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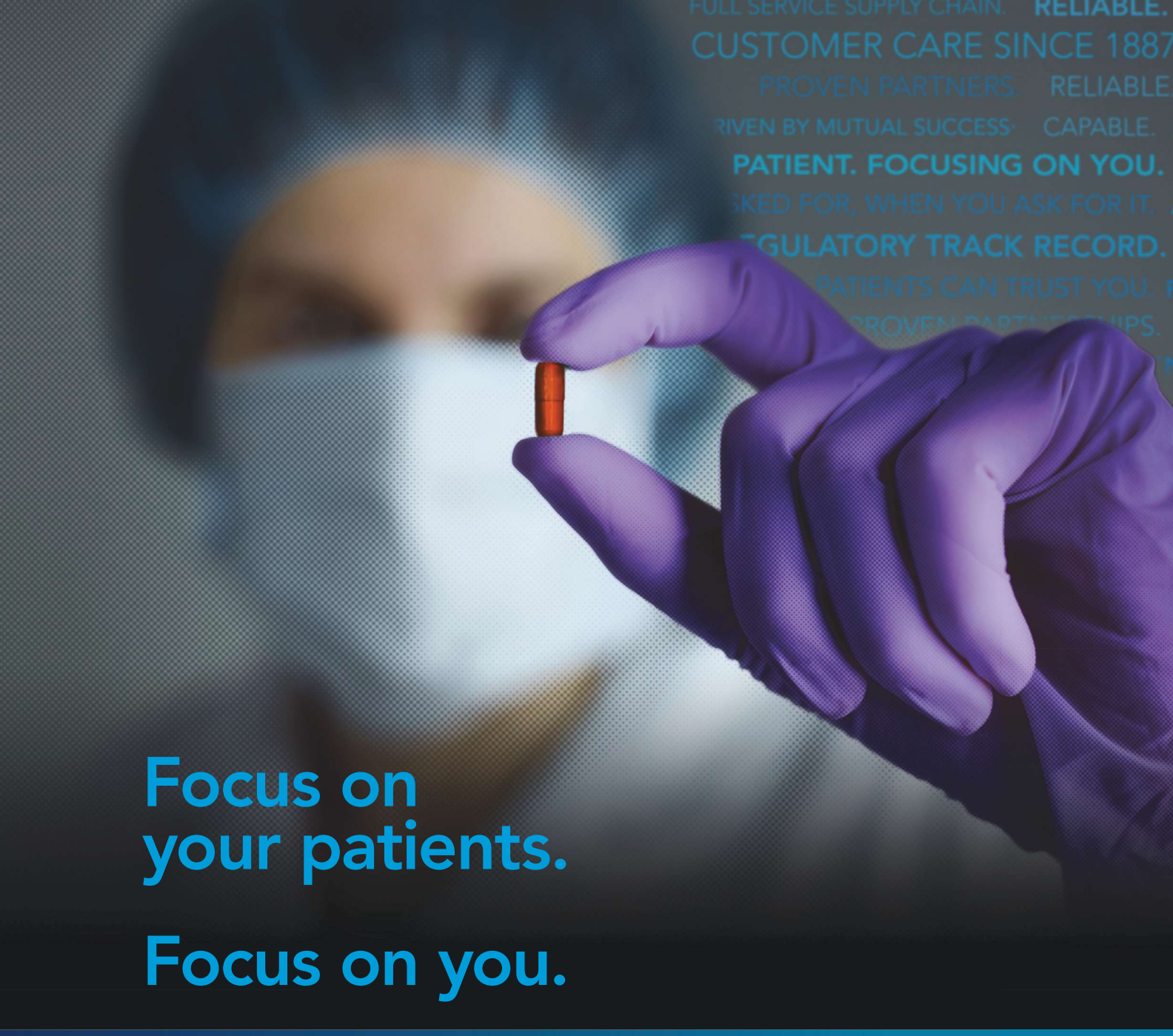
THE CMO LEADERSHIP AWARDS 2013

See which companies you and your peers picked as the top performing CMOs! p. 30



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Life Science Leader

The Significance Of Recognizing Excellence

Welcome to *Life Science Leader's* 3rd annual CMO Leadership Awards special supplement — recognizing excellence in pharmaceutical and biologic contract manufacturing. Unlike many other industry awards (e.g. Emmys, Oscars, Grammys), The CMO Leadership Awards are not a popularity contest nor are they determined by our writers and editors via a secret ballot (e.g. Motor Trend Car of the Year).

The CMO Leadership Awards were conceived as a means to better serve our readers — pharmaceutical and biopharmaceutical executives who indicated a high level of confusion regarding CMO selection approaches. Their feedback indicated a strong desire for information on what their peers think of a wide range of CMOs, to help them with the vetting and selection process. I am frequently asked how the CMO Leadership Awards are determined, so let me explain the process.

The awards are decided based on market research from Nice Insight in a manner similar to that of J.D. Power and Associates. Nice Insight annually surveys approximately 40,000 pharmaceutical and biopharmaceutical executives who are involved in the selection of outsourced services. This year's survey had more than 10,000 responses — a response rate of greater than 25 percent. Depending upon the survey, response rates can vary dramatically. An important incentive for respondents to participate is knowing that their opinions will be heard and action will be taken based on their feedback. This is why collecting responses, compiling and analyzing data to identify awareness and perception scores for CMOs serving the pharmaceutical and biopharmaceutical industry, and then "locking it up in a vault" simply won't do. Life science leaders want to know customer perception scores for CMOs. This year's winners rank in the top 20 percent in the following five categories — quality, reliability, innovation, productivity, and regulatory. CMO Leadership Award recipients can be recognized as being winners in one or more categories. Being a winner in one category is quite an accomplishment; winning in multiple categories is truly outstanding. This year, 8 companies were recognized as being in the top 20 percent in 4 different categories. Only 5 companies (Baxter, GSK, Norwich, Solvias, and Therapure) were recognized as being in the top 20 percent in all five categories. This is a truly remarkable achievement when you consider the award recipient pool is selected from over 100 CMOs worldwide. Congratulations to all of the 2013 CMO Leadership Award winners. Please mark your calendars for March 12, 2014, since that is the date when we will recognize all the winners at our annual CMO Leadership Awards ceremony in New York City.

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BIO INNOVATION NOTES

Client Relationships: How CMOs Can Avoid The Pitfalls

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

Outsourcing in the biomanufacturing industry is increasing, and biotherapeutic developers are starting to contract out activities previously considered too core or strategic. Competition has intensified among CMOs who are keen to respond to increased demand for their services. But how can CMOs best differentiate themselves?

Our latest study of the biopharmaceutical manufacturing industry (*10th Annual Report and Survey of Biopharmaceutical Manufacturers*) looks at the issues clients consider when outsourcing manufacturing to a CMO. Results from the study suggest that while technical expertise is obviously a factor, "soft" issues that surround communication skills and contract management are actually the crucial differentiating elements that clients focus on when evaluating potential partners.

We asked 238 biomanufacturing decision makers from around the world to assess the importance of numerous factors when making a decision to outsource to a CMO. The most common consideration, indicated by 94.7 percent of respondents to be either "very important" or "important," was for CMOs to offer a secure supply (control of capacity). Other common considerations included sticking to a schedule (91.2 percent), demonstrating a track record with similar products (89.5 percent), establishing a good working relationship (89.5 percent), and complying with the company's quality standards (85.9 percent).

On the other end of the spectrum, fewer respondents indicated that providing superior process development services, assistance in determining the value of capital avoidance, or "being local" were important considerations.

TOP DIFFERENTIATORS FOR CMOs

When it came to the most crucial differentiators, though, the rankings changed considerably. The top two factors viewed as "very important" by the most respondents were:

- Stick to a schedule (52.6 percent)
- Establish a good working relationship (49.1 percent).

It's interesting to see that while capacity control was most commonly cited by respondents as a general issue, it did not figure among the most important. This factor also seems to have become less important over the past few years after hitting something of a peak in 2009.

It's also worth noting that two of the top five most important factors relate to issues of communication. While those may appear to be "soft" factors, they strike at the core of these relationships, which are ultimately built on trust and a shared commitment. Each party has a stake in the outcome and must share in the responsibilities entailed. The prevailing sentiment in these relationships really needs to be that the contract and its associated negotiations are not the determiners of the relationship — it's the commitment and bond between the two parties that's most important.

Establishing a strong relationship allows both flexibility and a shared focus on a common cause. Benefits include improved time management, the most crucial consideration for most biomanufacturers. Clearly, formal agreements and processes do have to be in place – but when a good relationship has been established, the inevitable issues that arise can be better handled or avoided.

For CMOs seeking to differentiate themselves from their peers, fostering a reputation as an effective and cooperative partner can be just the nudge needed to sway a potential client's decision. The "technical" issues that are most important to clients should be part of a worthy CMO's expertise in any case. Obviously, everyone strives to avoid obvious patent infringement, and if a CMO did not practice "good intellectual business practice," it would not stay in business very long. The same could be said about complying with quality issues, these will clearly always be important to clients, but CMOs that cannot demonstrate a strong track record with quality issues are unlikely to last very long in the business. This is the ante required just to be in the game.

Another very important component of any customer-CMO relationship is that both sides must be flexible and cooperative, and make efforts to understand the perspective of the other party. This component will make itself evident during early conversations about the individual steps of the collaboration, when potential red flags can be identified and resolved.

This understanding of client needs appears to be lacking in the biopharmaceutical CMO space. Our study shows that many decision makers complain about a range of problems, including service suppliers' inflexibility and lack of responsiveness. Most CMOs claim to listen and communicate, but our data shows that these problems continue to top the list of relationship hurdles. Granted, this isn't universal, and many CMOs certainly listen to their clients' needs.

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For example, CMC Biologics recently purchased the XOMA Corp. facility in Berkeley, CA so that it could meet specific, emerging technical and equipment needs. According to Andy Walker, Ph.D., CMC's VP of process development, "We listened to our customers and determined that our acquisition of the former XOMA manufacturing facility will enable CMC to support some types of manufacturing processes which were not as easily supported at our facilities in Seattle and Copenhagen. In addition, being closer to some of our clients ensures we are providing the flexibility required for the relationship."

CMOs HAVE THEIR COMPLAINTS, TOO

Of course, it's not just the client that has issues when establishing or maintaining a relationship. We separately surveyed a sample of CMOs to see what they deemed to be the most common mistakes made by their biopharmaceutical clients.

The most commonly cited problem? Clients not communicating with them effectively. This was identified as a "very common problem" or "somewhat common problem" by every single CMO. Following that, a long list of the issues frequently mentioned by respondents included:

- "Clients don't build in sufficient time for the project (unrealistic timeframes)"
- "Clients want to contain cost by doing limited development runs but still expect successful full scale manufacturing"
- "Clients expect us to resolve the most difficult scientific or technical problems."

COMMUNICATION IS KEY

It's telling that two of the five most common issues cited by CMOs also relate to communication and scheduling. These appear to be real pain points on both sides of the coin — with the ability to screw up an otherwise solid relationship. Indeed, as the biomanufacturing contract manufacturing industry continues to mature, issues revolving around customer service and solid client-vendor relationships could become even more important, especially if CMOs find it difficult to differentiate themselves on the basis of non-negotiable issues such as quality compliance and IP protection. Ultimately, entering into a partnership requires trust and making a leap-in-faith that both parties will do things right and on schedule.

Figure 1: Selected Outsourcing Issues

Critical Issues When Considering Outsourcing Biopharmaceutical Manufacturing To A CMO, 2013

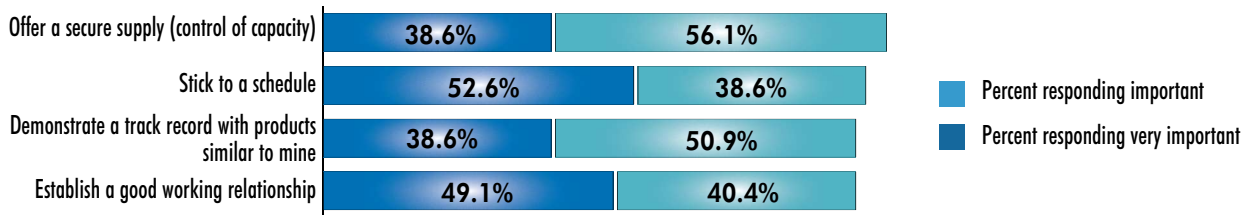
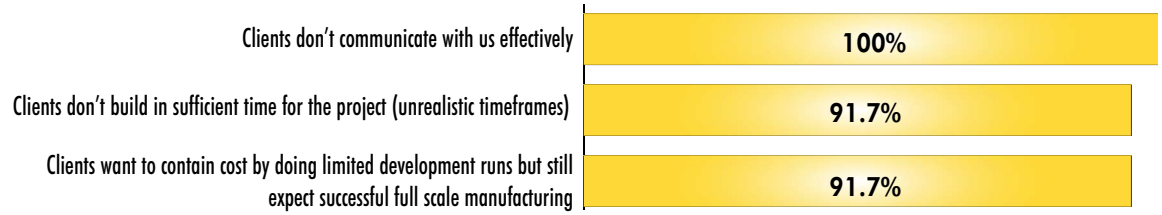


Figure 2: Most Common Mistakes Biopharmaceutical Sponsors Make With Their CMOs

"Very Common Problem" or "Somewhat Common Problem"



Survey Methodology: The 2013 Tenth Annual Report and Survey of Biopharmaceutical Manufacturing Capacity and Production yields a composite view and trend analysis from over 300 responsible individuals at biopharmaceutical manufacturers and CMOs in 29 countries. The survey included over 150 direct suppliers of materials, services, and equipment to this industry. This year's study covers such issues as: new product needs, facility budget changes, current capacity, future capacity constraints, expansions, use of disposables, 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.

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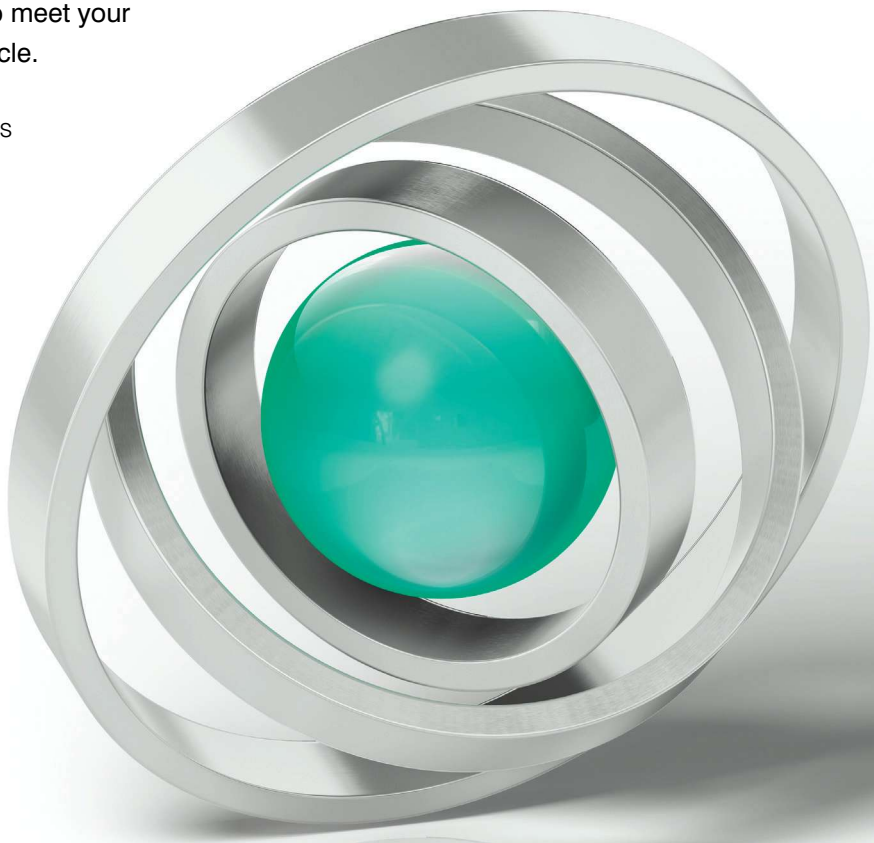

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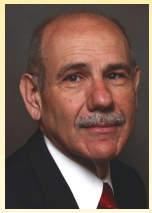
James Bruno


David Casebier


Llew Keltner


Heidi Kempinski


Michael O'Brien

Operational Excellence — The Solution To Rising Recalls

By Rob Wright

According to Frost & Sullivan's global pharmaceutical contract manufacturing market research, large pharmaceutical companies increasingly consider outsourcing manufacturing to CMOs because of the uncomplicated, timely, and cost-effective services these companies provide. And while the debate rages as to how big the market will grow over the next three to five years, one thing is certain — life sciences companies don't select a CMO in the hopes of increasing the number of products they can have recalled.

This past August, the Medicines and Healthcare Products Regulatory Agency (MHRA) recalled 16 drugs by one manufacturer after finding deficiencies at one of the company's factories in India. This was the second setback for Wockhardt, which had previously received an FDA-imposed import ban on products from one of its factories, which could result in lost revenues of approximately $100 million this fiscal year. This is not an isolated incident. For the first half of 2013, FDA recalls were higher for both pharmaceuticals (348, up 158 percent) and medical devices (726, up 40 percent) when compared to the same period in 2012. An increasing number of recalls occurring in the world's largest pharmaceutical market indicates the need for companies to take a closer look at their manufacturing operations, perhaps through the implementation of an operational excellence (OPEX) initiative. As a consequence, *Life Science Leader* magazine assembled a group of pharmaceutical industry veterans and posed a series of questions to gain their insights on OPEX in pharma/bio manufacturing. The group includes James Bruno, director, Chemical and Pharmaceutical (CAP) Solutions and past president of Drug, Chemical and Associated Technologies (DCAT); David Casebier, Ph.D. VP of chemistry, manufacturing and controls (CMC), Navidea Biopharmaceuticals; Llew Keltner, M.D., Ph.D., CEO and founder of EPISTAT and former CEO of Light Sciences Oncology; Heidi Kempinski, VP of pharmaceutical development and manufacturing operations, Tesaro; and Michael O'Brien, Ph.D., head of the pharmaceutical sciences & technology & innovation group and member of the pharmaceutical sciences executive leadership team, Pfizer.

WHAT ARE THE KEY COMPONENTS TO ACHIEVING OPEX IN BIO AND PHARMA MANUFACTURING?

James Bruno, CAP Solutions: We need to be looking at innovative ways to increase efficiencies and to reduce time and cost, as we are beyond the days of just handing projects over. This is a group effort which includes the sponsor as well as the CMO. It starts with understanding the problem, having clear goals and tactics as guidance, followed by an understanding of our capabilities and what is really critical in this area tied to well-defined outcomes and metrics. Start looking at incremental step improvements. Instead of a 20 percent or 30 percent increase in yield, perhaps look at 5 percent, followed by 5 percent more and so on. This will eventually net better growth and improvement.

Heidi Kempinski, Tesaro: OPEX involves achieving a level of quality beyond that required through compliance standards alone. A corporate-wide shift in thinking is necessary so quality becomes an imbedded part of the organization's culture. Fundamental components include gaining a deeper understanding of manufacturing processes, assuming risk-based approaches, and pursuing of continuous process improvement. As a result, one expects to see improvements in quality and safety, increased productivity in yields and cycle times, improved plant utilization and capacity, efficiency in compliance approaches, and lower utility and waste costs.

Michael O'Brien, Pfizer: The first step toward achieving supplier OPEX should occur at the vendor selection stage. There are a number of elements that collectively enable a robust assessment of the ability of an organization to provide sustained OPEX, including but not limited to, onsite due diligence visits, review of regulatory inspection, performance and financial records, and a "quality culture assessment." Through these mechanisms, we look for consistent reliability, demonstrated efficiency gains, reducing or holding down prices over time, structured efficiency programs (e.g. Lean, 6-Sigma, demonstrated quality by design [QbD] programs), and very importantly, senior leadership accountability.

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HOW WOULD YOU ASSESS OPEX IN AN OUTSOURCED-MANUFACTURING MODEL?

James Bruno, CAP Solutions: Having the same yields and few failed batches may seem like a good metric, but does it tell the real story? I consulted for a company that made over 1,200 batches of a product and had less than five failed batches in a year. While this sounded good, we could have increased the batch size with a minimal investment, reducing operating time and analytical costs. Since the process worked, no one wanted to make the investment. Two years later, they need to reduce their costs due to competition.

David Casebier: Navidea Biopharmaceuticals: I would look at the metrics of lag. The lag between manufacturing and release, release and availability of material for use in either a clinical or commercial sense, the delays that may be incurred on a plan due to material not being available, and material that is expired due to lack of use or inability to re-qualify. While just-in-time strategies are not what most CMC folks would advocate, it is important to manage supply for sufficient utility, as well as minimize an overstock of material for two reasons: potential expiry and needless expense brought forward (capital conservation).

Kempinski: This is challenging in an outsourcing model, given the corporatewide nature and multi-year commitment of attaining OPEX versus your limited view as a client. One can monitor the implementation of techniques such as Six Sigma which help provide overall methodologies and training for process improvement, process analytical technology (PAT) for identification of material, process, plant and release efficiencies, and overall equipment excellence to evaluate good production time versus total available plant time. Productivity is tied to capacity and quality systems and regulatory requirements, so metrics around inspection findings, deviation history, lead-times, cycle-times, unplanned equipment maintenance, plant utilization, safety issues, etc., can help provide insight to a CMO's progress toward OPEX.

O'Brien: We utilize a tiered approach to both the assessment and the management of our suppliers based on relationship categories, with basic and specialty suppliers low on the pyramid and collaborative and strategic suppliers at the top. The degree of oversight increases as we move toward the top of the pyramid. In general, our supplier management system integrates operations, quality and procurement and for top-tier relationships, mandates senior

management participation in governance and communication forums. Collectively, we develop a performance management process that integrates input from operations, quality, management, procurement, supporting groups such as EHS (environmental, health, and safety), and supplier counterparts. Key to the overall success of the collaboration is the Relationship Manager who focuses on a big picture view, is aware of day-to-day operations but not actively involved, and is the center of the formal communication matrix. Critical to quality metrics that clearly define whether or not a product or process is under quality control at all times, together with a periodic review and assessment of improvements based on audits and inspections, is important to the success of the model.

WHEN THESE AREN'T BEING ACHIEVED, WHAT STEPS SHOULD BE TAKEN TO RESOLVE?

Bruno: If you plan to implement some type of system (e.g. OPEX, Six Sigma, total quality) and the metrics that must go along with it, start with the people doing the work and make sure you get their input and gain their buy-in. Often the simplest solutions come from necessity and the workers know what that is. Understand the operation and the system and make sure that what you are trying to do makes sense for the factory and that the concept is carried forward from top to bottom.

Casebier: You need to improve projections and coordination with clinical/commercial. Get a better understanding and control of manufacturing projections and timing by modeling manufacture and distribution, as well as assess the duration assigned to activities in a timeline.

Llew Keltner, EPISTAT: Depends, of course, on the situation — but in a successful manufacturing campaign plan, virtually all of the responses to process failure should be built in at the initiation. There should be no doubt, in virtually every failure, of the response.

Kempinski: Ideally, the client and CMO are working in a collaborative partnership and a forum for discussing OPEX exists. Regular engagement with top management is critical. It is important to communicate your experiences to your CMO — both strengths and weaknesses — and share in the plan for continuous improve-

ment, including expected actions, timing and ongoing monitoring. It is useful to share your own objectives and drivers for cost reduction, increased productivity and real-time involvement in production planning and process data, and to similarly understand strategic drivers for your CMO. This common understanding enables both parties to assume responsibility for continuous improvement.

O'Brien: There are various indicators that can prompt a closer look at specific aspects of an operation, most notably, when issues arise that are not immediately communicated to the customer. Although oftentimes well-intentioned, when the vendor tries to fix a particular problem itself in order to avoid bothering the customer, negative consequences can follow. In our view, best practice is to communicate the issue immediately, while proposing corrective actions and/or a performance improvement plan in order to ensure that the right next steps are taken. When this process does not occur, the problem is often compounded, creating larger issues that could necessitate closing down the operation and shifting work elsewhere.

WHAT INITIATIVES SHOULD A CMO BE IMPLEMENTING TO ACHIEVE OPEX AND WHY?

Bruno: CMOs must understand their manufacturing processes and their capabilities. Looking at each step of the process and seeing what improvements can be made and how they can affect the outcome is critical. A 50 percent improvement in the yield may sound great, but if it makes a marginal improvement in the operation, I wasted my time and effort. The FDA is telling us today that if we have a better understanding of what we are doing, which means more work upfront, there will be a greater reward (ability to implement improvements quicker) in the end. What CMOs should have is reasonable targets with rewards for getting there and an understanding of what happened along the way. Sometimes we need to consider failure as success. Increasing yields or reducing production time may not be possible. Understanding this could yield benefits in the long run.

Casebier: Better estimation of resources needed for preproduction leads into scheduling of suite and plant time, as well as more surety of processes and simplification of procedures. CMOs tend to be confident and aggressive at the beginning of a project/relationship but become far more conservative and unwilling to push projects through as time goes on. Several I have worked with have what appear to be unnecessary bureaucracies and paperwork load.

Kempinski: Initiatives that bring client visibility in the following areas are desired: inven-

tory controls, quality management of materials sourcing, production plans and schedules, real-time production data, compliance findings, and risk assessment. Movement to automated data collection processes is important to provide the real-time access needed to engage in continuous improvement in quality, compliance, plant performance, etc. and to better afford the identification of true key performance indicators (KPIs) for ongoing monitoring. A set of shared continuous improvement initiatives needs to be defined and tracked over time; where practical, it may be helpful to benchmark against similar processes within the CMO or to processes placed with other CMOs.

SHARE AN EXAMPLE OF AN INITIATIVE BEING IMPLEMENTED EITHER EXTREMELY WELL OR THE CONVERSE.

Casebier: In general, the best implementation of programs or initiatives is accomplished by small, competent, and impassioned teams. I emphasize small, because once consensus of a large group becomes a priority smooth implementation and speed are lost. Focusing on the goal and how to get there is the most important aspect, as opposed to minimizing liabilities first. Being mindful of potential pitfalls is good, but the larger the group, the more focused on liabilities it becomes, either by the need for everyone to contribute something, or by statistical paranoia that emerges with a large enough population. What is needed is an important compelling vision combined with marching orders to technically competent people with a drive to exceed that vision.

Keltner: An API manufacturing process had failed at an outsourced manufacturer, primarily due to a tricky material testing and validation sequence for moisture control. The manufacturer was unable to suggest solutions, and setting up adequate communication was difficult, partially due to culture and language barriers. Another manufacturer was selected by the CMO. Both were located outside North America. To ensure that there was maximal likelihood of detection of process errors and maximal potential for interaction, webcams and web-enabled humidity sensors were mounted in the three critical manufacturing suite areas and available to staff 24/7 on any web-enabled device. On four occasions during the first API run, impending errors were detected and corrected before they occurred, likely saving almost nine months on the critical path to NDA submission.

Kempinski: At least one CMO I work with is engaged with Rx-360 whose stated mission is, "To protect patient safety by sharing information and developing processes related to the integrity of the healthcare supply chain and the quality of materials within the supply chain." Selection of vendors and the ongoing quality oversight required are highly time-consuming processes. Rx-360 has some interesting objectives to establish best practices for auditing standards and the use of expert third parties to conduct audits and authenticate supplies and suppliers. It is too early to categorize this as something being done extremely well or bound to fail, but it is a creative initiative that illustrates some progressive thinking toward improving the efficiency of quality management and compliance oversight of a global supply chain.

O'Brien: We recently implemented a new solution to increase our end-to-end oversight for distribution of clinical study supplies. Our prior model was highly decentralized and relied on local in-country Pfizer support to manage key importation activities such as brokerage services, import licensing, and duty and VAT payments/reclamation. Various factors prompted a re-assessment of this model, which resulted in the implementation of a centralized solution. Key factors for success in driving this change included aligning the ownership within our existing clinical distribution team and conducting a rigorous supplier selection process to ensure appropriate alignment of skills and expectations.

WHAT IS YOUR CMO DOING TO ENSURE SUPPLY CHAIN SECURITY AND INTEGRITY, AND HOW DOES THIS HELP IN ACHIEVING OPEX?

Bruno: As a consultant, I work with a number of CMOs. When you start the project and people are already thinking about what could go wrong and where problems exist, this is helpful and makes me more relaxed. Hearing people talking about equipment improvements and how they can reduce the operational time and increase throughput early on is helpful. I recognize that often you have good ideas which do not work.

Casebier: Never enough. We know that at the end of the day it is the responsibility of the sponsor to the Agency (e.g. FDA) for the drug. We expect qualification of the primary supplier and identification of alternate suppliers for raw materials and equipment. We expect this of ourselves for our own supply chain.

Kempinski: As the supply chain has gained increased dependence on sourcing from emerging regions such as China and India, some CMOs are working together on best practices as a means to obtain and share data regarding the quality and authenticity of supplies/suppliers. Many CMOs hire a local representative to help with vendor selection and real-time oversight, and others open a local office for building trusted relationships. OPEX improvements to control lead-time, process performance, and product quality cannot be achieved without trusted supplies. Additionally, a strong relationship between CMOs and supply vendors is critical to secure a compliant, cost-effective, and reproducible means to deliver quality products.

O'Brien: Of course, there is no higher priority than ensuring that consumers are provided safe and effective medicines. As such, we are relentlessly vigilant in our efforts to address threats to supply chain integrity, including counterfeiting, cargo/theft diversion, and economically motivated adulteration of products. We expect our CMOs to partner with us in these actions, and we constantly evaluate our CMOs to ensure that their processes, ranging from site security to core quality systems, are in place and aligned with these priorities.

HOW SHOULD A CMO BE AUDITING SUPPLY CHAIN SECURITY?

Bruno: The loss of material in the market can be a real disaster for companies and patients. Companies need to audit their supply lines on a regular basis. The audit needs to be looking at the complete supply line as well as the regulatory history of the company. I looked at this as a typical "risk/reward" situation. How great is the risk for each of the raw materials and how can I minimize that risk? Could anyone really predict a volcano erupting and the effect it had on shipping from Europe? Both sides need to understand the risks and how to mitigate them.

Kempinski: FDA and EMEA have issued guidelines for risk-based approaches in auditing, qualifying, and monitoring suppliers to assure the integrity of supplies. CMOs should follow these guidelines and tailor an approach based on material criticality, experience with the material and vendor, and compliance history. Based on these categories, audit formats can range from paper surveys to on-site inspections. Material acceptances can transition from a repeat of full release testing to acceptance based on certificate of analysis (CoA), and a one-to-three year audit frequency. It is important for CMOs to stay abreast of emerging trends that may compromise supply chain safety or security.

O'Brien: Methods and frequency regarding auditing practices are specific to a given scope of work being conducted by a CMO. On a macro level, we support serialization, electronic pedigree, and track and trace as important safeguards to the pharmaceutical supply chain. Success in these areas requires extensive and open partnerships across the industry (e.g., between pharma companies and CMOs) and more broadly with wholesalers, the pharmacy community, regulations, and law enforcement agencies.

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WHAT'S THE BIGGEST CHALLENGE FACING PHARMA AND BIO MANUFACTURERS, AND WHAT SHOULD A CMO BE DOING TO ADDRESS/MANAGE IT?

Casebier: Cost containment and time management. Accurate estimation of supply costs as well as the ability to schedule and project product availability are critical aspects for a virtual company like ours. While the adage that time is money may apply, I would rather have an accurate timeline for deliverables to plan with than an optimistic timeline that could potentially cause program issues when it is late.

Keltner: I believe the biggest challenge is changing regulations. There are many sources of change in regulations which can affect manufacturing process and flow — all geographic political jurisdictions as well as federal agencies like FDA, EPA, OSHA, and HHS. The CMO needs to have an internal or external resource to warn of upcoming changes which could affect processes in any way. This is hard to do on the local scale, but absolutely necessary. I once witnessed a change in a city's smoking ordinance shut down a critical commercial finished product facility for almost two months, putting the drug in very short supply and causing years of reputation problems for the seller.

Kempinski: Flexible access to capacity and technology is one of the biggest challenges facing pharma now. Important trends in the industry are: 1) continued needs to build Lean organizations, leading to increased dependence on outsourcing, 2) a desire to work with fewer, quality partners, putting pressure on CMOs to offer more capabilities across the entire development life-cycle versus a focus on early-stage or late-stage, and 3) a transition to lower volume, specialty products. CMOs must be thinking and acting strategically with their clients to understand how needs are evolving and where focus is needed over the long-term.

DO YOU THINK MANUFACTURING INITIATIVES ARE CRITICAL TO ACHIEVING OPEX, AND IF SO, WHICH ONES?

Bruno: I think that QbD (quality by design), if properly implemented and designed, will be a major help for achieving OPEX. Truly understanding the space that we work in and the risk that we face in these areas is critical. It should give a true picture of what we need to do and if not with a bias, give us areas of improvements which will lead to OPEX and, more importantly, lower cost.

Casebier: QbD is something that makes sense in light of the philosophy that quality cannot be tested into a product. This means understanding the process and having sufficient knowledge of manufacturing plant abilities and limitations such that both the sponsor and the CMO know the critical parameters of the process as they apply in that particular manufacturing environment.

Keltner: No. A good CMO can logically plan and determine best methods to get a campaign done. Outsourcers are well aware — if they are any good — of the best methods for optimization and efficiency. Lean and other "initiatives" are just rigid codifications of logical campaign planning and should never be needed if the right people and methods have been put in place and common sense is being exercised on a constant basis.

Kempinski: OPEX cannot be achieved without a systematic, corporatewide approach. Initiatives such as Lean or Six Sigma can be instrumental in building a foundation of methods and training to support continuous improvement, but more scientific initiatives such as QbD are critical to afford further progress. QbD facilitates a closer collaboration between development and manufacturing earlier in the product life-cycle, and affords better long-term results through continuous monitoring and improvement goals. The FDA has embraced QbD as a means of assuring product quality.

O'Brien: We are committed to the application of QbD principles and Lean in both development and manufacturing. We have demonstrated the value of these programs in quality, cost and efficiency metrics and consequently have reduced our business risks. When problems arise, this science-based approach better positions us to more quickly understand causative factors and develop corrective action or risk mitigation strategies.

WHAT ROLE DO SUSTAINABILITY INITIATIVES PLAY IN ACHIEVING OPEX, AND WHAT SHOULD YOUR CMO BE DOING AND WHY?

Bruno: Today, technology is changing more rapidly than in the past. If you do not take advantage of these constant improvements, you cannot sustain and grow your business. You cannot sustain growth simply by cutting costs. You need to make improvements and operational improvements can go a very long way to improve overall profitability and reduce cost. If you look at the CMO market today and our competition with lower cost countries like China and India, we can only maintain our businesses by constant improvements and by innovation. Increased yields, lower energy and waste costs, as well has higher throughputs, can negate the low labor rates of these regions.

Casebier: I believe that these are orthogonal issues, not necessarily inclusive or exclusive. The most important aspects of any drug are the safety, quality, and efficacy of the agent. Imposing sustainability initiatives in principal onto a process without understanding the precise impact is not a good idea — especially if done at the outset of the program, because one is implicitly endorsing the potential compromise of quality for an orthogonal property. If the process is well understood and the

sustainability initiative does not impact the final quality, then I am entirely for it.

Keltner: I don't believe sustainability initiatives have anything at all to do with OPEX. They are simply politically necessary and so have to be logically included in corporate and campaign planning. CMOs need to be aware of both the regulations and hot buttons in sustainability and be able to balance the inevitable additional cost with the costs of legal actions or bad PR. This is not to say that sustainability initiatives are bad — they are just quite separate from efficient drug manufacturing.

Kempinski: With cost-reduction pressures, it may seem attractive to take short-term decisions to reduce/delay spending in areas such as training or waste management, or select a supplier based on cost; unfortunately, all can lead to long-term challenges that work against OPEX objectives. Sustainability initiatives can broadly impact social, economic, and environmental outcomes for players across the supply chain. CMOs could follow the route of the Pharmaceutical Supply Chain Initiative (PSCI) to establish an alliance for responsible supplier business and environmental practices. Examples of smaller initiatives I am aware of include the use of solvent recycling, movement to reusable packing and temperature monitoring devices, and the use of green power sources.

O'Brien: In today's competitive business environment, the benefits of sustainability initiatives are key to improving business processes and operational efficiency. There are obvious cost savings that come from reducing energy and/or water consumption, all of which can contribute to company profitability. OPEX principles (continuous improvement, optimizing processes, etc) go hand in hand with sustainability initiatives. Be it developing new chemical entities or optimizing current processes, optimizing/minimizing such things as solvent volumes, reagent stoichiometries, reaction temperatures, processing times, and the like are critical. Similar sustainability initiatives, when employed by CMOs, can offer the same business benefits and a competitive advantage. In addition to the cost savings associated with continuously optimizing processes and reducing waste, CMOs are more likely to be regarded as highly ethical and a partner of choice. CMOs should embrace corporate sustainability and work closely with partner companies on these types of initiatives.

For additional insights on this and other outsourcing topics, go to www.outsourcedpharma.com.

Don't "Second-Class" Suppliers

By Wayne Koberstein, executive editor

When is a supplier more than a supplier? When it goes beyond simply supplying a needed product or service and leads its clients toward a more innovative future. In the life sciences industry today, if you search for innovation, more often than not you find it on the so-called supplier side.

Regular readers of my articles and blogs will likely hear an echo of my previous piece on the issue of suppliers vs. partners. But here I am concerned instead with the positive role of vendors, whether or not they claim partnership status with their clients. Perhaps you have seen the cable series "Life After People"; imagine this industry without its suppliers. How innovative, in any respect, could it be?

A fellow writer for this magazine, Eric Langer, recently delivered a wealth of examples that illustrate my central theme, in "CMOs Leading The Way In Biopharma Innovation — No Herd Mentality," (June 2013). Langer's main point was that the bioprocessing suppliers he cited offer a wide diversity of new technological approaches, thus maximizing their innovative value. If not for their inventiveness, biopharma plants would still look and function pretty much like traditional breweries, perhaps with less charm. Similar CMO-led innovation is operating, though perhaps not as effectively, on the small-molecule side.

CMOs make good examples of innovation, but they cannot by themselves represent the entire universe of suppliers in this industry. Their closest reflection is the CROs, but in the precommercial space so many other, often tiny, suppliers and supplier types exist. For many of the smaller vendors, their entire purpose amounts to innovation — pushing clients to adopt entirely new technologies, methods, and even organizational structures. They offer leaps forward in critical areas such as predictive toxicology, clinical trial design, patient segmentation, and, yes, new production tools.

Renaissance Capital's Linda Killian, in a conversation partly shared in my latest editor's blog, commented on a company that deserves, but has not received, the kind of financial support currently going into "hot" sectors such as cancer and liver disease. Cellular Dynamics is developing a possible advancement in preclinical, *in vitro* testing using its human stem-cell technology. "The company is certainly not as sexy as the life sciences companies that are developing treatments, but it may be one of the companies that is developing tools that will allow better predictive ability for clinical trials," she said. Though the "medical need" for better prediction of trial outcomes is significant, in this case lack of respect for a so-called supplier has apparently translated into a less-than-stellar IPO; as of press time, Cellular Dynamics' stock price has remained nearly flat.

Where and when did this stratification of industry players begin? I mean "industry players" in the sense of what drug sponsors and their suppliers have in common: They are all enterprises contributing to the development of new medicines, diagnostics, and devices designed to treat and, if possible, cure every disease known to humans. Then what is the critical factor that distinguishes one from another?

Sales. That is the factor. If your company is selling goods or services to another, your company is the other's supplier. You may be bigger or smaller, older or younger, more or less advanced in experience and technology, but the other company is your customer, and you must sell to it. Ask any salesperson, "Who holds the dominant position in such a conversation? Which one is always right?"

CHANGE THE VIEW, CHANGE THE GAME

I love to state the obvious, because it is precisely the obvious that people like to ignore. Here, again, is an echo of the supplier-partner dichotomy: Who handles your account on the other side — business development or procurement? At best, say when the procurement officer has enormous respect and consideration for you, your relative positions are unalterable inside such a structure. Only a miraculous conversion by the sponsor could change things. Face it.

But if suppliers sometimes chafe at the bit, effectively stifled from sharing — okay, selling — their best stuff while stuck in an obsequious posture toward clients, is it any better for the clients? The answer is clearly no; in fact, it may be worse. When the client is a drug sponsor, the lost-opportunity stakes are much higher. The supplier stands to lose some business, perhaps only in its most avant-garde wing, but the client could lose everything by forfeiting a critical advantage that might have made all the difference to its success or failure in development.

No company or supplier is likely to share

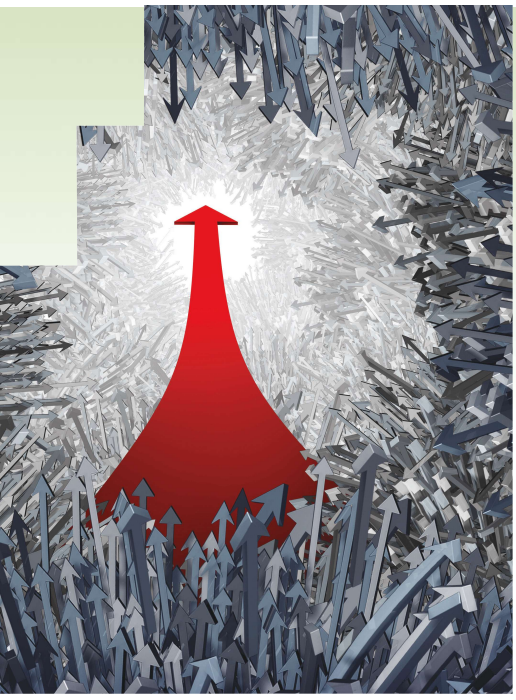
the details of a lost opportunity, so I will attempt to elaborate on my point with some hypotheticals. Consider the case of "Hypothetical Pharma," a drug sponsor, and Pretensin, a leading CMO. HP relies on Pretensin for both API and finished product for its novel drug in development, a potential blockbuster for neuralgia. Pretensin executives attempt to approach HP about a new technology for producing high-potency, ultra-pure formulations and bulk runs of compounds in the same class as the sponsor's product.

It starts with its chief contact at Hypothetical — yes, the procurement officer (PO) — who, unlike many other POs I'm sure, thoughtlessly assumes the CMO just wants to expand its business by selling "accessories" to its main line. As a result, the connection short-circuits, either because Pretensin's offer goes no further in HP or, when it does reach an executive who could make a decision, that person sees no reason to proceed. A year later, the drug washes out of clinical development because, at the purity and potency possible with existing technology, the sponsor fails to find a satisfactory dosage.

You could play out the same or a similar scenario substituting other suppliers and supplier types for the CMO; namely, drug-delivery, formulation, equipment, and so on. But the point in every case is simply this: The sponsor missed the boat because of an institutional bias. Like the "racially blind," it did so without seeing its own prejudice or learning anything from it. Yes, this really is discrimination, folks, and not the kind practiced by wine tasters. It is destructive (of opportunity), and it is costly.

The only lasting difference you could make in all this, however, is not by changing the players but by changing their minds. We don't treat doctors like servants just because they serve us. An alternate universe of opportunities could arise from a simple exchange of passive disinterest to active pursuit of innovative solutions developed by organizations outside the sponsor company, whether we call them contractors or partners or just late for dinner.

Suppliers are not second-class citizens. When they lead rather than follow, when they take steps forward not just give support, when they offer bold innovation instead of blind iteration to their clients, suppliers deserve a higher measure of credit. If not for them, this industry would feel little pressure for change from within, and its total reliance on R&D for innovation would wither because every other function it depends on — manufacturing, clinical research, preclinical testing, and more — would simply stand still, trapping industry in the past.



How To Solve High-Impact Problems In Pharma

By Mark Moody, VP of Analytical Science, Merrimack Pharmaceuticals

Biologics manufacturing is complex, and it's worth remembering that this complexity provides many opportunities for bad things to happen – with big consequences. At some point most biomanufacturing companies will have to deal with these sorts of problems, and a successful response to "big problems" requires effective leadership to direct the focused and coordinated efforts of many people in the organization.

Viral contaminations of bioreactors are rare but are high-impact events that illuminate the key factors of a successful response to big problems. Although often unreported, some of these contaminations have made the headlines, illustrating the potentially severe consequences from these types of events. First, there is a potential risk for patients, if not a direct risk from the virus, then from the indirect impacts of drug shortages. Second, there are the risks to the company. Dealing with the contamination can shut down production, divert the focus of employees, and lead to difficult conversations with regulatory authorities and investors.

THE PATH TO SUCCESSFUL RESOLUTION

In 2009, Merrimack Pharmaceuticals experienced a viral contamination, and the lessons learned from successfully resolving the problem demonstrate that, at a high level, there are three factors that can affect the problem: the quality systems that guide and document the work, the science and technology that can identify the root cause and mitigate risks, and most importantly — the people in the organization and how they work together in high-stress situations.

There has been much written on the subject of risk assessment, mitigation, and corrective and preventive actions (CAPAs). And while there are variations on how companies organize these processes, it is very important to follow the systems that your QA department has in place, as the FDA has issued many warning letters for not following established procedures. We have developed an integrated approach of emergency response, risk analysis, root cause determination, and CAPAs. This system utilizes tools such as failure mode and effect analysis (FMEA) for the multidimensional analysis of the risk to patients, the risk to the environment and the community, the impact on the drug supply, and the impact on the company. This analysis needs to be revisited and updated as new information is learned.

It should be noted that, due to different perceptions of harm and different knowledge of the facts, achieving a shared understanding of risk among diverse stakeholders is difficult. Reaching the most accurate understanding — and not a "consensus" assessment — is vitally important. This leads to a strategic question: Who should be on the response teams? With high-impact problems, there can be a desire to include all the stakeholders, but it is often better that the team that guides the response be limited rather than inclusive. If too many people are included who are not functional experts, the team will spend a lot of time on education, or worse, get led down the wrong path. It is important to keep all stakeholders informed, but they don't need to be part of the process of working toward a solution. The key factor when setting up the teams is to emphasize expertise.

Merrimack's core team consisted of fewer than a dozen people representing QA, manufacturing, quality control, clinical, and regulatory functions. An honest and systematic evaluation of the knowledge and experience of the team will identify any gaps, which can be filled with knowledge from consultants and guidance from professional associations. This assessment led Merrimack to include a consultant virologist who had worked on similar problems at other companies. Additionally, the teams should include skilled facilitators to help the team stay focused and ensure good chemistry among the team members while they work through this high-stress event.

While the teams are being assembled, it is essential to gain a commitment from senior management to empower the teams to carry out their work. A clear system for decision making should be outlined to determine who has responsibility and authority, and a communication plan should be developed to clarify what is communicated, when it is communicated, and who gets the information. Proactive formation of an emergency response team and development of a generic response plan will increase the likelihood of a quick and successful resolution.

Finally, everyone involved — the teams, the stakeholders, and senior management — should approach the problem with a positive attitude and the understanding that a properly supported team will reach a successful resolution.

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SOUTH AMERICA

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EUROPE

6. **Ireland:** API, Solid Dose
7. **UK:** Antibiotics API, API, Steriles, Clean Liquids, Solid Dose Antibiotics, Liquid Dispensing Technology, Liquids, Topicals
8. **Spain:** Clean Liquids, Solid Dose, Inhalation
9. **France:** Solid Dose Antibiotics, Inhalation, Liquids
10. **Italy:** Steriles, Sterile Ampoules, Clean Liquids, High Containment Sterile, High Containment Solid Dose, Sterile Antibiotics

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11. **Singapore:** Antibiotic API, API
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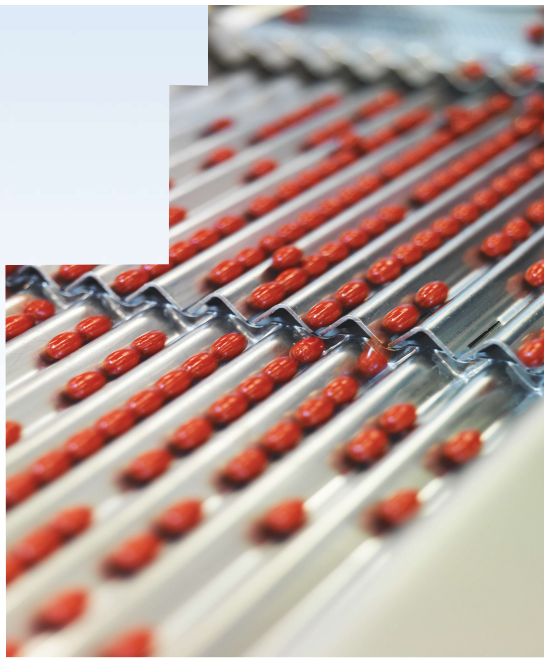

By Thomas Friedli and Daniel Bellm

The history of operational excellence (OPEX) in the pharma industry is short. Since the first serious initiatives were launched at the beginning of the 21st century, OPEX gained momentum and became a priority at all hierarchies in pharma manufacturers all over the world.

Simultaneously, the science of pharmaceutical manufacturing appeared on the agenda of the FDA. As a reaction to a continuously rising number of post-approval changes, the FDA started to push the industry toward developing a scientific understanding of pharmaceutical manufacturing processes and encouraged manufacturers to use innovative technologies like PAT (process analytical technology) for better process control. As a result, quality and productivity appeared on the agency's agenda, providing the industry with new opportunities and opening the way for OPEX. The incremental introduction of OPEX in the pharmaceutical industry happened in three major stages.

To date, there is no clear-cut definition of the term operational excellence. In fact, the term itself is often used for newly launched improvement activities or as a proxy for cost-cutting programs, Six Sigma, and Lean initiatives, all of which contribute to its dilution over time.

OPEX should be understood as the balanced management of cost, quality, and time while at the same time focusing on the customers' needs. To achieve these ends, OPEX comprises structural and behavioral changes thought to optimally support necessary activities. In order to maintain sustainability in changing or volatile environments, OPEX has to be pushed by top management and has to be designed to engage every employee. Obviously, OPEX is not only concerned with performance. It also encompasses the way leading to superior performance and to practices that allow an organization to continuously improve itself.

LAUNCHING AND MAINTAINING OPEX

The focus of managing an OPEX initiative has to change over time. Awareness of critical success factors and barriers in managing OPEX can provide guidelines as to how to design, review, and adapt an excellence program. Obviously, launching an initiative and introducing a company to continuous improvement addresses another set of managerial capabilities rather than maintains a system in a steady state. After the effective launch of an OPEX initiative, management will need to change. However, this does not imply disregard for the factors that were once relevant for the initiative's successful take-off. They should be further stressed but complemented by paying attention to new challenges and utilizing upcoming opportunities.

An OPEX initiative has to be aligned with a company's overall manufacturing and supply strategy. Consequently, in accordance with a constantly changing environment that an organization is exposed to as well as with changing maturity levels of manufacturing sites and the initiative itself, a time-based adaption of OPEX programs along with their focused priorities is required.

PROFESSIONALIZING AND EMBEDDING OPEX

Just as an organization changes over time, so too must the embedded OPEX organizational structure be developed and revised. Organizational subdimensions will require an adjustment at the right time in order to accelerate the sustainable implementation of OPEX.

Literature lacks evidence of the right structure and a guideline for practitioners as to how to optimally staff an OPEX initiative either on its launch or in its maintaining phase. Every company, however, needs to develop its own specific organizational model, including the right structures, in order to ensure a reasonable division of labor and to facilitate productivity and efficiency gains.

Despite the pharmaceutical industry discussing product and process optimization for more than a decade, predominately these discussions are still following a single plant perspective. The coordination of pharmaceutical manufacturing sites on a network level holds enormous potential. Therefore, the industry will have to follow the example of other more advanced manufacturing industries and systematically address production optimization from a true network perspective in the near future.

About the Authors

Dr. Thomas Friedli is a member of the faculty of the Institute of Technology Management at the University of St.Gallen (HSG) and leads a team of 14 researchers as head of the chair of production management.

Daniel Bellm is research associate at the chair of production management of the University of St.Gallen, and, as group coordinator responsible for the topic "Operational Excellence – Pharma."

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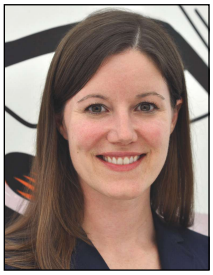

OUTSOURCING INSIGHTS

With Outsourcing On The Rise, Why Isn't Strategic Partnering Getting Easier?

By Kate Hammeke, director of marketing intelligence, Nice Insight

Since Nice Insight's first pharmaceutical and biotechnology outsourcing survey almost four years ago, the data has shown a steady incline in outsourcing. This comes in many forms, from increased outsourcing expenditure, higher percentages of respondents outsourcing various manufacturing services, reported increases in the number of projects outsourced each year, as well as the number of unique services outsourced. These changes reflect a shift in thinking as well. Not long ago, outsourcing elements of drug development was thought to be an option, one that could help reduce fixed costs and expedite time-to-market. But now, as 2013 winds to a close, outsourcing some aspects of drug development is virtually a requirement.

As this practice evolves, the desire for stronger relationships moves front and center, especially since trusting a third party with your compound/product can be both anxiety inducing and tricky — particularly when it is a first time collaboration between two parties. So how do you know which CMO to select for a project, let alone a long-term partnership? Fortunately, research shows that the time when the bidder with the lowest price would win the project was short-lived, and other metrics now take priority over affordability. In fact, only nine percent of respondents who outsource small molecule manufacturing said they select the provider with the lowest cost from their shortlist. Thirteen percent who outsource biologics manufacturing indicated the same.

Additionally, affordability dropped in rank from third position in the 2011 to 2012 study to fourth in the 2012 to 2013 research. Make no mistake, it is a good thing that price isn't the most influential deciding factor for CMO selection, as cost-based bidding wars are dangerous for patients, scientists, the environment, and others. When companies try to slash costs to win projects and still turn a profit, the corners cut can put us all at risk — not just the project at hand. Furthermore, strong relationships — an essential basis for strategic partnerships — don't usually form on an unbalanced foundation, where one party wins a great bargain and the other barely covers its expense. After all, when you collaborate, both parties receive value beyond the exchange of goods or money.

While various businesses have varying approaches to outsourcing, Nice Insight research shows that across all buyer groups there has been an increase in the percentage of respondents who expressed they are "very interested" in forming strategic partnerships with CMOs, up 8 percent from 24 percent in 2012 to 32 percent in 2013.

One of the key challenges we have observed in the industry is the absence of a set of hard traits, or quantifiable characteristics, that define the nature of a strategic partnership between a drug innovator and a CMO. Instead, strategic partnering tends to be outlined by a collection of softer traits, or nonmeasurable characteristics that impart a feeling rather than checklist facts.

THE FIRST STEP TOWARD A CMO PARTNERSHIP

The absence of hard traits can cause some issues when courting potential partners or frustrations when working with a company that was well reviewed and referred from a colleague who had different expectations and needs from their outsourcing relationship than your company. Thus, the first step in identifying potential CMOs for a strategic partnership is to establish a clear explanation of the goals of the collaboration, and then detail how these goals are different from the goals of a tactical or preferred provider relationship. When Nice Insight surveys buyers of outsourced services, we present the concept of a strategic partnership accordingly: a long-term, win-win commitment between two organizations for the purpose of achieving specific business objectives by maximizing the effectiveness of each participant's resources. This can serve as a starting point, but once the shortlist of suppliers has been established, it is crucial to fill in those "specific business objectives" with explicit and measurable milestones. The same goes for the resources each party will bring to the relationship, and gaining an understanding of what it is going to take for each party to consider the relationship a "win" is essential.

After identifying your company's goals in forming a strategic partnership with a CMO, opt for referrals from industry peers who share a similar ideology on outsourcing. If your company uses consultants or has

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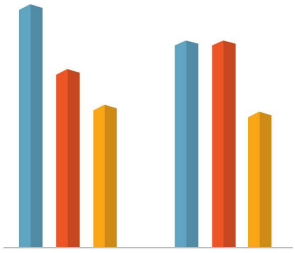
procurement staff, it is important to share the outsourcing objectives and goals so that everyone is working toward the same purpose. Laying the foundation for a true collaboration, which contributes to an environment of mutual giving, is where long-term savings will develop.

Then, it is time to seek out information on CMOs to see which companies may align with those goals. Start with investigating how the company is perceived in quality, reliability, regulatory track record, productivity, and innovation.

Annual Outsourcing Expenditure:



2011-2012	2012-2013	Change
43%	38%	↓
31%	38%	↑
25%	24%	↓

- Less than 10 million USD per year
- 10 to 50 million USD per year
- 50+ million USD per year

Average number of services outsourced by company type:

Biotech / Biologics	Emerging Biotech / Biologics	Specialty Pharma	Big Pharma	Emerging, Niche or Start-Up
2011-2012 4.03 ↑	'11-12 5.24 ↑	'11-12 4.26 ↑	'11-12 4.01 ↑	'11-12 3.88 ↑
2012-2013 4.90	'12-13 5.40	'12-13 5.00	'12-13 5.70	'12-13 4.00

Services Outsourced:

	2011-2012	2012-2013	Change
Chemical Synthesis	19%	24%	5%
Cytotoxic	9%	14%	5%
Drug Delivery Systems	14%	21%	7%
High Potency Compounds	9%	12%	3%
Lyophilization	8%	12%	4%
PEGs	6%	11%	5%

Rank of Outsourcing Drivers

	2011-2012	2012-2013	Change
Quality	1	1	
Reliability	2	2	
Affordability	3	4	↓
Productivity	4	5	↓
Regulatory	5	3	↑
Innovation	6	6	

Survey Methodology: The Nice Insight Pharmaceutical and Biotechnology Survey is deployed to outsourcing-facing pharmaceutical and biotechnology executives. The 2012-2013 report includes responses from 10,036 participants. 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 the top 100+ CMOs and top 50+ CROs servicing the drug development cycle. Over 900 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.


Walker

If you want to learn more about the report or how to participate, please contact Nigel Walker, managing director, or Salvatore Fazzolari, director of client services, at Nice Insight by sending an email to niceinsight.survey@thatsnice.com.

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Or contact:

Dina Iezzi
Director, Marketing & Special Projects
Phone: +1 (905) 286-6270
Mobile: +1 (647) 234-3395
Email: diezzi@therapurebio.com

THE CMO LEADERSHIP AWARDS 2013

Research Conducted By niceinsight
Marketing Intelligence by That's Nice

Presented By Life Science Leader
A LIFE SCIENCE CONNECT BRAND

The industry has recognized these companies as leaders in **all five** perception categories.

Baxter

gsk GlaxoSmithKline

NORWICH

solvias

therapure BIOPHARMA INC.

The industry has recognized these companies as leaders in **four** perception categories.

abbvie

Aesica

Boehringer Ingelheim

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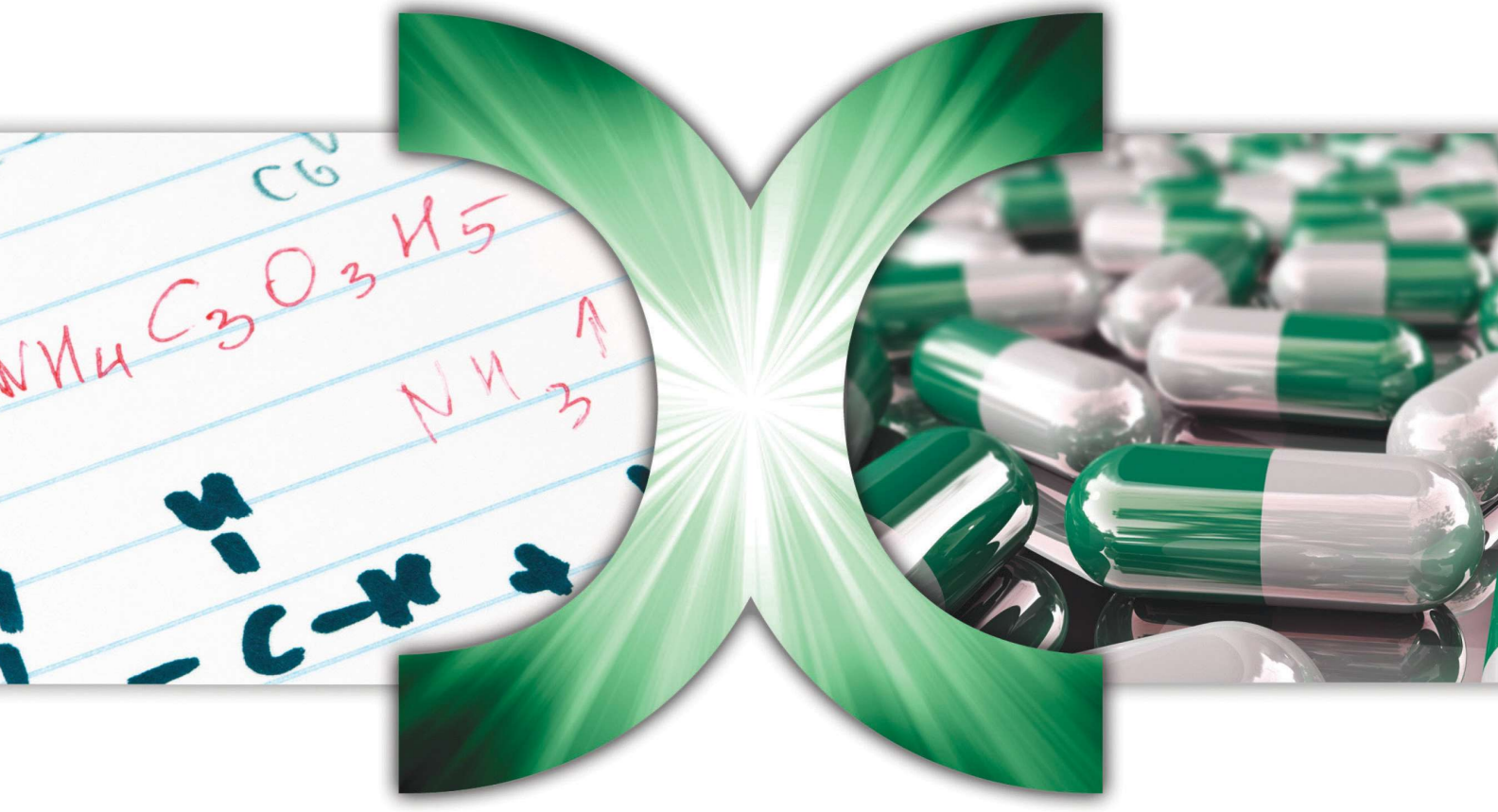

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Tampa, Florida 33607

Thank You

THE CMO LEADERSHIP AWARDS 2013 Quality Award

THE CMO LEADERSHIP AWARDS 2013 Innovation Award

THE CMO LEADERSHIP AWARDS 2013 Productivity Award

THE CMO LEADERSHIP AWARDS 2013 Regulatory Award

AAIPharma Services Corp.

Wilmington, NC
Manufacturing locations: Charleston, SC and Wilmington, NC
www.aaipharma.com (800) 575-4224 Contact: Rob Goshert rob.goshert@aaipharma.com

DRUG TYPE: Pharmaceuticals and Biopharmaceuticals

THE CMO LEADERSHIP AWARDS 2013 Quality Award

THE CMO LEADERSHIP AWARDS 2013 Reliability Award

DRUG LIFE CYCLE STAGES: Research & Development — preclinical 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, liquids, lyophilized products, nonsterile, parenterals (small volume), peptides, powders (nonsterile), proteins, solid dose, solutions & suspensions, sterile, and sustained release.

"This has been a period of building on AAIPharma's long history of providing the highest quality analytical testing, drug product development, and manufacturing services. Over the past year, AAIPharma has added a state-of-the-art technology center, more than doubled our solid dose manufacturing capacity, implemented new ERP and document management systems, moved to electronic lab notebooks, and will double our parenteral manufacturing capacity by year end. During this period our facilities also hosted very successful audits by the FDA, EMA, and DEA."
— Patrick Walsh, CEO

AbbVie Contract Manufacturing

North Chicago, IL
Manufacturing locations: Germany, Ireland, Italy, Puerto Rico, and United States
www.abbviecontractmfg.com (847) 938-8524 Contact: Lisa Wallerich lisa.wallerich@abbvie.com

DRUG TYPE: Pharmaceuticals and Biopharmaceuticals

THE CMO LEADERSHIP AWARDS 2013 Innovation Award

THE CMO LEADERSHIP AWARDS 2013 Productivity Award

THE CMO LEADERSHIP AWARDS 2013 Quality Award

THE CMO LEADERSHIP AWARDS 2013 Regulatory Award

DRUG LIFE CYCLE STAGES: Research & Development — preclinical 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, creams & ointments, cytotoxic & high-potency compounds, fermentation, gels, injectables, liquids, nonsterile, OTC, parenterals (small volume), proteins, semisolids, soft gels, solid dose, sustained release, syringes (prefilled), and topicals.

"AbbVie Contract Manufacturing is honored to be recognized globally for our expertise in quality, innovation, productivity and regulatory measures. This recognition affirms our commitment to our CMO partners and the patients who ultimately benefit from the therapies produced. At AbbVie, we share our partners' goals to combine innovative solutions and expertise in manufacturing to develop and deliver quality products that keep the patient at the center of our work."
— Azita Saleki-Gerhardt, Ph.D., senior vice president, operations

Aesica Pharmaceuticals

Newcastle upon Tyne, England
Manufacturing locations: Germany, Italy, and United Kingdom
www.aesica-pharma.com 0191 2181969 Contact: Georgia Linscott georgia.linscott@aesica-pharma.com

DRUG TYPE: Pharmaceuticals

THE CMO LEADERSHIP AWARDS 2013 Innovation Award

THE CMO LEADERSHIP AWARDS 2013 Productivity Award

THE CMO LEADERSHIP AWARDS 2013 Quality Award

THE CMO LEADERSHIP AWARDS 2013 Reliability Award

DRUG LIFE CYCLE STAGES: Research & Development — discovery, preclinical, 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, creams & ointments, cytotoxic & high-potency compounds, gels, generics, injectables, liquids, lyophilized products, nonsterile, parenterals (large volume), parenterals (small volume), peptides, powders (nonsterile), powders (sterile), proteins, semisolids, solid dose, solutions & suspensions, sterile, sustained release, syringes (prefilled), and topicals.

"We are delighted to have been recognized as a leader in the areas of quality, reliability, innovation, and productivity in order to have been awarded a 2013 CMO Leadership Award. The company remains focused on growth and we continue to increase our output and expand our global customer base."
— Robert Hardy, CEO

Albemarle Fine Chemistry Services DRUG TYPE: Pharmaceuticals
Baton Rouge, LA
Manufacturing locations: Pasadeana, TX; South Haven, MI; and Tyrone, PA
www.albemarle.com/FCS (225) 388-7402 Contact: Kurt Hoeprich kurt.hoeprich@albemarle.com

THE CMO LEADERSHIP AWARDS 2013 Quality Award
THE CMO LEADERSHIP AWARDS 2013 Reliability Award

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: Generics, injectables, liquids, and OTC.

"We are pleased that Albemarle's Fine Chemistry Services unit has won this custom manufacturing award. We have been involved in custom manufacturing for more than 30 years. Our dedication to finding and satisfying customers who want long-term supply arrangements through reliability, high quality, and superior customer responsiveness is what makes us successful. This award is a great testament to our manufacturing and technical teams at our manufacturing sites in North America."
— Kurt Hoeprich, global business manager, pharmaceuticals

Alkermes DRUG TYPE: Pharmaceuticals
Westmeath, Ireland
Manufacturing locations: Athlone, Ireland; and Gainesville, GA; and Wilmington, OH, U.S.A.
www.alkermes.com/contract +353 906495000 Contact: Fidelma Callanan fidelma.callanan@alkermes.com

THE CMO LEADERSHIP AWARDS 2013 Productivity Award

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 honored to be recognized by the industry through this CMO Leadership Award. To help measure productivity, Alkermes Contract Pharma Services makes available to its partners a suite of performance metrics including "On Time In Full" and "Right First Time" throughout a project's life cycle. We are proud to maintain a consistent track record of providing a fast, efficient service from development through scale up, registration support, and commercial manufacture of our partner's commercial products."
— Jim Botkin, SVP of operations

Almac Group DRUG TYPE: Pharmaceuticals
Craigavon, Northern Ireland
Manufacturing locations: Audubon, PA; Durham, NC; and Souderton, PA, U.S.A.; and Craigavon, Northern Ireland
www.almacgroup.com 44(0)28 38332200 Contact: Kerry Lyle kerry.lyle@almacgroup.com

THE CMO LEADERSHIP AWARDS 2013 Productivity Award
THE CMO LEADERSHIP AWARDS 2013 Regulatory Award
THE CMO LEADERSHIP AWARDS 2013 Reliability Award

DRUG LIFE CYCLE STAGES: Research & Development — discovery, preclinical, 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, controlled substances, cytotoxic & high-potency compounds, generics, nonsterile, peptides, powders (nonsterile), proteins, solid dose, and sustained release.

"It is extremely encouraging that our customers rate Almac so highly in terms of quality, innovation, productivity, reliability, and meeting high regulatory standards. We focus on these core values to achieve our overall aim of 'partnering to advance human health.' Working with all the global leaders in the pharmaceutical and biotech sectors, our aim is to establish long-term partnerships, based on trust and shared goals. The fact that over 95% of our business is from repeat customers is genuine evidence of our success."
— Alan Armstrong, CEO

AMRI (Albany Molecular Research Inc.)
Albany, NY
Manufacturing locations: India, United Kingdom, and United States
www.amriglobal.com **(518) 512-2000** **Contact: Louis Garguilo** **info@amriglobal.com**

DRUG TYPE: Pharmaceuticals

THE CMO LEADERSHIP AWARDS 2013 Quality Award

DRUG LIFE CYCLE STAGES: Research & Development — discovery, preclinical, clinical (phase 1, phase 2, and phase 3); Drug Substance Production — primary process development and drug substance production

SERVICES OFFERED: Aseptic fill/finish, capsules, controlled substances, creams & ointments, cytotoxic & high-potency compounds, gels, generics, injectables, liquids, lyophilized products, nonsterile, parenterals (small volume), powders (sterile), and proteins.

"Quality, commitment to purpose, and customer satisfaction and service are important AMRI core values that are part of our culture that we live by. To be recognized by our industry peers as a leading CMO in the area of quality is a great honor and testament to the dedication of my colleagues at AMRI to each and every customer. We are grateful that our customers recognize AMRI SMARTSOURCING™ as a high-quality global brand."
— Thomas E. D'Ambra, Ph.D., president and CEO

Ash Stevens Inc.
Riverview, MI
Manufacturing locations: Detroit and Riverview, MI
www.ashstevens.com **(734) 282-3370 ext. 1144** **Contact: James M. Hamby, Ph.D.** **jhamby@ashstevens.com**

DRUG TYPE: Pharmaceuticals

THE CMO LEADERSHIP AWARDS 2013 Regulatory Award

DRUG LIFE CYCLE STAGES: Research & Development — preclinical, 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 powders (nonsterile).

"To be recognized with a 2013 Leadership Award for our top-notch regulatory compliance and support services by Life Science Leader and Nice Insights is extremely gratifying. Regulatory compliance and quality are a part of our DNA, but to be in the top 20th percentile from out of more than a hundred worldwide CMOs based on the perceptions of consumers of those services is wonderful feedback on our commitment to quality."
— Dr. Stephen A. Munk, president & CEO

Baxter BioPharma Solutions
Deerfield, IL
Manufacturing locations: Germany, Italy, Puerto Rico, and United States
www.baxterbiopharmasolutions.com **(800) 4-Baxter** **Contact: Donna Abear** **biopharmasolutions@baxter.com**

DRUG TYPE: Pharmaceuticals and Biopharmaceuticals

THE CMO LEADERSHIP AWARDS 2013 Innovation Award
THE CMO LEADERSHIP AWARDS 2013 Productivity Award
THE CMO LEADERSHIP AWARDS 2013 Quality Award
THE CMO LEADERSHIP AWARDS 2013 Regulatory Award
THE CMO LEADERSHIP AWARDS 2013 Reliability Award

DRUG LIFE CYCLE STAGES: Research & Development — clinical (phase 1, 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, diluents, generics, injectables, liquids, lyophilized products, parenterals (large volume), parenterals (small volume), peptides, powders (sterile), proteins, solutions & suspensions, sterile, sustained release, syringes (prefilled), and vaccines.

"Baxter's heritage is built on 80+ years of parenteral expertise, including over 30 years of CMO experience. Combining scientific expertise, innovative products, global quality and regulatory systems, and an international manufacturing network, Baxter provides a firm foundation for the BioPharma Solutions contract manufacturing business. By leveraging this deep expertise in every functional area, BPS provides clients with confidence of delivery, service, and integrity, thereby helping them provide vital products to the patients they serve."
— Robert Felicelli, global franchise head

BioReliance by SAFC

BioReliance
Rockville, MD
Manufacturing locations: Carlsbad, CA, U.S.A. and Glasgow, Scotland, U.K.
www.bioreliance.com (301) 738-1000 Contact: Mike Garrett mike.garrett@bioreliance.com

DRUG TYPE: Biopharmaceuticals

THE CMO LEADERSHIP AWARDS 2013 Innovation Award
THE CMO LEADERSHIP AWARDS 2013 Productivity Award
THE CMO LEADERSHIP AWARDS 2013 Regulatory Award

DRUG LIFE CYCLE STAGES: Research & Development — discovery, preclinical, clinical (phase 1, phase 2, and phase 3); Drug Substance Production — primary process development and drug substance production

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

"BioReliance is pleased to once again be recognized in several categories of the CMO Leadership awards. Our entire organization is driven by the desire to supply customers with reliable on-quality and on-time delivery of expert scientific services. These wins serve as internal validation that drug developers and manufacturers feel they can rely on BioReliance, and we will continue to work towards delivering on that vote of confidence."
— Archie Cullen, president

Boehringer Ingelheim

Boehringer Ingelheim Biopharmaceuticals GmbH
Ingelheim, Germany
Manufacturing locations: Biberach, Germany; Fremont, CA, U.S.A.; Shanghai, China; and Vienna, Austria
www.bioxcellence.com +49 6132 770 Contact: Pauline Bronzel paulineeva.bronzel@boehringer-ingelheim.com

DRUG TYPE: Biopharmaceuticals

THE CMO LEADERSHIP AWARDS 2013 Productivity Award
THE CMO LEADERSHIP AWARDS 2013 Quality Award
THE CMO LEADERSHIP AWARDS 2013 Regulatory Award
THE CMO LEADERSHIP AWARDS 2013 Reliability Award

DRUG LIFE CYCLE STAGES: Research & Development — preclinical and clinical (phase 1, phase 2, and phase 3); Drug Substance Production — primary process development, drug substance production; Formulated Drug Production — dosage form development, dosage form production, and packaging

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

"We are a leading biopharma contract manufacturer with 35 years of experience and an outstanding track record of 22 products brought to market. As an independent, family-owned company, we see the contract manufacturing business as an important pillar of our biopharma activities, which is underlined with our new marketing brand Boehringer Ingelheim BioXcellence™. We offer tailor-made contract development and manufacturing services to the biopharmaceutical industry, providing the entire production technology chain, from DNA to fill and finish, under one roof at its facilities in Germany, Austria, U.S.A., and soon in China. With our global key account management team we are close to our customers and continue to put our customers first — We make outsourcing easy." — Folker Ruchatz, senior vice president contract manufacturing business biopharmaceutical

CANGENE bioPharma

Cangene bioPharma, Inc.
Baltimore, MD
Manufacturing locations: Baltimore, MD
www.cangenebiopharma.com (410) 843-5000 Contact: Pat DePalma depalmap@cangenebiopharma.com

DRUG TYPE: Pharmaceuticals and Biopharmaceuticals

THE CMO LEADERSHIP AWARDS 2013 Innovation Award
THE CMO LEADERSHIP AWARDS 2013 Productivity Award
THE CMO LEADERSHIP AWARDS 2013 Regulatory Award

DRUG LIFE CYCLE STAGES: Research & Development — clinical (phase 1, phase 2, and phase 3); Formulated Drug Production — dosage form production and packaging

SERVICES OFFERED: Aseptic fill/finish, generics, injectables, liquids, lyophilized products, ophthalmics, parenterals (small volume), peptides, sterile, and syringes (prefilled).

"Our Cangene team has earned these rankings. They are a reflection of us, the people. We are truly service-oriented and focused on making a difference with our customers and with our customers' customers, all the way to the people who need the drug products we manufacture. Although bound by industry regulations, we use creativity to improve as we continue to learn — this is the way we do business. Our customer-focused spirit and attention to quality are evident and recognized globally."
— Vicki Wolff-Long, Ph.D., general manager

Catalent Pharma Solutions

DRUG TYPE: Pharmaceuticals and Biopharmaceuticals

Somerset, NJ
Manufacturing locations: Germany, United Kingdom, and United States
www.catalent.com +44 0 1793 864000 Contact: Chris Halling media@catalent.com

THE CMO LEADERSHIP AWARDS 2013 Quality Award

THE CMO LEADERSHIP AWARDS 2013 Reliability Award

DRUG LIFE CYCLE STAGES: Research & Development — preclinical, 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, liquids, lyophilized products, nonsterile, ophthalmics, OTC, parenterals (large volume), parenterals (small volume), peptides, powders (sterile), proteins, semisolids, soft gels, solid dose, solutions & suspensions, sterile, sustained release, syringes (prefilled), and topicals.

"We are thrilled to again be recognized by pharmaceutical and biopharmaceutical leaders throughout the industry. Our innovative drug delivery technologies are built upon a solid foundation of reliability that spans our global network. Catalent has become a trusted partner through consistently demonstrating excellence in all areas of safety, quality, delivery, and cost. Our world-class programs in these areas set the tone of discipline that carries through everything that we do, ensuring customer satisfaction and trust."
— Steve Leonard, SVP global operations

Cedarburg Hauser Pharmaceuticals

DRUG TYPE: Pharmaceuticals

Grafton, WI
Manufacturing locations: Denver, CO and Grafton, WI
www.cedarburghauser.com (262) 376-1467 Contact: Bob Forner bob.forner@cedarburgpharma.com

THE CMO LEADERSHIP AWARDS 2013 Productivity Award

DRUG LIFE CYCLE STAGES: Drug Substance Production — primary process development and drug substance production

SERVICES OFFERED: Controlled substances, cytotoxic & high-potency compounds, and generics.

"Productivity is vital to Cedarburg Hauser's success, as it allows us to deliver on-time solutions to our customers. At Cedarburg Hauser, productivity is ensured with a project management team that effectively brings together scientists and operational resources to meet and exceed our customer's expectations. Receiving a CMO Leadership Award in productivity for a second consecutive year is a testament to the hard work of our team."
— Tony Laughrey, CEO

CEPiA Sanofi

DRUG TYPE: Pharmaceuticals and Biopharmaceuticals

Bridgewater, NJ
Manufacturing locations: France, Germany, Hungary, United Kingdom, United States, and several others
www.cepia-sanofi.com (908) 981-4140 Contact: Edward King Edward.king@sanofi.com

THE CMO LEADERSHIP AWARDS 2013 Regulatory Award

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, cartridges, controlled substances, creams & ointments, cytotoxic & high-potency compounds, gels, generics, injectables, lyophilized products, nonsterile, ophthalmics, OTC, parenterals (large volume), parenterals (small volume), peptides, powders (nonsterile), proteins, solid dose, sterile, sustained release, syringes (prefilled), topicals, and vaccines.

"As a major CMO, Sanofi CEPiA continues to base its success on its strengths: a strong commitment to quality and regulatory compliance, as well as technical innovation. Both API and drug products are manufactured with the highest quality standards and strict regulatory compliance. Sanofi CEPiA customers receive the highest quality products and are provided with outstanding customer service."
— Jacques Tavernier, vice president

CMC Biologics
Bothell, WA
Manufacturing locations: Berkeley, CA, and Bothell, WA, U.S.A; Copenhagen, Denmark
www.cmcbiologics.com (206) 660-2588 Contact: Stacie Byars sbyars@cmcbio.com

DRUG TYPE: Biopharmaceuticals

THE CMO LEADERSHIP AWARDS 2013 Innovation Award
THE CMO LEADERSHIP AWARDS 2013 Quality Award
THE CMO LEADERSHIP AWARDS 2013 Reliability Award

DRUG LIFE CYCLE STAGES: Drug Substance Production — primary process development and drug substance production; Formulated Drug Production — dosage form development

SERVICES OFFERED: Lyophilized products, parenterals (large volume), parenterals (small volume), and proteins.

"CMC Biologics continually strives for 100% customer satisfaction and to being the industry leader among CMOs in reliability, technical excellence, and quality. Our expertise in cGMP process development and manufacturing puts our clients' projects in an optimal position to succeed. Right. On Time."
— Claes Glassell, CEO

Coldstream Laboratories, Inc.
Lexington, KY
Manufacturing locations: Lexington, KY
www.coldstreamlabs.com (859) 977-8600 Contact: Christopher Verbicky, Ph.D. customerservice@coldstreamlabs.com

DRUG TYPE: Pharmaceuticals and Biopharmaceuticals

THE CMO LEADERSHIP AWARDS 2013 Innovation Award
THE CMO LEADERSHIP AWARDS 2013 Quality Award

DRUG LIFE CYCLE STAGES: Research & Development — preclinical, 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), peptides, solutions & suspensions, and sterile.

"Coldstream's focus on quality and innovation ensures exceptional service for our partners. Delivering creative solutions and skillful manufacture of challenging parenteral products using unique mobile isolator technology is central to Coldstream's business. We are growing to include a second filling line to accommodate a wider range of products and larger batch sizes. Establishing relationships, such as our partnership with Goodwin Biotechnology, for ADCs leverages our strengths with those of others to bring added value to our customers."
— Eric Smart, president and CEO

Cook Pharmica
Bloomington, IN
Manufacturing locations: Bloomington, IN
www.cookpharmica.com (877) 312-2665 Contact: Cory Lewis bus.dev@cookpharmica.com

DRUG TYPE: Biopharmaceuticals

THE CMO LEADERSHIP AWARDS 2013 Reliability Award

DRUG LIFE CYCLE STAGES: Research & Development — preclinical, 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, injectables, liquids, lyophilized products, parenterals (large volume), parenterals (small volume), sterile, syringes (prefilled), and vaccines.

"From the beginning, Cook Pharmica's goal has been simple: deliver quality products in a timely manner. Achieving key milestones and fulfilling timeline expectations has been an integral part of our strategy in supporting biopharmaceutical development and production for our customers. Our focus on being a flexible and reliable partner of choice has proven to be a differentiator for us in the marketplace. We are grateful to receive this award and to be recognized by those customers that we serve."
— Tedd M. Green, president

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

DRUG TYPE: Pharmaceuticals

THE CMO LEADERSHIP AWARDS 2013 Productivity Award

DRUG LIFE CYCLE STAGES: Research & Development — discovery, preclinical, clinical (phase 1, phase 2, and phase 3); Formulated Drug Production —dosage form development, dosage form production, and packaging

SERVICES OFFERED: Capsules, controlled substances, creams & ointments, gels, generics, injectables, liquids, lyophilized products, nonsterile, powders (nonsterile), solid dose, solutions & suspensions, sustained release, syringes (prefilled), topicals, and vaccines.

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

DSM Pharmaceutical Products
Parsippany, NJ
Manufacturing locations: Australia, Austria, Germany, Italy, The Netherlands, United States
www.dsm.com/pharma **(973) 257-8160** **Contact: Guy Tiene** **guy.tiene@dsm.com**

DRUG TYPE: Pharmaceuticals and Biopharmaceuticals

THE CMO LEADERSHIP AWARDS 2013 Innovation Award
THE CMO LEADERSHIP AWARDS 2013 Productivity Award
THE CMO LEADERSHIP AWARDS 2013 Quality Award
THE CMO LEADERSHIP AWARDS 2013 Reliability Award

DRUG LIFE CYCLE STAGES: Research & Development — preclinical & 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: Active pharmaceutical ingredients, advanced intermediates, antibodies, aseptic fill/finish, capsules, controlled substances, cytotoxic & high-potency compounds, generics, injectables, liquids, lyophilized products, microbial fermentation, nonsterile, OTC, parenterals (large volume), parenterals (small volume), peptides, proteins, solid dose, solutions & suspensions, sterile, sustained release, and vaccines.

"DSM is honored to receive CMO Leadership Awards in these four categories. Based on the fact that the awards represent the opinions of the customers who are using our services, we take this as confirmation that our commitment to delivering quality, on time, and in full is recognized."
— Lukas Utiger, Ph.D., president and CEO

Ei, A Pharmaceutical Solutionworks
Kannapolis, NC
Manufacturing locations: Kannapolis, NC
www.eisolutionworks.com **(704) 939-4300** **Contact: Diana Ritch** **dritch@eisolutionworks.com**

DRUG TYPE: Pharmaceuticals

THE CMO LEADERSHIP AWARDS 2013 Innovation Award
THE CMO LEADERSHIP AWARDS 2013 Productivity Award
THE CMO LEADERSHIP AWARDS 2013 Regulatory Award
THE CMO LEADERSHIP AWARDS 2013 Reliability Award

DRUG LIFE CYCLE STAGES: Formulated Drug Production — dosage form development, dosage form production, and packaging

SERVICES OFFERED: Creams & ointments, gels, generics, liquids, nonsterile, OTC, powders (nonsterile), semisolids, solutions & suspensions, and topicals.

"Ei is proud to have earned CMO Leadership Awards in four categories, which is a tribute to both our customers and our employees. Everyone at Ei has worked diligently to ensure every product we produce is done so with precision, care, and quality. Brand protection is our top priority at Ei, and these awards reinforce that we are on task regarding our mission."
— Roger Martin, president

Fujifilm Diosynth Biotechnologies
Morrisville, NC
Manufacturing locations: Billingham, Teesside, U.K.; and Research Triangle Park, NC, U.S.A.
www.fujifilmdiosynth.com (919) 337-4400 Contact: Dave Lescinski dave.lescinski@fujifilmdb.com

DRUG TYPE: Biopharmaceuticals

THE CMO LEADERSHIP AWARDS 2013 Productivity Award

THE CMO LEADERSHIP AWARDS 2013 Regulatory Award

DRUG LIFE CYCLE STAGES: Research & Development — preclinical, clinical (phase 1, phase 2, and phase 3); Drug Substance Production — primary process development and drug substance production

SERVICES OFFERED: Nonsterile, proteins, and vaccines.

"We are honored to be recognized for the 2013 CMO Leadership Awards in the categories of regulatory & productivity. Quality sets the foundation of everything we do to ensure patient safety and this is exemplified by our successful inspection history at our U.S.A. and U.K. sites. As a global leader in the contract development and manufacture of biopharmaceuticals, we look forward to building on this reputation."
— Stephen A. Spearman, Ph.D., MBA, president

Gallus BioPharmaceuticals
St. Louis, MO
Manufacturing locations: St. Louis, MO
www.gallusbiopharma.com (314) 426-5000 Contact: Claire Ruzicka claire.ruzicka@gallusbiopharma.com

DRUG TYPE: Biopharmaceuticals

THE CMO LEADERSHIP AWARDS 2013 Regulatory Award

DRUG LIFE CYCLE STAGES: Research & Development — discovery, preclinical, clinical (phase 1, phase 2, and phase 3); Drug Substance Production — primary process development and drug substance production

SERVICES OFFERED: Generics, peptides, proteins, and sterile.

"Gallus is delighted to be recognized for its regulatory leadership. Gallus is a uniquely flexible CMO with over a decade of commercial production based on an outstanding regulatory track record, with approval to supply product globally. The last FDA inspection resulted in zero Form 483 observations. Gallus continues to build on this performance through the dedication and commitment of our employees and ongoing investment in single-use and flexible stainless-steel bioreactors and advanced downstream technologies."
— Mark Bamforth, president and CEO

GlaxoSmithKline Contract Manufacturing
Brentford, Middlesex, UK
Manufacturing locations: Australia, China, Europe, Japan, Middle East, North America, and South America
www.gsk.com Contact: Russell Harris russell.b.harris@gsk.com

DRUG TYPE: Pharmaceuticals and Biopharmaceuticals

THE CMO LEADERSHIP AWARDS 2013 Innovation Award

THE CMO LEADERSHIP AWARDS 2013 Productivity Award

THE CMO LEADERSHIP AWARDS 2013 Quality Award

THE CMO LEADERSHIP AWARDS 2013 Regulatory Award

THE CMO LEADERSHIP AWARDS 2013 Reliability Award

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, packaging, and logistics

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

"GSK is continually striving to fulfill the contract manufacturing needs of our customers in today's challenging environment. We are proud to be seen as a leading company in the areas of quality, reliability, innovation, productivity, and regulatory. We do everything we can to offer a sustainable, robust value proposition that is at the leading edge within the contract manufacturing field. We are looking forward to another successful year."
— Russell Harris, director, business development and third-party sales

JHP Pharmaceuticals
Parsippany, NJ
Manufacturing locations: Rochester, MI
www.jhppharma.com (877) 906-7556 Contact: Bill Conway jhpcontractservices@jhppharma.com

DRUG TYPE: Pharmaceuticals and Biopharmaceuticals

THE CMO LEADERSHIP AWARDS 2013 Innovation Award
THE CMO LEADERSHIP AWARDS 2013 Productivity Award
THE CMO LEADERSHIP AWARDS 2013 Regulatory Award

DRUG LIFE CYCLE STAGES: Research & Development — clinical (phase 1, phase 2, and phase 3); Formulated Drug Production — dosage form production

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

"We are very pleased that JHP was recognized as a leading contract manufacturer. Our Rochester, Michigan site has a 27-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

Neuland Laboratories Limited
Hyderabad, Andhra Pradesh, India
Manufacturing locations: Medak, Andhra Pradesh, India
www.neulandlabs.com 914030211600 Contact: D. Saharsh Rao saharsh@neulandlabs.com

DRUG TYPE: Pharmaceuticals

THE CMO LEADERSHIP AWARDS 2013 Regulatory Award

DRUG LIFE CYCLE STAGES: Research & Development — preclinical, clinical (phase 1, phase 2, and phase 3); Drug Substance Production — primary process development and drug substance production

SERVICES OFFERED: API, clinical trial services, contract manufacturing — APIs, generics — APIs, and peptides.

"For almost 30 years, quality and regulatory focus have been Neuland's key drivers. In fact, creating a quality-conscious organization was part of Neuland's foundation. We are honored that our regulatory achievements have been recognized by our customers, as we strive to extend and strengthen this record of outstanding achievement. We want to acknowledge the exceptional team at Neuland who made this award possible, with their ongoing daily commitment to quality and excellence."
— Sucheth Rao Davuluri, CEO

NextPharma
Send, Surrey, United Kingdom
Manufacturing locations: France and Germany
www.nextpharma.com (305) 542-1258 Contact: Matthew Wilder matthew.wilder@nextpharma.com

DRUG TYPE: Pharmaceuticals

THE CMO LEADERSHIP AWARDS 2013 Productivity Award
THE CMO LEADERSHIP AWARDS 2013 Regulatory Award

DRUG LIFE CYCLE STAGES: Research & Development — preclinical, 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, gels, generics, liquids, nonsterile, OTC, powders (nonsterile), semisolids, solid dose, solutions & suspensions, sustained release, and topicals.

"NextPharma is delighted to again be recognized as a CMO leadership award winner. Achieving this award shows that we are successfully evolving and establishing our position as a leader in the global CDMO space. It is with our strong focus on technical expertise and project management that allows NextPharma to excel, delivering smart solutions on time and on budget to our customers worldwide."
— Franck Latrille, CEO

Norwich Pharmaceuticals
Norwich, NY
Manufacturing locations: Norwich, NY
www.norwichpharma.com (866) 674-7979 Contact: Stephanie Ferrell Stephanie.Ferrell@norwichpharma.com

DRUG TYPE: Pharmaceuticals

THE CMO LEADERSHIP AWARDS 2013 Innovation Award
THE CMO LEADERSHIP AWARDS 2013 Productivity Award
THE CMO LEADERSHIP AWARDS 2013 Quality Award
THE CMO LEADERSHIP AWARDS 2013 Regulatory Award
THE CMO LEADERSHIP AWARDS 2013 Reliability Award

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, cytotoxic & high-potency compounds, generics, OTC, solid dose, and sustained release.

"Norwich is honored to have received the CMO Leadership Award two years in a row. We believe that Norwich's high rank in all five perception categories reflects our commitment to our customers and their patients. Norwich is dedicated to the success of our customers, and it shows through the hard work of our employees every day to achieve and maintain the highest level of quality, reliability, innovation, productivity, and regulatory compliance."
— Terry Novak, president

Novasep
Pompey, France
Manufacturing locations: Belgium, France, and Germany
www.novasep.com 0033 3 83 49 71 30 Contact: Michel Blanc Michel.blanc@novasep.com

DRUG TYPE: Pharmaceuticals and Biopharmaceuticals

THE CMO LEADERSHIP AWARDS 2013 Quality Award
THE CMO LEADERSHIP AWARDS 2013 Reliability Award

DRUG LIFE CYCLE STAGES: Research & Development — preclinical, 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: API and advanced intermediate custom synthesis, aseptic fill/finish, BSL3 pathogens production, custom purification, cytotoxic & high-potency compounds, generics, lyophilized products, nonsterile, peptides, powders (nonsterile), powders (sterile), process development, proteins, sterile, and vaccines.

"Novasep is a leading provider of global manufacturing solutions for Life Science molecules, with differentiated capabilities in hazardous chemistry, high-potency chemistry, biomanufacturing, and high-efficiency purification technologies, from process development to commercial production. The quality and reliability leadership awards acknowledge Novasep's quality system and the robustness of its global manufacturing capabilities. Beyond strict regulatory compliance, we believe that the commitment of Novasep people in serving our customers is an essential part of our success."
— Michel Spagnol, CEO

OSO BioPharmaceuticals Manufacturing, LLC
Albuquerque, NM
Manufacturing locations: Albuquerque, NM
www.osobio.com (505) 923-2112 Contact: Bob Cashman bob.cashman@osobio.com

DRUG TYPE: Pharmaceuticals and Biopharmaceuticals

THE CMO LEADERSHIP AWARDS 2013 Productivity Award
THE CMO LEADERSHIP AWARDS 2013 Regulatory Award

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), solutions & suspensions, sterile, and vaccines.

"We are grateful once again to be recognized by our industry peers and clients as a leading CMO in the pharmaceutical and biopharmaceutical industries. In our current environment, regulatory compliance is the cornerstone for success for both the CMO and the drug sponsor. This award validates our vision and strategies that emphasize compliance, productivity, and world-class customer service in helping bring lifesaving drugs to the market. We sincerely appreciate this honor."
— Milton Boyer, president

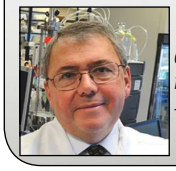
PARAGON BIOSERVICES

PARAGON BIOSERVICES, Inc. DRUG TYPE: Biopharmaceuticals
Baltimore, MD **Manufacturing locations: Baltimore, MD**
www.paragonbioservices.com **(410) 975-4050**
Contacts: Philip Wills pwills@paragonbioservices.com Tarran Pierfelice, Ph.D. tpierfelice@paragonbioservices.com

THE CMO LEADERSHIP AWARDS 2013 Quality Award
THE CMO LEADERSHIP AWARDS 2013 Reliability Award

DRUG LIFE CYCLE STAGES: Research & Development — discovery, preclinical, clinical (phase 1 and phase 2); Drug Substance Production — primary process development and drug substance production; Formulated Drug Production — dosage form production and packaging

SERVICES OFFERED: Aseptic fill/finish, injectables, liquids, proteins, sterile, and vaccines.



"Paragon Bioservices has a top-notch team of scientists and engineers with decades of collective experience working with biologics — from research services and process development to GMP manufacturing. For more than twenty years, we have helped pharmaceutical companies, biotechnology companies, and government agencies (DoD, NIH) move forward in the development of viral vectors, vaccines, and VLPs — as well as the production and purification of monoclonal antibodies and recombinant proteins."
— Marco Chacón, CEO

Patheon

Patheon DRUG TYPE: Pharmaceuticals and Biopharmaceuticals
Durham, NC
Manufacturing locations: Canada, France, Italy, United Kingdom, and United States
www.patheon.com (919) 226-3200 Contact: Joe Principe Joe.Principe@Patheon.com

THE CMO LEADERSHIP AWARDS 2013 Innovation Award
THE CMO LEADERSHIP AWARDS 2013 Productivity Award
THE CMO LEADERSHIP AWARDS 2013 Quality Award
THE CMO LEADERSHIP AWARDS 2013 Reliability Award

DRUG LIFE CYCLE STAGES: Research & Development — preclinical, clinical (phase 1, phase 2, and phase 3); Drug Substance Production — primary process development Formulated Drug Production — dosage form development, dosage form production, packaging, and logistics

SERVICES OFFERED: Aseptic fill/finish, capsules, cartridges, controlled substances, cytotoxic & high-potency compounds, generics, injectables, liquids, lyophilized products, nonsterile, OTC, parenterals (large volume), parenterals (small volume), powders (nonsterile), powders (sterile), soft gels, solid dose, solutions & suspensions, sterile, sustained release, and syringes (prefilled).

"Every day at Patheon we are committed to providing our clients with the industry's leading customer experience. Quality, reliability, innovation, and productivity are cornerstones to our vision, and it is rewarding to be recognized for the third consecutive year by our customers and the industry. It is because of our customers that we are able to improve the quality of life for patients, and it is because of our employees that we help them excel."
— Jim Mullen, CEO

Penn Pharma

Penn Pharmaceutical Services Limited DRUG TYPE: Pharmaceuticals
Tredegar, Gwent, United Kingdom
Manufacturing locations: Tredegar, Gwent, United Kingdom
www.pennpharm.com 01495 711222 Contact: Joanne Phelps joanne.phelps@pennpharm.com

THE CMO LEADERSHIP AWARDS 2013 Innovation Award
THE CMO LEADERSHIP AWARDS 2013 Productivity Award
THE CMO LEADERSHIP AWARDS 2013 Regulatory Award

DRUG LIFE CYCLE STAGES: Research & Development — 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, generics, liquids, nonsterile, OTC, powders (nonsterile), semisolids, solid dose, solutions & suspensions, sustained release, and topicals.

"Penn constantly listens to its customers to hear what they need today, and what they think they will need tomorrow. We then invest in the capacity and capabilities to support those market needs. Alongside this, staff are trained and developed to ensure we can deliver great performance across our range of services. A culture of continuous improvement has been instilled in the organization, and this drives superior delivery, quality, and value to the benefit of our customers."
— Richard Yarwood, CEO

PFIZER CENTRESOURCE
Partnering with our Customers for a Healthier World

Pfizer CentreSource
Kalamazoo, MI
DRUG TYPE: Pharmaceuticals and Biopharmaceuticals
Manufacturing locations: Australia, Belgium, Germany, Ireland, Italy, Puerto Rico, and United States
www.pfizercentresource.com (269) 833-5844 Contact: Kenneth Ball Kenneth.f.ball@pfizer.com

THE CMO LEADERSHIP AWARDS 2013 Innovation Award
THE CMO LEADERSHIP AWARDS 2013 Productivity Award
THE CMO LEADERSHIP AWARDS 2013 Regulatory Award
THE CMO LEADERSHIP AWARDS 2013 Reliability Award

DRUG LIFE CYCLE STAGES: Research & Development — clinical (phase 2 and phase 3); Drug Substance Production — 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, gels, generics, injectables, liquids, lyophilized products, nonsterile, OTC, parenterals (small volume), powders (nonsterile), proteins, semisolids, solid dose, solutions & suspensions, sterile, syringes (prefilled), and topicals.

"PCS is once again pleased to be recognized by Life Science Leader and our industry peers for our leadership in the areas of reliability, innovation, productivity, and regulatory. The award once again confirms our application of operational excellence to our strategic partners, and our long-standing commitment to offer Pfizer Global Supply's strengths to customers. PCS would like to extend our sincere thanks to all the colleagues in Pfizer Global Supply and Pharmaceutical Development, whose dedication and commitment to our "Own It" culture make this award possible. Being recognized now for three years in a row demonstrates our commitment to serve as a long-term, trustworthy partner to our customers."
— Cristin Grove, director, contract manufacturing

PHARMATEK
PHARMACEUTICAL CHEMISTRY DEVELOPMENT

Pharmatek
San Diego, CA
DRUG TYPE: Pharmaceuticals
Manufacturing locations: San Diego, CA
www.pharmatek.com (858) 805-6383 Contact: Elizabeth Hickman inquire@pharmatek.com

THE CMO LEADERSHIP AWARDS 2013 Innovation Award
THE CMO LEADERSHIP AWARDS 2013 Productivity Award
THE CMO LEADERSHIP AWARDS 2013 Regulatory Award

DRUG LIFE CYCLE STAGES: Research & Development — preclinical, clinical (phase 1 and phase 2); Formulated Drug Production — dosage form development, dosage form production, and packaging

SERVICES OFFERED: Capsules, cytotoxic & high-potency compounds, injectables, liquids, lyophilized products, nonsterile, peptides, powders (nonsterile), semisolids, solid dose, solutions & suspensions, and sustained release.

"Since our founding, Pharmatek's goal has been to provide client-centric services. We believe that to truly serve our clients well, we must listen to them, empathize with their unique situations, and adapt our systems to better meet their needs. Pharmatek's client-centric approach to drug development brings quality people, science, and systems to every project. Insisting on excellence in everything we do, we are passionate about our client's success and bring energy and enthusiasm to every project."
— Tim Scott, president

Piramal | Healthcare
knowledge action care

Piramal I Healthcare
Mumbai, Maharashtra, India
DRUG TYPE: Pharmaceuticals and Biopharmaceuticals
Manufacturing locations: Ahmedabad, Digwal, Ennore, and Pithampur, India; Grangemouth and Morpeth, U.K.; & Toronto, Canada
www.piramalpharmasolutions.com +91-22-30956666 Contact: Brian Shaughnessy brian.shaughnessy@piramal.com

THE CMO LEADERSHIP AWARDS 2013 Quality Award
THE CMO LEADERSHIP AWARDS 2013 Reliability Award

DRUG LIFE CYCLE STAGES: Research & Development — discovery, preclinical, 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, ophthalmics, OTC, solid dose, solutions & suspensions, and sterile.

"We are a globally integrated service provider amongst the top CMOs in the world, serving clientele from our U.S. and EU accredited manufacturing and R&D centers located across the globe. As a global company, we rely on our dedicated team of 1,600 employees, including 450 scientists. We have achieved excellence in pharma by following stringent processes and have achieved various accreditation and acclaims."
— Vijay Shah, executive director and COO

Recipharm AB

Jordbro, Sweden
Manufacturing locations: France, Germany, Spain, Sweden, and U.K.
www.recipharm.com 0046 8 6025200 Contact: Kenth Berg info@recipharm.com

DRUG TYPE: Pharmaceuticals

THE CMO LEADERSHIP AWARDS 2013 Innovation Award

DRUG LIFE CYCLE STAGES: Research & Development — preclinical 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, cartridges, controlled substances, creams & ointments, cytotoxic & high-potency compounds, gels, generics, injectables, liquids, lyophilized products, nonsterile, OTC, parenterals (small volume), powders (nonsterile), semisolids, solid dose, solutions & suspensions, sterile, sustained release, and topicals.

"I am very pleased that Recipharm has once again won a CMO Leadership Award and particularly in the innovation category. I like to believe that the way we combine our pharmaceutical development expertise with our broad commercial manufacturing capabilities provides our customers with not only a cost-effective and reliable service, but also something which adds true value to their ideas. Customers consistently tell us that this is what they are looking for."
— Thomas Eldered, CEO

SAI Life Sciences Ltd

Hyderabad, A.P., India
Manufacturing locations: Hyderabad and Karnataka, India
www.sailife.com +91 40 6677 7555 Contact: Marcel Velterop marcel.v@sailife.com

DRUG TYPE: Pharmaceuticals

THE CMO LEADERSHIP AWARDS 2013 Reliability Award

DRUG LIFE CYCLE STAGES: Research & Development — discovery, preclinical, clinical (phase 1, phase 2, and phase 3); Drug Substance Production — primary process development and drug substance production; Formulated Drug Production — dosage form development

"SAI is honored to have been recognized by many of its existing customers for its performance and reliability of the services provided. We have a very strong focus on delivery of services, sometimes requiring efforts beyond the call of duty. We also realize that we still have a way to go to achieve complete customer satisfaction in all cases, and we see this award as a strong encouragement that we are on the right track. We thank all our customers for their feedback and look forward to more."
— Krishna Kanumuri, CEO

Samsung BioLogics

Incheon, South Korea
Manufacturing locations: Incheon, South Korea
www.samsungbiologics.com 82 2 2255 8505 Contact: Jeremy Caudill biologics@samsung.com

DRUG TYPE: Biopharmaceuticals

THE CMO LEADERSHIP AWARDS 2013 Productivity Award

DRUG LIFE CYCLE STAGES: Research & Development — preclinical and clinical (phase 1, phase 2, and phase 3); Drug Substance Production — primary process development, drug substance production; Formulated Drug Production — dosage form development, dosage form production, packaging, and logistics

SERVICES OFFERED: Aseptic fill/finish, cartridges, injectables, liquids, lyophilized products, parenterals (large volume), parenterals (small volume), proteins, sterile, and syringes (prefilled).

"We are honored to be recognized by our clients as a global biopharmaceutical manufacturing leader for productivity. Samsung BioLogics takes pride in delivering best-in-class manufacturing services, with the highest global quality standards, to our clients. Our success is possible thanks to our highly experienced employees, that consistently demonstrate their commitment to execution excellence. We accept this award as a testament to the dedication and hard work of many within Samsung BioLogics."
— Jeremy Caudill, vice president of business development

SANDOZ

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

DRUG TYPE: Pharmaceuticals and Biopharmaceuticals

THE CMO LEADERSHIP AWARDS 2013 Innovation Award
THE CMO LEADERSHIP AWARDS 2013 Productivity Award
THE CMO LEADERSHIP AWARDS 2013 Regulatory Award

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.

"Sandoz is honored to be recognized once again with the CMO Award. We are grateful to our customers and look forward to many more decades of working with them to bring important medicines to patients. We have a distinguished history as a global leader in contract manufacturing — both in fermentation-derived intermediates and APIs, and recombinant proteins and peptides (microbial and mammalian). We are also thankful for our great people, whose collaborative approach has been a key driver of our success."
— Friedrich Nachtmann, head of biotech cooperations; and Gerhard Santer, head of global development and strategy

solvias

Solvias
Kaiseraugst, Switzerland
Manufacturing locations: Basel, Switzerland
www.solvias.com (908) 249-7693 Contact: Ron Yarger ron.yarger@solvias.com

DRUG TYPE: Pharmaceuticals

THE CMO LEADERSHIP AWARDS 2013 Innovation Award
THE CMO LEADERSHIP AWARDS 2013 Productivity Award
THE CMO LEADERSHIP AWARDS 2013 Quality Award
THE CMO LEADERSHIP AWARDS 2013 Regulatory Award
THE CMO LEADERSHIP AWARDS 2013 Reliability Award

DRUG LIFE CYCLE STAGES: Research & Development — discovery, preclinical, clinical (phase 1 and phase 2); Drug Substance Production — primary process development and drug substance production

SERVICES OFFERED: APIs and intermediates.

"We offer increased capacity and profound know-how for analytical and chemical development. Our strong portfolio of services and products can accommodate the full spectrum of our customers' requirements — from initial drug characterization, through analytical and chemical process development capabilities, to release testing and production support. We develop flexible, customized solutions that meet our customers' specific drug-development criteria."
— Dr. Hansjörg Walther, CEO

Takeda

Takeda Pharma
Roskilde, Denmark
Manufacturing locations: Austria, Brazil, China, Germany, Mexico, Poland, and Russia
www.takeda.com Contact: Kim Wochner kim.wochner@takeda.com

DRUG TYPE: Pharmaceuticals

THE CMO LEADERSHIP AWARDS 2013 Quality Award
THE CMO LEADERSHIP AWARDS 2013 Reliability Award

DRUG LIFE CYCLE STAGES: Formulated Drug Production — dosage form development, dosage form production, packaging, and logistics.

SERVICES OFFERED: Capsules, cartridges, controlled substances, creams & ointments, compounds, gels, generics, liquids, nonsterile, OTC, powders (nonsterile), semisolids, soft gels, solid dose, solutions & suspensions, sterile, and syringes (prefilled).

"Takeda is very proud of receiving this award within the areas of quality and reliability. We believe this is a key to success within contract manufacturing. Our consistent focus over the years in building quality in everything we do has with this award been recognized by our clients and the industry. Many years within pharmaceutical production and long-lasting partnerships have demonstrated the reliability in our services. Thank you all for this award."
— Kim Wochner, director, contract manufacturing business

Therapure Biopharma Inc.

Therapure Biopharma Inc.
Mississauga, Ontario, Canada
Manufacturing locations: Mississauga, Ontario, Canada
www.therapurebio.com **(905) 286-6270** **Contact: Dina Iezzi** **diezzi@therapurebio.com**

DRUG TYPE: Pharmaceuticals and Biopharmaceuticals

THE CMO LEADERSHIP AWARDS 2013 Innovation Award
THE CMO LEADERSHIP AWARDS 2013 Productivity Award
THE CMO LEADERSHIP AWARDS 2013 Quality Award
THE CMO LEADERSHIP AWARDS 2013 Regulatory Award
THE CMO LEADERSHIP AWARDS 2013 Reliability Award

DRUG LIFE CYCLE STAGES: Research & Development — discovery, preclinical, and clinical (phase 1, phase 2, and 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 (prefilled), and vaccines.

"It is an honor to be recognized for a third consecutive year for the CMO Leadership Award, and once again in all five categories (quality, reliability, innovation, productivity, and regulatory). This award reinforces the diligence, passion, and contribution of our employees, who strive to produce the highest quality therapeutics possible. The five categories are critical to our clients', as well as our organization's success, but more importantly, critical for patient wellbeing."
– Nick Green, president and CEO

UPM Pharmaceuticals

UPM Pharmaceuticals, Inc.
Baltimore, MD
Manufacturing locations: Baltimore, MD
www.upm-inc.com **(410) 843-3700** **Contact: Mike Raum** **raum@upm-inc.com**

DRUG TYPE: Pharmaceuticals

THE CMO LEADERSHIP AWARDS 2013 Innovation Award
THE CMO LEADERSHIP AWARDS 2013 Productivity Award
THE CMO LEADERSHIP AWARDS 2013 Regulatory Award

DRUG LIFE CYCLE STAGES: Research & Development — preclinical, clinical (phase 1, phase 2, and phase 3); Formulated Drug Production — dosage form development, dosage form production, packaging (phase 1 through commercial)

SERVICES OFFERED: Capsules, tablets, controlled substances, cytotoxic & high-potency compounds, gels, generics, liquids, nonsterile peptides, powders (nonsterile), semisolids, 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 winning and keeping business in this highly competitive industry is about producing results for our clients."
— Jim Gregory, president and COO

Vetter

Vetter
Ravensburg, Germany
Manufacturing locations: Langenargen, Germany; Ravensburg, Germany; Skokie, IL, U.S.A.
www.vetter-pharma.com **+49-751-3700-0** **Contact: Oskar Gold** **info@vetter-pharma.com**

DRUG TYPE: Pharmaceuticals and Biopharmaceuticals

THE CMO LEADERSHIP AWARDS 2013 Quality Award
THE CMO LEADERSHIP AWARDS 2013 Reliability Award

DRUG LIFE CYCLE STAGES: Research & Development — preclinical, clinical (phase 1, phase 2, and/or phase 3); Formulated Drug Production — dosage form production, packaging, and logistics

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Create A Symbiotic Relationship To Reduce Outsourcing Risk

By David Lowndes

Outsourcing has the potential of lowering manufacturing costs. However, there remains a fundamental mismatch between the revenue desired on behalf of the sponsor, the margin required by CMOs, the price that insurance is willing to reimburse, and the out-of-pocket expense a patient can afford to pay. No longer can sponsors expect to win via squeezing their suppliers on margins. A significant manufacturing issue resulting from trying to cut costs can interrupt supply, damage a company's reputation — and most importantly — have negative consequences on the most important person in the entire equation — the patient. Just calculate the contribution to the bottom line for your CMO of each batch it makes for you, and then think about the decisions made daily that impact your product. It gives you a real appreciation for the integrity a majority of our CMOs have when balancing the viability of their business with the needs of ensuring a safe, high-quality, and reliable drug supply. I am not advocating higher margins for CMOs. That is something the market establishes. Notwithstanding, it is clear that negotiating the last dime out of your CMO partner does not help the situation. The truth, though, is that this calculation cannot be balanced simply by paying more. If this were the case, we should move back to manufacturing the product ourselves. The solution is much broader.

AS GOOD AS OR BETTER THAN VERTICAL INTEGRATION

So how do we create an outsourcing model that is as good as, or better than, a vertical model without adding unnecessary risk? For the last couple of years I have had responsibility for the supply activities in the specialty pharmaceuticals division of Shire (NASDAQ: SHPG). With the exception of our U.S. distribution center, these activities are built upon a fully outsourced supply chain. Two years ago, Shire was in the final stages of closing its in-house manufacturing capabilities and consolidating these into DSM's Greenville, NC, contract manufacturing facility. The decision made DSM Shire's biggest CMO partner and Shire DSM's biggest client. The question became, "How would we address both the challenges and the opportunities this symbiotic relationship would present?"

BEST PRACTICES OF CREATING A SYMBIOTIC RELATIONSHIP

The relationship between your company and your CMO should be founded on a few simple principles. First, the outcome for the patient, in safety, quality, and availability of product cannot be different for either the sponsor or CMO, simply because we have chosen to outsource. Second, in order to achieve the desired outcome, the sponsor and CMO MUST work together as if they are one company. Finally, both the CMO and sponsor have to be accountable according to your own business models.

Think of the cost-of-quality model. The lowest cost of quality is the one that best supports the CMO's business model. On the other hand, with our accountability to the patient, those that care for them, regulators, and payers, the lowest cost of quality is usually not the best place for us to be, as we have the reputational risk and the higher margin risk. If we do not work to prevent quality issues, the cost of failure will be very high — recalls, batch rejections, poor yields, etc. Typically, our manufacturing and supply contracts allow us to hold our CMOs accountable for their mistakes, and with the margins they make, these costs are very damaging. However, it is not in our best interest to release them from this liability; rather, it is critical to maintain their accountability as this is what drives failure out of their processes. As a sponsor, it suits our business model to be higher up the preventative curve, increasing the cost of quality. Because this additional cost is not something that suits the usual CMO's business model, we must be willing to provide funding and/or resources for preventative measures that reduce failure beyond the lowest cost of quality. It is equally critical to the success and longevity of the relationship that we remain accountable for this.

Based on these principles, teams from our two organizations worked together to create more a plant-in-plant approach, not full blown customization of one section of the facility to our needs, but far beyond a person-in-plant approach. Teams focused on people, plant, process, technology, and risk, then built a multilayered joint governance structure to drive toward the performance and outcomes desired by both parties. We have taken patients to our CMO to help share our motivation with the teams that make our products. A compliance index has been implemented and 100% performance achieved. A collaborative approach between our QA functions during batch review has cut the Shire batch-release time from seven days to half a day. On-time delivery has increased notably, and cycle times have been halved across the board. Seven years' worth of production data for our products has been uploaded into our Discoverent system, and joint teams are using the data together to develop a more QbD approach and to drive process capability. We have worked together to introduce a lab-cell approach, cutting lab-cycle time from 20 days to 2 days. We are delivering on a wide range of collab-

orative initiatives as if we were one company.

THE INTEGRATED OUTSOURCED SUPPLY CHAIN

If the FDA's concerns cause *me* to have sleepless nights, then so they must for those who run CMOs. Add to this the significant improvement in performance achieved with DSM, benefiting both our businesses, and we have the basis for a constructive conversation with other CMO partners, those for whom we are not a big client. Many of these companies have long known that the approach needs to change; they have been squeezed by clients and have felt the increased scrutiny from the agency. What we found was that they were looking for partners who were willing to join them in driving the change.

So we have now embarked on a journey to create the "Integrated Outsourced Supply Chain." Starting with the supply chain for our biggest product, we are meeting with the supply sites for that product to discuss how we all work together to deliver the safety, quality, and availability of products required by our patients. The same principles apply, so we will do this behaving as if we are one company. This is a difficult concept when the supply chain is fully dual sourced, because CMOs normally compete with each other for work, but within a single product's supply chain the needs of patients are best served by sharing best practices.

If the benchmark is the vertically integrated supply chain, for our outsourced supply chain to be as effective or better, we need to behave as if we are one company, and we need to make things happen in those vertically integrated supply chains to improve performance. This means that when a lab at one site is struggling with an analytical method that another site's lab has no issues with, we should be able to get those analysts together to figure out what is going on and resolve it. This is what would be done in a vertically integrated supply chain, and the fact that we have chosen an outsourced model should not prevent us from doing the right thing. Of course, Shire needs to pick up the costs, as this is beyond the preventative measures that make sense for the CMO, and in rare cases we may need to address issues of IP.

About the Author

At Shire, David is senior VP for supply chain management, which includes accountability for all external manufacturing. He previously held positions as SVP global supply chain and quality and VP supply chain strategy and product commercialization within Shire's Specialty Pharma Division.

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CMO Management Assessment

By Angie Green

Is your supply chain network running seamlessly? Are your CMOs clear on your company's goals for the next five years? What is your CMO's capability expansion plan? An important tool for reducing business risk is having a clear CMO/supplier network strategy. Developing and maintaining those key supplier relationships takes dedicated focus and commitment within your organization. The table below outlines three types of relationship management models: functional, collaborative, and full trust. Find out which model your company emulates. Evaluate your strategic path. Companies that manage CMOs well will directly yield positive results for supply chain protection.

Assessment Areas	Types Of Relationship Models		
	FUNCTIONAL	COLLABORATIVE	FULL TRUST
Communication	Inconsistent and reactionary communication Symptoms are: 1) Conference calls – ad hoc 2) Emails/voicemails often remain unanswered for several days. 3) Only urgent face-to-face (F2F) operational meetings occur. 4) Misunderstandings are frequent.	Communication plan agreed upon up front Symptoms are: 1) Weekly conference call meetings have an assigned team. Agendas are sent pre-meeting. 2) Email flow is satisfactory. 3) Quarterly F2F operational meetings occur. 4) Management intervention is needed for difficult conversations to reach resolution.	Open conversation occurs at all managerial levels Symptoms are: 1) Conference calls are short with clear agendas and consistent participation. 2) Email/telephone communication flow is excellent. Leadership also speaks with some regularity about business issues. 3) F2F meetings – operations meets quarterly; strategic leadership meets annually or semiannually. 4) All mgt. levels are proactive toward any issue requiring resolution.
Visibility And Planning	Little or no visibility into suppliers' schedules for our products Symptoms are: Data from CMO is inconsistent and sometimes unreliable. Yields are unclear. Purchase orders are reactionary. Stock-outs occur from uncertainty.	Some visibility into suppliers' schedule for our products Symptoms are: Data is fairly consistent and reliable. Some surprises. Yields are known. Purchase orders are cut proactively to leverage the needed production slots. Stock-outs and delays are a risk but do not occur with any frequency.	Full visibility into suppliers' schedule for our products Symptoms are: Data is consistent and reliable for short-term and long-term planning. Yield improvement is achieved. Customer and supplier meet F2F to progress the annual plan and make the appropriate adjustments to reduce stock-out risks.
Short-Term Problem Solving	Constant tension between customer and supplier Symptoms are: Constant delays, altered production slots, and a lack of momentum overall. Angry conversations and managerial intervention occur frequently. Actions feel forced and reactionary.	Project management levels aligned with some supervisory guidance Symptoms are: Delays are not common but sometimes occur. Cooperative teams discuss potential roadblocks and often resolve issues quickly. Most issues never reach upper-management.	Project management teams completely aligned Symptoms are: Frequent communication reduces any short-term problems that impact deliveries or schedules. Project managers are empowered to get the correct experts and managerial resources to resolve problems quickly. Problems are invisible to upper management.
Long-Term Problem Solving	No forum for this type of discussion Symptoms are: A reactionary supply chain with frequent problems leaves no time to discuss any long-term solutions.	Discussed at annual/semiannual business steering meetings Symptoms are: Project teams identify long-term issues for the next steering meeting agenda. Upper management is not always aware of these issues. Questions and discussion during the meeting lead to more offline discussion.	Discussed at annual or semiannual business steering meetings and in small managerial groups Symptoms are: All management levels have scheduling clarity on steering meeting frequency, location, and agenda. There is often managerial discussion beforehand, sometimes in a smaller setting first to lay the groundwork for alignment. New strategic opportunities are also discussed.
Summary: Supplier/Customer Relationship	Your supply chain is at risk. Your process is reactionary with little guidance or cooperation from your CMO. It is time to sit down and formulate a new strategic mgt. plan in a F2F meeting with your CMO.	Your company maintains a successful supply chain due to the high level of trust between project management teams. Get the next level of management aligned on both sides for better results.	Your product is very well protected because of the openness and visibility into each other's businesses. People are energized on both sides. A high level of trust greatly helps the supplier/customer relationship succeed.

About the Author

Angie Green is the former VP of global outsourced manufacturing operations at The Medicines Company. She has worked in the pharma industry for 9 years and manufacturing for 16 years. Her former role at The Medicines Company included responsibility for global CMOs in a virtual manufacturing environment.

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A Portfolio Approach To Achieving Excellence In Pharmaceutical Manufacturing

By Booma Yandava

The pharmaceutical industry has traditionally been guaranteed relatively high ROI and profit margins from blockbuster products, thereby enabling investments in drug R&D rather than in operational efficiencies or cost-containment measures. However, increased global demand for less expensive generics and complex biologics, along with complexities in producing and delivering quality therapeutic products, has resulted in a shift in pharmaceutical product portfolio, manufacturing, and supply chain strategies.

In addition, pharmaceutical companies wishing to do business in emerging markets are being pushed to revisit their supplier and collaboration configurations, as well as invest in local manufacturing facilities — a strategy of "in country, for country." As a result of these changes, there is clearly a need to elevate manufacturing and supply chain management to more strategic and tightly integrated roles. Such elevation can be achieved by applying a portfolio approach wherein synergies between the product portfolio, supply chain models, and manufacturing processes are aligned to anticipate demand and quickly adjust output capacity. This paradigm is already being implemented in the technology and retail industries, where product-specific fulfillment and manufacturing are becoming more commonplace.

PORTFOLIO APPROACH — ONE SIZE DOES NOT FIT ALL

A supply chain portfolio approach to achieving manufacturing excellence is not a "one-size-fits-all" process of converting materials into therapeutic agents via a monolithic, siloed, replenishment-based supply chain. Rather, it is achieved when manufacturing takes responsibility for productivity and process innovation, and responds to global demands by closely aligning with supply chain strategies, driven by the company's long-term strategic and financial goals for optimal performance. The best place to start is with the product portfolio.

UNDERSTANDING THE PRODUCT PORTFOLIO

Given the highly dynamic nature of the pharmaceuticals industry, business strategies shift, as do their product categories and their associated complexities for manufacturing. Understanding and evaluating a company's product portfolio for core and noncore fit and aligning sources of value creation with the delivery process are both key to understanding how supply chain and manufacturing choices can be evaluated.

For instance, manufacturing and order fulfillment demands on biologics are not the same as those of generics or branded therapeutics. While current models tend to limit the analysis of products to demand forecasts, clinical trials, manufacturing costs, price, and other parameters, products must be evaluated in the context of a product portfolio for manufacturing and fulfillment needs. Further, a product portfolio must be assessed for product design, supply chain response requirements, manufacturing flexibility, and financial goals.

Examples of such criteria include:

- product design and packaging considerations, such as product shelf life, dimensions, quality, and supply base that will feed into the bill of material (BOM)
- order-to-delivery needs for each product line, product mix, region, and customer segment to evaluate speed versus predictability
- customer/partner integration
- cost considerations and asset management goals to align with overall strategic and financial goals
- determination of commercialization and manufacturing characteristics early on during the new product introduction stage for complex products
- a robust integrated business planning model to support product portfolio management, product commercialization, supply chain portfolio, and manufacturing.

THE SUPPLY CHAIN PORTFOLIO

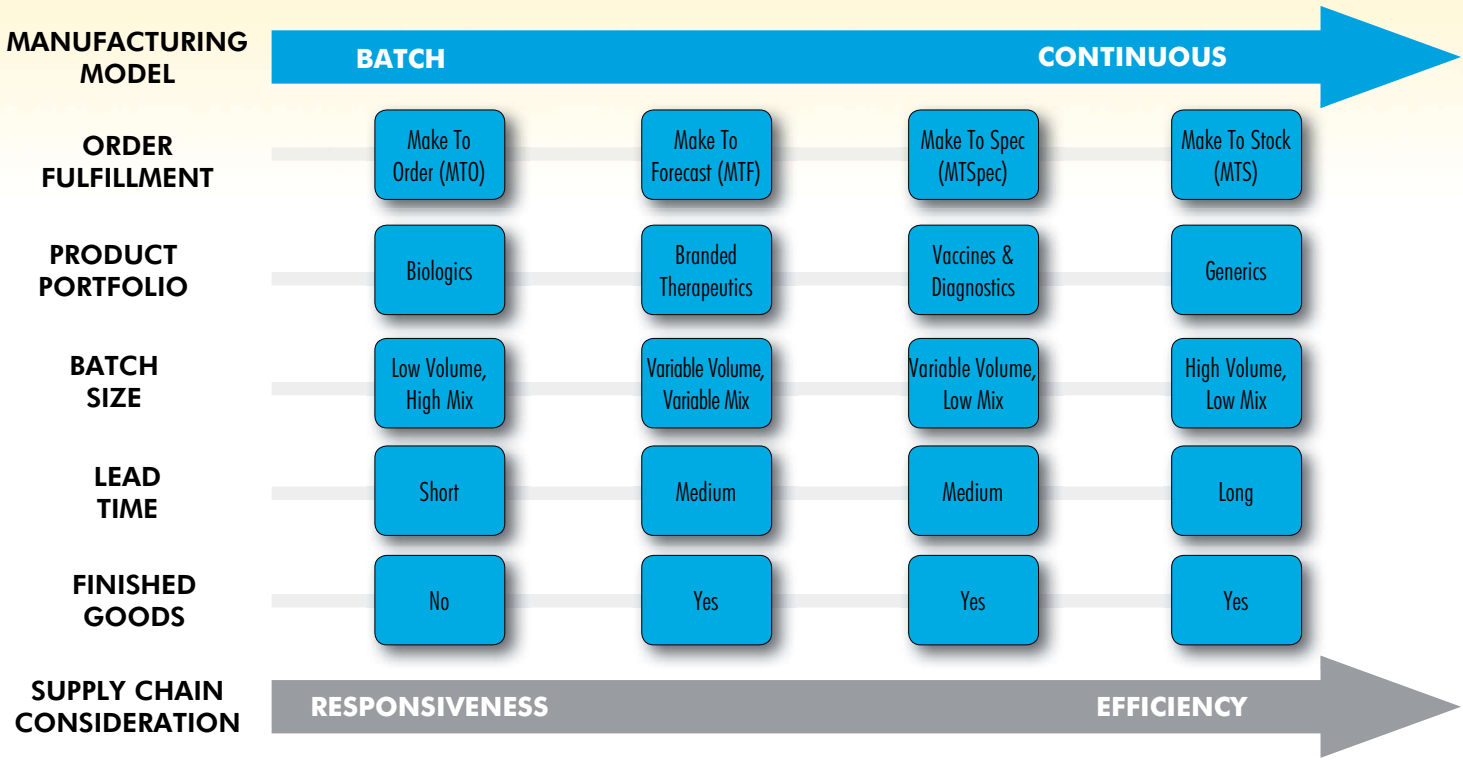
Biologics are characterized by low-volume, disease-defined small batch sizes, and shorter lead-time. The make-to-order (MTO) fulfillment model, along with demand-driven capacity planning, can be leveraged for manufacturing such therapeutic agents. Batch processes with single-use equipment can be adapted to biologics for niche markets where scalability is not a factor. Batch processing also makes it easy to switch production of one product to another, either for clinical trials or sustained manufacturing. Biologics are more amenable to a response-driven fulfillment model that favors on-time delivery, personalized customer service, and flexible supplier contracts.

Generic products, with their mix of high volume and low variety, can be fulfilled by leveraging make-to-stock (MTS) or make-to-forecast (MTF), since batch sizes are large and products can be customized for a given market. Manufacturing follows smooth production with low-cost sourcing strategies. Demand forecast, product quality, asset utilization, and Lean manufacturing are key considerations to being more efficiency-driven than responsiveness-driven.

On one end of the spectrum is the responsiveness-driven pull model; on the other end is the efficiency-driven push model. A product portfolio may not conform to one or the other supply chain model neatly, due to the nature of the products in a portfolio. For example, biologics will have subportfolios of products based on disease states, delivery mechanism, shelf life, and so forth. Although inventory reduction is ideal, the demand-based pull model is highly complex, and does not always lead to cost reduction in every situation. Degrees of agility, responsiveness, and efficiency trade-offs can be achieved further by applying supply chain strategies such as product postponement, vendor-managed inventory, and other supply chain network considerations where finished goods inventory (FGI) is not owned by the companies until they are shipped out to end customers. A small amount of safety stock is maintained at the regional distribution centers (RDCs) based on the replenishment lead time and variability of demand.

Postponement strategies are specifically useful when local design and manufacturing are desired. Trade-offs between cost and responsiveness determine the best possible supply chain model.

The keys to achieving excellence in pharmaceutical manufacturing and the supply chain are understanding the demand pat-



terns by SKUs and then defining the order fulfillment process for the finished goods. Further, upstream processes, such as raw material (RM) supply chain, procurement, and warehousing, can be decoupled and refined across the spectrum of push to pull to achieve an optimal supply chain model. This can be achieved by conducting a detailed mapping of the fulfillment process from formulation to quality control to packaging and distribution, with a focus on lead time at every node, minimum safety-stock requirements, impact of major events on inventory levels such as approval of drugs, total landed cost, and manufacturing constraints for each product portfolio. Further, the supply chain model can be optimized for resource, transportation, supplier contracts, cross-border delivery, and other criteria.

ALIGNING MANUFACTURING WITH THE SUPPLY CHAIN PORTFOLIO

Today's pharmaceutical manufacturing functions largely as a disconnected business with little alignment with fulfillment models. The right supply chain model for a product or a portfolio of products depends on how well the supply meets the demand.

With increased yield and efficiencies, lower capital and operating expenditure, less waste, and greater product recovery and economies of scale, continuous manufacturing is well suited for generics-based MTS or MTspec therapeutic agents. Continuous manufacturing offers an advantage in that capacity can be adjusted to market demand. Local manufacturing plants can be configured to reduce transportation and stocking to meet local demands. Various manufacturing sites dispersed globally can be brought to the same level of quality standards. Product demand for generics can come from various sources, including online. Therefore, it is imperative that manufacturing be cost-efficient such that order fulfillment is always ready to meet any demand with a cost-effective push model.

Biologics with an MTO fulfillment model are well-suited for batch processes where sales forecasts are unstable, the customer population is small, and product and manufacturing complexities are high. Batch processing enables careful considerations of product modifications, such as accurate post-translational modifications, safety, quality, and downstream processing. For metabolite-based therapeutic agents, the batch process may be preferable due to strain degradation and stability issues that are often associated with continuous manufacturing technology. Recombinant DNA-based biologics are better produced using batch processes where optimal culture conditions are achieved for improved yields.

Further, a fed-based culture system — a hybrid system between continuous and batch processing — can be adopted where quality, cost, order-to-delivery time, cycle time, and other factors can be easily controlled to align with a selected supply chain model.

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product portfolio and supply chain model will reduce complexity and enable optimal capacity utilization. A responsive manufacturing process that avoids the risk of inventory pile-ups and obsolescence can be achieved by adopting a flexible manufacturing model in which it is easy to switch between a batch process and a continuous process according to the fulfillment model identified based on the product portfolio.

With the recent trend of moving to a continuous manufacturing process, the looming question is: Does adopting one or the other process for all product types and supply chain models yield desirable results?

Defining pharmaceutical manufacturing that extends well beyond production cost and labor arbitrage and that generates value from supply chain fulfillment and product portfolio encompasses the following key elements, at minimum:

- a segmented manufacturing approach such as a "job-shop factory" for low-volume, highly-differentiated MTO products, and a dedicated production line for high-volume, low-mix, MTS-based products
- a sophisticated modeling tool to simulate various plant configurations to enable testing various plant configurations for varying fulfillment models and product portfolios
- a postponement capability to enable packaging, labeling, and just-in-time delivery of products in a location-specific manner
- standardized business processes to optimize trade-offs among performance, yield, and price
- Engaging manufacturing business units or CMOs from the very product portfolio definition stage.

GUIDELINES FOR EXCELLENCE

Plant efficiency and ideal full capacity utilization cannot be achieved without tight integration of supply chain processes and a product portfolio assessment, of which new product introduction (NPI) is a key part. Regardless of the supply chain model and manufacturing processes, a visionary manufacturing organization will have shorter cycle time, pull-based API consumption, capacity planning that is closely aligned with NPI planning, tighter finished inventory for goods, order tracing, shipment tracing, integrated quality, and transparency. These are just a few examples of levers to elevate manufacturing execution to a more strategic role. In addition, the product portfolio should be continually renewed with a focus on shorter time-to-market, maximized forecast accuracy, and end-to-end efficiency to ensure responsiveness and efficiency of producing and fulfilling orders.

Cycle time and customer experience are key metrics to track for improving responsiveness, and customer experience is a key consideration for generics or products that are in a steady state. In addition, assessing of inventory levels on an ongoing basis is imperative for cost reduction and efficiency management.

Regardless of the products, place, and manufacturing model, the following are some of the best practice recommendations that can save money and improve margins:

- With increasing costs and lower return on investments, pharmaceutical manufacturing under a one-size-fits-all umbrella is no longer sustainable.
- A portfolio approach that starts with a product portfolio assessment to match manufacturing strategies with the supply chain and fulfillment model will not only decrease inefficiencies and cost but also improve time-to-market in a sustainable way.
- With demand-based pull strategies and a supply-based push model, pharmaceutical manufacturing can become more responsive with clear visibility into the quality of products. External collaboration with suppliers and customers and internal collaboration with product development teams, supply chain operations, sales and marketing will help build tighter links along the value chain to strengthen manufacturing.

Above all, integrated manufacturing planning must carefully consider risks, such as increasing demand uncertainty, exploding product proliferation and complexities, and global uncertainties.

CONCLUSION

The proposed approach is not without challenges. For example, it is not clear how a continuous manufacturing process characterized by economies of scale can be adopted for a pull strategy. Similarly, Lean, Six-Sigma concepts that are well adopted for a continuous manufacturing process with high-volume, low-mix and repetitive operations lines pose challenges when adopted to biologics-based therapeutics agents.

But with cross-pollination from other industries' improvements in technology and changing market conditions, pharmaceutical manufacturing can address these challenges and deliver on its parent company's business and strategic objectives of being responsive and efficient to meet customer needs.

About the Author

Booma Yandava works for KPMG. She received her MBA from Babson - Olin Graduate School of Business and is a certified global business professional with several years of experience with manufacturing and supply chain in the pharmaceutical industry.

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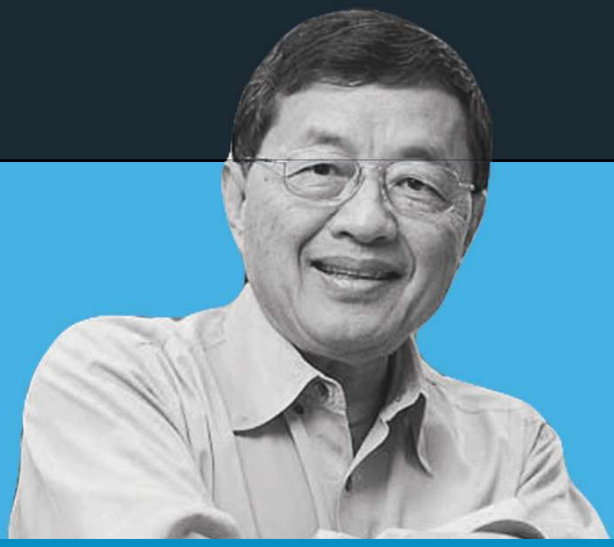

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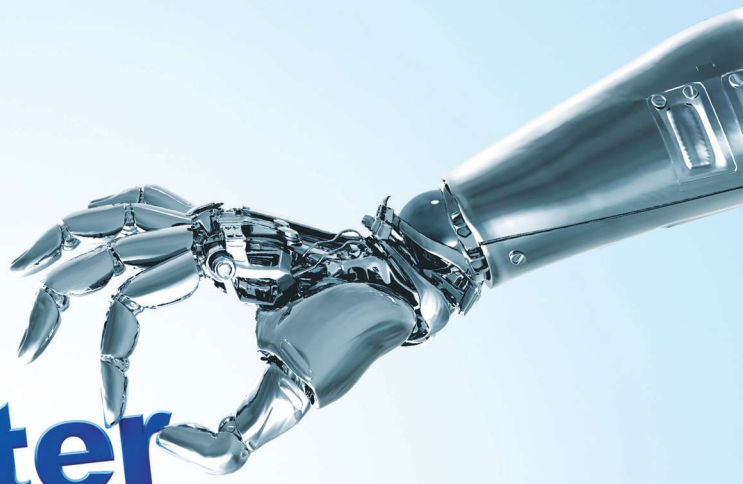

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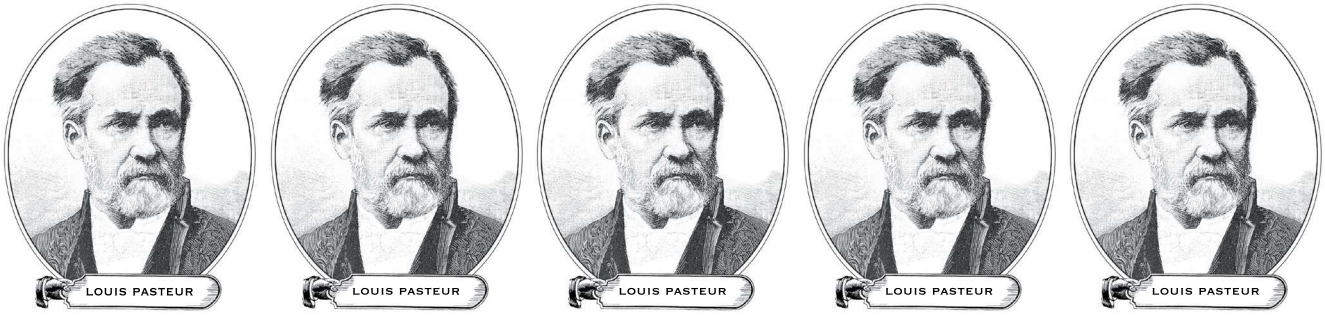

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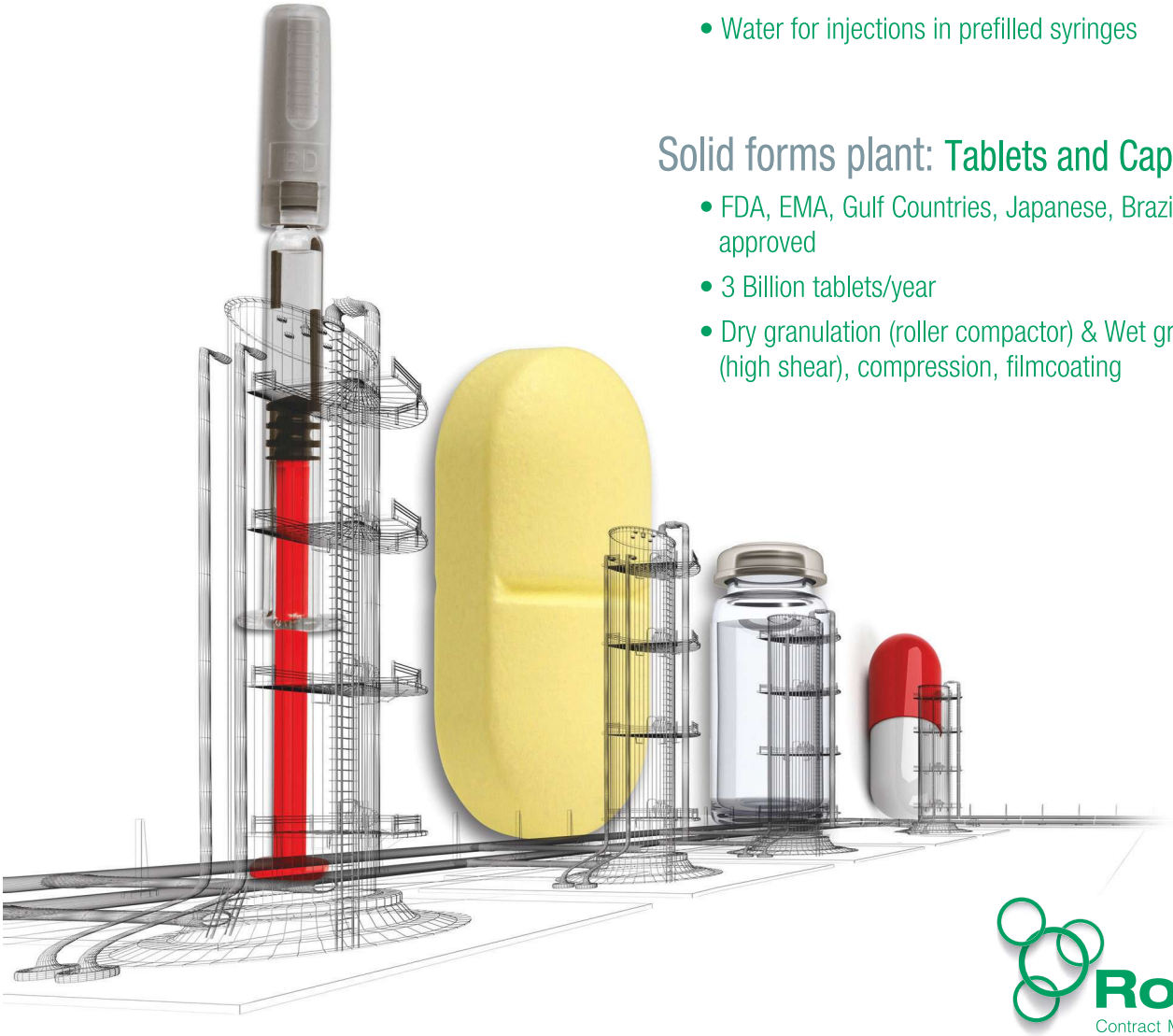

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Industry Leader

Biopharm Manufacturing: Matching Capabilities To Requirements

Günter Jagschies

Dr. Günter Jagschies has held senior management positions in sales, marketing, and R&D within the bioprocess division of GE Healthcare Life Sciences. His current role is senior director of strategic customer relations.

The biopharmaceutical industry is witnessing a shift toward "flexible" manufacturing. Businesses start with just ideas and perhaps one product in the pipeline and no product in market. In this initial high-risk phase, it is important to form the foundation of flexibility, the understanding of the product, and the establishment of the process. Once pilot-scale manufacturing appears on the horizon, the investment that is required must consider flexibility for the time when the business succeeds and matures and thus gets busier. But do all of us know what we mean by "flexible"? I want to explore the term and show how a greater appreciation of it can reap huge benefits for any company, from reducing capital expenditure to increasing agility in the marketplace.

Numerous economic and technical influences have brought us to the point of wanting greater flexibility in manufacturing, but there is no single approach to achieving the "right" level of flexibility. It depends on both production requirements and a company's corporate culture, and, therefore, has to take into account philosophical, economic, and technical considerations. Originally, flexibility was strongly linked to single-use (disposable) systems for a particular operation/procedure/campaign, but it is now a more complex proposition, linking many elements connected with new and established technologies, facility design, staffing levels, regulatory framework, cost, and the political climate. A company will know when it has a "flexible facility" when it can accommodate the next surprise, such as a change in campaign or demand for a specific product, without a redesign.

FLEXIBLE BIOMANUFACTURING

Flexibility in biomanufacturing can mean manufacturing various products simultaneously or the ability to switch between campaigns easily and quickly. The highest demand for flexibility occurs in the non-GMP phase of a busy pilot plant, but for more established businesses, with several clinical projects ongoing in parallel, this may even be true for GMP manufacturing supporting trials. Typically, there is much less and a different type of flexibility demand in late-stage clinical trial support and the manufacturing of marketed products. At these stages, flexibility becomes more related to changes in scheduling than to the number of molecules and projects. Flexibility requires the design of processes that can be reconfigured or the ability to provide a wider range of options to produce drugs in the same facility that use different scales, technology platforms, and upstream and downstream processes. Making preclinical or clinical and commercial batches in the same facility also has different quality and compliance requirements.

THE IMPACT OF SINGLE-USE

Single-use equipment offers a way to improve flexibility over fixed stainless-steel installations, including traditional mono-facilities built to produce large volumes of a blockbuster drug. The choice between stainless steel and single- use is influenced not just by the economics of producing a batch size and the cost of goods, but also by the speed by which processes can be configured and operations started. These factors take operational flexibility to a new height, offering a choice when capital investment is at considerable risk because a biotherapeutic has not yet been approved or a marketing forecast changes.

The ability to install capacity that matches a company's product forecast with closer certainty is very valuable. One such approach involves implementing new flexible factory platforms and modules that will accelerate biomanufacturing capacity while lowering risk, increasing speed, and reducing capital costs. These modules enable the deployment of new production capabilities in 9 to 18 months (versus 3 to 5 years for approaches used routinely today) at a total cost of less than 50 to 80 percent of conventional plants. They offer a solution that enables a gradual ramp up of capacity and which also readily supports localized manufacturing in emerging markets.

In conclusion, it is important to consider how flexibility can benefit the organization at all stages of the company's development and those of its pipeline and products. This article has highlighted factors to consider and weigh in the drive to incorporate and benefit from flexible manufacturing for today and for tomorrow.

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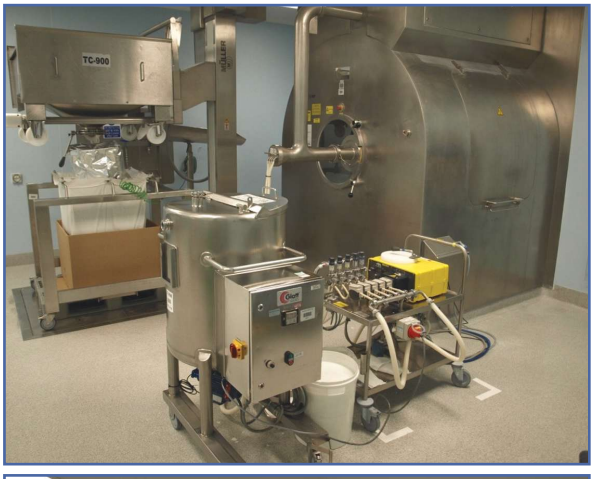

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Addressing The Challenges In Biopharm Manufacturing

Biopharmaceuticals are more in demand than ever, but the biomanufacturing industry faces increasing pressure to reduce costs without sacrificing quality. Some might say this is an impossible dilemma. One way to address the challenge is to increase the productivity of bioprocessing without increasing its footprint, which means producing more of the same product without increasing facility space requirements or the use of raw materials.

In this context, a line tends to be drawn between upstream production and downstream processing/purification. In monoclonal antibody (mAb) manufacturing, upstream production methods have improved more than 100-fold over the past 25 years, thanks to strain development and improved media and bioreactor technology. In process development, companies are regularly achieving titers of 5 to10 grams of mAb per liter of culture broth without a significant increase in the footprint. But downstream processing is a different story. Although there have been significant productivity improvements, they have been incremental rather than game changing, and therefore, much of the improvement in upstream productivity has been matched by increasing the scale of the purification train, including peripheral utilities. Such changes use more space and raw materials, and therefore, equate to a larger footprint, which makes it much more difficult to keep the costs of production under control.

INNOVATION IS THE KEY

Under pressure from all sides, biopharmaceutical manufacturing needs to embrace smart new ways to produce high-quality products without escalating costs. Incremental changes are no longer sufficient to keep up with demand, so innovative approaches are required.

For example, both product developers and CMOs are increasingly turning to disposable solutions. Single-use concepts in biomanufacturing are not new. Disposable filters have been with us for many years. However, the scope of single-use equipment is increasing as more manufacturers come to appreciate its benefits. For example, as disposable bioreactors, filters, and chromatography modules become more common, it becomes more likely that the processing train of the future could be assembled completely from disposable units, thus reducing investment in bricks and mortar and allowing production to move from centralized "superfacilities" to regional centers serving local markets.

Vaccine and mAb manufacturers, in particular, are beginning to take advantage of leaner processes with reduced construction, technology transfer, and validation requirements. This trend will gain further momentum with the success of biosimilars, which seem to be gaining the most attention from innovator companies. Disposable manufacturing is being considered for the rapid production of clinical material and — with the current trend toward smaller process trains — such approaches are bound to be applied more often at the commercial scale.

INNOVATIVE REINTRODUCTION OF OLDER TECHNOLOGIES

Innovation implies a requirement for novel technologies, but this is not always necessary, as shown by the innovative reintroduction of older technologies, once abandoned, but now considered from a fresh perspective. Lessons can be learned from other manufacturing industries where these inexpensive bulk-processing technologies have been highly successful. Several recent developments suggest that simpler technologies could indeed find a niche in biopharm manufacturing, particularly in the early processing steps where the complex mixture of particulates and solutes has the greatest potential to foul expensive membranes and resins. Therefore, although tangential flow microfiltration, depth filtration, and (continuous) centrifugation are seen as the industry workhorses for clarification, simpler approaches, such as flocculation and precipitation, are now being introduced as alternative clarification steps.

Novel technical solutions currently appear to be favored for upstream production, including new media compositions, new bioreactor designs, and new cell strains with greater intrinsic productivity. However, closer scrutiny shows that cutting-edge technologies (e.g. convective media such as membrane chromatography modules) are being used to improve the closing stages of downstream processing, providing new strategies to overcome known bottlenecks.

Uwe Gottschalk

Uwe Gottschalk is group VP for purification technologies at Sartorius Stedim Biotech. He worked in different capacities for Bayer Health Care from 1991 to 2004, overseeing the purification of monoclonal antibodies and other recombinant proteins.

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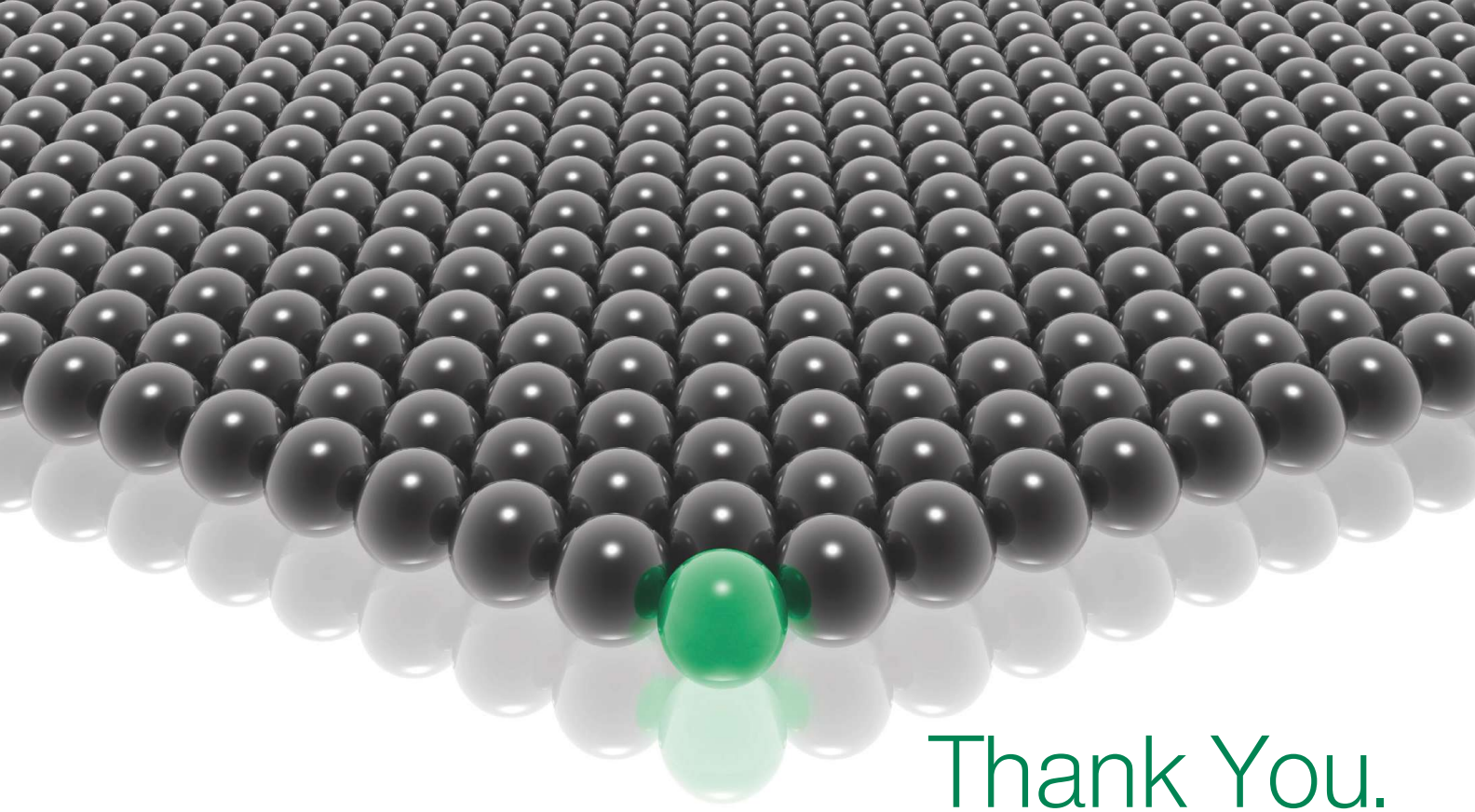

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