponsor is the one responsible for patients' safety — and the one who will get sued if adverse events lead to lawsuits," says Dr. Brian James, Ph.D., VP of operations, Rondaxe.

We spoke with James because of his experience with both sides of the pharma-company/CMO relationship, formerly managing outsourcing of key intermediates at Bristol-Myers Squibb and now overseeing independent manufacturing audits for pharma and CMO clients. His insights form the backbone of this article as a guide to dealing with potential disruptions — and sometimes significant interruption — in product supply when your CMO develops problems noted by FDA inspectors in Form 483s and warning letters.

Examining the various situations and worst-case scenarios companies may face — such as Ben Venue's shutdown of Doxil production for Janssen — James outlines ways to determine the best course of action when the CMO faces regulatory problems. He suggests how you can define and mitigate the risks and evaluate the potential costs associated with switching suppliers. But his most important advice may be directed at pharma-company CEOs and other top management, who, he says, must learn to recognize manufacturing quality as a strategic issue of risk management, warranting their personal involvement and support.

WEIGHING PREVENTION

Most production errors found in FDA inspections are minor, James says, so they can quickly be addressed and fixed, often before the inspector leaves the plant. Bigger problems emerge or become more obvious when errors pile up beyond the two or three items typically noted in 483s. But the origins of large faults in a production line can lie in small or even overlooked errors.

"In audits, when the CMO managers tell me proudly that their last inspection produced no 483s, I say the inspector must have missed something," recalls James. "Usually I find several minor items that were overlooked. A good auditor stays a step ahead

of the regulators by taking an even tougher approach, pointing out problems that could grow more serious if ignored."

Before getting into what you should do after a problem occurs, James emphasizes what you should do before it happens. "Prevention is always the best course, and the best thing a sponsor can do is audit the facility regularly and have a good quality agreement. You really need to focus on the CMO Quality unit's standard operating procedures. Change control and reporting to sponsor are also very important."

Prevention of CMO-related regulatory problems is a chain of observations and preparations that extend from the beginning to the end of the supply chain. If you wish to avoid regulatory problems, not just react to them, you will not wait for them to occur but make it your business to know your CMO inside and out.

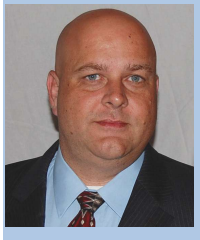
CMOs naturally have a duty to keep their pharma clients informed of problems, as well as a broad interest in doing so. After all, their business depends on satisfying customers; 483s are public, and a fair number of the problems they herald may be expected to come home to roost, possibly harming the CMO's reputation. (Find 483s at www.fda.gov/AboutFDA/CentersOffices/officeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/default.htm.) Unfortunately, however, because some CMOs are not always candid, you cannot count on being informed in every case unless you insist on it. Commonly, because 483s and warning letters are specific to a given product, another company using the same CMO for other products may not see them. Even if your contract with the CMO stipulates that it share all 483s and warning letters it receives, take steps to ensure that happens.

Sometimes, a CMO inadvertently fails to inform the sponsor — as when it makes a change for one client but does not realize the change affects another client. "There has to be a good change control system in place," says James. "That's very critical. The CMO project managers need to know who they should inform about such changes. I don't think there is anybody who has a really good system for that, at least not that I've come across yet."

For ongoing prevention, James says regular communication between you and your CMO has no substitute. In the best cases he has seen, the responsible managers on both sides hold weekly or biweekly teleconferences to go over everything from process development to production schedules. During early runs, the companies have someone on site to supervise and report back any issues that might arise.

Even with the best communication, however, he says that analytical tests can complicate matters, mainly by delaying problem identification and sometimes limiting candor. Too often, he says, the CMO fails to follow through with the client, believing

Who Is Brian James?



Brian James, MBA, Ph.D., is now a VP of operations at Rondaxe, a firm that audits and advises pharma manufacturing operations and companies. He has broad development expertise that includes API, drug product, and CMO sourcing, and he is well experienced with regulatory issues that arise between drug sponsors and their CMOs. At Rondaxe, he oversees project management, API synthesis design, and API/formulation sourcing support to clients. He manages and oversees projects ranging from pre-IND (investigational new drug) chemistry development to prelaunch validation and material sourcing for late-stage clinical trials. Previously, Dr. James was associate director, global actives and intermediates, Bristol-Myers Squibb (BMS) Company, and before that, senior scientist, technical operations planning and sourcing, and Chemical Development Laboratories, at BMS. He earned his Ph.D. in chemistry at the University of California and his MBA at LeMoyne College.

it has fixed a problem and doesn't need to share it. Analytical data may also be something your CMO resists sharing for proprietary or technology-transfer reasons.

To some extent, new Web-based systems like SharePoint help overcome communication blocks between CMOs and their clients. Both parties can post and share documents on a secure website, conquering time-zone differences and other displacements between multiple locations spread around the world.

The ultimate technological solution may start on the shop floor, however. The FDA supports universal adoption

Your To-Do List

The following is a checklist of the basic steps you — your company and management — should take when a CMO you depend on receives an FDA Form 483 or warning letter.

FORM 483s

1) Make sure you are fully informed and involved in coordinating with your CMO in the response to any 483. For fixing major problems, draw up an action plan together.
2) If the FDA inspector notes only a few minor errors, the CMO may fix them immediately and report the changes, but should still inform you.
3) If the errors are more serious or numerous for immediate repair, the 483 recipient should respond with a letter to the FDA outlining the action plan for fixing them.
4) If you don't already have a backup supplier, move quickly to obtain one; you may have some lead time should more serious problems develop.
5) If lacking, set up ongoing communications between your company and the CMO team responsible for your product, involving frequent assessment meetings and daily postings on a secure Web-based system such as SharePoint.
6) Trust but verify. Invest in independent auditing of CMO facilities to ensure production quality and compliance.

WARNING LETTERS

1) Realize that warning letters arrive only when 483s are ignored — or when they fail to identify deeper problems. If you haven't read the signs already, get with your CMO and go into full alert.
2) As with 483s, coordinate with the CMO to develop an action plan.
3) Request another FDA inspection after the problems are fixed.
4) If the CMO cannot afford or is unwilling to fix the problems, weigh the cost of underwriting the repairs versus potential lost sales or the costs of obtaining additional supply.
5) If you already have a second supplier, prepare to shift as much production as needed and as possible to it.
6) Prepare communications and, if necessary because of supply shutdown, a rationing program for affected patients and others such as physicians and payers.

You, the sponsor, must put a high priority on manufacturing quality and be involved with your CMO's efforts to maintain and improve it!

of quality by design (QbD) among all pharma manufacturers — partly because the transparency of QbD systems could illuminate many of the now hidden or ambiguous signs of quality problems in production and prevent the need for most 483s and warning letters. James agrees: "Not only is QbD important, it is an absolute necessity. I know one company that has basically inflicted QbD on every one of its manufacturers over the past three years. As a result, its last drug-product validation went incredibly smoothly. QbD is a life-cycle validation approach that the agency is pushing forward. It is the wave of the future, and if the CMOs don't get on board with QbD, they will get left behind."

PREVENTION PAYOFFS

Ironically, as with most measures of prevention, you may never know for certain that your efforts succeeded. Only failure produces solid evidence of a measure's degree of effectiveness: success means nothing happens. So lack of evidence offers no proof of concept. But what would you rather have — the certainty of failure or the uncertainty of success?

The answer depends on cost. What is the cost of CMO-related regulatory problems? "A lot of the cost will depend on what stage of development you're in," James says. "For example, we had a client that had their only CMO back out of the project just as the initial clinical materials were to be prepared." For many small companies, the cost of the resulting clinical delay would likely exceed available funds, even if their clinical development could otherwise continue past the disruption.

"All of a sudden, your manufacturer is gone. And it's literally cost you nine months of your development timeline to go through the entire process, validating a new supplier for quality, and then transferring the process and getting the new group up to speed — just to be where you were nine months ago," James says.

Supplier shutdown can also have fatal consequences for a small company beyond the financial factors. Say the company is in the middle of a Phase 3 trial when it suddenly loses its supplier. No amount of money can restart the trial after a six-month delay to resource the compound; patients have progressed and many will no longer qualify.

For a product already on the market, the costs of plant closure and loss of supply may greatly outweigh the expense of landing a new supplier. "Certainly, there is cost in identifying and transferring the process to a new supplier at that point, but those costs are nothing compared to the cost of roughly six months of peak sales," James says.

Usually, he says, there will be some lead time after finding out a supplier will not be able to supply — the period between the 483 and the warning letter or closure — in which you can transfer production to your other supplier, if you have one, and as long as you're not losing the primary supplier. The problem is that, if the market is shorted on an approved drug, patients will have to move to another therapy if available and you will permanently lose some of your market share, potentially costing you millions.

In either case, the liability is probably less than that of a class-action lawsuit if a compromised product gets out to the market. For example, James says, "Baxter's problems with heparin will be expensive — possibly tens of millions."

CALL FOR BACKUP

Backup production seems the obvious way to prevent supply disruptions, of course. But it may only be possible for the largest companies, and even difficult in some cases for them, according to James. Having backup suppliers in Phase 1 or 2 is impractical for any product that requires process development, which usually continues through those stages. Unfortunately, he says, that is exactly where many small companies go wrong — choosing a supplier that may not be equipped to complete the process development, as James described. "Some of these small companies, if they

The Trouble With Doxil

(Originally published in "Unity In More Than Name" (Janssen Biotech), Life Science Leader, March 2012.)

One of Janssen Biotech's key oncology products is Doxil (doxorubicin HCl liposome injection), which made headlines in 2011 when Boehringer Ingelheim's (BI) Ben Venue Laboratories (BVL) unit, the contract manufacturer (CMO) with sole responsibility for making the product, suddenly announced it could no longer do so. President Rob Bazemore speaks about his company's response to the crisis, its support for affected patients, and the lessons learned:

BAZEMORE: Like most companies, we will always rely on strategic partnerships with CMOs, because some of these products that we make are extremely complex, difficult products to make. For ten years now, we've had the partnership with BVL without a single issue of quality or missing shipments or any other problem. Here are some lessons I have learned about what to do when a crisis occurs:

- Communicate quickly and frequently with the FDA, physicians, and patients to make sure they understand the issue and its potential impact. Seek out the FDA to help you create solutions.

- Provide whatever resources you can, even if it means sending your own company people to the contract manufacturer to help resolve the issue as quickly as possible.

- Probably the most important lesson is to be ready to do some extraordinary things, as we've done with Doxil. We put together a program that helped us to quickly identify patients who were on the drug and who should be prioritized for receiving the drug when we had it. It prevented product hoarding and price gouging. If we had just put the available drug in the market on a monthly basis, there was no certainty that the patients who got the drug one month would be the same patients who got the drug the next month.

To this day, although we could have done some things better, our response has stood the test of time, and I believe it will be a best practice example of how to handle situations like this when you can't completely supply the market with drug.

make the wrong decision, they're out of business."

That means picking the right supplier initially is one of the most critical strategic decisions a small company makes. Of course, the stakes are even higher for a start-up with a highly novel molecule to characterize, produce, and develop. James recommends being a "pest" — interacting constantly with your CMO — if that's what it takes, along with good luck, to avoid a catastrophic loss of supply when your company is so vulnerable.

Does The CMO Apple Fall Far From The Branded-Parent Tree?

By Rob Wright

What do you do when you see the list of 483s from the FDA and the branded parent of your CMO partner is on the list? Expertise and best practices can pass from parent to child as can faults and weaknesses. It's like the old adage, the apple does not fall far from the tree. But does it apply when working with a CMO division of a branded parent company? The answer is a resounding maybe.

Many household names in the pharmaceutical industry have CMO divisions: Pfizer, Baxter, GSK, Boehringer Ingelheim, Hospira, Abbott, and others. According to industry consultancy PharmSource, there are approximately 70 excess-capacity CMOs in the fill-finish category alone. As outsourcing of pharmaceutical and biopharma manufacturing is on the rise, it may become quite common for your CMO's parent to get bad news from the FDA. The big question is, "How does that impact your project?" For example, in 2010, Hospira (NYSE: HSP), a $4.1 billion dollar company known for manufacturing injectable drugs and infusion technologies, received a warning letter from the FDA in connection with an inspection of the company's pharmaceutical manufacturing facilities located in Clayton and Rocky Mount, NC. Follow-up inspections by the FDA in 2011 resulted in the Rocky Mount facility receiving additional 483 observations. While 483s are quite common, they all demand a high level of attention from the industry.

Being a Fortune 1000 company, Hospira, as of December 31, 2011, operates 12 manufacturing facilities around the globe, and offers a variety of products and services. In addition to manufacturing approximately 200 generic injectable drugs, IV sets, and infusion pumps, Hospira offers contract manufacturing services through its subsidiary, One2One, which provides formulation development, filling, and finishing of injectable drugs. If you are a pharmaceutical or biotech company who secured Hospira's One2One as your CMO, seeing news about Hospira receiving 483s and launching product recalls may tempt you to shop for a different CMO or pull out all together. Doing so, without due diligence, could be a costly mistake.

According to its website, One2One works with several manufacturing facilities, such as McPherson, KS, or Liscate, Italy, which, according to FDA data, were not under warning letters during this time period. Given Hospira's size, you might imagine the company has excess manufacturing capacity at those plants and that One2One probably utilizes some of this excess capacity. You would be correct. This still does not mean that your product is not at risk. Trust, but verify.

Companies which have experienced similar scenarios advise the following. First, be sure to differentiate between parent company problems, in this case Hospira, and your own CMO's performance (e.g. One2One). Second, communicate openly and honestly your concerns with your CMO partner. If you vetted your CMO properly during the process of creating a quality agreement, there should be a level of trust between established organizations. Now, verify. Conduct your own quality and risk assessments based on factual performance. Conduct inspections at relevant plants/lines to ensure your CMO is in compliance.

Finally, thoroughly consider vendor-switching costs, such as knowledge and tech transfer, lost productivity, and contract termination fees. Deloitte conducted a 2012 global outsourcing and insourcing survey covering all industry sectors. The single biggest factor in the decision to terminate a contract was perceived overall quality of service. Major business disruptions were reported by 5% of respondents, while 59% reported minor business disruptions. More than half of the respondents (54%) reported transitioning vendors to last between 90 to 180 days. Consider all of these factors, and do not base your decision on emotion. Trust, but verify.

For products in Phase 3 with good commercial potential, James says having more than a single supplier is absolutely essential. Ideally, the company will validate a second CMO with the product's NDA or as soon after NDA approval as possible, even if the volume is split as much as 80/20 between it and the primary supplier. Beyond the backup potential, secondary suppliers also make commercial sense, says James. "What happens if the product takes off and your sales are three times what you were expecting in projected volume?"

Backups for the CMOs themselves may prove still more important, he observes. In an example from his pharma outsourcing days, he describes how his company lost three big CMOs for a key product when the raw-materials supplier they all shared suddenly went out of business. "At least dig into their supply and understand your hidden risk."

REACTION MODE

Despite all steps to prevent the problem, or for lack of them, your CMO may still get into regulatory trouble, starting with a surge in 483s and ending in the worst case with a production shutdown. What then? Most would agree with James's advice, at least in theory: "The most important thing to do when your CMO gets a list of 483s is to take it seriously and deal with it," he says. "The CMO will have to develop and implement a corrective action plan. That plan should be laid in conjunction with the affected sponsor(s) and their manufacturing consultants or auditors. Most of the problems can be easily corrected — not to say cheaply. But the main thing is to head it off before you get a warning letter."

Remediation projects usually involve preapproval inspection (PAI) audits of the production facilities, which are usually even tougher than FDA inspections, according to James. "Sponsors unfortunately want to see the bright side and will sometimes miss details, and unless the company is a giant pharma, it probably doesn't do a lot of audits. It is not uncommon for a biotech/mid-size company to send in one or two people for one to two days, and you can't really catch everything in that short period."

A set of basic steps to follow in most 483 and warning-letter events appears in the sidebar, "Your To-Do List." The steps follow from the experience of James and others, including Janssen, all of whom faced serious consequences with CMO-related problems. Two other sidebars, "The Trouble With Doxil" and "Does The CMO Apple Fall Far From The Branded-Parent Tree?," draw specific lessons from how those companies and their suppliers dealt with the crises.

James summarizes the options you must consider: "If it does come to the point where either your supplier is exiting or if you decide to leave them, that's when it gets expensive and that's why you see a company sticking with a supplier longer than it should have, perhaps, in retrospect. If you're lucky enough to have a secondary supplier, hopefully you can move on with it quickly. But if not, you have to weigh the cost and delay of switching to another one versus the prospect of waiting for your current supplier to fix the problems. Even if you move to a backup supplier, you need to bring in another backup supplier to back them up, as well as a backup for any suppliers of raw materials and so on needed for production."

Still, says James, prevention always costs less than a cure — and for the pharma company, prevention of CMO regulatory problems begins at the top. CEOs too often delegate quality management to the Quality group and never get involved in CMO issues — thus setting themselves up for nasty surprises. But top-management involvement is essential to support budgeting for adequate auditing and monitoring beyond the narrower scope of QA teams. Message for the CEOs: If you don't understand why you should spend money on prevention, you need to learn about the risks of being unprepared.

OUTSOURCING INSIGHTS

Evolution In The Research Used For The CMO Awards

By Nigel Walker, managing director, That's Nice

With Nice Insight about to move into its third year of conducting primary research on the outsourcing practices of pharmaceutical and biotechnology executives, we have collected a vast amount of data on more than 100 CMOs and learned a fair amount about the information that buyers of our research want and how they can best apply it. As a result, we've made a few key changes to evolve the product. Nice Insight now provides more in-depth information about each profiled company, and a greater variety of segmentation options is available online to subscribers. These two developments made perfect sense, and we added a few key questions to the survey that would flesh out areas of customer interest and offer additional ways to cross-tabulate information or drill down into more specific/refined results. However, a third customer need that was evident came as a surprise but has led to the biggest change we are likely to make.

At Nice Insight, we continually strive to be a better asset to clients by using the same methodology we advocate to our clients and the pharmaceutical outsourcing industry at large — we ask the market key questions about the strengths and weaknesses of our service offering so we can develop a more customized and valuable product. Our research on how we could deliver more useful marketing intelligence to our subscribers brought to light some conditions and limitations that influence how Nice Insight data might be applied. So, when clients relayed the nature of their marketing planning and sales cycles, and expressed concerns about whether a quarterly research cycle was long enough to gauge the impact of a new campaign reaching the audience, we began to think seriously about revising our research strategy to better fit client needs. And from September 2012, our research cycle will become annual and aligned with the timing of clients' typical annual strategic planning.

The core of Nice Insight's research remains focused on understanding customer awareness — or how well a CMO and its service offering is known within the outsourcing industry — and customer perception — or how the business is regarded by potential and current buyers of outsourced services. Each year, the research team conducts in-depth interviews with industry thought leaders to learn which attributes they see as most important when selecting a CMO. For 2012, the key outsourcing drivers, in descending order, are quality, reliability, regulatory track record, productivity, affordability, and innovation.

Quality has remained in the leading position since the inception of Nice Insight's pharmaceutical and biotechnology outsourcing survey, and it relates to a CMO's ability to deliver to the standards established by the sponsor at the onset of the project. The benchmark score for quality increased from 70% to 71% from 2011 to 2012. Another promising sign of improved quality from CMOs is that the lowest quality customer perception score rose from 56% to 61%, and the highest customer perception score for quality also increased from 72% to 77%. Our goal is to help companies improve performance and provide a better platform for successful outsourcing relationships, so this is a good trend to see.

Likewise, reliability consistently has ranked second in 2011 and 2012. Contract manufacturers that receive high scores in reliability are regarded as able to meet the project milestones set forth in the master document established at the start of the project. The CMO benchmark for reliability showed the greatest increase of any driver last year, with an improvement of 69% to 72%. When considering a new contract manufacturer for a project, sponsors are typically going to focus on companies with scores at or above the industry benchmark on these crucial outsourcing drivers.

A CMO's regulatory track record – or its reputation for cGMP compliance – moved up in priority from fourth place in 2011 to third place in 2012. This shift in ranking was almost certainly influenced by a perceived increase in FDA surveillance across the drug development industry, leading to sponsors more heavily scrutinizing prospective outsourcing partners' compliance history. The encouraging news is that the CMO benchmark for regulatory improved over the past year from 73% to 74%. This is also the highest benchmark score across the six customer perception measures.

Contract manufacturers' technical and scientific competence in meeting the research and development goals of a project can have a substantial impact on the project timeline. As such, productivity ranked fourth in priority – one position up from the 2011 ranking. Selecting a partner with a high productivity score also contributes to a sponsor's ability to focus on its core competencies with confidence that outsourced aspects of the project are being fulfilled to its required standard. The CMO benchmark for productivity rose from 71% in 2011 to 73% in 2012.

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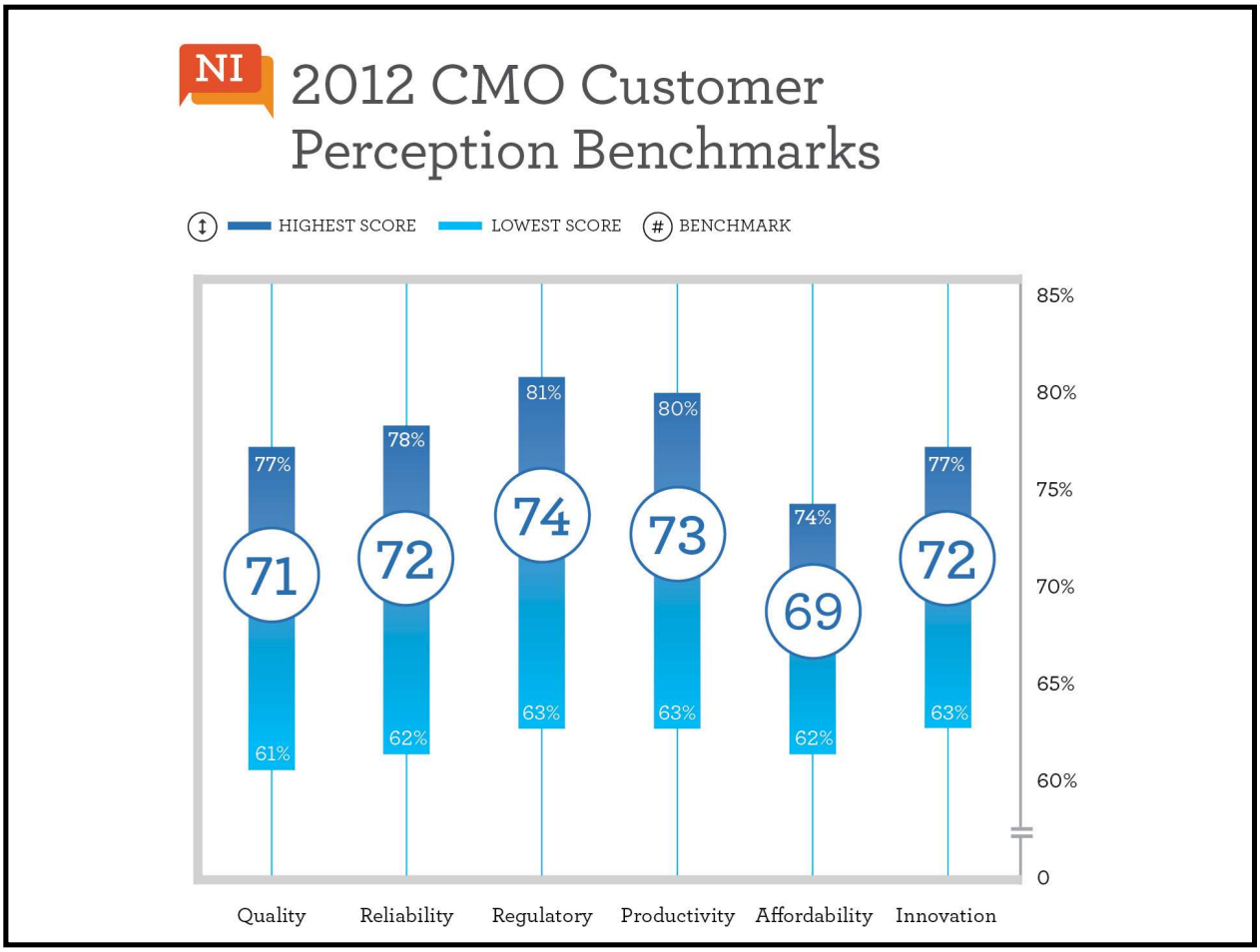
Affordability received the lowest benchmark average of the key outsourcing drivers, at 69%. However, there was a modest increase of one percentage point over the last year. And interestingly, affordability dropped in priority when selecting a CMO from third place in 2011 to fifth in 2012. This change is supported by a trend we continue to see in research results – while price is important to sponsors, it tends not to be among the highest defining factors in selection decisions. At the same time, sponsors indicated that CMOs are improving their ability to provide accurate pricing on projects, which was reflected in an increase from 53% in 2011 to 62% in 2012 for the lowest scoring CMO in our survey.

As motivations for outsourcing shift from tactical to strategic, CMOs gain the opportunity to take on a more significant role in drug development. This change was part of what prompted Nice Insight to add a customer perception measure on contract manufacturers' ability to innovate. This driver indicates the CMO's ability to improve on the sponsor's in-house capabilities by using or developing customized solutions. While this measure ranked sixth in priority among the overall respondent group, the CMOs fared well, with the benchmark for innovation being 72%.

Since Nice Insight began researching sponsors' preferences and practices in pharmaceutical outsourcing, it has become evident there are two distinct groups of CMOs. The first is the well-established, well-funded, and highly process-driven CMOs within Big Pharma. And the second is "everybody else." This second group tends to articulate their core competency as the reason to engage them on a project, which doesn't necessarily position them strongly for consideration. As the contract manufacturing industry continues to compress, it is essential to have a clear understanding of sponsors' needs and build messaging that focuses in on the key drivers for outsourcing.



Survey Methodology: The Nice Insight Pharmaceutical and Biotechnology Survey is deployed to outsourcing-facing pharmaceutical and biotechnology executives on an annual basis. The 2012 sample size is 10,036 respondents. The survey comprises 500+ questions and randomly presents ~30 questions to each respondent in order to collect baseline information with respect to customer awareness and customer perceptions on 170 companies that service the drug development cycle. More than 800 marketing communications, including branding, websites, print advertisements, corporate literature, and trade show booths are reviewed by our panel of respondents. Five levels of awareness from "I've never heard of them" to "I've worked with them" factor into the overall customer awareness score. The customer perception score is based on six drivers in outsourcing: Quality, Innovation, Regulatory Track Record, Affordability, Productivity, and Reliability.

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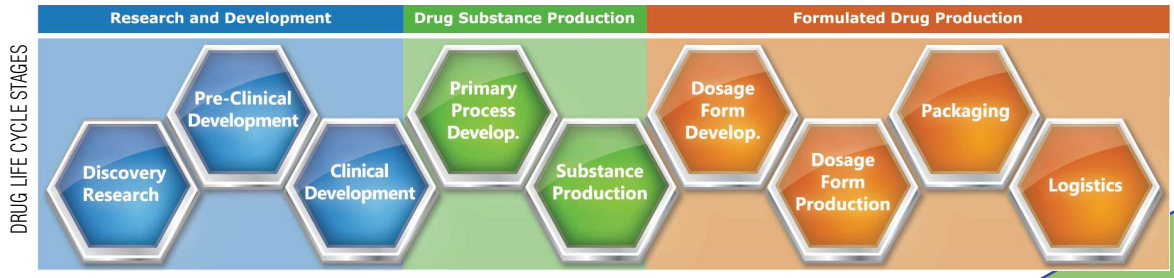

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Almac Group
AmbioPharma, Inc.
Aptuit
Avrio Biopharmaceuticals, LLC
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CMC Biologics
Cook Pharmica
Ei Inc.
GlaxoSmithKline
Halo Pharmaceutical
Lyophilization Technology, Inc.
Norwich Pharmaceuticals
NOVASEP
Paragon Bioservices, Inc.
Patheon
P.J. Noyes Company, Inc.
Roche Custom Biotech
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Dow Pharmaceutical Sciences
Ei Inc.
Euticals SPA
FujiFilm Diosynth Biotechnologies
Gallus BioPharmaceuticals, LLC
Goodwin Biotechnology, Inc.
Haupt Pharma AG
NextPharma Technologies LTD
Norwich Pharmaceuticals
OSO BioPharmaceuticals
Paragon Bioservices, Inc.
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Porton Fine Chemicals
PYRAMID Laboratories, Inc.
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Avrio Biopharmaceuticals, LLC
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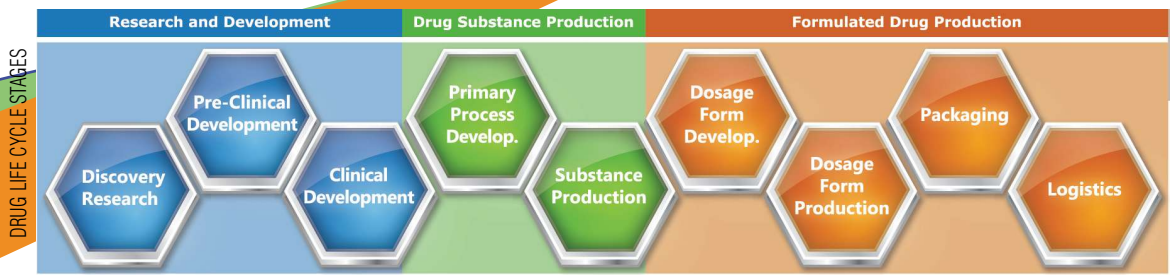
CMC Biologics
Cook Pharmica
Cytovance Biologics, Inc.
Dow Pharmaceutical Services
Ei Inc.
Euticals SPA
GlaxoSmithKline
Lyophilization Technology, Inc.
Norwich Pharmaceuticals
NOVASEP
Paragon Bioservices, Inc.
Patheon
Pfizer CentreSource (PCS)
Roche Custom Biotech
SAFC
Sandoz GmbH
Therapure Biopharma Inc.
UPM Pharmaceuticals, Inc.
Vetter Pharma International GmbH

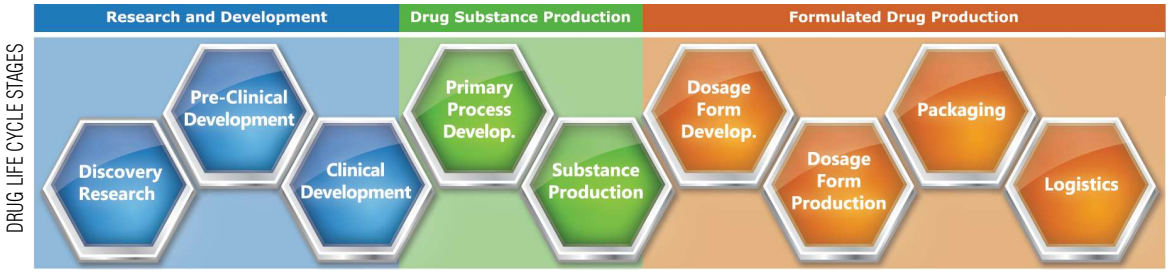


THE CMO LEADERSHIP AWARDS PRODUCTIVITY AWARD

ACIC
Akorn Inc.
Almac Group
Cedarburg Hauser Pharmaceuticals
Cook Pharmica
CoreRx, Inc
Ei Inc.
Euticals SPA
FujiFilm Diosynth Biotechnologies
Gallus BioPharmaceuticals, LLC
Goodwin Biotechnology, Inc.
Laureate Biopharmaceutical
Lyophilization Technology, Inc.
Norwich Pharmaceuticals
OSO BioPharmaceuticals
Patheon
Pfizer CentreSource (PCS)
Pharma Tech Industries
Pharmatek Laboratories, Inc.
Phyton Biotech
Porton Fine Chemicals
RohnerChem
SAFC
Sandoz GmbH
Therapure Biopharma Inc.
Uman Pharma Inc.
UPM Pharmaceuticals, Inc.
Xcelience

THE CMO LEADERSHIP AWARDS INNOVATION AWARD

ACIC
Aesica Pharmaceuticals
Almac Group
Baxter BioPharma Solutions
CMC Biologics
Coldstream Laboratories, Inc.
Cook Pharmica
Dalton Pharma Services
Dow Pharmaceutical Sciences
DPT Laboratories
DSM Pharmaceutical Products
Euticals SPA
Flamma
FujiFilm Diosynth Biotechnologies
Gallus BioPharmaceuticals, LLC
Goodwin Biotechnology, Inc.
Haupt Pharma AG
JHP Pharmaceuticals
Kemwell Biopharma
Laureate Biopharmaceutical
Norwich Pharmaceuticals
Patheon
Pfizer CentreSource (PCS)
Pharma Tech Industries
Pharmatek Laboratories, Inc.
P.J. Noyes Company, Inc.
Recipharm AB
RohnerChem
SAFC
Sandoz GmbH
Senn Chemicals AG
Siegfried AG
Therapure Biopharma Inc.
Uman Pharma Inc.
UPM Pharmaceuticals, Inc.



3M

3M Drug Delivery Systems Division
St. Paul, MN
www.3m.com/dds
(800) 643-8086
Manufacturing locations: Argentina, United Kingdom, and United States
Contact: Anne Roush
aroush@mmm.com

DRUG TYPE: Biopharmaceuticals

DRUG LIFE CYCLE STAGES:

Formulated Drug Production – dosage form development and dosage form production

SERVICES OFFERED: Capsules, creams & ointments, generics, hollow and solid microneedle systems, injectables, integrated dose-by-dose counters and inhalation drug delivery components, metered dose inhalers, packaging films, solid dose, topicals, and transdermal drug delivery systems and components.

"3M Drug Delivery Systems is proud to be recognized globally for our expertise in drug delivery systems development and manufacturing, integrated with quality assurance and regulatory support. Our success is driven by our dedication to taking care of customers, and our commitment to high standards for safety and compliance. We combine 3M state-of-the-art technology with our expertise in formulation and a full range of capabilities, to offer pharmaceutical companies an outstanding value in partnership and contract manufacturing services."
— James Ingebrand, president and general manager

AAIPHARMA®

AAIPharma Services Corp.
Wilmington, NC
www.aaipharma.com
(800) 575-4224
Manufacturing locations: Charleston, SC, and Wilmington, NC
Contact: Timothy R. Compton
Timothy.Compton@aaipharma.com

DRUG TYPE: Pharmaceuticals

DRUG LIFE CYCLE STAGES:

Research & Development – pre-clinical and clinical (phase 1, phase 2, and phase 3)

Formulated Drug Production – dosage form development, dosage form production, packaging, and logistics

SERVICES OFFERED: Aseptic fill/finish, capsules, controlled substances, cytotoxic & high-potency compounds, generics, injectables, lyophilized products, non-sterile, parenterals (small volume), peptides, powders (non-sterile), proteins, semisolids, solid dose, solutions & suspensions, sterile, and sustained release.

"Our world-class scientific and technical teams are dedicated to delivering consistent, quality results with each project. Supported by integrated operations and project management, we collaborate directly with our clients to meet all analytical testing needs accurately and quickly. AAIPharma's exemplary audit and compliance track record reflect our commitment to developing the highest-quality formulations, dosage forms, and analytical results. Our clients recognize our desire to provide first-rate service across every service offering in our portfolio."
— Patrick Walsh, chief executive officer

acic

ACIC
Brantford, Ontario, Canada
www.acic.com
(519) 751-3668
Manufacturing locations: Contact for details
Contact: Chris Rayfield
Crayfield@acic.com

DRUG TYPE: Pharmaceuticals

DRUG LIFE CYCLE STAGES:

Drug Substance Production – drug substance production

Formulated Drug Production – dosage form development, dosage form production, packaging, and logistics

SERVICES OFFERED: Capsules, cytotoxic & high potency compounds, generics, injectables, lyophilized products, ophthalmics, parenterals (large volume), parenterals (small volume), powders (non-sterile), powders (sterile), soft gels, solid dose, sterile, and sustained release.

"The ACIC group is a supplier of APIs, finished dosage forms, and services to the pharmaceutical industry. Since 1974, we have helped move projects from 'Molecule to Market.' In addition to our own capabilities, we are able to leverage a network of research, API, and FDF manufacturing facilities. Our regulatory expertise covers DMFs, ANDAs, and NDAs. Whether you require a few grams or tons, a solid or semi-solid, or an injectable product, we have the fully integrated means to assist you."
— Luciano Calenti, president

Aesica

Aesica Pharmaceuticals
Newcastle upon Tyne, United Kingdom
www.aesica-pharma.com
44 191 218 1960
Manufacturing locations: Germany, Italy, and United Kingdom
Contact: Alison Doering
alison.doering@aesica-pharma.com

DRUG TYPE: Pharmaceuticals and Biopharmaceuticals

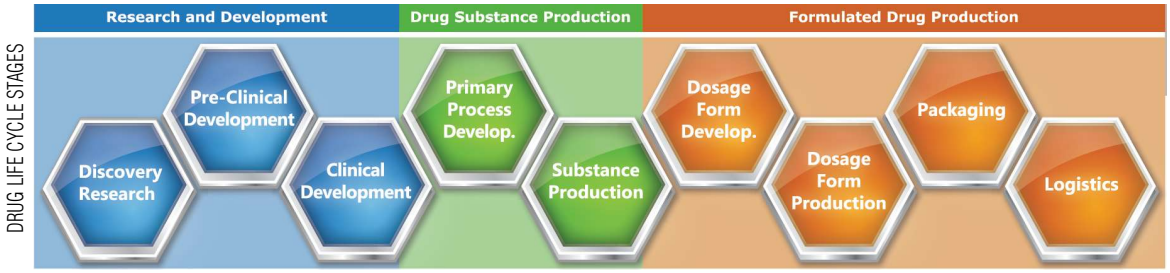
DRUG LIFE CYCLE STAGES:

Drug Substance Production – primary process development and drug substance production

Formulated Drug Production – dosage form development, dosage form production, packaging, and logistics

SERVICES OFFERED: Aseptic fill/finish, capsules, controlled substances, creams & ointments, cytotoxic & high-potency compounds, generics, injectables, liquids, non-sterile, OTC, parenterals (large volume), parenterals (small volume), solid dose, solutions & suspensions, sterile, sustained release, and topicals.

"It's an honour to receive the CMO Leadership award and be recognized as a leader in the fields of quality, reliability, and innovation, as we believe these areas play a fundamental role in the overarching offer of an integrated CMO. While the last 18 months have seen us double our workforce and expand our manufacturing presence in Europe, we are committed to continually expanding and enhancing our service to ensure we remain at the forefront of our field."
— Dr. Robert Hardy, CEO



AKORN

Akorn Inc.
Lake Forest, IL
www.akorn.com
(800) 932 5676
Manufacturing locations: Decatur, IL, Paonta Sahib, HP (site with available capacity), India, Somerset, NJ
Contact: Sumeet Dagar, Ph.D.
sumeet.dagar@akorn.com

DRUG TYPE: Pharmaceuticals

DRUG LIFE CYCLE STAGES:

Formulated Drug Production – dosage form development, dosage form production, packaging, and logistics

SERVICES OFFERED: Aseptic fill/finish, controlled substances, creams & ointments, cytotoxic & high-potency compounds, generics, injectables, liquids, lyophilized products, ophthalmics, oral powders, OTC, parenterals (small volume), peptides, powders (sterile), solutions & suspensions, and sterile.

Alkermes

Alkermes
Westmeath, Ireland
www.alkermes.com/contract
353 906495000
Manufacturing locations: Ireland and United States
Contact: Fidelma Callanan
fidelma.callanan@alkermes.com

DRUG TYPE: Pharmaceuticals

DRUG LIFE CYCLE STAGES:

Research & Development – clinical (phase 2 and phase 3)

Formulated Drug Production – dosage form development, dosage form production, and packaging

SERVICES OFFERED: Aseptic fill/finish, capsules, controlled substances, high-potency compounds, injectables, parenterals (small volume), powders (sterile), solid dose, sterile, and sustained release.

"Alkermes Contract Pharma Services are honoured to be recognized by our peers through this CMO Leadership Award. We have a proud history of quality with multiple regulatory authorities including the EMA and U.S. FDA, across our global sites. We strive to have the highest regulatory and quality standards, exemplified by our culture of 'Building Quality' in everything we do for our partners."
— James Botkin, SVP of operations

ALMAC

Almac Group
Craigavon, Northern Ireland
www.almacgroup.com
44(0)28 38332200
Manufacturing locations: Craigavon, Northern Ireland, Pennsylvania, U.S.A., and North Carolina, U.S.A.
Contact: Kerry Lyle
kerry.lyle@almacgroup.com

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 and drug substance production

Formulated Drug Production – dosage form development, dosage form production, packaging, and logistics

SERVICES OFFERED: Capsules, controlled substances, cytotoxic & high-potency compounds, generics, non-sterile, peptides, powders (non-sterile), proteins, solid dose, and sustained release.

"It is extremely encouraging that our customers regard Almac so highly in quality, innovation, productivity, regulatory, and reliability which is how we strive to be perceived through our core values and our overall aim of "partnering to advance human health".

Working with all the leaders in the pharmaceutical and biotech sectors, our aim is to establish long-term partnerships and the fact that over 95% of our business is repeat is genuine evidence of our success."
— Alan Armstrong, CEO

API

AmbioPharm,Inc.
North Augusta, SC
www.ambiopharm.com
(415) 921-3593
Manufacturing locations: North Augusta, SC and Shanghai, PRC
Contact: Jim Hampton
sales@ambiopharm.com

DRUG TYPE: Biopharmaceuticals

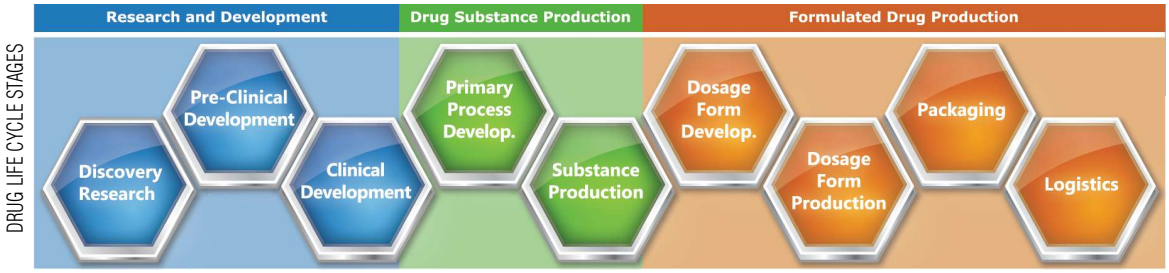
DRUG LIFE CYCLE STAGES:

Research & Development – discovery, pre-clinical, & clinical (phase 1, phase 2, & phase 3)

Drug Substance Production – primary process development and drug substance production

SERVICES OFFERED: Generics and peptides.

"AmbioPharm, Inc. (APi) is a full-service peptide manufacturing company headquartered at our cGMP peptide manufacturing facility in North Augusta, SC. In our cGMP manufacturing facility in Shanghai, China, we manufacture peptides on very large scales, provide pilot manufacturing and process development, and manufacture raw materials, building blocks, and custom peptides."
— Chris Bai, president and CEO



aptuit

Aptuit
Greenwich, CT
www.aptuit.com
(855) 506-6360
Contact: Stuart Needleman
Stuart.needleman@aptuit.com

DRUG TYPE: Pharmaceuticals and Biopharmaceuticals

DRUG LIFE CYCLE STAGES:

Research & Development – discovery, pre-clinical, & clinical (phase 1, phase 2, & phase 3)

Drug Substance Production – primary process development and drug substance production

Formulated Drug Production – dosage form development and dosage form production

SERVICES OFFERED: Aseptic fill/finish, capsules, controlled substances, creams & ointments, cytotoxic & high-potency compounds, gels, generics, injectables, liquids, lyophilized products, non-sterile, parenterals (large volume), parenterals (small volume), powders (non-sterile), powders (sterile), semisolids, solid dose, solutions & suspensions, sterile, and syringes (pre-filled).

"As a leading global pharmaceutical services company delivering early- to mid-phase drug development solutions, Aptuit is honored to be recognized for quality across all dosage forms. By applying scientific excellence, outstanding service and a team of some of the foremost scientific professionals in the industry, our aim is to help customers realize their goals as efficiently, expeditiously and economically as possible … always at the highest level of quality."
— Chris Bland Ph. D., site director, Aptuit (Glasgow) Ltd.

AVRIO BIOPHARMA

Avrio Biopharmaceuticals, LLC
Irvine, CA
www.avriobiopharma.com
(866) 98-AVRIO [28746]
Manufacturing location: Irvine, CA
Contact: Katee Fry
katee.fry@avriobiopharma.com

DRUG TYPE: Pharmaceuticals and Biopharmaceuticals

DRUG LIFE CYCLE STAGES:

Research & Development – clinical (phase 1, phase 2, and phase 3)

Drug Substance Production – primary process development and drug substance production

Formulated Drug Production – dosage form development and dosage form production

SERVICES OFFERED: Aseptic fill/finish, generics, liquids, lyophilized products, medical devices, parenterals (small volume), peptides, proteins, solutions & suspensions, and sterile.

"Avrio Biopharma, an affiliate of Irvine Pharmaceutical Services, is dedicated to delivering high quality, flexible, and on-time cGMP aseptic fill-finish and CMC development services to the pharmaceutical, biopharmaceutical, and medical device industries. We have a 25 year history of understanding the importance of exceeding client expectations and we are committed to continuously enhancing and streamlining our services to provide clients with scientific solutions in an efficient manner."
— Dr. Assad J. Kazeminy, president, founder, and CEO

Baxter

Baxter BioPharma Solutions
Deerfield, IL
www.baxterbiopharmasolutions.com
(800) 4-Baxter [229837]
Manufacturing locations: Bloomington, IN, Englewood, CO, Halle/Westfalen, Germany, Hayward, CA, and Round Lake, IL
Contact: Donna Abear
biopharmasolutions@baxter.com

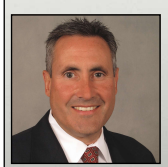
DRUG TYPE: Pharmaceuticals and Biopharmaceuticals

DRUG LIFE CYCLE STAGES:

Research & Development – clinical (phase 2 and phase 3)

Formulated Drug Production – dosage form development, dosage form production, packaging, and logistics

SERVICES OFFERED: ADCs (antibody-drug conjugates) Aseptic fill/finish, cartridges, cytotoxic & high-potency compounds, generics, injectables, liquids, lyophilized products, parenterals (large volume), parenterals (small volume), peptides, powders (sterile), proteins, solutions & suspensions, sterile, sustained release, syringes (pre-filled), and vaccines.



"Baxter's heritage is built on 80+ years of healthcare innovation, including a long list of "firsts", such as the first closed system IV containers. Combining scientific expertise, quality and regulatory systems, sustainability and a global manufacturing network, Baxter provides a firm foundation to support the BioPharma Solutions contract manufacturing business. From formulation and development to lifecycle management, we are able to offer key capabilities to align with our clients' commercialization objectives and our mutual goal of moving patient care forward."
— Robert Felicelli,
global franchise head, Baxter's BioPharma Solutions business

Boehringer Ingelheim

Boehringer Ingelheim
Ingelheim, Germany
www.bioxcellence.com
49 6132-77-95614
Manufacturing locations: Biberach, Germany (mammalian), Fremont, CA, U.S.A. (mammalian), and Vienna, Austria, (microbial)
Contact: Dr. Julia Knebel
Julia.Knebel@boehringer-ingelheim.com

DRUG TYPE: Biopharmaceuticals

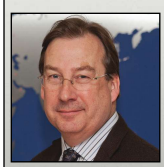
DRUG LIFE CYCLE STAGES:

Research & Development – pre-clinical, clinical (phase 1, phase 2, and phase 3)

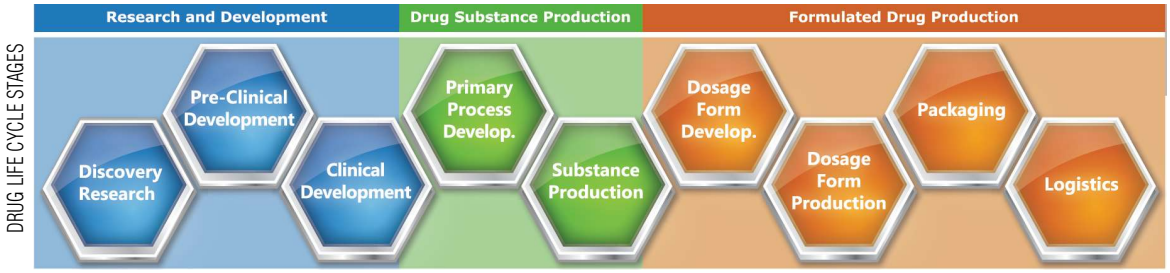
Drug Substance Production – primary process development and drug substance production

Formulated Drug Production – dosage form development, dosage form production, packaging, and logistics

SERVICES OFFERED: Aseptic fill/finish, cartridges, injectables, liquids, lyophilized products, parenterals (large volume), parenterals (small volume), peptides, proteins, sterile, sustained release, syringes (pre-filled), and vaccines.



"We are a leading biopharma contract manufacturer with 35 years of experience and an outstanding track record of 19 products brought to market. As an independent family-owned company, we see the contract manufacturing business as strategic priority which we underline with our new marketing brand Boehringer Ingelheim BioXcellence™. Our "one-stop-shop" concept from DNA to fill & finish makes outsourcing easy and provides tailor-made service solutions according to our customer's needs. With our global key account management team we are close to our customers and continue to put our customers first."
— Simon Sturge, corporate senior vice president biopharmaceutical



Cedarburg Hauser Pharmaceuticals

Cedarburg Hauser Pharmaceuticals
Grafton, WI
www.cedarburghauser.com
(262) 376-1467
Manufacturing locations:
Denver, CO and Grafton, WI
Contact: Mark Millar
info@cedarburghauser.com

DRUG TYPE: Pharmaceuticals

DRUG LIFE CYCLE STAGES:

Drug Substance Production – primary process development and drug substance production

SERVICES OFFERED: Active pharmaceutical ingredients , controlled substances, cytotoxic & potent compounds, drug conjugates, generics, lyophilized products, and non-sterile.

"Satisfaction with a CMO is a function of the strength of its project management. Effective communication by project management not only improves productivity, but also ensures on-time delivery."
— Tony Laughrey, CEO

CMC Biologics

CMC Biologics
Bothell, WA
www.cmcbiologics.com
(425) 415-5438
Manufacturing locations:
California, U.S.A., Washington, U.S.A., and Copenhagen, Denmark
Contact: Stacie D. Byars
sbyars@cmcbio.com

DRUG TYPE: Biopharmaceuticals

DRUG LIFE CYCLE STAGES:

Research & Development – pre-clinical and clinical (phase 1, phase 2, and phase 3)

Drug Substance Production – primary process development and drug substance production

SERVICES OFFERED: Injectables, liquids, parenterals (large volume), parenterals (small volume), and proteins.

"CMC Biologics continually innovates to advance biopharmaceutical manufacturing to the next level. Our expertise in cGMP process development and manufacturing puts our clients' projects in an optimal position to succeed. The recent MHRA approval demonstrates our continued commitment toward compliance and high-quality systems, which is the foundation of our customers' clinical and commercial success. CMC Biologics is the industry leader among CMO's in reliability, technical excellence, and quality. Right. On Time."
— Claes Glassell, chief executive officer

Coldstream Laboratories Inc.

Coldstream Laboratories, Inc.
Lexington, KY
www.coldstreamlabs.com
(859) 977-8600
Manufacturing location:
Lexington, KY
Contact: Eric Smart,
executive vice president
esmart@coldstreamlabs.com

DRUG TYPE: Pharmaceuticals and Biopharmaceuticals

DRUG LIFE CYCLE STAGES:

Research & Development – pre-clinical and clinical (phase 1, phase 2, and phase 3)

Formulated Drug Production – dosage form development and dosage form production

SERVICES OFFERED: Aseptic fill/finish, cytotoxic & high-potency compounds, generics, injectables, liquids, lyophilized products, parenterals (small volume), proteins, solutions & suspensions, and sterile.

"Coldstream develops and manufactures parenteral products in liquid and lyophilized dosage forms. We have built a foundation around creating a winning team environment based on solid strategy. When the workforce is fully engaged in producing a high quality product, you develop effective efficiency models based on both scientific knowledge and the engineering capabilities of the process and equipment. We are constantly improving, with the addition of state-of-the-art equipment and the expansion of physical production areas and laboratory space."
— Larry Kranking, president & CEO

Cook Pharmica

Cook Pharmica
Bloomingtom, IN
www.cookpharmica.com
(812) 355-6746
Manufacturing location:
Bloomington, IN
Contact: Brian Lange
bus.dev@cookpharmica.com

DRUG TYPE: Pharmaceuticals and Biopharmaceuticals

DRUG LIFE CYCLE STAGES:

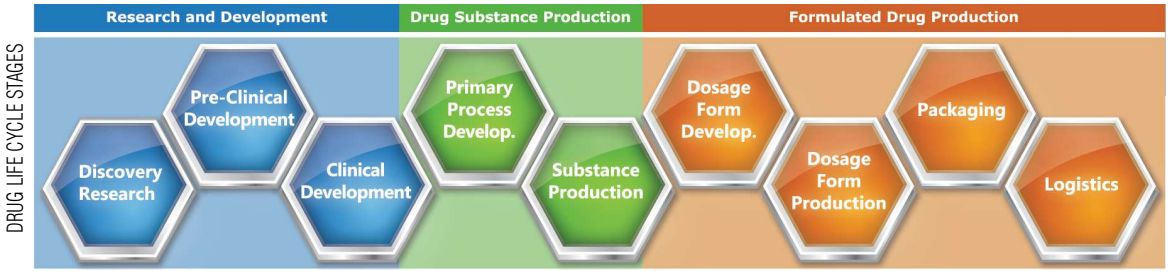
Research & Development – clinical (phase 1, phase 2, and phase 3)

Drug Substance Production – primary process development and drug substance production

Formulated Drug Production – dosage form development, dosage form production, and packaging

SERVICES OFFERED: Aseptic fill/finish, generics, injectables, liquids, lyophilized products, parenterals (large volume), parenterals (small volume), proteins, solutions & suspensions, sterile, syringes (pre-filled), and vaccines.

"There are many reasons why biopharmaceutical companies count on us to produce a consistently dependable product. First, we have a manufacturing facility with the right capabilities, equipment, and location, and a team of collaborative, experienced subject-matter experts. We have also put in place a flexible infrastructure with processes that allow for client customization and have strived as an organization to learn from our mistakes, becoming better listeners throughout the process."
— Cory Lewis, vice president of business development & marketing



CoreRx, Inc

Clearwater, FL
www.corerxpharma.com
(727) 259-6950
Manufacturing location: Clearwater, FL
Contact: Jenna Leitao
jenna.leitao@corerxpharma.com

DRUG TYPE: Pharmaceuticals

DRUG LIFE CYCLE STAGES:

Research & Development – discovery, pre-clinical, & clinical (phase 1, phase 2, & phase 3)

Formulated Drug Production – dosage form development, dosage form production, packaging, and logistics

SERVICES OFFERED: Capsules, controlled substances, creams & ointments, gels, generics, injectables, liquids, lyophilized products, non-sterile, ophthalmics, OTC, parenterals (large volume), parenterals (small volume), powders (non-sterile), semisolids, soft gels, solid dose, solutions & suspensions, sustained release, syringes (pre-filled), and topicals.

"CoreRx is proud to be recognized by our clients for the CMO Leadership Award in productivity. We strive to exceed industry standards by providing unparalleled levels of customer service, reliability, and quality across all platforms. Our move to a new 35,000 sq. ft. cGMP facility has enabled CoreRx's scientific staff to custom formulate, analyze, and manufacture the highest quality pharmaceutical products for their client-partners. Our strong customer-centric approach, coupled with the highest technical/scientific and quality services, has enabled us to grow into one of the most respectable in the industry."
— Todd R. Daviau, Ph.D., president & CEO

Cytovance Biologics, Inc.

Oklahoma City, OK
www.cytovance.com
PH: (405) 319-8310
Manufacturing location: Oklahoma City, OK
Contact: Valerie McDonnell
vmcdonnell@cytovance.com

DRUG TYPE: Biopharmaceuticals

DRUG LIFE CYCLE STAGES:

Research & Development – pre-clinical and clinical (phase 1, phase 2, and phase 3)

Drug Substance Production – primary process development and drug substance production

Formulated Drug Production – dosage form development, packaging, and logistics

SERVICES OFFERED: Aseptic fill/finish, injectables, liquids, parenterals (large volume), proteins, sterile, and vaccines.

"We are honored to be recognized by our clients as a liquid dose manufacturing leader for reliability. Cytovance Biologics takes pride in being a reliable, value-added partner with our clients in providing integral pathways of converting today's novel protein discoveries into future life-saving therapies. This award is possible thanks to our highly experienced employees who consistently demonstrate commitment to service. We accept this award as a testament to the dedication and hard work of many within our remarkable company."
— Darren Head, president and chief executive officer

Dalton Pharma Services

Toronto, Ontario, Canada
www.dalton.com
(416) 661-2102
Manufacturing location: Toronto, Canada
Contact: Kevin McCarthy, assoc. director, sales & marketing
chemist@dalton.com

DRUG TYPE: Pharmaceuticals and Biopharmaceuticals

DRUG LIFE CYCLE STAGES:

Research & Development – discovery, pre-clinical, & clinical (phase 1, phase 2, & phase 3)

Drug Substance Production – primary process development and drug substance production

Formulated Drug Production – dosage form development, dosage form production, and packaging

SERVICES OFFERED: Aseptic fill/finish, capsules, controlled substances, creams & ointments, generics, injectables, liquids, lyophilized products, non-sterile, ophthalmics, OTC, parenterals (large volume), parenterals (small volume), peptides, powders (non-sterile), powders (sterile), proteins, semisolids, solid dose, solutions & suspensions, sterile, sustained release, syringes (pre-filled), topicals, and vaccines.

"Since Dalton's inception 26 years ago, we have challenged ourselves to find innovative ways to achieve our clients' goals. This has included applying innovative thinking to business deals as well as developing novel processes and products. Dalton's role is to enhance the success of our customers by delivering cutting edge science and exceptional customer service. Innovation is at the core of everything we do at Dalton."
— Peter Pekos, president and CEO

Dow Pharmaceutical Sciences

Petaluma, CA
www.dowpharmsci.com
(707) 937-2600
Manufacturing location: Petaluma, CA
Contact: Karen Hanley, director of business development
karen.hanley@dowpharmsci.com

DRUG TYPE: Pharmaceuticals and Biopharmaceuticals

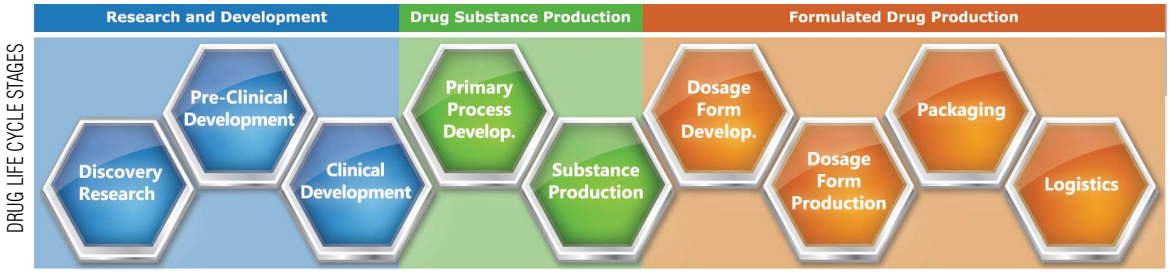
DRUG LIFE CYCLE STAGES:

Research & Development – pre-clinical, clinical (phase 1, phase 2, and phase 3)

Formulated Drug Production – dosage form development, dosage form production, packaging, and logistics

SERVICES OFFERED: Aseptic fill/finish, controlled substances, creams & ointments, gels, generics, liquids, lotions, non-sterile, ointments, ophthalmics, OTC, peptides, proteins, semisolids, solutions & suspensions, sterile, topicals, and vaginal applicators.

"Dow is very pleased to receive these awards. We are honored to be recognized for our efforts and to be highlighted as a premier semi-solid and liquid product development company. We have focused on meeting and exceeding our customers' expectations for more than 34 years. Being acknowledged for innovation, reliability, and regulatory, speaks not only to our exceptional technical expertise, but to the quality service our entire organization provides to our clients."
— Karen Yu, Ph.D., general manager



DPT Laboratories

DPT Laboratories
San Antonio, TX
www.DPTLabs.com
(866) CALL-DPT [225-5378]
Manufacturing locations: Lakewood, NJ, and San Antonio, TX
Contact: Craig Zabojnik
craig.zabojnik@dptlabs.com

DRUG TYPE: Pharmaceuticals

DRUG LIFE CYCLE STAGES:

Research & Development – pre-clinical and clinical (phase 1, phase 2, and phase 3)

Drug Substance Production – primary process development and drug substance production

Formulated Drug Production – dosage form development, dosage form production, and packaging

SERVICES OFFERED: Aseptic fill/finish, controlled substances, creams & ointments, gels, injectables, liquids, non-sterile, ophthalmics, OTC, parenterals (small volume), semisolids, solutions & suspensions, sterile, sustained release, and topicals.

"DPT continues to evolve in innovation by adding capabilities that complement what we do best, providing industry-leading development and manufacturing services in sterile and non-sterile semi-solids and liquids. We monitor market trends, strive to understand current and potential challenges, and respond to changing needs. Our vision emphasizes innovation, high-quality service, and the best technology. Our goal is to be the best at what we do, with success defined by customer satisfaction."
— Paul Johnson, DPT Group president & COO

DSM Pharmaceutical Products

DSM Pharmaceutical Products
Parsippany, NJ
www.dsm.com/pharma
(973) 257-8160
Manufacturing locations: Australia (2013), Austria, Germany, Italy, The Netherlands, and The United States
Contact: Hank Nowak
hank.nowak@dsm.com

DRUG TYPE: Pharmaceuticals and Biopharmaceuticals

DRUG LIFE CYCLE STAGES:

Research & Development – pre-clinical and clinical (phase 1, phase 2, and phase 3)

Drug Substance Production – primary process development and drug substance production

Formulated Drug Production – dosage form development, dosage form production, and packaging

SERVICES OFFERED: Aseptic fill/finish, capsules, controlled substances, cytotoxic & high-potency compounds, generics, injectables, liquids, lyophilized products, ophthalmics, OTC, parenterals (large volume), parenterals (small volume), proteins, solid dose, sterile, sustained release, and vaccines.

"DSM is honored to receive a CMO Leadership Award based on the fact that the awards represent the opinions of the customer, pharmaceutical, and biopharmaceutical companies who are using our services. To be recognized in the innovation category is truly an honor."
—Alexander R. Wessels, MSc, MBA, chief executive officer

Ei Inc.

Ei Inc.
Kannapolis, NC
www.eisolutionworks.com
(704) 939-4300
Manufacturing locations: Kannapolis, NC, and Landis, NC
Contact: Diana Ritch
dritch@eisolutionworks.com

DRUG TYPE: Pharmaceuticals and Biopharmaceuticals

DRUG LIFE CYCLE STAGES:

Formulated Drug Production – dosage form development, dosage form production, and packaging

SERVICES OFFERED: Creams & ointments, cytotoxic & high-potency compounds, gels, generics, non-sterile, OTC, powders (non-sterile), semisolids, solutions & suspensions, and topicals.

""Ei is honored to be recognized as a top tier organization and industry leader. We have a singular goal to improve products, strengthen brands, and create better lives by setting a new standard in topical pharmaceutical development and manufacturing. This is accomplished through cutting-edge science and state-of-the-art manufacturing wielded by people who understand that, although we provide a product, what we really do is protect a brand."
— Michael Kane, president & CEO

Euticals SPA

Euticals SPA
Rozzano, Milan, Italy
www.euticals.com
3902 8227 2214
Manufacturing locations: France, Germany, Italy, United Kingdom, and United States
Contact: Varadaraj Elango
v.elango@euticals.com

DRUG TYPE: Pharmaceuticals

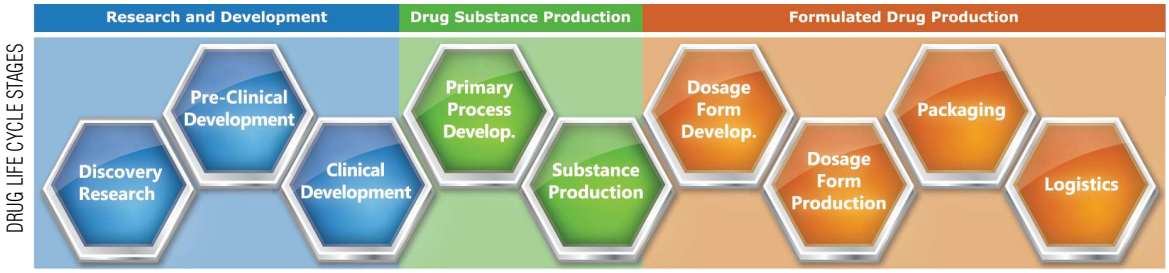
DRUG LIFE CYCLE STAGES:

Research & Development – clinical (phase 1, phase 2, and phase 3)

Drug Substance Production – drug substance production

Formulated Drug Production – dosage form production

SERVICES OFFERED: Controlled substances, cytotoxic & high-potency compounds, generics, injectables, lyophilized products, non-sterile, OTC, peptides, powders (non-sterile), and powders (sterile).



Flamma
Bergamo, Italy, and Boston, MA
www.flammagroup.com
(617) 515-0975
Manufacturing locations: Chignolo d'Isola, Bergamo, Italy (cGMP), Dalian, China (non-cGMP), and Isso, Bergamo, Italy (cGMP)
Contact: Kenneth Drew, Ph.D. director, U.S. sales and business development
flamma2012@flammagroup.com

DRUG TYPE: Pharmaceuticals

DRUG LIFE CYCLE STAGES:

Research & Development – discovery, pre-clinical, & clinical (phase 1, phase 2, & phase 3)

SERVICES OFFERED: Analytical development, cGMP manufacturing, contract manufacturing of NCEs and APIs, generics, peptides, process R&D, and scale-up.

"Flamma is appreciative to be recognized for our ability to be innovative. A CMO Leadership Award is evidence that Flamma consistently works with our customers by treating them as if they are family. Flamma relies on its expertise in high value chiral materials (specifically, amino acid related materials) to be a difference maker and problem solver for difficult projects. Flamma is a fully integrated company with production facilities located in Europe and China. Check us out."
— Kenneth Drew, Ph.D., director, U.S. sales and business development

Fujifilm Diosynth Biotechnologies
Morrisville, NC
www.fujifilmdiosynth.com
(919) 337-4400
Manufacturing locations: Billingham, Teesside, UK, and Research Triangle Park, NC, U.S.A.
Contact: Jozef Orpiszewski
enquiries@fujifilmdb.com

DRUG TYPE: Biopharmaceuticals

DRUG LIFE CYCLE STAGES:

Research & Development – pre-clinical, & clinical (phase 1, phase 2, & phase 3)

Drug Substance Production – primary process development and drug substance production

SERVICES OFFERED: Non-sterile, proteins, and vaccines.

"In our first year of operation as Fujifilm Diosynth Biotechnologies, we are delighted to be recognized for our regulatory reputation. Quality underpins everything we do to ensure patient safety and this is exemplified by our successful inspection history at both our U.S. and UK sites. As a global leader in the contract development and manufacture of biopharmaceuticals, we look forward to building on this reputation."
— Stephen Spearman, Ph. D., MBA, president

Gallus BioPharmaceuticals, LLC
St. Louis, MO
www.gallusbiopharma.com
(314) 426-5000
Manufacturing location: St. Louis, MO
Contact: Shelly Adams
shelly.adams@gallusbiopharma.com

DRUG TYPE: Biopharmaceuticals

DRUG LIFE CYCLE STAGES:

Research & Development – pre-clinical and clinical (phase 1, phase 2, & phase 3)

Drug Substance Production – primary process development and drug substance production

Formulated Drug Production – dosage form development and dosage form production

SERVICES OFFERED: Aseptic fill/finish, process development, proteins, and vaccines.

"Gallus is delighted to be recognized in the CMO Leadership Award for its innovation, productivity, and regulatory performance. Gallus is innovating with the first Xcellerex 2000L FlexFactory™ installed in the U.S. to provide highly flexible clinical manufacturing capacity. Gallus' productivity is epitomized by its 10-year history of commercial manufacturing, with over 200 commercial batches of product manufactured for 75 countries. This is enabled by an outstanding regulatory record with a recent no-483 FDA inspection."
— Mark Bamforth, president and CEO

GlaxoSmithKline
Brentford, Middlesex, UK
www.gsk.com/collaborations
44 (0) 20 8047 5000
Manufacturing locations: Australia, China, Europe, Japan, North America, and South America
Contact: Russell Harris
russell.b.harris@gsk.com

DRUG TYPE: Pharmaceuticals and Biopharmaceuticals

DRUG LIFE CYCLE STAGES:

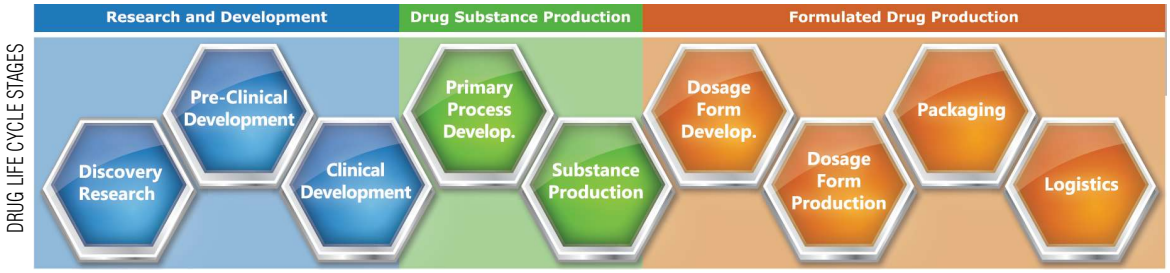
Research & Development – clinical (phase 2 and phase 3)

Drug Substance Production – primary process development and drug substance production

Formulated Drug Production – dosage form development, dosage form production, and packaging

SERVICES OFFERED: Aseptic fill/finish, capsules, controlled substances, creams & ointments, cytotoxic & high-potency compounds, generics, injectables, liquids, lyophilized products, non-sterile, ophthalmics, OTC, parenterals (large volume), peptides, powders (sterile), proteins, semisolids, solid dose, solutions & suspensions, sterile, sustained release, syringes (pre-filled), and topicals.

"GSK is very pleased to receive this award and the recognition it brings to our efforts to be a pharmaceutical company that offers a trustworthy and dependable manufacturing service. We are invested in our partnership approach, listening to our customers and understanding their business requirements. GSK knows how important it is to continually deliver value in the eyes of the customer, and we look forward to building upon this success."
— Kristof Szent-Ivanyi, business development director



Goodwin Biotechnology, Inc.
Plantation, FL
www.GoodwinBio.com
(954) 327-9639
Manufacturing location: Plantation, FL
Contact: Dave Cunningham
DCunningham@GoodwinBio.com

DRUG TYPE: Biopharmaceuticals

DRUG LIFE CYCLE STAGES:

Research & Development – pre-clinical and clinical (phase 1, phase 2, & phase 3)

Drug Substance Production – primary process development and drug substance production

Formulated Drug Production – packaging

SERVICES OFFERED: Aseptic fill/finish, controlled substances, cytotoxic & high-potency compounds, generics, injectables, lyophilized products, parenterals (large volume), parenterals (small volume), peptides, proteins, sterile, and vaccines.

"We at GBI are honored to be recognized in three categories of the CMO Leadership Awards, and consider it a testament to the quality of our people and their dedication to our customers.
Innovation: Our scientists consistently identify solutions to the most complex challenges.
Regulatory: We focus on quality and compliance from cell line engineering through cGMP manufacturing of late-stage clinical trial material.
Reliability: Our unique approach helps ensure that we meet and exceed client expectations on every project."
— Bansi K. Bhan, interim CEO

Halo Pharmaceutical
Whippany, NJ
www.halopharma.com
(973) 428-4000
Manufacturing locations: Whippany, NJ, and Mirabel, Québec, Canada
Contact: Sally Langa
slanga@halopharma.com

DRUG TYPE: Pharmaceuticals

DRUG LIFE CYCLE STAGES:

Drug Substance Production – primary process development and drug substance production

Formulated Drug Production – dosage form development, dosage form production, and packaging

SERVICES OFFERED: Capsules, controlled substances, creams & ointments, gels, high-potency compounds, liquids, non-sterile, powders (non-sterile), semisolids, solid dose, solutions & suspensions, sustained release, and topicals.

"We are delighted to have received this award from Life Science Leader for the second year in a row. It acknowledges the tremendous emphasis Halo Pharma puts on product quality and regulatory compliance, indeed the emphasis on quality in everything we do."
— Clive Bennett, president and CEO

Haupt Pharma AG
Wolfratshausen, Germany and Chesterfield, MO
www.haupt-pharma.com
1 314 5 75 00 51
Manufacturing locations: France, Germany, Italy, and Japan
Contact: Kevin Koziatek, VP of north american business development
Kevin.Koziatek@haupt-pharma.com

DRUG TYPE: Pharmaceuticals

DRUG LIFE CYCLE STAGES:

Research & Development – clincal (phase 1, phase 2, and phase 3)

Formulated Drug Production – dosage form development, dosage form production, packaging, and logistics

SERVICES OFFERED: 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), peptides, powders (non-sterile), powders (sterile), proteins, semisolids, soft gels, solid dose, solutions & suspensions, sterile, sustained release, topicals, and vaccines.

"Haupt Pharma is one of the largest European companies for pharmaceutical contract development and manufacturing. In manufacturing highly potent products, both product safety and employee safety are particularly important to us. This is ensured with our dedicated production area. Under the closed and high-containment principle, processing of highly efficient active ingredients is performed in a closed system. This significantly reduces the risk of contamination of the machine environment and ensures protection of the product, employees and the environment."
— Dr. Karl Heinz Brücher, COO of Haupt Pharma AG.

JHP Pharmaceuticals
Parsippany, NJ
www.jhppharma.com
(877) 906-7556
Manufacturing location: Rochester, MI
Contact: Daniel Leone
jhpcontractservices@jhppharma.com

DRUG TYPE: Pharmaceuticals and Biopharmaceuticals

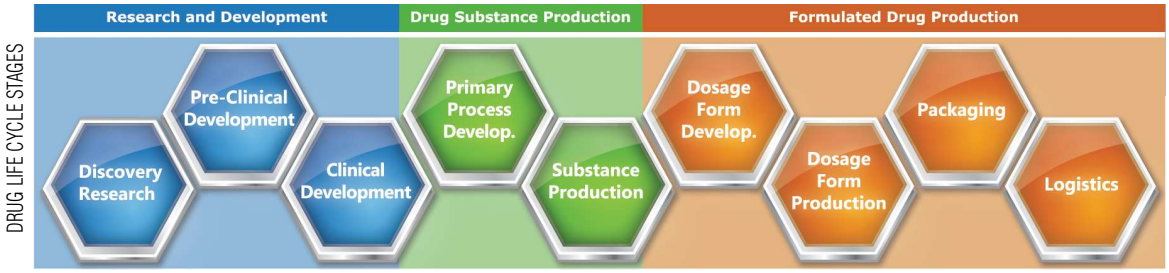
DRUG LIFE CYCLE STAGES:

Research & Development – clincal (phase 1, phase 2, and phase 3)

Formulated Drug Production – dosage form production

SERVICES OFFERED: Aseptic fill/finish, controlled substances, injectables, liquids, lyophilized products, ophthalmics, parenterals (small volume), peptides, proteins, solutions & suspensions, sterile, and vaccines.

"We are pleased that JHP was recognized as a leading contract manufacturer. Our Rochester, Michigan site has a 26-year history in contract manufacturing. We've achieved success through a quality-driven, experienced staff and a customer-centric approach. JHP's established infrastructure and deep experience allow us to focus on innovative approaches to meet complex manufacturing needs. Additionally, JHP's extensive experience working with products through their life cycle provides customers with the confidence to focus on their day-to-day business priorities."
— Stuart Hinchen, CEO



KEMWELL
Keeping You Competitive

Kemwell Biopharma
Bangalore, India
www.kemwellbiopharma.com
(919) 397-3000
Manufacturing locations: Bangalore, India, and Uppsala, Sweden
Contact: Christian Ahlmark
Christian.ahlmark@kemwellpharma.com

DRUG TYPE: Pharmaceuticals and Biopharmaceuticals

DRUG LIFE CYCLE STAGES:

Research & Development – pre-clinical and clinical (phase 1, phase 2, & phase 3)

Formulated Drug Production – dosage form development, dosage form production, packaging, and logistics

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

"In today's competitive marketplace, it's wonderful to hear positive customer & industry feedback like this. It tells us that we are on the right track. For over 30 years, Kemwell has maintained a strong history of manufacturing quality, flexibility, and customer service. We continuously try to improve on our model by investing in our staff and facilities to provide innovative solutions, in-line with our customers' needs and goals."
— Anurag Bagaria, managing director & CEO

LAUREATE BIOPHARMA

Laureate Biopharmaceutical Services, Inc.
Princeton, NJ
www.LBioS.com
(609) 919-3390
Manufacturing location: Princeton, NJ
Contact: Lisa Cozza, vice president, business development
lisa.cozza@LBioS.com

DRUG TYPE: Pharmaceuticals and Biopharmaceuticals

DRUG LIFE CYCLE STAGES:

Research & Development – pre-clinical and clinical (phase 1, phase 2, and phase 3)

Drug Substance Production – primary process development and drug substance production

Formulated Drug Production – dosage form development and dosage form production

SERVICES OFFERED: Aseptic fill/finish, injectables, liquids, parenterals (large volume), parenterals (small volume), proteins, solutions & suspensions, and sterile.

"Laureate Biopharma has 30 years of innovation in biopharmaceutical development and processing. We were early adopters of single-use technologies, chemically defined culture media, high-speed chromatographic resins and membranes. We work collaboratively with our clients and suppliers to produce quality protein therapeutics with modern, efficient processes using innovative materials and techniques."
— Michael A. Griffith, chief executive officer

LYOPHILIZATION TECHNOLOGY, INC.
Integrating Science and Technology

Lyophilization Technology, Inc.
Ivyland, PA
www.Lyotechnology.com
(215) 396-8373
Manufacturing location: Ivyland, PA
Contact: Christine Adams
cadams@lyo-t.com

DRUG TYPE: Pharmaceuticals and Biopharmaceuticals

DRUG LIFE CYCLE STAGES:

Research & Development – discovery, pre-clinical, & clinical (phase 1, phase 2, & phase 3)

Formulated Drug Production – dosage form development and dosage form production

SERVICES OFFERED: Aseptic fill/finish, cartridges, controlled substances, cytotoxic & high-potency compounds, generics, injectables, liquids, lyophilized products, ophthalmics, parenterals (large volume), parenterals (small volume), peptides, powders (sterile), proteins, solutions & suspensions, sterile, sustained release, syringes (pre-filled), and vaccines.

"Lyophilization Technology is a group of experienced and knowledgeable scientists, technicians, and support staff focused on providing development, technical services and clinical supply manufacturing for lyophilized products. Closely collaborating with our clients, we see our mission as applying our capabilities and expertise to the challenges of developing new and innovative products. Thank you to all the survey respondents in bestowing LTI with the CMO Leadership Awards for quality, reliability, and productivity."
— Edward H. Trappler, president

NextPharma

NextPharma Technologies LTD
Send, Surrey, England
www.nextpharma.com
+44 1483 479120
Manufacturing locations: France and Germany (Austrian and Swiss Logistic Centers)
Contact: Pierre Delavaud
pierre.delavaud@nextpharma.com

DRUG TYPE: Pharmaceuticals

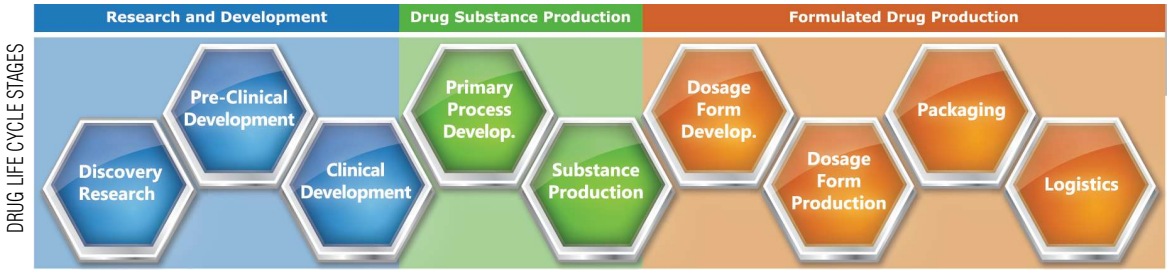
DRUG LIFE CYCLE STAGES:

Research & Development – pre-clinical and clinical (phase 1, phase 2, and phase 3)

Formulated Drug Production – dosage form development, dosage form production, packaging, and logistics

SERVICES OFFERED: Beta-lactams, capsules, controlled substances, creams & ointments, cytotoxic & high-potency compounds, gels, generics, hormone, humidity sensitive, liquids, non-sterile, opthalmics, OTC, peptides, powders (non-sterile), semisolids, soft gels, solid dose, solutions & suspensions, sustained release, and topicals.

"Our strategy focuses on providing customer satisfaction, and pivotal to this is consistent compliance with regulatory standards. We work with our customers, in partnership, to ensure that quality is 'built in' to the products, processes and services that we offer. Our teams have a reputation for openness and transparency. Our culture of continuous improvement facilitates our desire to apply regulatory guidance in a way that benefits our customers, our business, and ensures continued regulatory success."
— Dr. Franck Latrille, CEO



NORWICH

Norwich Pharmaceuticals
Norwich, NY
www.norwichpharma.com
(888) 674-7979
Manufacturing location: Norwich, NY
Contact: Stephanie Ferrell
stephanie.ferrell@norwichpharma.com

DRUG TYPE: Pharmaceuticals

DRUG LIFE CYCLE STAGES:

Research & Development – clinical (phase 2 and phase 3)

Formulated Drug Production – dosage form development, dosage form production, and packaging

SERVICES OFFERED: Capsules, controlled substances, cytotoxic & high-potency compounds, generics, non-sterile, OTC, semisolids, soft gels, solid dose, and sustained release.

"At Norwich, we have dedicated ourselves to focus on our customers and the patients they serve. We understand that CMO Leadership Award recognition is directly tied to the success of our customers, and we are proud to be a reliable partner for all stages of the product life cycle from product development to scale-up and commercial manufacturing through clinical services. Patients put trust into our customers' products, and Norwich's 125-year history of quality and compliance provides a foundation for that trust."
— Terry Novak, president

novasep

When purity is key.

NOVASEP
Pompey, France
www.novasep.com
+ 33 3 83 49 71 00
Manufacturing locations:
Belgium, France, and Germany
Contact: Michel Blanc
michel.blanc@novasep.com

DRUG TYPE: Pharmaceuticals and Biopharmaceuticals

DRUG LIFE CYCLE STAGES:

Research & Development – pre-clinical and clinical (phase 1, phase 2, and phase 3)

Drug Substance Production – primary process development and drug substance production

Formulated Drug Production – dosage form development, dosage form production, packaging, and logistics

SERVICES OFFERED: Aseptic fill/finish, controlled substances, cytotoxic & high potency compounds, downstream processing , generics, injectables, lyophilized products, non-sterile, peptides, powders (non-sterile), powders (sterile), purification, proteins, solutions & suspensions, sterile, and vaccines.

"The need for better and safer products, particularly in life-science industries, commands ever purer and more complex molecules. Novasep's unique offerings, which include contract manufacturing services and the supply of purification technologies, enables us to develop and implement cost-effective and sustainable solutions for the production of synthetic and biomolecules at the required purity. Furthermore, I believe that our commitment to the projects of our customers is key in building fruitful and durable relationships with them."
— Roger-Marc Nicoud, CEO

OSOBIO®

The injectables cmo

OSO BioPharmaceuticals Manufacturing, LLC
Albuquerque, NM
www.osobio.com
(505) 923-2112
Manufacturing location:
Albuquerque, NM
Contact: Kristin Calloway
Kristin.calloway@osobio.com

DRUG TYPE: Pharmaceuticals and Biopharmaceuticals

DRUG LIFE CYCLE STAGES:

Formulated Drug Production – dosage form production and packaging

SERVICES OFFERED: Aseptic fill/finish, controlled substances, cytotoxic & high-potency compounds, generics, injectables, liquids, lyophilized products, parenterals (small volume), peptides, proteins, solutions & suspensions, sterile, syringes (pre-filled), and vaccines.

"We are very pleased at OsoBio to have been recognized as a leading CMO in the categories for productivity and regulatory. We believe a strong commitment to regulatory compliance is the cornerstone to productivity. Our site history reveals a demonstrated track record of regulatory success, having been inspected by almost every worldwide regulatory agency in the commercialization of more than 250 distinct product codes. We are honored this commitment is recognized by our industry peers."
— Milton Boyer, president

PARAGON BIOSERVICES

Paragon Bioservices, Inc.
Baltimore, MD
www.paragonbioservices.com
www.twitter.com/paragonbio
(410) 975-4050/(800) 545-6569
Manufacturing location:
Baltimore, MD
Philip W. Wills, Ph.D.
pwills@paragonbioservices.com

DRUG TYPE: Biopharmaceuticals

DRUG LIFE CYCLE STAGES:

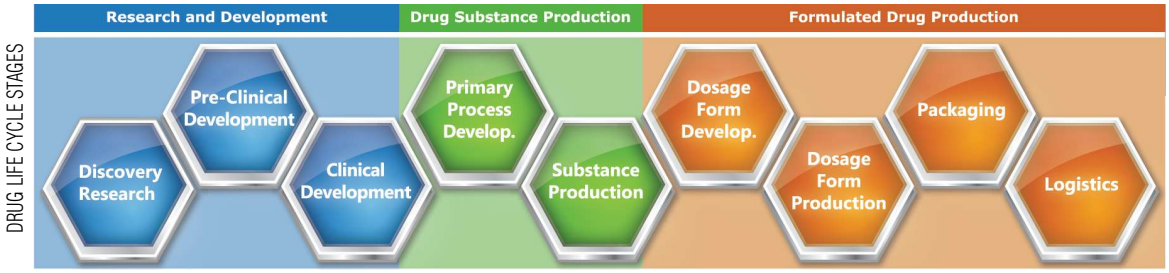
Research & Development – discovery, pre-clinical, & clinical (phase 1, phase 2, & phase 3)

Drug Substance Production – primary process development and drug substance production

Formulated Drug Production – dosage form development and dosage form production

SERVICES OFFERED: Aseptic fill/finish, generics, GMP manufacturing of biopharmaceuticals (including vaccines), injectables, liquids, process development, proteins, research services, sterile, and vaccines.

"With more than 20 years in business, Paragon's associates provide decades of collective experience working with biologics — from our scientists and engineers to our project managers, quality and regulatory personnel. We're very proud of that. Also, fueled by ongoing consolidation in the pharmaceutical industry, the demand for Paragon's areas of expertise (development of biopharmaceuticals — including recombinant proteins, viral vectors and vaccines) is expected to continue to increase in double digits for years to come."
— Marco A. Chacón, Ph.D., president & CEO



Patheon
Durham, NC
www.patheon.com
(866) Patheon [728-4366]
Manufacturing locations: Canada, France, Italy, Puerto Rico, and the United States
Contact: Mike Stout
DoingBusiness@Patheon.com

DRUG TYPE: Pharmaceuticals and Biopharmaceuticals

DRUG LIFE CYCLE STAGES:

Research & Development – pre-clinical and clinical (phase 1, phase 2, and phase 3)

Formulated Drug Production – dosage form development, dosage form production, and packaging

SERVICES OFFERED: 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, soft gels, solid dose, solutions & suspensions, sterile, sustained release, and syringes (pre-filled).

"Patheon strives to exceed customer's expectations. Innovative technical and scientific solutions, high quality, and commitment to excellence are at the foundation of our work. It is gratifying to know that we have been recognized for this award. For customers to acknowledge our industry leadership in quality, innovation, productivity, regulatory and reliability is especially important, as these are the metrics we judge ourselves by and strive to perfect every day. Congratulations to Patheon's global workforce. It's their hard work that made this award possible."
— Jim Mullen, CEO

Pfizer CentreSource (PCS)
Kalamazoo, MI
www.pfizercentresource.com
(269) 833-5844
Manufacturing locations: Australia, Belgium, Germany, Sweden, U.S.A.
Contact: Cristin Grove
Cristin.grove@pfizer.com

DRUG TYPE: Pharmaceuticals and Biopharmaceuticals

DRUG LIFE CYCLE STAGES:

Research & Development – clinical (phase 2 and phase 3)

Drug Substance Production – drug substance production

Formulated Drug Production – dosage form development and dosage form production

SERVICES OFFERED: Aseptic fill/finish, controlled substances, creams & ointments, cytotoxic & high-potency compounds, injectables, liquids, lyophilized products, non-sterile, ophthalmics, proteins, semisolids, solid dose, syringes (pre-filled), and topicals.

"PCS is pleased to be recognized by Life Science Leader for our operational excellence in the areas of reliability, innovation, productivity, and regulatory. The award confirms the long-standing commitment of our business to establish strategic partnerships between our customers and Pfizer Global Supply. This award validates the confidence our customers have when working with PCS and assures them that they are dealing with a business that has very high standards and expectations as a trustworthy contract development and manufacturing organization."
— Cristin Grove , director contract manufacturing

Pharma Tech Industries
Royston, GA
www.pharma-tech.com
(706) 246-3527
Manufacturing locations: Royston, GA, and Union, MO
Contact: Tee Noland
tee@pharma-tech.com

DRUG TYPE: Pharmaceuticals

DRUG LIFE CYCLE STAGES:

Research & Development – clinical (phase 3)

Formulated Drug Production – dosage form production and packaging

SERVICES OFFERED: Cartridges, effervescent products, OTC, plastics molding, powders (non-sterile), solid dose, and topicals.

"Cohesive productivity is crucial for a start-to-finish CMO such as us, and the best assurance we can provide potential customers is a strong reputation built on regulatory compliance. For over 40 years, PTI has been serving the supply chain needs of leading global pharmaceutical and personal care companies with manufacturing, packaging, and molding services. Our experienced quality and regulatory personnel address a broad range of domestic and international regulatory environments including cosmetic, over-the-counter, prescription (Rx), and medical device."
— Carl Oberg, president

Pharmatek Laboratories, Inc.
San Diego, CA
www.pharmatek.com
(858) 805-6383
Manufacturing location: San Diego, CA
Contact: Tim Scott
tscott@pharmatek.com

DRUG TYPE: Pharmaceuticals

DRUG LIFE CYCLE STAGES:

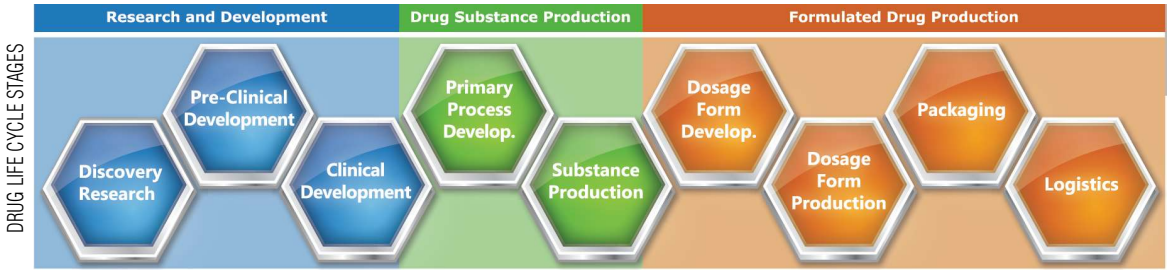
Research & Development – discovery, pre-clinical, & clinical (phase 1, phase 2, & phase 3)

Drug Substance Production – primary process development and drug substance production

Formulated Drug Production – dosage form development, dosage form production, packaging, and logistics

SERVICES OFFERED: Capsules, controlled substances, cytotoxic & high-potency compounds, injectables, liquids, lyophilized products, non-sterile, parenterals (small volume), peptides, powders (non-sterile), semisolids, solid dose, solutions & suspensions, sustained release, and topicals.

"In this new pharma economy where outsourcing has become its own ecosystem of suppliers, consultants and partnerships, leadership in contract manufacturing is a matter of staying focused on what makes each manufacturing run successful. Bringing high quality people, facilities and systems to any project will yield a high-quality product. While the business of pharma is ever-changing, the focus on quality is the undeniable core of success."
— Timothy Scott, president



Phyton Biotech

Phyton Biotech
Delta, BC, Canada
www.phytonbiotech.com
(604) 777-2340
Manufacturing locations: Hamburg, Germany, and Vancouver, BC, Canada
Contact: Jackie Labbe
jackie.labbe@phytonbiotech.com

DRUG TYPE: Pharmaceuticals and Biopharmaceuticals

DRUG LIFE CYCLE STAGES:

Research & Development – pre-clinical, clinical (phase 1, phase 2, and phase 3)

Drug Substance Production – primary process development and drug substance production

SERVICES OFFERED: Cytotoxic & high-potency compounds and proteins.

"At Phyton, we have the best scientists in the world dedicated to API development and manufacturing via plant cell fermentation (PCF™), semi-synthesis, and purification. Our productivity is high because we empower our people to make decisions and resolve issues, measure our performance, and hold each other accountable for moving projects forward the right way. And most important, our attitude is focused on success and service for our customers."
— Marc Iacobucci, general manager

P.J. Noyes Contract Manufacturing & Packaging

P.J. Noyes Company, Inc.
Lancaster, NH
www.pjnoyes.com
(603) 788-4952
Manufacturing location: USA
Contact: Jennifer Cusick
jcusick@pjnoyes.com

DRUG TYPE: Pharmaceuticals

DRUG LIFE CYCLE STAGES:

Drug Substance Production – manufacture and package finish goods

Formulated Drug Production – dosage form production and packaging

SERVICES OFFERED: Capsules, compressed tablets, creams & ointments, gels, liquids, non-sterile, OTC, solid dose, and topicals.

"P.J. Noyes Company is honored to be recognized by the market and its peers with the leadership awards in quality and innovation. As an FDA registered, NSF Certified, cGMP compliant manufacturer and packager, we have consistently instilled quality throughout our processes, ensuring that the finished product meets and exceeds standards established by our customer, and regulatory agencies. We continue to work with our customers in developing new innovative products and delivery methods, which support their continued growth."
— David Hill, president

PORTON

Porton Fine Chemicals
Chongqing, China
www.porton.cn
(973) 432-1200
Manufacturing location: Chongqing, China
Contact: Steve Spardel
steven.spardel@portonamericas.com

DRUG TYPE: Pharmaceuticals

DRUG LIFE CYCLE STAGES:

Research & Development – clinical (phase 1, phase 2, and phase 3)

Drug Substance Production – primary process development and drug substance production

SERVICES OFFERED: API and intermediates.

"I am honored and proud of my colleagues to have been recognized by Life Science Leader Magazine. It is particularly rewarding to know that this award emanates from survey comments from our clients. It validates the hard work and strategic alignment we foster among all of our employees at Porton."
— Oliver Ju, President and CEO

PYRAMID Laboratories, Inc.

PYRAMID Laboratories, Inc.
Costa Mesa, CA
www.pyramidlabs.com
(714) 435-9800
Manufacturing location: Costa Mesa, CA
Contact: Medhat Gorgy
info@pyramidlabs.com

DRUG TYPE: Pharmaceuticals and Biopharmaceuticals

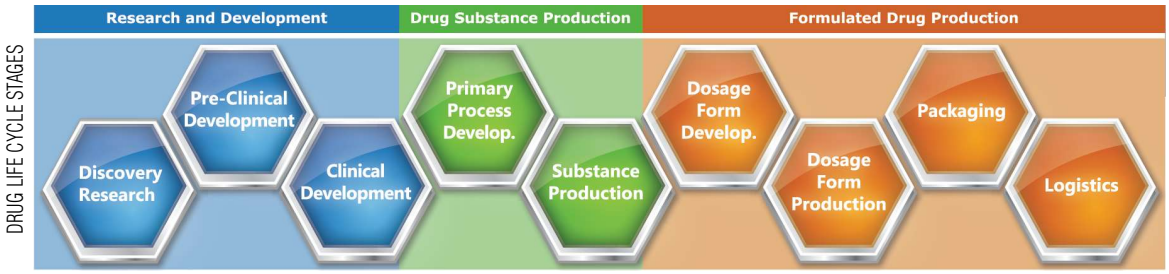
DRUG LIFE CYCLE STAGES:

Research & Development – pre-clinical, clinical (phase 1, phase 2, and phase 3)

Formulated Drug Production – dosage form development, dosage form production, packaging, and logistics

SERVICES OFFERED: Aseptic fill/finish, generics, injectables, liquids, lyophilized products, ophthalmics, parenterals (large volume), parenterals (small volume), peptides, proteins, solutions & suspensions, sterile, syringes (pre-filled), and topicals.

"Our expertise and advanced technological environment allows us to provide the client with highly skilled individual attention, professional service, and documented high quality in the most efficient and cost-effective manner.
At PYRAMID we guarantee quality, performance and integrity combined with a personal commitment."
— Medhat Gorgy, president & chief executive officer



Recipharm

Recipharm AB
Jordbro, Sweden
www.recipharm.com
46 8 602 52 00
Manufacturing locations: France, Germany, Spain, Sweden, and United Kingdom
Contact: Mark Quick
info@recipharm.com

DRUG TYPE: Pharmaceuticals

DRUG LIFE CYCLE STAGES:

Formulated Drug Production – dosage form development, dosage form production, and packaging

SERVICES OFFERED: Aseptic fill/finish, capsules, cartridges, controlled substances, creams & ointments, cytotoxic & high-potency compounds, gels, generics, injectables, liquids, lyophilized products, non-sterile, OTC, parenterals (large volume), parenterals (small volume), powders (non-sterile), semisolids, solid dose, solutions & suspensions, sterile, and topicals.

"I am very honoured that Recipharm has won this innovation award. We adopt a partnering approach to customer relations, consequently delivering bespoke services that deliver real value to each customer. Whether this is managing their supply chains and inventory, devising novel technical solutions or taking a share in the risk in product development, Recipharm offers a comprehensive, end-to-end solution. We constantly strive to find ways to enhance the scope and services we offer."
— Thomas Eldered, CEO

CUSTOMBIOTECH by Roche

Roche Custom Biotech
Indianapolis, IN
www.roche-applied-science.com/custom-biotech
(800) 428-5433, ext. 14649
Manufacturing locations: Branchburg, NJ, and Penzberg, Germany
Contact: Pat Sankhavaram
custombiotech.ussales@roche.com

DRUG LIFE CYCLE STAGES:

Research & Development – discovery and pre-clinical

Drug Substance Production – primary process development and drug substance production

SERVICES OFFERED: Bioanalytical tools, custom product development, diagnostic assay development, liquids, lyophilized products, non-sterile, peptides, powders (non-sterile), powders (sterile), and proteins.

"I am pleased to see Custom Biotech being recognized within the top five once again. Being part of the Roche organization allows us to provide expertise as well as state-of-the-art equipment and technologies from across all Roche business units to address our customer's needs."
Our goal is to enable the healthcare industry by providing state of the art, customized solutions and services for development and manufacturing of diagnostic and therapeutic products."
— Peter Schramm, VP

ROHNER | CHEM

RohnerChem
Pratteln, Switzerland
www.rohnerchem.ch
41 61 825 1111
Manufacturing location: Pratteln, Switzerland
Contact: Dr. Andreas Meudt
andreas.meudt@rohnerchem.ch

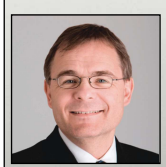
DRUG TYPE: Pharmaceuticals

DRUG LIFE CYCLE STAGES:

Research & Development – clinical (phase 1, phase 2, and phase 3)

Drug Substance Production – primary process development and drug substance production

SERVICES OFFERED: Controlled substances, liquids, non-sterile, polymers, and powders (non-sterile).



"RohnerChem is very proud to be rated so positively by our valued customers. We are a Swiss based, highly reliable and flexible CMO organization. We pay tremendous attention to project management as well as rapid and open communication with our customers. We can rapidly develop a process and scale up to commercial level. This efficiency has also been rewarded with the "Syngenta Supplier award for innovation 2012" and earlier with "The European Outsourcing Award" together with Solvias."
— Dr. Thomas Rosatzin, CEO

SAFC®

SAFC
St. Louis, MO
www.safcglobal.com
(800) 244-1173
Manufacturing locations: Arklow, Ireland; Buchs, Switzerland; Bangalore; Carlsbad; Jerusalem; Madison/Verona; St. Louis, U.S.A.
Contact: Sobia Nayyar
sobia.nayyar@sial.com

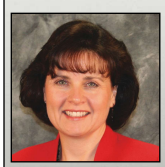
DRUG TYPE: Pharmaceuticals and Biopharmaceuticals

DRUG LIFE CYCLE STAGES:

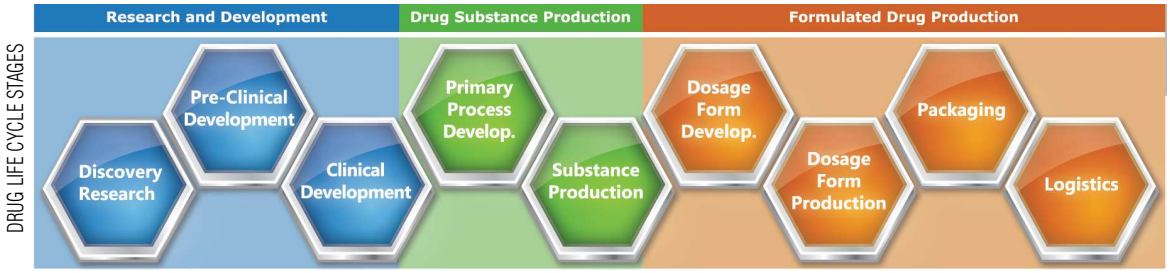
Research & Development – discovery, pre-clinical, & clinical (phase 1, phase 2, & phase 3)

Drug Substance Production – primary process development and drug substance production

SERVICES OFFERED: Cytotoxic & high-potency compounds, generics, injectables, liquids, lyophilized products, non-sterile, ophthalmics, parenterals (large volume), parenterals (small volume), powders (non-sterile), powders (sterile), proteins, solutions & suspensions, sterile, and vaccines.



"As a CMO, SAFC aims to be the supplier of choice in the market. Reliability, innovation, productivity, and regulatory are more than words to our customers. We try to keep that fact in mind at all times and complement that approach with a comprehensive solutions offering. This kind of customer recognition is a true testament to the quality of that solution working in perfect harmony with the fantastic team we have here at SAFC."
— Deborah Slagle, vice president of marketing and R&D



SANDOZ

Sandoz GmbH
Kundl, Tirol, Austria
www.sandoz.com
Manufacturing locations:
Austria and Germany

DRUG TYPE: Pharmaceuticals and Biopharmaceuticals

DRUG LIFE CYCLE STAGES:

Research & Development – clinical (phase 1, phase 2, and phase 3)

Drug Substance Production – primary process development and drug substance production

SERVICES OFFERED: Aseptic fill/finish, cytotoxic & high-potency compounds, generics, injectables, liquids, peptides, proteins, and small molecules.

"We are delighted to be a recipient of the 2012 CMO Leadership Awards and sincerely thank our customers for this honor. Sandoz is proud of its strong heritage in contract manufacturing services. We have over 60 years of experience in the manufacturing of fermentation-derived intermediates and APIs across various therapeutic areas — as well as process enzymes — and over 30 years of experience in development and manufacturing of recombinant proteins and peptides (microbial and mammalian). Central to our success are our talented people who take a collaborative approach with our customers by offering end-to-end support by helping them develop and commercialize important medicines."
— Friedrich Nachtmann, head of biotech corporations, and Gerhard Santer, head of global development & strategy

SENN

Senn Chemicals AG
Dielsdorf, Switzerland
www.sennchem.com
+41 (0)43 422 2400
Manufacturing location:
Dielsdorf, Switzerland
Contact: Elizabeth Hoffner
Sales@sennchem.com

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 and drug substance production

SERVICES OFFERED: Generics, lyophilized products, and peptides.

"Senn is committed to continuous innovation and quality excellence. Our flexible infrastructure allows us to provide viable and inventive custom manufacturing solutions. We work with our clients to develop project plans that facilitate efficient productions, realistic timelines, while adhering to set budgets. We are truly grateful to be acknowledged by our global clients with this CMO Leadership Award. We appreciate this very meaningful honor as it exemplifies our commitment to innovative excellence."
— Carlo Hächler, CEO

Siegfried

Siegfried AG
Zofingen, Argau, Switzerland
www.siegfried.ch
0041 62 7461520
Manufacturing locations:
Malta, Switzerland, and United States
Contact: Marianne Späne
marianne.spaene@siegfried.ch

DRUG TYPE: Pharmaceuticals and Biopharmaceuticals

DRUG LIFE CYCLE STAGES:

Research & Development – clinical (phase 1, phase 2, and phase 3)

Drug Substance Production – primary process development and drug substance production

Formulated Drug Production – dosage form development, dosage form production, packaging, and logistics

SERVICES OFFERED: Aseptic fill/finish, capsules, cartridges, controlled substances, creams & ointments, cytotoxic & high-potency compounds, gels, generics, injectables, liquids, non-sterile, ophthalmics, parenterals (small volume), peptides, powders (sterile), proteins, semisolids, solid dose, solutions & suspensions, sterile, sustained release, topicals, and vaccines.

"Finding the right outsourcing relationship is critical for pharmaceutical companies today. At Siegfried we share their belief in high quality, innovation, productivity, and compliance. Siegfried, together with AMP, provides products and tailor-made services which seamlessly integrate our customers' value chain. Whether it's custom development services, producing APIs and drug products (oral or sterile), or controlled substances and higher potency you desire, I am convinced you can expect more with Siegfried as your preferred integrated-partner."
— Dr. Rudolf Hanko, CEO

therapure BIOPHARMA INC.

Therapure Biopharma Inc.
Mississauga, Ontario, Canada
www.therapurebio.com
(905) 286-6270
Manufacturing location:
Mississauga, Ontario, Canada
Contact: Dina Iezzi, director of marketing & special projects
diezzi@therapurebio.com

DRUG TYPE: Pharmaceuticals and Biopharmaceuticals

DRUG LIFE CYCLE STAGES:

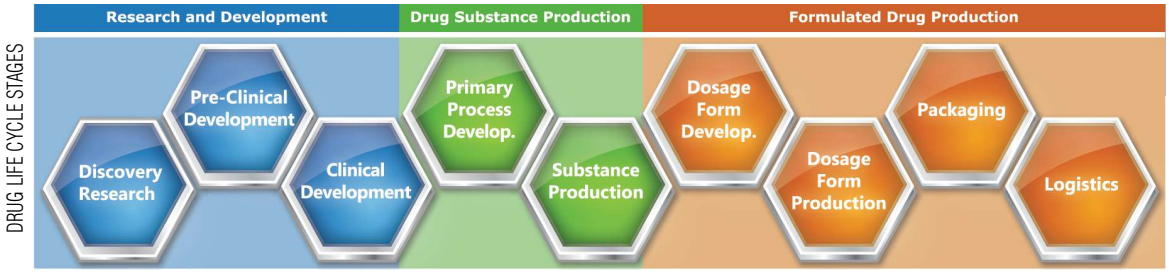
Research & Development – discovery, pre-clinical, & clinical (phase 1, phase 2, & phase 3)

Drug Substance Production – primary process development and drug substance production

Formulated Drug Production – dosage form production, packaging, and logistics

SERVICES OFFERED: Aseptic fill/finish, injectables, lyophilized products, ophthalmics, parenterals (small volume), proteins, sterile, syringes (pre-filled), and vaccines.

"Once again, we are privileged to receive the CMO Leadership award and honoured to be recognized by biopharma executives surveyed by Nice Insight as a leader in all categories (quality, reliability, innovation, productivity, and regulatory). I would like to take this opportunity to thank all the employees of Therapure, whose daily contributions and diligence are the driving force behind our company's success as well as our clients, without whom this would not have been possible."
— Nick Green, president and CEO



Uman Pharma Inc.

Candiac, Québec, Canada
www.umanpharma.com
(450) 444-9989
Manufacturing location:
Candiac, Québec, Canada
Contact: Alain Huneault
alain.huneault@umanpharma.com

DRUG TYPE: Pharmaceuticals

DRUG LIFE CYCLE STAGES:

Research & Development – pre-clinical and clinical (phase 1, phase 2, and phase 3)

Drug Substance Production – primary process development and drug substance production

Formulated Drug Production – dosage form development, dosage form production, packaging, and logistics

SERVICES OFFERED: Capsules, cytotoxic & high-potency compounds, generics, injectables, liquids, lyophilized products, non-sterile, OTC, solid dose, solutions & suspensions, sterile, and syringes (pre-filled).

"We are very happy to have been bestowed this honor by Life Science Leader, especially since this CMO Leadership Award comes from within the industry. As a young company, we are extremely proud of our accomplishments to date, and our mission has always been to provide excellence in both products and services. We recognize and are fortunate to have an experienced, professional and dedicated team that is committed to the highest pharmaceutical quality standards. To have and to bring a Uman touch is our motto and it drives us to attain new heights."
— Sylvain Duvernay, CEO

UPM Pharmaceuticals, Inc.

Baltimore, MD
www.upm-inc.com
(410) 843-3700
Manufacturing location:
Baltimore, MD
Contact: Mike Raum
raum@upm-inc.com

DRUG TYPE: Pharmaceuticals

DRUG LIFE CYCLE STAGES:

Research & Development – clinical (phase 1, phase 2, and phase 3)

Formulated Drug Production – dosage form development, dosage form production, and packaging

SERVICES OFFERED: Capsules, controlled substances, cytotoxic & high-potency compounds, gels, generics, liquids, non-sterile, peptides, powders (non-sterile), semisolids, soft gels, solutions & suspensions, and topicals.

"UPM Pharmaceuticals focuses on meeting challenging timelines for development work, provision of clinical supplies, and associated lab services. UPM maintains a lean and flat corporate structure. This allows production decisions and quality oversight on every project to be made and driven daily with input from every department and overseen at the highest levels of our operations. We pride ourselves on providing constant communication with our clients. UPM clearly understands that winning and keeping business in this highly competitive industry is about producing results for our clients."
— Jim Gregory, president and COO

Vetter Pharma International GmbH

Ravensburg, Germany
www.vetter-pharma.com
+49-751-3700-0
Manufacturing locations:
Langenargen, Germany, Ravensburg, Germany, and Skokie, IL
Contact: Oskar Gold
info@vetter-pharma.com

DRUG TYPE: Pharmaceuticals and Biopharmaceuticals

DRUG LIFE CYCLE STAGES:

Research & Development – pre-clinical and clinical (phase 1, phase 2, and phase 3)

Formulated Drug Production – dosage form production, packaging, and logistics

SERVICES OFFERED: Aseptic fill/finish, cartridges, injectables, liquids, lyophilized products, parenterals (large volume), parenterals (small volume), peptides, powders (sterile), proteins, solutions & suspensions, sterile, syringes (pre-filled), and vaccines.

"We never lose sight that the products we manufacture for our clients are used by patients they serve. For more than 25 years, Vetter has provided high-quality aseptic fill and finish with reliable delivery. We appreciate recognition of our dedication to our customers with this award."
— Peter Soelkner, Vetter Managing Director

WuXi AppTec

Shanghai, People's Republic of China
www.WuXiAppTec.com
86 (21) 5046-1111
Manufacturing locations:
Changzhou, Jinshan, WuXi City, and Shanghai WGQ, China
Contact: Yu Lu
Yu.Lu@WuXiAppTec.com

DRUG TYPE: Pharmaceuticals and Biopharmaceuticals

DRUG LIFE CYCLE STAGES:

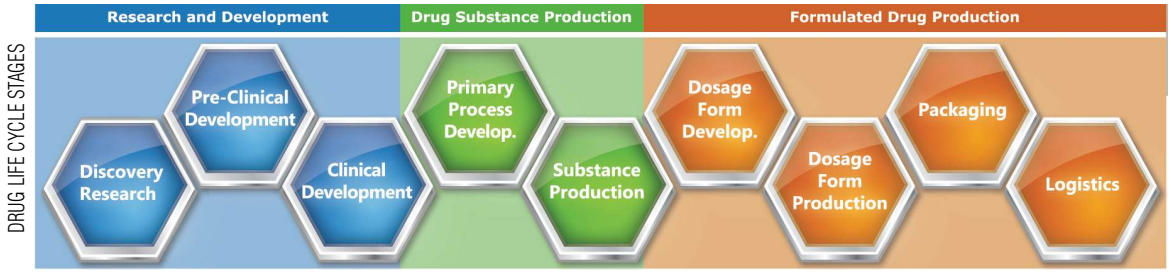
Research & Development – discovery, pre-clinical, & clinical (phase 1, phase 2, & phase 3)

Drug Substance Production – primary process development and drug substance production

Formulated Drug Production – dosage form development, dosage form production, packaging, and logistics

SERVICES OFFERED: Capsules, liquids, non-sterile, peptides, powders (non-sterile), solid dose, solutions & suspensions, sustained release, and vaccines.

"We are honored to be consistently recognized as a top outsourcing company in China. This speaks volume for WuXi's service business model. As a leading life science R&D service company, we will strive to improve our capabilities and capacities to better serve our pharmaceutical, biotechnology, and medical device customers and partners, to help bring new products into market sooner and more cost effectively to benefit patients needs."
— Suhan Tang, Ph.D., chief manufacturing officer



Xcelience Formulation Development

DRUG TYPE: Pharmaceuticals

Xcelience
Tampa, FL
www.xcelience.com
(813) 286-0404
Manufacturing location: Tampa, FL
Contact: Sharon L. Burgess, vice president
Sharon.burgess@xcelience.com

DRUG LIFE CYCLE STAGES:

Research & Development – pre-clinical and clinical (phase 1, phase 2, and phase 3)

Formulated Drug Production – dosage form development, dosage form production, packaging, and logistics

SERVICES OFFERED: Capsules, controlled substances, creams & ointments, cytotoxic & high-potency compounds, gels, liquids, non-sterile, semisolids, solid dose, sustained release, and topicals.

""It is an honor to be recognized with top rankings in productivity and regulatory by Life Science Leader and Nice Insight. Our commitment to quality, productivity, and willingness to customize, anchor our position of service leadership in the CMO marketplace. We are proud of the work that we do to help pharmaceutical and biotechnology companies bring new medicines to market."
— Derek G. Hennecke, CEO & president

Industry Leader

Implementing On-Demand Visibility To Improve Outcomes

Two decades ago, most life sciences companies were vertically integrated. Raw material came in one end of the operation, and finished goods went out the other.

Around that time, industry and regulators began to collaborate to change the pharma manufacturing paradigm from "testing quality out" to "building quality in." This resulted in approaches such as process analytical technology (PAT) and quality by design (QbD), which drove industry to gain a deeper understanding of product characteristics and manufacturing processes to allow for tight controls over critical-to-quality parameters.

Around the same time, life sciences companies began experimenting with outsourcing. Today, outsourcing is common, but has an unintended consequence — many brand owners have lost the ability to collect and capitalize on critical-to-quality parameters stored at an external facility. This data is not only needed to improve productivity, quality, and reliability, but also can have a significant effect on product safety and efficacy as well as innovation and regulatory compliance.

OUTSOURCING VISIBILITY

Globalization and outsourcing are here to stay. However, increases in outsourcing and globalization do not translate to a loss of visibility or responsibility.

A key challenge is that, today, visibility into the outsourced supply chain is primarily based on snapshots in time with little sharing of common practices and information. Our research shows that 77% of organizations rely on periodic audits as the primary method to gain visibility into suppliers. Yet surprisingly, only 25% of organizations share common practices and information with suppliers, and only 3% have access to suppliers' data in real time.

IMPROVING OUTCOMES WITH ON-DEMAND VISIBILITY

To address these challenges, brand owners must implement strategies to provide on-demand visibility across every stakeholder in their supply network. On-demand-visibility would ensure that organizations could actually get the information they need in order to support full genealogy and traceability across the supply chain. A key component to this is the willingness of partners to share information. In an age when outsourcers are outsourcing, the chain gets longer and even more difficult to assess. As a result, brand owners need to treat outsourced organizations as an extension of their quality systems, so they maintain consistent standards across all sites. To achieve control outside the corporate walls, brand owners should deploy processes and systems that enable them to connect the dots and bridge the gaps, regardless of who made a component or ingredient, or where it was made.

A key business practice is for brand owners to require suppliers and partners to provide a complete batch-history record for the raw materials/components being delivered, instead of a certificate representing a snapshot in time. Batch records provide visibility into critical-to-quality parameters, facilitating the ability to adjust downstream processes.

To support this level of transparency, brand owners and their supply networks should collaborate to integrate rigid command and control systems (e.g. ERP [enterprise resource planning], QMS [quality management system]) with Web portals and cloud-based supply chain intelligence infrastructures. This approach would allow life sciences stakeholders to be able to take full advantage of tools such as scorecards, dashboards, and event management approaches to support global supply chain optimization, transparency, and control.

On-demand visibility strategies provide the ability to obtain relevant information about the life sciences product at the appropriate time to enable decisions with a high degree of confidence based on the analysis of contemporary data. This approach would provide brand owners the opportunity to improve quality and manage costs by enabling process optimization and adjustment of critical-to-quality in-process parameters within a design space. Maintaining on-demand visibility of upstream processes (whether internal or outsourced, local or global) allows downstream control strategies to take into account the actual characteristics of raw materials, ingredients, and components. This approach would support improved productivity, quality, and reliability, as well as foster innovation and facilitate regulatory compliance.

Daniel Matlis

Daniel Matlis is president of Axendia, a life sciences and healthcare analyst and strategic advisory firm. Matlis has more than 22 years of industry experience, having previously held positions with J&J's Ethicon division and Stelex.

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- Innovation in process development
- Confidence in both mammalian and microbial systems
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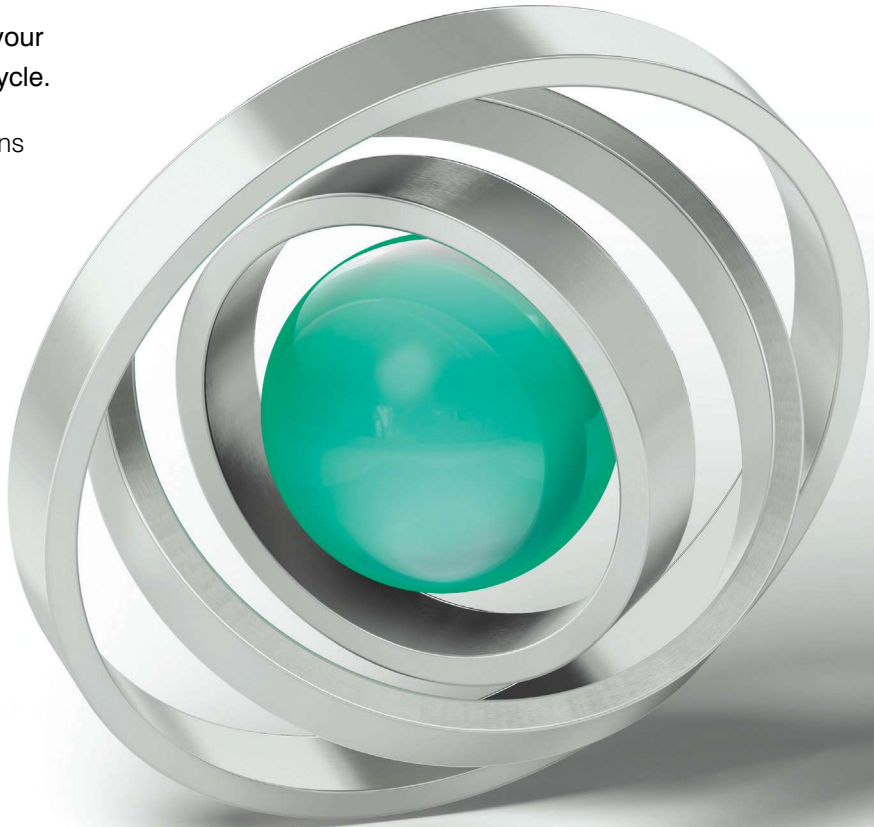

www.fujifilmdiosynth.com

3 Keys To Successful Life Sciences Partnerships

Life science companies like Epizyme increasingly rely on contract research and manufacturing organizations to achieve their goals. Whether a company is "virtual," "strategically outsourcing," or "capital light," its success is dependent on great partners. At Epizyme, we believe fostering and establishing long-term partnerships is essential to our goal of building a great company committed to discovering personalized treatments for patients with genetically defined cancers. As a venture-backed, private company, we have a mixed model of outsourcing where activities are developed internally, with the intention to find a partner organization that can execute those activities superbly and with precision. We believe that while successful execution may occur with many companies by setting clear goals and priorities, ensuring follow through, insisting on realistic deliverables, and rewarding the doers, there are very few companies where the journey together is a journey of mutual progress toward building greatness.

Building a great company requires a commitment to core values, and great partnerships succeed when all parties share core values. Jim Collins and Jerry Poras highlighted in their 1994 classic book *Built To Last* that visionary and successful companies were committed to "essential and enduring tenets" upon which the success of the company was built, even though those core values may sound nothing alike from company to company. However, there are common themes in all the tenets of the companies highlighted in *Built to Last*. Those themes are commitments to superior quality, unwavering reliability, and constant communication.

In the world of life sciences, where the output is improved quality or quantity of human life, those themes take on an even greater importance. Quality, reliability, and communication have to occur in every business relationship in the life sciences arena in order for both the client and the CMO to achieve their common goal of greatness, and for the suffering of human beings to be relieved.

"QUALITY IS NOT AN ACT, IT IS A HABIT." — ARISTOTLE

It takes energy to act. Habits occur almost without thinking. In a CMO, quality has to be so engrained that the company lives quality. The leaders of a company must set the standard for quality and habitually expect quality, not tolerating a "good enough" attitude. In some cases, the quality of the output is binary: the compound is made or not made, specifications are met or not met. In many cases, however, quality is more difficult to judge. For example, how many data tables should be checked to accept the entirety of a data set and the validity of the conclusions?

We assess quality from the first interactions with a company. Is the correspondence free of typographical or grammatical errors? Does the potential partner listen to how your team introduces themselves and then address them appropriately? While these things in and of themselves are trivial, they can reflect a company culture that accepts something as "good enough." If quality is a habit in the company, then it will pervade every interaction with the company.

Quality assessment continues through contract discussion and negotiations. Do the potential partners listen well, and do edits to contracts reflect the discussions? Are documents prepared accurately?

Robert Gould, Ph.D.

Robert Gould, Ph.D. is president and CEO of Epizyme, Inc., a privately held biopharma company. He has more than 25 years of research and management experience.

"A DOUBTFUL FRIEND IS WORSE THAN A CERTAIN ENEMY." — AESOP

Reliability and consistency are critical to enjoying the journey together. For an early-stage, privately funded company, the silent sound of time is the silent sound of money moving out the door. We therefore need the confidence from our partners that timelines can be met, and met reliably. Both parties must set realistic expectations for key deliverables both in quality and timeliness, but those have to be balanced carefully with the need for speed to move product.

"THE SECRET OF WAR LIES IN COMMUNICATION." — NAPOLEON BONAPARTE

How does a contract organization balance the drive for speed, set realistic expectations, and assure that quality specifications are clear and can be addressed? The answer is through frequent and regular communications. With the explosion of electronic communication capabilities like Skype, WebEx, or FaceTime, there can be no reason not to have direct and informed communication on the status of projects. Even the five-minute conversation that says "everything is on track" is important. Never assume with your partner that no news is good news.

FERRO | Pfanstiehl

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- Custom synthesis of Active Pharmaceutical Ingredients and advanced intermediates
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- Process validation
- Stability testing
- Test method development and validation
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- Drug Master File (DMF) development and maintenance

Working closely with clients ranging from virtual pharmaceutical companies to the world's largest multinational pharmaceutical and biopharmaceutical producers, we synthesize proprietary and commercial compounds in quantities ranging from grams to tons. Manufacturing and development take place within a 13-building campus located near Chicago, Illinois.

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Phone: 847-623-0370 | Toll Free: 1-800-383-0126 | Fax: 847-623-9173
Email custserv@ferro.com | www.ferro.com

FCPA Compliance For CMOs

In recent months, Pfizer and several medical device companies, including Johnson and Johnson, Orthofix, Biomet, and Smith & Nephew, were fined millions of dollars for violations of the Foreign Corrupt Practices Act (FCPA). The FCPA was also recently the cause for a potential SEC investigation of Teva Pharmaceutical. This recent increase in charges and fines against life sciences companies is evidence that the SEC and the DOJ are working alongside the U.S. Attorney's Office to uncover violations of the FCPA. It hence behooves life sciences organizations and their contractors, including CMOs, to be compliant with these organizations.

IMPACT ON CMOs

Violations of the FCPA can arise in multiple ways for a CMO. Specifically, CMOs, their employees, contractors, and/or agents are routinely required to deal with U.S. and non-U.S. governmental agencies. These interactions may occur in multiple ways, including (1) requiring routine for-cause or pre-approval inspections, and (2) working with politicians and/or government employees to obtain routine approvals. Potential violations of the FCPA can occur during these visits.

INSPECTIONS

CMOs often work on tight margins. Inspections by U.S. and non-U.S. governmental organizations can mean the difference between a large contract and shutting down business. As a result, during these governmental inspections, individuals within the companies may feel pressured to ensure a clean and clear record for a favorable decision. In foreign countries, where "facilitation payments" are part of doing business, bribes may be exchanged. In such situations, life sciences companies and their CMOs may unwittingly expose themselves to FCPA fines and penalties. It is critical to recognize that the actions of the CMO and its contractors and agents can expose not only the CMO but also its clients to fines and penalties under the FCPA.

ROUTINE APPROVALS

Working with government officials is often a routine part of doing business in several developing countries. Opportunities to work with these officials vary from the relatively innocuous (e.g. getting an "occupancy certificate" for a building) to getting approvals for drug products that were deemed safe and effective. These governmental officials are often the "oil" that prevents the machinery of government bureaucracy from slowing down business.

Being "welcoming" to these government officials is hence often treated as a usual cost of doing business. Such "welcoming" behavior varies from the minor — getting tea and small talk — to grander gestures like gifts during festivals and special occasions such as birthdays of not only the government officials, but also their family and friends. It is critical for CMOs that work globally to recognize that these behaviors, though "normal" for the country they do business in, may, without appropriate controls, expose their customers to potentially multiple millions in fines and penalties.

POTENTIAL INADEQUACIES OF CURRENT PROCESSES

Companies that are working overseas are now becoming wise to the potential violations of these laws and are beginning to require their contractors and affiliates to ensure that individuals who work with them do not violate FCPA requirements. These assurances are typically obtained via language inserted into contracts that are routinely signed by the contractors. Unfortunately, while this language may serve as a "brick" in the wall of taking appropriate preventative steps to avoid FCPA violations, it does not constitute the wall itself. A full compliance program requires not only mere language in a contract, but also the development of policies and procedures, including appropriate training programs, program audits, and appropriate corrective action mechanisms.

CMOs must take the threat of FCPA violations seriously. CMOs who undertake such an FCPA compliance program may be able to advertise such compliance and hence market themselves to potential life sciences clients as an "ethical" and compliant organization. Explaining the potential cost savings associated with such compliance could be lucrative for CMOs.

DISCLAIMER: *The opinions stated in this article are the sole and present opinions of Dr. Kulkarni as of the time of writing of the article in question. Such opinion(s) may change over time. This article does not constitute legal advice, and does not create an attorney-client relationship, and should not be construed as such. Please contact your attorney for legal advice that is appropriate for you.*

Darshan Kulkarni

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As the development of highly complex regenerative medicines continues to advance, the level of precision and quality necessary in all phases of manufacturing is reaching new heights. At Aastrom, our lead product candidate ixmyelocel-T is a regenerative, patient-specific cell therapy, which is developed using a proprietary production process. We depend on the availability of very high-quality components, including the bioreactors that are essential to the production process for ixmyelocel-T. We have identified the necessary steps to find the optimal CMO partner and to then work in collaboration with the CMO team at every stage to help them understand and meet our requirements in terms of product quality and precision.

Our team recently went through an extensive vetting process to identify a CMO to supply necessary cell development technologies. We also outlined a process to help the CMO team execute the tech transfer and then put into place a range of reporting and monitoring procedures to maintain the necessary levels of quality with our CMO partner.

KEYS TO SUCCESS: COMMUNICATION, SUPPORT, AND CLEAR INSTRUCTIONS

In the first phase of this effort, our internal team developed a comprehensive list of criteria for a CMO partner. We used this to create a short list of potential CMO partners and then individually reviewed the capabilities and experience of each. We toured their facilities and also talked with previous industry partners for insights on CMO strengths and abilities to work in partnership to set up systems and address challenges. We carefully evaluated the depth of experience of all members of the project team and conducted a company audit. In evaluating the project leader, we assessed strengths in several key areas, including communications, project management, validation, and quality control. We also asked the transfer team to review some recent examples of technology transfer and verified the results with end users.

Once we selected a CMO, we began an intensive technical review and training program to bring them fully up to speed. In this effort, we were able to work with a consultant who was a member of our previous CMO team. Based on the complexity of the bioreactor assembly, a clear and open line of communication with the CMO team was essential. We held weekly review meetings to monitor progress and to identify and address any problems early. We also invited the manufacturing team to Aastrom so they could see our production process first hand and fully understand and appreciate the impact that their work has in producing ixmyelocel-T.

Following this phase, we took several steps to make sure that our ongoing relationship with the CMO positioned us to work in an effective, long-term, mutually beneficial partnership. This includes establishing all procedures related to manufacturing and quality testing. We also outlined a strategy and provided all the resources necessary to address any changes to the team working on our program at the CMO and to keep our team at full strength in a transition. All quality issues were entered in both Aastrom's and the CMO's quality systems and were reviewed and tracked during our weekly meetings. Constant quality feedback is an integral part of our normal production process. Aastrom team members participate in evaluation of production anomalies, trends, and official reviews of changes in real time with the CMO.

Management of the CMO relationship is a very important function at Aastrom. We have two full-time engineers positioned to manage all aspects of our relationship with our CMO partner, including daily contact to review progress and address technical issues quickly. This close relationship enables our team to continuously work with the CMO to identify strategies to improve production and maintain all standards in quality. They also manage project lists to track all efforts to improve production.

In our experience, the keys to sustaining an effective CMO relationship in regenerative medicine are clearly defined requirements and expectations as well as the resources and support necessary to get the CMO team fully up to speed. This structure will promote the early identification of problems and rapid-response strategies to address them. We also recognize that both parties have a responsibility to focus on quality and to provide the other party with all of the support necessary to position them to do their jobs and meet their goals successfully.

Tod Borton

Tod Borton, VP of technical operations at Aastrom Biosciences, joined Aastrom in July of 2006 and has more than 25 years of product development, manufacturing, and quality experience in the domestic, international, biotechnology, and medical device industries.

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Collaboration Can Lead To A True Extension Of Your Own Supply Chain

Luc Ruelens

Luc Ruelens is the senior director for external supply integration, Asia Pacific, for Janssen Supply Chain in Singapore. He began his career in 1981, and has held various roles with increased responsibilities in chemical development, quality, new product introduction, and API external manufacturing.

Historically, most of the chemical synthesis (execution of chemical reactions to obtain a product) for active pharmaceutical ingredients (APIs) at Janssen were done in-house. In the past decade, however, Janssen has increasingly sourced a substantial part of the early synthesis steps for new molecular entities (NMEs) from CMOs — mainly located in Asia.

KNOWING WHAT WE WANT, COLLABORATING TO GET IT

In the early 2000s, Janssen was specifically looking for CMOs in Asia that had chemical synthesis and process development capabilities to make the chemical building blocks for complex NMEs. We were also looking for partners who could produce these building blocks in large volumes once the NME was approved. But most importantly, we needed to trust that we could develop the CMO into a reliable, flexible, and compliant partner for multiple products and under various business dynamics. We knew what we wanted, and we were ready and willing to collaborate to achieve it. The goal was to develop a few preferred partners for the early API synthesis steps in Asia.

TAKING COLLABORATION TO NEW LEVELS

One particular experience added a new dimension to how we at Janssen wanted to work with emerging CMOs in Asia. When we started working with Porton, a CMO located in Chongqing, China, it was for the supply of key building blocks for Janssen's HIV protease inhibitor darunavir, launched in 2006. We put forward the objective for this NME to have a cost-effective, high-quality, reliable product that we could offer at affordable prices to HIV patients. There were ample challenges, but Porton was confident it could deliver.

Initially, Porton's focus was on providing the supplies. However, both parties soon recognized the need to collaborate in multiple areas. Porton was looking at Janssen's expertise at implementing quality and environmental, health, and safety systems, as well as its ability to design, retrofit, and build workshops. So, it made sense for Janssen to dedicate a full-time person to work with Porton to develop a multiyear milestone plan where Janssen experts acted as consultants. Porton took full ownership and hired dedicated resources to quickly translate the consultancy advice and reach the next level of excellence as a capable and mature CMO.

When I look back at Porton's investments in capacity and capabilities, in attracting experienced leaders in multiple functional areas, as well as Janssen's focus on systems integration, it's clear that we came together as partners focused on a common goal. Our collaboration resulted in an integrated API supply chain with the upstream work being done by the CMO and the final API "assembly" steps being done by Janssen.

CARRYING LEARNINGS FORWARD VIA CUSTOMIZED COLLABORATION

More often than not, we've seen that partnerships with CMOs are strongest in the areas of technology transfer, building capacity, quality systems and cGMP deployment, environmental, health and safety support, and continuous improvement. But we have also observed that it can be challenging for Asian partners to interpret the best way to "create value beyond the contract" and proactively translate the knowledge into sustainable, effective, and autonomous actions.

As a result of our experience with Porton, which clearly demonstrated the value of strategic collaboration, Janssen is investing in the development of its CMOs to help strengthen their ability to strategically partner and collaborate. With the help of a consultant, Janssen has developed a program to aid our Asian partners to better understand and build specific organizational capabilities. The program includes a survey on how the partner perceives Janssen as a customer, a tool to define the partner's capabilities in the area of strategy and leadership development, communication effectiveness, organization and talent development, financial health, and finally, deep-dive strategy workshops for information sharing. The next step in the program is the addition of a competency model that can be used by the CMO.

Having now completed this program with a few CMOs in China and India, we often see that companies are able to target their investment choices as well as their talent gaps. What's more, company owners become more aware of their broader role as leaders and collaborators.

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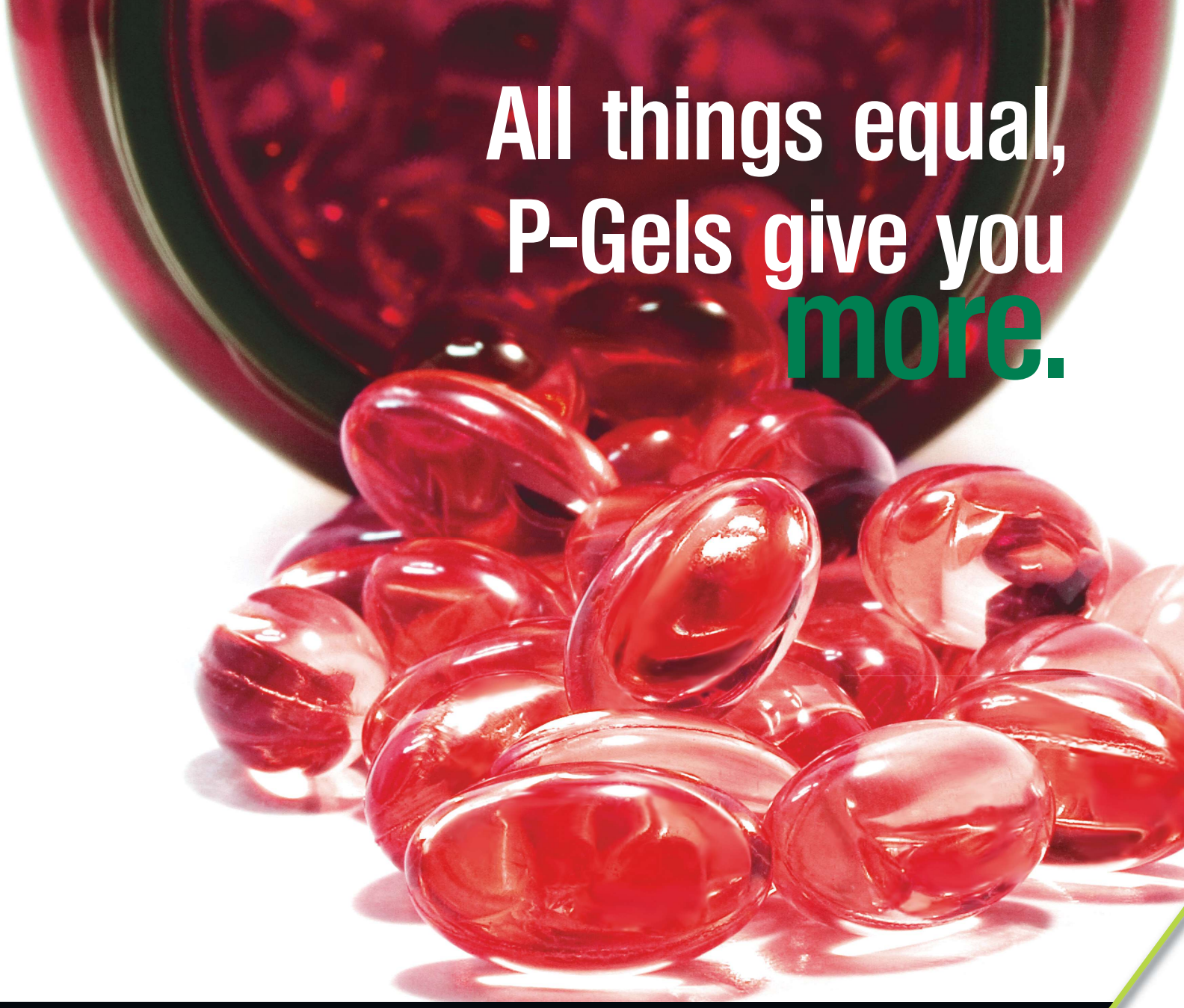

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