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Facing pressure to improve timelines in drug development and reduce costs in drug development and commercialization, the pharmaceutical majors are increasing their level of external development and manufacturing. At the same time, they are looking to manage these external relationships more efficiently and cost-effectively. The result is the preferred-provider relationship in outsourcing. Unlike simple transactional or fee-for-service outsourcing, preferred-provider relationships represent a deeper, more collaborative, and enhanced strategic partnership between sponsor companies and their third-party providers and satisfy an interest by pharmaceutical companies to work with fewer suppliers. During the past several years, select pharmaceutical majors have entered into preferred-provider relationships, particularly with CROs, although manufacturing-based relationships also have been formed.

Big Pharma partners

Pfizer. In May 2011, Pfizer formed strategic partnerships with the CROs Icon and Parexel, both of which will serve as strategic providers of clinical-trial implementation services over a five-year period beginning in June 2011. The new partnerships will be fully implemented over an 18- to 24-month period.

In announcing the collaborations with Icon and Parexel, Pfizer said that the two-partner model will simplify its processes by reducing the number of external service providers that the company uses for clinical-trial execution. Pfizer says this new strategic partnership model does not substantially change the proportion of clinical-trial implementation services that the company outsources. Pfizer is retaining scientific ownership of the clinical-development process and is maintaining oversight and quality standards relating to patient safety and regulatory compliance.

“We’ve also [have] taken a look at the value chain inside our research organization and have outsourced a lot of our clinical work with a strategic partnership with Icon and Parexel,” said Ian Read, chairman and CEO at Pfizer at the JPMorgan Healthcare Conference, which was held in January 2012 (1). “I think that’s a major strategy for us. We’ve rationalized our efforts there. Before we were dealing with 18, 19, 20 plus partners. It was very difficult to control. It was very difficult to get quality work and get savings. We now have a strategic partnership with two global players.”

Bristol-Myers Squibb. Pfizer’s partnership with Icon and Parexel followed an earlier partnership made by Bristol-Myers Squibb with Icon and Parexel. In June 2010, Bristol-Myers Squibb signed three-year agreements with Icon and Parexel for joint strategic,
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Partnerships

Table I: Publicly announced preferred-provider deals.

<table>
<thead>
<tr>
<th>Segment</th>
<th>CRO/CMO</th>
<th>Client</th>
<th>Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multiservice</td>
<td>Covance</td>
<td>Sanofi</td>
<td>2010</td>
</tr>
<tr>
<td>Multiservice</td>
<td>Aptuit</td>
<td>GlaxoSmithKline</td>
<td>2010</td>
</tr>
<tr>
<td>Multiservice</td>
<td>Covance</td>
<td>Eli Lilly</td>
<td>2008</td>
</tr>
<tr>
<td>CMC</td>
<td>WuXi AppTec</td>
<td>Bristol-Myers Squibb</td>
<td>2011</td>
</tr>
<tr>
<td>Clinical packaging</td>
<td>Fisher Clinical</td>
<td>Eli Lilly</td>
<td>2010</td>
</tr>
<tr>
<td>CMO (biologics)</td>
<td>Lonza</td>
<td>GlaxoSmithKline</td>
<td>2010</td>
</tr>
<tr>
<td>CMO (biologics)</td>
<td>Lonza</td>
<td>Novartis</td>
<td>2009</td>
</tr>
<tr>
<td>CMO (biologics)</td>
<td>Lonza</td>
<td>Genentech</td>
<td>2008</td>
</tr>
<tr>
<td>CRO</td>
<td>Icon, Parexel</td>
<td>Pfizer</td>
<td>2011</td>
</tr>
<tr>
<td>CRO</td>
<td>Icon, Parexel</td>
<td>Bristol-Myers Squibb</td>
<td>2010</td>
</tr>
<tr>
<td>CRO</td>
<td>Covance, Quintiles</td>
<td>Takeda</td>
<td>2010</td>
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</tbody>
</table>

CMC is chemistry, manufacturing, and controls. Roche acquired Genentech in 2009.

operational, and capability support of Bristol-Myers Squibb’s clinical-development program. In August 2011, Bristol-Myers Squibb selected Icon as a preferred provider for full-service clinical pharmacology and exploratory clinical studies.

Bristol-Myers Squibb has since followed with other preferred-provider arrangements. In March 2011, Bristol-Myers Squibb and the CRO WuXi AppTec formed a strategic partnership for stability studies of small-molecule new chemical entities. Under the agreement, WuXi will build, equip, and operate a dedicated, fully cGMP-compliant 25,000-ft² analytical testing facility in Shanghai to store and test stability samples and to perform other services for Bristol-Myers Squibb. WuXi also will employ a dedicated staff for stability testing, sample management, analytical testing, pharmaceutical science, quality assurance, metrology, and other services, including stability-data reporting in support of all global dossier submissions by Bristol-Myers Squibb.

Bristol-Myers Squibb also had adopted a facility component in its preferred-provider relationship with Syngene International, a subsidiary of the Indian biotechnology company Biocon. In March 2009, Syngene opened a fully dedicated R&D facility for Bristol-Myers Squibb in Bangalore, India. The 200,000-ft² facility is focused on discovery and early-drug development. Construction on the facility began in March 2007 when Bristol-Myers Squibb and Biocon entered into an agreement to develop integrated drug-discovery and development capabilities at Syngene.

Sanofi. In October 2010, Sanofi and the CRO Covance finalized a 10-year, $2 billion R&D alliance, which included an asset and staff transfer of two R&D facilities and approximately 300 associated scientific and technical staff. Under the agreement, Sanofi sold its Porcheville, France, and Alnwick, United Kingdom, sites and facilities to Covance for approximately $25 million. Under the agreements, Sanofi is using Covance’s global R&D portfolio of discovery support, toxicology, chemistry, clinical Phase I–IV, central-laboratory, and market-access services with annual commitments for these services increasing over the next decade. These agreements included a 10-year sole-source relationship for central-laboratory services. Covance gained chemistry, manufacturing, and controls (CMC) services with the addition of the Porcheville and Alnwick sites, including preformulation, drug formulation, preclinical, early-stage clinical API manufacturing, and radiolabeled chemistry.

When announced in 2010, Covance expected the alliance to generate revenues between $1.2 billion and $2.2 billion.

Eli Lilly. Covance’s partnership with Sanofi followed another long-term, high-value partnership with Eli Lilly. In August 2008, Eli Lilly and Covance entered into a long-term strategic alliance in which Covance acquired Eli Lilly’s preclinical research facility in Greenfield, Indiana, for $50 million. As part of the agreement, Covance hired 264 former Eli Lilly employees, and Eli Lilly committed to providing $1.6 billion in work to Covance over 10 years for a broad range of drug-development services. Covance also assumed responsibility for all of Lilly’s toxicology testing and discovery support activities at Greenfield.

Eli Lilly has further used the preferred-provider model in its clinical-trial-materials supply activities. In March 2010, Thermo Fisher Scientific expanded its clinical-trial material supply relationship with Eli Lilly as part of a new, five-year agreement. Under the agreement, Fisher Clinical Services, a business of Thermo Fisher, took over responsibility for Eli Lilly’s in-house clinical-trial-materials manufacturing, packaging, and labeling operations onsite at the Lilly Technology Center North in Indianapolis, Indiana. Fisher Clinical Services also is handling the distribution of clinical-trial materials for Eli Lilly throughout North America. The agreement included Fisher Clinical Services’ purchase of Lilly’s clinical-trial-manufacturing and packaging equipment. This relationship was expanded to support Lilly’s new operating model, which is designed to speed drug development while reducing fixed costs.

Eli Lilly adopted a preferred-provider approach in API manufacturing as well. In January 2010, Eli Lilly finalized the sale of its Tippecanoe Laboratories API manufacturing facility in Lafayette, Indiana, to Evonik Industries in a deal first announced in 2009. The facility produces APIs, fine chemicals, and animal-health products. In connection with the sale of the site, the two companies entered into a nine-year supply and services agreement, whereby Evonik will manufacture final APIs and intermediates for certain Eli Lilly human and animal-health products. The sale of Tippecanoe Laboratories was the culmination of Lilly’s strategic review of the site that was announced in July.
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2008. The decision to sell the site was based upon a projected decline in utilization of the site due to several factors, including upcoming patent expirations on certain medicines made at the site, Lilly’s strategic decision to purchase, rather than manufacture, many late-stage chemical intermediates, and the evolution of the Lilly pipeline toward more biotechnology medicines.

**GlaxoSmithKline.** Two preferred-provider relationships from GlaxoSmithKline (GSK) involve manufacturing with the CMO Lonza and R&D with the CDMO Aptuit. On the manufacturing side, GSK partnered with Lonza in September 2010 for securing capacity and expertise in biological manufacturing by which Lonza is supplying manufacturing capacity for five early-stage monoclonal antibodies of GSK.

Under the terms of the agreement, Lonza will initially manufacture clinical-trial batches of five compounds currently in Phase I and II for GSK. Lonza also will provide access to flexible capacity to enable GSK to respond to future demand dependent upon progression of the molecules through late-stage development and commercial launch. As part of the agreement, GSK will work with Lonza to assess options for the design, specification, location, and construction of a biopharmaceutical manufacturing facility within the UK.

On the R&D side, in July 2010, GSK and Aptuit finalized an agreement under which Aptuit acquired operations at GSK’s Medicines Research Center in Verona, Italy, for supplying R&D services to GSK. Aptuit gained the scientific expertise and knowledge of approximately 500 staff at the research center through the transfer of the facility. The agreement allows Aptuit to combine its expertise with the Verona Medicines Research Center’s expertise in drug discovery, lead optimization, API development and manufacturing, and preclinical and clinical drug development.

**Other relationships**

Although the high-profile deals with the pharmaceutical majors garner much of the attention in preferred-provider partnerships, smaller bio/pharmaceutical companies also may use this model with their outsourcing partners. For example, in January 2012, AMRI, a contract research and manufacturing organization, entered into a preferred-provider agreement with BioPontis Alliance, an asset-based investment capital fund and R&D company that has scientific alliances with research universities. BioPontis focuses on developing treatments for cancer, neurology, inflammation, and infectious diseases.

The BioPontis Alliance has agreements with New York University, Columbia University, Memorial Sloan–Kettering Cancer Center, University of Pennsylvania, University of North Carolina (Chapel Hill), University of Virginia, University of Kansas, Oregon Health and Sciences University, Thomas Jefferson University, and the University of Florida. In addition to these partnerships aimed at identifying early technology, BioPontis has entered into preferred-partnership agreements...
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<tr>
<td>Facility &amp; Process Validation</td>
<td>Mycoplasma Testing</td>
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Partnerships

with pharmaceutical companies, including Janssen Biotech (wholly owned by Johnson & Johnson), Pfizer, and Merck & Co.

The goal of the BioPontis Alliance is to identify promising early-stage product opportunities and use a preferred network of CROs and research companies to apply appropriate expertise to develop these opportunities enough to attract pharmaceutical companies as licensing partners. Under BioPontis Alliance’s agreement with AMRI, AMRI will provide its services in small-molecule discovery, development, and manufacturing in support of BioPontis’ drug-discovery research programs and need for proof-of-concept data that is required for pharmaceutical-company licensing.

In September 2011, the regenerative-medicine company Mesoblast and Lonza entered into a strategic alliance for clinical and long-term commercial production of Mesoblast’s off-the-shelf (allogeneic) adult stem-cell products. The alliance provides Mesoblast with certainty of capacity to meet long-term global supply of its proprietary Mesenchymal Precursor Cell (MPC) products. Under the agreement, Lonza will supply Mesoblast’s clinical and long-term commercial MPC product needs globally. Mesoblast can trigger a process requiring Lonza to construct a purpose-built manufacturing facility exclusively for Mesoblast’s marketed products. In return, Mesoblast will purchase agreed quantities of marketed products from the facility. Mesoblast can exercise its right to buy out this manufacturing facility at a pre-agreed purchase price two years after the facility receives regulatory approval. Mesoblast will have exclusive access to Lonza’s cell-therapy facilities in Singapore for the manufacture of allogeneic cell-therapy products, subject to certain exceptions. Lonza will use its proprietary intellectual property to facilitate reductions in Mesoblast’s manufacturing costs and help enable development of enhanced second-generation products.

Although not strictly a preferred-provider relationship, contract service providers also may partner in highly strategic ways to expand their range of capabilities. For example, the CMO Kemwell partnered with the contract services business of Boehringer Ingelheim in 2009 for building a biopharmaceutical manufacturing plant in Bangalore, India. The 15,000-m² facility was designed for process development, production, purification, and formulation of biologics for early-phase preclinical and clinical studies. The facility consists of a cGMP drug-substance manufacturing facility and a sterile fill–finish facility for drug products with a floor for process-development laboratories to support production of protein therapeutics from mammalian-cell culture or microbial fermentation. Boehringer Ingelheim is contributing cell-line development with its BI Hex technology platform and preferred access to its large-scale commercial production facilities in Europe.

Reference


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Case Studies in Pharmaceutical Project Management

A Technical Forum

Moderated by Patricia Van Arnum

Project management underpins successful relationships between contract technology and service providers and their sponsor companies. As pharmaceutical companies increase their level of outsourcing, it becomes increasingly important for contract technology and service providers to provide not only the technical capabilities needed to execute a given project, but the management skills to deliver a project on time, to specifications, and with the necessary communication to prevent or mitigate project delays. To illustrate the importance of project management in outsourcing, several industry members provided case studies on how to coordinate, organize, and implement a successful project. Participating in this technical forum on project management are Norman Weichbrodt, strategic account manager at Catalent Pharma Solutions; Nick Johnson, marketing manager at SAFC; and Saharsh Rao Davuluri, president of contract research at Neuland Laboratories.

Blow/fill/seal manufacturing

Norman Weichbrodt, strategic account manager at Catalent Pharma Solutions

Catalent Pharma Solutions is a provider of drug and biologic development services, delivery technologies, and supply solutions. Effective project management is the cornerstone of being a complete provider of services ranging from development of new products to technical transfer of existing products. Building the proper project team and employing the correct methodology for handling a complex project is the foundation on which success is achieved.

In July 2010, Catalent was approached by a major pharmaceutical customer to transfer an ophthalmic product approved for sale in Europe to Catalent’s blow/fill/seal (BFS) manufacturing site in Woodstock, Illinois. The successful technical transfer of the manufacturing process for this product would potentially lead, following FDA approval of the product already made in the European facility, to approval of the drug for manufacture and sale in the United States.

Project scope. The actual scope of this project was much larger for the Woodstock facility than a simple technical transfer. The project required the following:

Effective project management is an invaluable competency in a successful outsourcing relationship. Catalent Pharma Solutions, SAFC, and Neuland Laboratories, offer examples of successful project management, respectively in blow/fill/seal operations, viral-product manufacturing, and real-time project management in API manufacturing.
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Project Management

- A complete renovation of a formulation and filling suite, including a new separate air-handling system
- Designing, building, and qualifying an automated formulation skid
- Upgrading an existing BFS filling machine to match the capacity requirements for the product
- Designing, building, and qualifying new vial molding and filling systems to duplicate the existing European design
- Qualifying the room, formulation skid, BFS machine, and secondary packaging to produce stability and process-validation batches to support the customer’s submission and approval timeline
- Developing and approving the required documentation for supply-chain, manufacturing, and quality assurance functions to meet the production timeline
- Analytical-method transfer for chemistry and microbial testing
- Complete process-validation protocols, test plans, and final reports to meet the submission timeline.

Cross-functional teams. To manage a project of this scope, the Catalent New Product Development (NPD) group and the site-management team agreed to form a group of cross-functional resources. The team members served as the primary representative of their functional area for the project and were assigned for the duration of the project. The project team consisted of a project manager from NPD, an engineering project manager, a development scientist, an operations specialist, a validation specialist, a quality-assurance product specialist, a technical writer, and various contract resources as required. A strategic account manager had overall responsibility for the project team. The establishment and use of an expanded core project team of cross-functional resources was a new approach for Catalent’s Woodstock facility, but the scope and timeline for this project and the Catalent goal of meeting customer needs required an innovative solution.

The project was divided into six major activities: the room, the formulation skid, the BFS machine, method transfer, secondary packaging, and documentation. The NPD project manager was the owner of the overall project timeline. Each major activity was included in a Microsoft project schedule and maintained by the project manager. The engineering project manager handled all activities involving the renovation of the filling suite, making use of contractors from design through construction and qualification. He also participated in the design and construction of the formulation skid, primarily focusing on the software development. The development scientist and the operations specialist focused on the design of the formulation skid and the interface of the skid with the BFS machine to ensure the system had the proper design and controls to replicate the process already being used in Europe. The validation specialist developed the installation qualification, operational qualification, and product qualification protocols and had oversight of all factory acceptance testing (FAT) and site-acceptance (SAT) activities. The technical writer and the quality-assurance product specialist worked with the NPD project manager to manage the change-control process for the project and to complete all the required documentation, including material specifications, standard operating procedures, and manufacturing batch records. The NPD Project manager also provided oversight of the analytical method transfer, development of secondary packaging materials, and the documentation of project activities.

Technology transfer. The technology-transfer process was initiated by creating a comparability document that detailed every aspect of the manufacturing process. The process used in the European manufacture was listed step by step in the document with Catalent’s suggestions and capabilities side by side. A final agreement for each step was included and served as the approved path forward. The specifications for in-process testing at each stage of the formulation as well as finished-product specifications were included in the document. The formulation process required bulk sterilization of a multicomponent polymer base with a relatively tight viscosity range. Two APIs were combined in a second part of the formulation and transferred to the polymer solution by sterile filtration. Of course, the entire formulation skid required steam sterilization of the product path through the BFS machine and maintenance of the sterile boundaries for the product during the entire filling process. Electronic documentation of all temperatures, times, and controls for each process step also were also required.

Communication. The NPD project manager and the strategic account manager facilitated weekly calls with the original equipment manufacturers of the formulation and BFS equipment as well as construction meetings during that phase of the project. Weekly calls were held with the customer representatives who were in liaison with the project team. A standard methodology was used to ensure that the meetings had a structured agenda and minutes issued for review in a timely fashion. A joint Project Steering Committee was formed, which was comprised of customer senior leadership members, Woodstock site leadership members, and Catalent business-development members.

Project Steering Committee meetings were held every three weeks during the course of the project. A formal presentation was made at each meeting to discuss progress toward major milestones in the project plan. Strategic decisions were discussed and developed through the Project Steering Committee meetings, and the decisions were ultimately made by the joint project team. This management design reduced the cycle time for critical decision-making between the customer and Catalent.

An example of such decision making was approval of a change to the SAT/FAT strategy originally planned for the formulation skid. The formulation skid is a fully automated two-tank system with over 100 control and process valves that are actuated in approximately 20 sequences. When the
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software development lagged behind the construction of the hardware, the opportunity arose to do a mechanical FAT, ship the formulation skid to the Woodstock site, complete the installation and mechanical troubleshooting of the skid and wait for the software to complete the qualification as a SAT. This decision saved as much as six weeks in the project schedule and enabled Catalent to meet the customer’s timeline for stability and process-validation manufacturing. It also resulted in a formulation system that is part of a robust technical transfer process from the customer through the NPD group to Catalent’s commercial manufacturing team.

**Execution.** To date, all of the engineering, stability, and process-validation batches have met the in-process and final-product test specifications. With nine batches produced, there have been no out-of-specification results for bulk or final product. In addition, no human error deviations have occurred in the formulation and filling of these batches.

Figures 1–3 (Catalent) show the facility upgrade and project equipment after installation.

In summary, Catalent did not employ new or groundbreaking methodology for this project. However, supplying the proper structure and resources for a project team is the crucial first step in meeting a customer’s timeline and supplying the customer with quality product, reliably supplied.

**Viral product manufacturing**

*Nick Johnson, marketing manager at SAFC*

This case study in project management involved the partnership between SAFC and Oncolytics Biotech, a biotechnology company headquartered in Calgary, Canada, which has developed a novel cancer treatment, Reolysin, based on a modified wild-type reovirus expressed in suspension-adapted human embryonic kidney cells (HEK 293). In 2007, Oncolytics partnered with SAFC’s Carlsbad, California, site as part of the commercialization process for Reolysin. After officially announcing SAFC as the contract manufacturer for the project in early 2011, Oncolytics announced in November 2011 that validation studies were underway. Now in Phase III clinical trials, SAFC and Oncolytics have worked as partners to manage this project from the initial phases of identifying how to make the technology work through to making the consistent batches required for licensure. The current goal is to obtain a successful regulatory approval for Reolysin.

**Project challenges.** The production of the modified reovirus presented a significant manufacturing challenge. Not only was it going to be the first time for this type of product to be
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made on such a large scale, it also involved transferring technology from a contract development organization (CDO) in Canada to the SAFC site in Carlsbad. At the beginning of the project, there were four partners in different locations, including Oncolytics, its CDO, SAFC, and SAFC Biosciences in St Louis, which developed the novel media used in the production process.

SAFC Carlsbad already was filling the bulk product for clinical trials out of a product that was being made at another CMO in the United Kingdom. As the product progressed into later-stage clinical trials, the production was ramped up and transferred to Carlsbad, at first on a 40-L scale, and up to the present 100-L batches. The technology transfer was a whole new ballgame in terms of scale and complexity and required a new project team to be formed. On the SAFC side, this included a director of operations plus senior managers in manufacturing, quality assurance, quality control, and project management. Business-development support was also brought in when new scopes of work and new contracts needed to be worked out and finalized.

Despite the disparate locations, the communication between the teams in the different sites worked well with routine weekly conference calls and many coordinating activities carried out electronically. Some face-to-face meetings were essential, including the manufacturing representative and project manager visiting the CDO to address process scale-up. A week also was spent with all partners, including the CDO, watching the process and filming it so that it could later be used for operator training in Carlsbad.

The whole process took quite some time with many technical challenges, leading to a stop-start of operations from late 2008 through to 2009. By the end of 2009, however, sufficient clinical material had been made to continue with the trials, so there was less urgency from that perspective. Once the 100-L scale was reached, one or two batches were made per year until the program was ready to initiate process validation phase, a second project manager was added to increase bandwidth. The way all parties worked together allowed the product to meet specifications and the issue was resolved.

A key factor in the overall project’s success was the customer relationship. A key factor in the overall project’s success was the customer relationship. In addition to the customer having a very good project manager, the relationship was developed based on trust and a common goal. Another key factor was ensuring that we had the resources needed to move the project forward. When the program moved into the process-validation phase, a second project manager was added to increase bandwidth. The way all parties worked together allowed the manufacturing to enter into conformance batches within a relatively short period of time with only a limited number of clinical batches having been completed.

**Issue resolution.** One issue the team faced was the presence of an impurity that prevented the product from meeting specifications. The teams were brought together, and all the possibilities that might have led to the impurity were considered. From there, action items were distributed to the teams for them to pursue, including the review of historical data. This approach was successful as by the time of the next team meeting, the problem had been pinpointed. By adapting the process for the next batch slightly, a solution was found allowing the product to meet specifications and the issue was resolved.

**Real-time project management**

Saharsh Rao Davuluri, president of contract research at Neuland Laboratories

On-time execution of API project development is a challenge for manufacturers. Neuland Laboratories has designed its GuarD project-management system around the principles of critical chain project management (CCPM), a concept developed by Eliyahu Goldratt, a prominent management consultant, who introduced the theory of constraints business model. Unlike other project-management systems, CCPM emphasizes flexible start dates and shared project resources. CCPM also uses buffers as a shared project resource rather than an individual task resource, thus enabling the overall project to be completed on time without requiring the individual tasks to be completed on time.

**Tracking progress.** From a production standpoint, Gantt charts (i.e. charts used to show the project’s schedule) are used for all SAFC projects. They are mapped out further than just a single department and include everything that might affect the timeline from the vendor through to the customer. The anticipated timings were all shared with the customer as well as the troubleshooting of possible technology-transfer issues that the technical team mapped. The team was tasked to look through historical data from the previous partnership to identify where there were areas for improvement and to help resolve issues quickly with input from both the SAFC team and the CDO. Specifically, SAFC Biosciences also helped by developing a custom growth media that increased the viral productivity and eased the purification process.

When SAFC inherited the contract, it already contained the required specifications that were used as an ultimate metric for success. The new goal became making and purifying the product to the required level for a commercial launch. After a number of changes to the process on the CDO’s side and a few creative manufacturing approaches from SAFC, these specifications were exceeded and brought the project to the current point. Oncolytics is now in a position where accessing materials for its clinical needs is no longer a constraint, and the project has advanced into process validation in anticipation of commercial launch.
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process and organization. Neuland is an API and contract manufacturer based in Hyderabad, India. Almost 80% of the company’s products are sold into the US and European markets, and these products must meet strict regulatory standards. In a typical year, Neuland scientists complete 30–40 projects ranging from complete API development, production of starting materials, and development of alternate processes for new molecular or chemical entities, as well as a variety of contract-manufacturing assignments for pharmaceutical ingredients and peptides. Depending on their complexity, projects may require process chemistry, analytical chemistry, technology transfer, production, developmental quality assurance, supply-chain management, regulatory affairs support, and project-management services.

Organizational framework and real-time monitoring. Under GuarD’s CCPM approach, each project is broken down into its basic tasks by a cross-functional team. The project has a designated team leader, usually an experienced scientist from the process-chemistry department, and a project manager responsible for managing timelines and communications. The team leader is the technical head of the project and responsible for overall execution.

Once the project has been divided into the basic tasks and sub-tasks, the details are transferred to a Microsoft project software template. This ensures that all the dependencies, resource requirements, and tentative start and end dates are recorded. The project is not considered “live” until the cross-functional team signs off on the detailed project plan. The finalized project document is uploaded to a web portal, and managers update respective tasks and sub-tasks as the project progresses. Managers can make qualitative updates detailing how tasks are proceeding, or quantitative updates to help respective task managers track how long a task will take to complete. Teams are encouraged to make at least one status update per day.

The ability to make both qualitative and quantitative updates in the GuarD project-management system is highly useful. Personnel in downstream operations, and more importantly the client, get an accurate picture of progress upstream and can plan accordingly. Neuland’s customers also can track a project’s progress and participate directly through the GuarD web portal.

Benefits. A key advantage of the GuarD system is that its detail and interactive nature make it easier to promptly identify and manage delays at any step, thereby facilitating on-time completion. For example, when the process-chemistry department requires more time to complete their tasks, the project manager is immediately aware of the situation and can work with all task managers to identify opportunities downstream to recover that time. Although it is important for the project manager to investigate the reasons for the delay, the immediate focus is on finding ways to deliver a quality project on time. Solutions might include running additional shifts or vessels or staggering batches. In most cases, customers are invited to join these discussions and contribute to the solution based on their experience and priorities.

Neuland’s project-management system helps its clients in several ways. It provides a platform of almost 100% transparency, providing more insight than weekly calls or project reports. A smart phone app will soon allow customers to access their projects real-time. It also enables higher on-time completion rates. Although the GuarD approach cannot promise 100% on-time completion, it has enabled Neuland to make considerable progress towards this goal.

Customer trends: biopharmaceutical companies

Access to capital and a lack of innovation and productivity in R&D are some threats to the biomedical industry’s growth during the next five years, according to a recent survey by the California Healthcare Institute, BayBio, and the management-consulting firm PwC US.

The CEO Survey found that nearly 74% of biomedical industry CEOs surveyed said their companies have had to delay a research or development project in the past year. Lack of funding was the top reason for project delays and accounted for 40% of delays. Forty-four percent of biomedical CEOs surveyed said they will look to licensing agreements and corporate partnerships as a source of finance in the next 12 months—that is double the number of CEOs who last year said their companies are using this avenue for finance. Corporate-venture funding, the investment of corporate funds into external endeavors, is expected to become a much more crucial source of funding to the industry, with 30% of CEOs surveyed saying they will tap corporate-venture capital as a finance source in the next 12 months, versus only 10% who did so in the past 12 months. Although still only a small contributor to the finance equation, disease foundations and nongovernmental organizations are growing as a funding source—11% of CEOs plan to use these funds in the next 12 months versus only 4% who did last year.
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Contract Relationships

Managing the Quality Relationship for a Contractual Agreement

A CMO Perspective

Susan J. Schniepp

The author describes an equation that can be used to define the Quality relationship between a contract manufacturing organization and a client, including how to factor in both party’s needs and regulatory commitments.

Contract manufacturing organizations (CMOs) occupy a special niche in the pharmaceutical industry and therefore face problems not encountered by traditional pharmaceutical manufacturing companies. One particular challenge facing CMOs is how to define the responsibility for Quality in a relationship. Which party, the contract giver or the contract provider, has which responsibilities? Although the answer may be straightforward for companies with their own manufacturing operations, it is quite complicated for a CMO. When defining ownership of “Quality,” a CMO must consider the compliance needs and regulatory commitments for multiple clients. The CMO also must look at Quality as a function of product lifecycle—in a similar manner to how their clients would look at Quality if they were manufacturing the product themselves.

The basic equation

If one views the Quality relationship as a simple mathematical equation, it may look something like this:

$$A + B + C + D = E \quad [\text{Eq. 1}]$$

where A is the CMO needs, B is the compliance needs, C is the client’s needs, D is regulatory commitments, and E is defined as the elements of the Quality relationship. By analyzing this equation, it is clear that there are no constants, only variables. Each variable is based on the consideration of certain elements from each party in the relationship.

Variable A: CMO Needs. A CMO’s needs are based on maintaining as much operational consistency as possible when managing internal and subcontracted resources. This approach enables cost management for the CMO and cost savings for the customer. Variable A should take into account the audit, testing, sourcing, and customer-specific requirements needed to manufacture the product. The CMO should make sure these requirements are included as part of the Quality Agreement. When defining auditing responsibilities, consideration must be given to determining the appropriate involvement of the client for internal, external, and regulatory audits and should be somewhat consistent between clients.

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Contract Relationships

Testing requirements (e.g., final product, raw material, and environmental) should include what is required not only to manufacture the product, but also to maintain the environment in which the product is manufactured. For example, testing requirements might be traditional compendial testing, but may also include product-specific testing as defined by the client. In the case of a raw material, the CMO must consider whether the item is used in multiple products and whether it is available from a single or multiple sources. Consider this example: in some cases, the client may dictate the supplier of the component in question because it has an established relationship. In other cases, the CMO may have the more established relationship with the supplier. In such situations, the CMO, in conjunction with the client, must determine who will be responsible for providing the qualification and follow-up audits of that supplier. This type of scenario should be defined in the Quality Agreement so that there is little confusion between the parties. A well-drafted Quality Agreement can save a lot of confusion and duplication of effort on behalf of the client and contract provider and facilitate productive communication.

Variable B: compliance needs. Multiple customers, regulatory agencies, and standard-setting organizations influence compliance requirements maintained by a CMO. Each requirement needs to be implemented to accommodate the broad spectrum of these influences. Variable B of the equation defines the compliance needs for the manufacture of all products at the given facility. Company standard operating procedures (SOPs), customer SOPs, audit observations, and compendial requirements need to be considered in discussion with the client and the CMO. Clients should make every effort to understand their CMO’s SOPs.

It is equally important for the CMO to make sure that its SOPs are robust enough to accommodate multiple clients’ needs. It is difficult for a CMO with multiple clients to operate using duplicate SOPs for the same process or procedure. The CMO and the client should therefore spend a sufficient amount of time ensuring that the compliance needs of both parties are defined and met.

Similar to variable A, variable B also has an audit element to consider. In this case, the effectiveness and appropriateness of a CMO’s audit program is considered. The audit program must meet the regulatory expectations for internal and supplier audits while also meeting the client’s expectations on these points.

Two-way communication is crucial because each organization could be vulnerable for a regulatory audit.

In addition to these audit requirements, the CMO and the client must discuss the communication expectations for regulatory audits either conducted at the CMO’s or the client’s place of business. The need for the CMO to communicate with the client when a regulatory audit is being conducted at their facility is evident but it is equally important that the client communicate with the CMO when the positions are reversed. Two-way communication is crucial because each organization could be vulnerable for a regulatory audit based on the outcome of the regulatory audit being conducted at either facility.

In addition to SOPs and audit requirements, compliance to the compendia must be considered under variable B. The client should confirm that the CMO has a process in place for reviewing and updating test procedures to maintain compliance with the applicable monographs, test chapters, and informational chapters maintained by the United States, Japanese, and European pharmacopeial authorities.

Variable C: client needs. Customers bring requirements to the table that may be needed due to factors that are not within the purview of the CMO. These requirements might be influenced by development data, regulatory registration commitments, sourcing strategies, or partnerships. Under variable C, the CMO must consider the needs of the client in order to effectively provide them service. For example, the phase of drug-product development and whether the client is virtual or has in-house capabilities are elements that may affect the allocation of responsibilities within the Quality Agreement. If the product is under a cooperative arrangement with multiple companies, there may be more than one Quality Agreement associated with the manufacturing, packaging, and labeling of the product.

If this is the case, the client should let the CMO know of these agreements and of the expectations when the product is passed to another responsible party during the manufacturing process. In addition, it is important that the client communicate with the CMO whether another contract provider is having regulatory difficulties. Finally, the client and the CMO need to determine whether any special testing protocols are needed for products in Phase 2 or 3 of the development process. If the testing of excipients used in the product is being performed by another organization other than the CMO client, this fact should be disclosed to ensure that excipient compendial requirements are met. The same situation is important with regard to where the material is sourced—whether it be a single source or multiple sources.

Variable D: regulatory commitments. Regulatory commitments are an evolving body of knowledge that may necessitate flexibility to adapt to CMO and client interpretations of new or impending regulations. Variable D considers the regulatory commitments of the client and/or the CMO. CMOs can indicate which regulatory authorities have audited their facilities, when they were last audited, and the outcome of these audits. A CMO must also communicate to their clients the changes and commitments made to
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their Quality Systems based on the responses to the regulatory audits because these changes may affect the regulatory filings of the clients. Each client will have its own interpretation of how to comply with the audit observation and what filing strategy should be used to update their filings, if any.

The CMO must ensure that its responses to regulatory audits do not jeopardize any of their clients’ commitments. On the other hand, clients must communicate with the CMO regarding commitments they have made in their registrations. Among other information, they should disclose to the CMO whether they are using novel excipients as opposed to compendial excipients and whether any special specifications or testing must be performed.

**Variable E: The Quality Agreement.** The solution to the equation noted above (A+B+C+D) is E, which represents Quality as a function of product lifecycle. The document that contains the information defining the various responsibilities that comprise E is the Quality Agreement. This master document should define the CMO’s needs, the client’s needs, the compliance needs for the product and both parties, and any pertinent regulatory commitments. The Quality Agreement should be a living document that is reviewed and revised as often as needed to clarify the responsibilities of the client and the CMO as the product progresses through its lifecycle. The Quality Agreement is akin to a marriage license between two parties and should clearly identify the roles and responsibilities needed for a successful partnership.

In general, Quality Agreements are legally binding agreements between the Quality functions of the contract provider and the contract giver. Many companies use a matrix approach for defining these activities which can include but are not limited to compliance, manufacturing, packaging and labeling, documentation, change control, nonconformance, out of specification (OOS), deviations, complaints, recalls, and auditing. Each document should be tailored to address the expectations of the specific operations to be undertaken by the CMO as well as external actions that may have an impact on those operations. Clients and CMOs should communicate frequently to make sure that the product being manufactured meets the necessary specifications required to meet the minimum Quality requirements. In order for the relationship between the client and the CMO to be effective, the two parties should communicate often.

**Conclusion**
Defining the Quality relationship between a CMO and a client is complex and requires extensive discussion and attention to detail. The relationship should be open and communication between the two parties should be as frequent as required to assure that the product being manufactured meets the highest Quality standards for the client and for the patients.
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A multitude of contract service providers compete in the outsourcing segments for API manufacturing and finished drug product manufacturing. **Added to this mix are the contract manufacturing activities of large innovator-drug companies and generic-drug companies.** The author examines the opportunities and positioning of such players.

**Contract Manufacturing**

**Evaluating Competitive Forces in Contract Manufacturing**

Patricia Van Arnun

**Contract manufacturing of APIs and finished drug products is an important sector in the pharmaceutical outsourcing market. Although these contract services generally are provided by pure-play third-party providers, such as CDMOs and CMOs, pharmaceutical companies themselves can be a part of the supply base for contract-manufacturing activities. Seeking to monetize internal manufacturing capacity through external manufacturing activities, third-party manufacturing can be an attractive proposition for pharmaceutical companies.**

**Crunching the numbers**

Recent analysis shows moderate to strong growth for contract pharmaceutical manufacturing, depending on the specific sector involved. Global pharmaceutical contracting revenues totaled nearly $218 billion in 2011, and are expected to reach nearly $361 billion in 2016, increasing at a compound annual growth rate (CAGR) of 10.6%, according to recent research by the market research firm Business Communications Company (BCC). BCC divides pharmaceutical contracting into four segments: contract manufacture of over-the-counter (OTC) drugs and nutraceuticals; contract manufacture of bulk drugs and dosage forms; contract research; and contract packaging.

The OTC drug and nutraceutical segment accounted for nearly $128 billion in 2011, and is expected to grow at a CAGR of 10.9% to reach nearly $215 billion in 2016, according to BCC. Global revenues for contract manufacturing of bulk drugs and dosage forms were valued at $53.4 billion in 2011, and are expected to increase at a CAGR of 10.1% to reach $86.3 billion in 2016. The contract-research segment was worth $30.2 billion in 2011, and is expected to increase to $50.5 billion in 2016, a CAGR of 10.8%, according to BCC. The packaging segment, worth $6.4 billion in 2011, and is expected to grow to $9.3 billion in 2016, a CAGR of 7.8%.

Drilling down specifically to APIs, moderate growth is expected for contract manufacturing of APIs. The global market for APIs for human use was valued at $101 billion in 2010, according to data from the Italian Chemical Pharmaceutical Generic Association (CPA) in its recent report, "Competition in the World API Market." Of the total market value, the captive market (i.e., APIs produced within pharmaceutical companies themselves for their own needs) accounted for 61.4% of the total API market, or $62 billion in 2010. The merchant market for APIs (i.e., APIs sold by third parties) ac-
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counted for the remaining 38.6%, or $39 billion, according to CPA. For purposes of this market, “API” refers to the active ingredient and advanced intermediates (i.e., intermediates requiring GMP compliance). The global API merchant market is almost evenly divided between APIs supplied to the generic-drug market and APIs supplied to the innovator-drug market. Of the global merchant market for APIs, generic APIs accounted for approximately 48.7%, or $19 billion, in 2010, and branded (i.e., innovator) APIs accounted for the remaining 51.3%, or $20 billion, according to CPA (1).

The world merchant API market (i.e., APIs sold by third parties) for both generic and branded/innovator APIs is projected to increase at an average rate of 5.1% during the next five years to reach $50 billion by 2015, up from $39 billion in 2010, according to CPA. The demand for generic APIs, however, will outpace growth for branded/innovator APIs. The merchant market for generic APIs is projected to increase at an annual rate of 7.3% to reach $27 billion by 2015. The merchant market for branded/innovator APIs is forecast to increase at the annual rate of only 2.8% to reach $23 billion by 2015, according to CPA. This differential in growth rates will cause the share of generic APIs in the merchant market to increase from 49.7% in 2010 to 54% by 2015 and for the share of innovator APIs in the merchant market to decrease from 51.3% in 2010 to 46% by 2015, according to CPA (1).

Company activity

Providing contract-manufacturing services is not in of itself new for pharmaceutical companies, and several large pharmaceutical companies have well-established contract activities. As the underlying fundamentals for cost-effectively managing a manufacturing and supply network evolve, however, these third-party services provide another way to monetize capacity and fixed assets. The interest of Big Pharma companies in highlighting their contract-manufacturing activities was evident by the participation of pharmaceutical companies at recent trade shows. A case in point is CPhI Worldwide, the large trade show of contract API manufacturers and fine-chemical producers, which is colocated with the International Contract Service Expo (ICSE), which includes contract manufacturers of finished drug products. At the recent CPhI/ICSE event held in Frankfurt, Germany, in October 2011, the contract-manufacturing arms of several large pharmaceutical companies, both innovator-drug companies and generic drug companies, were on display.

On the innovator-drug company side, these companies included the contract services of Pfizer (Pfizer CentreSource), Sanofi (Commercial and External Partnership, Industrial Affairs [CePiA]), GlaxoSmithKline, Mitsubishi Tanabe Pharma (API Corporation), Bayer (Bayer Healthcare Pharmaceuticals), Boehringer Ingelheim, Abbott, and Merck & Co. (MSD API). Generic-drug companies at CPhI/ICSE offering contract services included Sandoz (the generic-drug business of Novartis), Teva Pharmaceutical Industries (Teva Active Pharmaceutical Ingredients [TAPI]), Activas, and Mylan. A review of these companies’ activities shows capabilities in both API and finished product manufacturing.

For example, Pfizer CentreSource, headquartered in Kalamazoo, Michigan, is a provider of APIs and dosage-form manufacturing. It is a supplier of fine chemicals, steroid APIs (e.g., corticosteroids and hormonal steroids), and steroid intermediates. It also provides custom fermentation services as well as sterile manufacturing (blow/fill/seal/services) and solid dosage manufacturing, including high-containment services.

The CMO division of Sanofi, CEPiA, provides corticosteroids, steroid diuretics, vitamin B12, cardiovascularals, analgesics, anti-inflammatory agents, antihistamines, antibiotics, prostaglandins, and opioids (morphine and codeine salts). The company has expertise is multistep custom synthesis, steroid chemistry, prostaglandins chemistry, enzymatic conversions, synthesis of high-potency compounds, peptide and protein chemistry, micronization, and large-scale chromatography. The contract arm uses Sanofi’s chemical, fermentation, and biotechnological facilities in France, Germany, Italy, Hungary, Eastern Europe, Singapore, and India.

On the API side, Bayer Healthcare Pharmaceuticals uses several plants for its contract activities. Its supply center in Bergkamen, Germany, is Bayer Pharma’s major facility for the production of intermediates, active ingredients, and bulk pharmaceutical chemicals for steroid hormones through chemical and microbiological synthesis. It also has a micronization plant in Berlin-Charlottenburg, another API plant in Elberfeld, Germany, and a second major chemical facility for hormone and steroid production in Orizaba, Mexico.

On the API side, the contract-services arm of Boehringer Ingelheim provides contract manufacturing of biologic-based APIs, chemical APIs, and fine chemicals. On the biologics side, a key offering is its Bi Hex high-expression system for monoclonal antibody production. The company recently launched a new program, “Lean-to-Clinic,” which consists of streamlined work packages and which speeds up cell-line development, Phase I process development, and preclinical and clinical supplies from mammalian cell cultures.

Although small relative to the revenues generated by drug sales, the contract-manufacturing activities of pharmaceutical companies can contribute positively to a company’s bottom line. For example, TAPI, the contract manufacturing arm of Teva Pharmaceutical Industries, the largest generic-drug company, generates approximately $640 million in annual third-party sales, according to company information. The contract-services arm operates through 21 production plants, which includes the company’s major manufacturing facility in Israel.

Through its acquisition of a controlling interest in Matrix Laboratories in 2007, the generic-drug and specialty pharmaceutical company Mylan gained a position in API manufacturing. Based in Hyderabad, India, Mylan Laboratories (the former Matrix Laboratories) has several operating units, including a network of API and intermediate manufacturing facilities in India and China.

Reference

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Global macroeconomic trends will continue to affect the pharmaceutical and biotechnology outsourcing sector for the foreseeable future. Beginning in the second half of 2009, uncertainty developed among investors concerning the rising government debt levels across the globe followed by a series of downgraded government bonds of certain European states. During the past three years, affected governments have proposed austerity measures (e.g., higher taxes and lower expenses). Consequently, many investors moved their portfolios to safer markets such as Germany and Switzerland. By the end of 2011, Germany was estimated to have made more than €9 billion (approximately US $13.8 billion) out of the crisis while Switzerland also benefited from a substantial influx of foreign capital. In October 2011, the 17 member countries of the Eurozone agreed on intergovernmental measures aimed at preventing the collapse of member economies.

**Austerity pricing**

Constrained by compressed government budgets and sovereign debt issues, many European countries have imposed reductions in pharmaceutical pricing. Most of the pricing cuts have been in the 4–5% range, with deeper reductions generally seen in countries with sovereign debt issues or serious budgetary problems. France announced plans to reduce its 2011 pharmaceutical budget by close to $700 million, while simultaneously curtailing tax incentives for orphan-designated drugs. Another noteworthy announcement is a program in Greece designed to save more than $2.5 billion by reducing drug prices by at least 20%. Italy aims to achieve close to $2 billion in savings through price reductions and tightened consumption. As a result, the aggregate growth has been weak for the top five European pharmaceutical markets, rising approximately 2–3% in 2011.

**Outsourcing to Emerging Markets**

The Effect of the European Economic Crisis

Victor Coker

With Europe’s economic troubles causing domestic profitability concerns, established pharmaceutical companies may look to emerging markets for outsourcing partners. Each developing economy has unique economic, political, and cultural issues that help define its pharmaceutical market. To succeed, multinational pharmaceutical companies will have to adapt differently depending on the distinctive needs of each country.

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Emerging Markets

Price cuts
At the micro level, deficit-led pricing pressures have had a considerable effect on financial performance for many companies that rely heavily on revenues from European pharmaceutical markets. The collective impact involves a complex matrix of price-erosion mechanisms, ranging from price reductions across the market, to pricing restrictions in certain countries. The effects of these mechanisms on company revenues, earnings and valuations have not yet fully manifested. Regardless of the massive slowdown, developed markets continue to provide core revenue streams for major pharmaceutical companies. The key to maintaining revenues involves strengthening late-stage pipelines through innovation.

Pharmaceutical manufacturers are turning to emerging markets to provide the impetus for top-line growth in the coming years.

The emerging-markets fix
As European governments restrict spending on healthcare, pharmaceutical manufacturers are increasingly turning to emerging markets to provide the impetus for top-line growth in the coming years. From the standpoint of large multinational pharmaceutical companies, margins and operating profits from emerging markets are typically much lower than those in developed nations. Seventy percent of global spending on generic drugs is expected to come from developing markets by 2015. Off-patent branded generic drugs are popular in developing nations because brand names are associated with quality, which is appealing in markets where domestically manufactured drugs often lack the same level of quality control.

Developing nations, generally speaking, have been enjoying rapid growth rates in gross domestic product and rising levels of disposable income. An increasing number of people in such countries are able to buy goods and services they previously could not afford. Healthcare expenditure, including spending on pharmaceuticals, typically increases with rising standards of living. Furthermore, these populations are now becoming subject to ailments and conditions—such as cardiovascular disease, cancer, and diabetes—that previously have primarily affected those in developed nations.

Emerging Markets
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Emerging markets also yield additional benefits in terms of raw materials and production. Often, developing nations provide opportunities for attractive low labor-cost manufacturing bases. This allows multinational drug makers to establish new manufacturing plants where pharmaceuticals may be sold to other emerging markets, as well as to developed countries.

Despite positive growth prospects for emerging markets, multinational pharmaceutical manufacturers still face some obstacles. Although significant progress has been made in recent years, protecting intellectual property (IP) rights and enforcing patents remain distinct challenges. Increased pricing and market-access issues will also negatively affect growth in emerging markets.

Primary research data from Nice Insights’ recent Pharmaceutical and Biotechnology Outsourcing survey reveals the desired market when outsourcing 23 services (see Figures 1a–1c). With domestic profitability concerns, established European pharmaceutical companies may look to emerging markets for outsourcing partners or as locations for expansion. Any treatment of emerging markets would be incomplete without a discussion of the EM–7 regions, China, India, Brazil, Russia, South Korea, Mexico, and Turkey. Currently, the most prominent emerging markets include Brazil, China, India, Russia, Turkey, Mexico, and South Korea. These markets are uniform in that per-capita drug consumption is low, and each country’s healthcare infrastructure is still evolving, relative to more mature markets. However, each country has its own unique economic, political, and cultural issues that help define its pharmaceutical market. Thus, to succeed in the EM–7, multinational pharmaceutical companies have to adapt differently depending on the distinctive needs of each country.

Rising per-capita GDP correlates strongly with rising per-capita healthcare. The EM–7 regions are attractive in this regard, as their GDP in aggregate is forecast to nearly triple by 2020. Nice Insight’s research provides perspectives on issues associated with partnerships in these markets, and projects the portion of their anticipated spending, as outlined below.
If you want to rest easy, it pays to partner with the right CMO.

The journey to commercial drug supply can be a real nightmare—unless you choose the right CMO partner. When you choose JHP Pharmaceuticals, you can count on a team of specialists who have spent years developing the systems, expertise and invaluable insight necessary to help you steer clear of potential problems that can keep you up at night. We’ve helped some of the biggest names in the drug and biotech world bring sterile injectable products to market quickly and efficiently.

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Emerging Markets

China
According to IMS, with projected drug sales increasing over 25% in 2011 to close to $50 billion, China is expected to be the world’s third largest pharmaceutical market in 2011, after the US and Japan. The Chinese pharmaceutical industry primarily comprises an increasing number of manufacturers of low-cost generic products. The increase in research and development capacity is directly offset by the government’s failure to implement and enforce fully internationally compliant patent laws. Presently, local producers lack any real capacity to innovate, although joint ventures and partnerships with foreign players are likely to reverse this trend. Realizing the economic and social benefits of pharmaceuticals, China is embraced by drugmakers from abroad and encourages local manufacturing and R&D by foreign firms.

Brazil
The Brazilian pharmaceutical market has continued to grow at a rapid rate in recent years, fueled by a strong overall economy. Brazil’s pharmaceutical market was valued at $25.8 billion in 2011, and there are more than 300 pharmaceutical companies in operation—of which an estimated one-fifth are multinationals. However, given their larger size and capabilities, multinational companies are estimated to account for 75% of the entire market. In recent years, the government has moved to align the drug regulatory environment with international standards, including significant IP reforms. The local biotechnology industry is also developing rapidly, presenting a number of opportunities for international players.

Although the number of manufacturing facilities has more than doubled over the past five years, the country is plagued by a weak labor market and has a strong dependence on imports of active pharmaceutical ingredients. Unless periphery industries step up investment in skilled labor and local production of raw materials, Brazil’s drug industry will be unable to meet domestic needs, let alone meet export demand and become self-sustaining. The shortage derives from a lack of technical schools catering to the pharmaceutical market, with just one such school—the Institute of Science, Technology, and Industrial Quality—currently in existence. However, Brazil launched a major 10-year biotechnology initiative in 2007 that provides incentives for private sector R&D and production. Clinical trials opportunities also abound, as a number of contract research organizations (CROs) expand their capacity for Latin American trials.

Russia
The Russian pharmaceutical market is projected to expand 12.1%, to about $20.1 billion in 2011. A small
number of strong domestic players are emerging, amid signs of consolidation in the manufacturing sector, with growing domestic and cross-border mergers and acquisitions activity. New legislation imposes a domestic clinical trials requirement, potentially imposing significant new costs for drug registration. The government’s drug pricing, reimbursement, and purchasing policies are complex and opaque—including a history of sudden changes in policy without consultation with manufacturers. Domestic patent law also remains well below international standards, and enforcement is especially weak with little recent progress on the ground.

India
India is home to a reasonably advanced native pharmaceutical sector, albeit one specializing in generic drugs. The Indian pharmaceutical industry accounts for about 10% of the world’s total pharmaceutical output. India’s market is expected to reach $67.1 billion in 2011, and comprises domestic pharmaceutical manufacturers (primarily research-based companies with international links) organized under the Organization of Pharmaceutical Producers of India (OPPI), and foreign players operating from abroad. Local producers supply more than 70% of the market for bulk drugs, intermediates, formulations, capsules, and injectables. A large and cheap labor force, low production and R&D costs, and a strong balance of trade guarantee high output. Internal resources and international connections also make India one of the regional leaders in biotechnology.

Drug manufacturing is one of the relatively few industries in India open to 100% foreign ownership. They will continue to encourage international interest in the local market, which is increasing with the growing population and economic improvements. However, foreign interest will be a challenge to local players, especially in the face of rising scrutiny of IP and manufacturing quality standards. Western pharmaceutical companies have also been establishing their own manufacturing facilities in India, as the cost of setting up and operating such facilities is a fraction of that in the west.

Mexico
The decline of the Mexican pharmaceutical market can be attributed to competition from low-cost Asian producers, high investment costs, weak product development, and a lack of intermediate materials. The manufacturing sector is highly dependent on imported raw materials and active pharmaceutical ingredients—approximately 30% of exports are in a semi-finished form. A growing number of manufacturing firms are currently opting to pursue bioequivalent generic drugs. Even manufactur-
ers who have opposed tougher bioequivalence requirements now see legitimate generic drugs as the only way to secure market position domestically in the long term. Despite recent reforms, the enforcement of domestic patent law remains problematic and continued failure to enforce these laws may limit both investment and product launches by multinationals.

South Korea
South Korea boasts approximately 250 pharmaceutical manufacturers, including 47 multinationals, which operate either independently or under a joint venture. However, the rise of China and India as more financially viable regional manufacturing bases has led to the closure of a number of internationally operated production facilities. Foreign companies are instead shifting their focus to R&D in the face of difficulties experienced in Japan. Failure by the government to align domestic patent law with international standards, with particular concern surrounding illegal copying and the enforcement of existing legislation, is proving detrimental to investment. However, South Korea recently signed a free trade agreement with the US to improve the intellectual property environment and trade regimes between the two countries. In effort to lure foreign investment and potentially boost the biotech sector, an international stem-cell research agency was recently established in Seoul.

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There will likely be heightened negotiations for partnerships between global pharmaceutical companies and locally based CMOs and CROs.

Turkey
The Turkish pharmaceutical industry still lacks capital investment and subsequently has minimal R&D capabilities. Foreign investors are free to repatriate their profits outside Turkey as an incentive—subject to certain limited restrictions—and to acquire immovable property or rights in Turkey. As a result, a number of major developers have chosen to make Turkey a production base for pharmaceuticals serving the Middle East, Asia, and Eastern Europe (especially given the possibility of EU accession on the cards in the medium term). Among the 49 manufacturing facilities in the country, multinational firms own 13. The availability of a skilled workforce keeps improving but domestic patenting law is below international standards, with the protection of confidential test data and counterfeiting being key concerns.

Conclusion
The EM–7 region, while still a comparatively minor contributor to overall global drug sales for most global pharmaceutical companies, will likely grow in size and importance over time. In light of the primarily positive macro growth indicators across all the profiled EM–7 pharmaceutical markets, there will likely be heightened negotiations for partnerships between global pharmaceutical companies and locally based CMOs and CROs. Although European drug companies are showing more interest in these partnership opportunities, the US is not far behind. The key to ongoing success for the pharmaceutical industry in emerging markets remains the improvement of R&D productivity to a point where the discovery of new, meaningful products that can serve remaining unmet medical needs become a reality. Products like these could then see sustainable demand in both established and emerging markets alike.
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Tel: +1-816-525-1150
Email: trosanske@accelerationkc.com
Website: www.accelerationkc.com
Business Unit Head: Tom Rosanske Ph. D., Dir of Bus Dev
Sales Contact: Robb Poe
Year Founded: 2003
Number of Employees: 1-25
Annual Revenues: $50-10 million

CONTRACT SUITE OFFERINGS
Analytical services: Analytical chemistry & stability; Microbiology; Particle characterization; Product characterization.
Consulting services: Project & sourcing management services.
Packaging & logistics: Clinical labels; Clinical packaging & distribution.

Acceleration Laboratory Services, Inc., a highly experienced GMP contract drug development research organization, provides top quality laboratory services at all levels of drug development. Our accomplished associates average 15+ years of experience in the industry and truly understand your business. Acceleration serves pharmaceutical, animal health, and life science industries by offering analytical chemistry evaluation, method development and validation, stability and GLP toxicology dose analysis, as well as microbiology, early CTM, packaging, labeling, storage, and distribution. Acceleration’s quality is paramount and service is superior.

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Business Unit Head: Folker Ruchatz, Mng Dir & Head of Custom Synthesis Bus
Sales Contact: Luca Parlanti, Head of Global Sls & Mkgt Custom Synthesis
Year Founded: 1952
Number of Employees: 501+
Annual Revenues: $251 million+

CONTRACT SUITE OFFERINGS
Development & Phase I/II Clinical Trial
Commercial manufacturing: Active Pharmaceutical Ingredients (API) and advanced intermediates manufacturing (cGMP, small molecule).
Analytical services: Analytical chemistry & stability; Particle characterization.
Consulting services: Project & sourcing management services; Regulatory, validation, IT, and QA/QC services.

API and intermediates (cGMP, small molecule) manufacturing capabilities: Acetylenic chemistry; Acid chlorides; Acylation; Amidation; Amino acids and analogs; Asymmetric synthesis or chiral chemistry; Azide chemistry; Borane chemistry; Bromine chemistry/bromination; Cryogenics (low-temperature reactions); Cyanide chemistry; Heterocyclic chemistry; Hydrazine chemistry; Lithium chemistry; Organometallic chemistry; Phosgenation; Sulfonation.

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Fax: 262-437-0282
Email: info@c-mlabs.com
Website: www.c-mlabs.com
Business Unit Head: Brian Scanlan, Pres & CEO
Sales Contact: Sean Diver
Year Founded: 1999
Number of Employees: 101-250
Annual Revenues: $51-100 million

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Analytical services: Analytical chemistry & stability; Particle characterization.

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Commercial manufacturing: Active Pharmaceutical Ingredients (API) and advanced intermediates manufacturing (cGMP, small molecule); Specialty dosage forms.

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Consulting services: Project & sourcing management services.

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Tel: 609-395-9700
Fax: 609-395-8824
Email: pmatrafailo@cmicmousa.com
Website: www.cmics.mousa.com
Business Unit Head: Gary Wada, Exec VP & Gen Mgr
Sales Contact: Pat Matrafailo, Mgr Bus Dev
Year Founded: 2007
Number of Employees: 26-50
Annual Revenues: $11-25 million

CONTRACT SUITE OFFERINGS
Development & Phase I/II Clinical Trial Materials (CTM): Process development - small molecule.

Commercial manufacturing: Ingredient processing (milling, coating, etc.); Solid dose manufacturing; Specialty dosage forms.

Analytical services: Analytical chemistry & stability.

CMIC CMO USA Corporation is a member of the CMIC Group, a company with 22 facilities in eight countries and over 4500 employees worldwide. We are a contract manufacturing organization that specializes in the formulation development and commercial services for oral solid dosage products. Our role in this process is to create and deliver value to our customers through the pharmaceutical services we offer.

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Email: busdev@cookpharma.com
Website: www.cookpharma.com
Business Unit Head: Tedd Green, Pres
Sales Contact: Cory Lewis
Year Founded: 2004
Number of Employees: 251-500

**CONTRACT SUITE OFFERINGS**

**Development & Phase I/II Clinical Trial Materials (CTM):** Injectable products development.

**Commercial manufacturing:** Injectable products manufacturing.

**Biomanufacturing:** Cell culture.

**Analytical services:** Analytical chemistry & stability; Bioanalytical testing; Microbiology; Particle characterization; Product characterization.

**Consulting services:** Project & sourcing management services; Regulatory, validation, IT, and QA/QC services.

**Packaging & logistics:** Clinical labels; Clinical packaging & distribution; Commercial packaging.

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**Analytical services:** Analytical chemistry & stability; Particle characterization; Product characterization.

**Packaging & logistics:** Clinical packaging & distribution; Commercial packaging.

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Email: cps@dreddys.com
Website: www.dreddys-cps.com
Business Unit Head: Brian M. Shaughnessy, Dir North America & Bus Dev
Sales Contact: Ana Cristina Cruz-Rocha
Year Founded: 1984
Number of Employees: 501+
Annual Revenues: $251 million+

**CONTRACT SUITE OFFERINGS**

**Development & Phase I/II Clinical Trial Materials (CTM):** Process development - small molecule.

**Commercial manufacturing:** Active Pharmaceutical Ingredients (API) and advanced intermediates manufacturing (cGMP, small molecule); Ingredient processing (milling, coating, etc.); Injectables manufacturing; Specialty dosage forms.

**Analytical services:** Analytical chemistry & stability; Microbiology; Particle characterization.

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**DSM**

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Email: info.dsmpharma@dsm.com
Website: www.dsmpharmaceuticalproducts.com
Number of Employees: 501+
Annual Revenues: $251 million+

**CONTRACT SUITE OFFERINGS**

**Development & Phase I/II Clinical Trial Materials (CTM):** Other delivery forms (transdermal, inhalable...); Injectable products development; Solid dose, semi-solids & liquids development; Process development - small molecule.

**Commercial manufacturing:** Active Pharmaceutical Ingredients (API) and advanced intermediates manufacturing (cGMP, small molecule); Ingredient processing (milling, coating, etc.); Injectables manufacturing; Solid dose manufacturing; Specialty dosage forms.

**Biomachining:** Cell culture.

**Analytical services:** Analytical chemistry & stability; Bioanalytical testing; Microbiology; Particle characterization; Product characterization.

**Consulting services:** Regulatory, validation, IT, and QA/QC services.

**Packaging & logistics:** Commercial packaging.

**API and intermediates (cGMP, small molecule) manufacturing capabilities:** Acetylenic chemistry; Acylation; Amidation; Amino acids and analogs; Asymmetric synthesis or chiral chemistry; Biocatalysts; Bromine chemistry/bromination; Carbohydrate chemistry; Chemocatalysis; Cryogenics (low-temperature reactions); Heterocyclic chemistry; High-potency or high-containment manufacturing; Hydrazine chemistry; Organometallic chemistry; Nitration; Sulfonation.

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**Business Unit Head:** Lee Bates, Sr VP
**Sales Contact:** Ima Proffitt, Customer Relations Rep
**Year Founded:** 1950
**Number of Employees:** 51-100
**Annual Revenues:** $0-10 million

**CONTRACT SUITE OFFERINGS**

**Analytical services:** Analytical chemistry & stability.

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Website: www.one2onecmo.com
**Business Unit Head:** Anthony Cacich, CVP & Gen Mgr

**Year Founded:** 1988
**Number of Employees:** 501+
**Annual Revenues:** $251 million+

**CONTRACT SUITE OFFERINGS**

**Commercial manufacturing:** Injectables manufacturing.

Packaging & logistics: Commercial packaging.

One 2 One utilizes dual-layer Program Management approach focusing on timeliness and transparency of projects in developmental stages. One 2 One business provides customers with:
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- Global reach, delivering security of supply and geographical convenience.

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**JHP Pharmaceuticals**
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**Email:** jhpcontractservices@jhppharma.com

**Website:** www.jhppharma.com

**Business Unit Head:** Daniel Leone, Sr Dir Bus Dev

**Sales Contact:** Christine Fath

**Year Founded:** 2007
**Number of Employees:** 251-500

**CONTRACT SUITE OFFERINGS**

**Commercial manufacturing:** Injectables manufacturing.

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**Halo Pharmaceutical**
30 N Jefferson Rd
Whippany, NJ 07981 USA
Tel: 973-428-4000
**Email:** services@halopharma.com
**Website:** www.halopharma.com

**Business Unit Head:** Sally Langa, Mktg Dir
**Sales Contact:** Sally Langa, Mktg Dir

**Year Founded:** 2008

A New Jersey based CDMO, Halo Pharma provides scientific, regulatory and development expertise as well as a spectrum of manufacturing services to help customers bring their products to market quickly and effectively. Halo’s capabilities in the areas of tech transfer, process and product development, production scale-up and validation, and analytical method development, allow it to partner with clients from development through commercialization or at any point along the way.

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**Email:** labinfo@galbraith.com
**Website:** www.galbraith.com

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**Federal Equipment Company**
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**Email:** deals@fedequip.com
**Website:** www.fedequip.com

**Sales Contact:** Adam Covitt

**Year Founded:** 1957

**CONTRACT SUITE OFFERINGS**

**Consulting services:** Project & sourcing management services.

Federal Equipment Company, with more than 50 years of experience delivering, quality used equipment and outstanding service at competitive prices, is the trusted name in pharmaceutical equipment. Federal Equipment maintains strategic partnerships with firms, such as Pfizer Inc., ensuring the availability of the finest used pharmaceutical process and packaging equipment.

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**Email:** services@halopharma.com
**Website:** www.halopharma.com

**Business Unit Head:** Sally Langa, Mktg Dir
**Sales Contact:** Sally Langa, Mktg Dir

**Year Founded:** 2008

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Parsippany, NY 07054 USA
**Email:** jhpcontractservices@jhppharma.com
**Website:** www.jhppharma.com

**Business Unit Head:** Daniel Leone, Sr Dir Bus Dev

**Sales Contact:** Christine Fath
**Year Founded:** 2007

**Number of Employees:** 251-500

**CONTRACT SUITE OFFERINGS**

**Commercial manufacturing:** Injectables manufacturing.

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Tel: 877-449-8797/865-546-1335
Fax: 865-546-7209
**Email:** labinfo@galbraith.com
**Website:** www.galbraith.com

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8200 Bessemer
Cleveland, OH 44127 USA
Tel: 800-652-2466
**Email:** deals@fedequip.com
**Website:** www.fedequip.com

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**Year Founded:** 1957

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JHP Pharmaceuticals is proud of a 25 year heritage in sterile injectable manufacturing. As a contract manufacturer, JHP partners with global pharmaceutical and biotech companies to provide services including aseptic fill/finish, lyophilization/freeze-drying and terminal sterilization. JHP has the capability to manufacture small-scale clinical through large-scale commercial products.

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3525 N Regal St
Spokane, WA 99207 USA
Tel: 509-489-5656
Email: info@jublhs.com
Website: www.jublhs.com
Business Unit Head: Curtis Gingles, VP Mktg & Sls
Sales Contact: David Flowers
Year Founded: 1921
Number of Employees: 501+

CONTRACT SUITE OFFERINGS
Development & Phase I/II Clinical Trial Materials (CTM): Active Pharmaceutical Ingredients (API) - small molecule; Active Pharmaceutical Ingredients (API) - large molecule/ biologics.

Commercial manufacturing: Active Pharmaceutical Ingredients (API) and advanced intermediates manufacturing (cGMP, small molecule); Active Pharmaceutical Ingredients (API) manufacturing - (cGMP, large molecules/biologics); Ingredient processing (milling, coating, etc.); Injectables manufacturing; Semi-solids & liquids manufacturing; Solid dose manufacturing.

Analytical services: Analytical chemistry & stability; Bioanalytical testing; Microbiology; Particle characterization; Product characterization.

Packaging & logistics: Commercial packaging.

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Lancaster Laboratories
2425 New Holland Pike
PO Box 12425 (17605)
Lancaster, PA 17601 USA
Tel: 717-656-2300
Fax: 717-656-3772
Email: pha@lancasterlabs.com
Website: www.lancasterlabspharm.com
Business Unit Head: Timothy S. Oostdyk Ph. D., Pres
Sales Contact: Michael McDowell, Dir of Bus Dev
Year Founded: 1961
Number of Employees: 501+
Annual Revenues: $101-250 million

CONTRACT SUITE OFFERINGS
Biomanufacturing: Cell culture.
Analytical services: Analytical chemistry & stability; Bioanalytical testing; Microbiology; Particle characterization; Product characterization.

Lancaster Laboratories, a global leader in comprehensive laboratory services, enables pharmaceutical and biopharmaceutical companies to advance candidates from development through commercialization, ensuring regulatory compliance, cost effectiveness, and achievement of timelines. See why 800+ leading Pharmaceutical & Biotech customers continue to trust us with their laboratory testing needs at www.lancasterlabspharm.com.

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Fax: 252-758-8522
Email: marketing@metricsinc.com
Website: www.metricsinc.com
Business Unit Head: Jeffery C. Basham, VP Bus Dev
Sales Contact: Jeffery C. Basham
Year Founded: 1994
Number of Employees: 251-500

CONTRACT SUITE OFFERINGS
Development & Phase I/II Clinical Trial Materials (CTM): Other delivery forms (transdermal, inhalable...); Solid dose, semi-solids & liquids development.

Commercial manufacturing: Ingredient processing (milling, coating, etc.); Solid dose manufacturing; Specialty dosage forms.

Analytical services: Analytical chemistry & stability; Microbiology; Particle characterization; Product characterization.

Packaging & logistics: Commercial packaging.

Metrics Inc. is one of the most respected CDMOs in the US today. Three critical differences set Metrics apart. One, clients work directly with a senior Metrics pharmaceutical scientist or analytical development chemist. Two, projects are expedited quickly and efficiently; they don’t languish in an analytical development queue, so timelines are met consistently. Three, Metrics’ quality assurance team is highly experienced, ensuring compliance with all regulatory issues.
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Fax: 404-350-0432
Email: sales@mikart.com
Website: www.mikart.com
Business Unit Head: Blair Jones, VP Sls & Mktg
Sales Contact: Blair Jones
Year Founded: 1975
Number of Employees: 101-250
CONTRACT SUITE OFFERINGS
Development & Phase I/II Clinical Trial
Analytical services: Analytical chemistry & stability.
Packaging & logistics: Clinical packaging & distribution; Commercial packaging.

Since 1975, Mikart has been a recognized leader in providing contract development, manufacturing and packaging services to the pharmaceutical industry. We offer a broad range of capabilities including formulation development, analytical services, solid and liquid dose manufacturing, packaging (bottles, blisters, and multi-laminate pouches) and regulatory services.

See our ad on page 13
Patheon
4721 Emperor Blvd Ste 200
Durham, NC 27703-8580 USA
Tel: 866-728-4366/919-226-3200
Fax: 919-474-2269
Email: doingbusiness@patheon.com
Website: www.patheon.com
Business Unit Head: Geoffrey M. Glass, Exec VP, Global Sls & Mktg
Sales Contact: Mike Stout
Year Founded: 1974
Number of Employees: 501+
Annual Revenues: $251 million+
CONTRACT SUITE OFFERINGS
Development & Phase I/II Clinical Trial
Materials (CTM): Other delivery forms (transdermal, inhalable...); Injectable products development; Solid dose, semi-solids & liquids development; Process development - small molecule.
Commercial manufacturing: Ingredient processing (milling, coating, etc.); Injectables manufacturing; Semi-solids & liquids manufacturing; Solid dose manufacturing; Specialty dosage forms.
Analytical services: Analytical chemistry & stability; Bioanalytical testing; Microbiology; Particle characterization; Product characterization.
Consulting services: Project & sourcing management services.

Patheon is a leading provider of contract development and manufacturing services to the global pharmaceutical industry, providing products and services to approximately 300 of the world’s leading pharmaceutical and biotechnical companies. Through its fully integrated worldwide network, it ensures that customer products can be launched with confidence anywhere in the world.

See our ad on page 5
Pfizer CentreSource
7000 Portage Rd
Kalamazoo, MI 49001 USA
Tel: 269-833-5844
Fax: 269-833-3604
Email: centresource.info@pfizer.com
Website: www.pfizercentresource.com
Business Unit Head: Michael J. Kosko, Pres
Sales Contact: Kenneth Ball, Sr Mgr, Mktg
Year Founded: 1960
Number of Employees: 51-100
Annual Revenues: $251 million +
CONTRACT SUITE OFFERINGS
Commercial manufacturing: Active Pharmaceutical Ingredients (API) and advanced intermediates manufacturing (cGMP, small molecule); Injectables manufacturing; Solid dose manufacturing.
Biomanufacturing: Cell culture; Microbial manufacturing
Packaging & logistics: Clinical packaging & distribution; Commercial packaging.
API and intermediates (cGMP, small molecule) manufacturing capabilities: High-potency or high-containment manufacturing.

Pfizer CentreSource (PCS) is a recognized industry leader in high-quality, high-value services, backed by the capabilities of Pfizer: steroid APIs and antibiotics; GMP custom fermentation services; finished dosage forms; product development, process development, and advanced manufacturing for high potency oral solid drug product; and offers therapeutic bioprocessing development and manufacturing.
See our ad on page 51
Pharma Tech Industries
545 Old Ebert Rd
Royston, GA 30662 USA
Tel: 706-246-3555
Fax: 706-246-3330
Email: sales@pharma-tech.com
Website: www.pharma-tech.com
Business Unit Head: Carl Oberg, Pres
Sales Contact: Tee Noland
Year Founded: 1972
Number of Employees: 251-500
Annual Revenues: $50-100 million

CONTRACT SUITE OFFERINGS
Development & Phase I/II Clinical Trial
Materials (CTM): Injectable products development; Process development - small molecule.
Commercial manufacturing: Injectable manufacturing; Specialty dosage forms.
Analytical services: Analytical chemistry & stability; Microbiology; Particle characterization.
Consulting services: Project & sourcing management services; Regulatory, validation, IT, and QA/QC services.
Packaging & logistics: Clinical labels; Clinical packaging & distribution.

PYRAMID provides expertise in formulation and process development, aseptic filling for vials and syringes, as well as lyophilization applications for clinical and commercial products. Our knowledge and advanced technological environment allow us to provide clients with highly skilled individual attention, professional service and documented high quality in the most efficient and cost effective manner.

See our ad on page 28
Regis Technologies
8210 Austin Ave
Morton Grove, IL 60053 USA
Tel: 847-967-6000
Email: pflynn@registech.com
Website: www.registech.com
Business Unit Head: Louis Glunz IV, Pres
Sales Contact: Paul Flynn
Year Founded: 1956
Number of Employees: 51-100
Annual Revenues: $11 - 25 million

CONTRACT SUITE OFFERINGS
Development & Phase I/II Clinical Trial
Commercial manufacturing: Active Pharmaceutical Ingredients (API) and advanced intermediates manufacturing (cGMP, small molecule).
Analytical services: Analytical chemistry & stability.
Consulting services: Regulatory, validation, IT, and QA/QC services.

API and intermediates (cGMP, small molecule) manufacturing capabilities: Acid chlorides; Acylation; Amidation; Asymmetric synthesis or chiral chemistry; Borane chemistry; Bromine chemistry/bromination; Carbohydrate chemistry; Chemocatalysis; Cryogenics (low-temperature reactions); Heterocyclic chemistry; Lithium chemistry; Organometallic chemistry; Nitration; Sulfonation.

Regis uses its knowledge of the entire drug development process to ensure you are building a commercially viable procedure from the start.

See our ad on page 25
Morton Grove, IL 60053 USA
Tel: 847-967-6000
Email: pflynn@registech.com
Website: www.registech.com
Business Unit Head: Louis Glunz IV, Pres
Sales Contact: Paul Flynn
Year Founded: 1956
Number of Employees: 51-100
Annual Revenues: $11 - 25 million

CONTRACT SUITE OFFERINGS
Development & Phase I/II Clinical Trial
Commercial manufacturing: Active Pharmaceutical Ingredients (API) and advanced intermediates manufacturing (cGMP, small molecule).
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Regis uses its knowledge of the entire drug development process to ensure you are building a commercially viable procedure from the start.

See our ad on page 37
Therapex
11065 Boul L-H Lafontaine
Anjou, Quebec H1J 2Z4 Canada
Tel: 800-465-5820/514-353-5820
Fax: 514-353-9968
Email: info+@therapex.com
Website: www.therapex.com
Business Unit Head: Paul Salloum, VP & Gen Mgr
Sales Contact: Michelle Frenette
Year Founded: 1968
Number of Employees: 251-500

CONTRACT SUITE OFFERINGS
Development & Phase I/II Clinical Trial
Analytical services: Analytical chemistry & stability; Microbiology.

Therapex is a contract development and manufacturing organization specializing in non-sterile liquid and semi solid products. For over 40 years we have been recognized for consistently providing quality services in product development, technology transfer, commercial manufacturing and packaging. All activities are supported by in-house laboratory services. Located in Montreal, Canada, Therapex is acknowledged by the Canadian (HPFB), American (FDA) and European Union regulatory agencies for our outstanding quality and regulatory compliance history.
Workforce: 300. Therapex, a division of E-Z-EM Canada Inc. is owned by Bracco Diagnostics Inc.
UPM Pharmaceuticals

6200 Seaforth St
Baltimore, MD 21403 USA
Tel: 410-843-3700
Fax: 410-633-4438
Email: info@upm-inc.com
Website: www.upm-inc.com
Business Unit Head: Frances Spaven Ph. D., VP Contract Svcs
Sales Contact: Mike Raum
Year Founded: 1997
Number of Employees: 51-100
Annual Revenues: $11-25 million

CONTRACT SUITE OFFERINGS
Development & Phase I/II Clinical Trial
Commercial manufacturing: Ingredient processing (milling, coating, etc.); Semi-solids & liquids manufacturing; Solid dose manufacturing; Specialty dosage forms.
Analytical services: Analytical chemistry & stability; Particle characterization.
Consulting services: Project & sourcing management services.
Packaging & logistics: Clinical labels; Clinical packaging & distribution.

UPM Pharmaceuticals® is a Baltimore-based, independent provider of contract drug development, cGMP manufacturing and analytical testing. We specialize in oral routes of administration with a focus on solid dosage forms. With our commitment to quality, timeliness, and flexibility, we deliver industry-savvy, customer focused services.

Xcelience LLC

5415 W Laurel St
Tampa, FL 33607 USA
Tel: 813-286-0404
Fax: 813-286-1105
Email: info@xcelience.com
Website: www.xcelience.com
Business Unit Head: Derek G. Hennecke, Pres/CEO
Sales Contact: Randall H. Guthrie, VP
Year Founded: 1997
Number of Employees: 51-100

CONTRACT SUITE OFFERINGS
Development & Phase I/II Clinical Trial
Materials (CTM): Other delivery forms (transdermal, inhalable...); Solid dose, semi-solids & liquids development; Process development - small molecule.
Analytical services: Analytical chemistry & stability; Particle characterization; Product characterization.
Packaging & logistics: Clinical labels; Clinical packaging & distribution.

Xcelience is a premier provider of formulation development and clinical trial supplies manufacturing solutions with a solid reputation for accelerating early phase development. Our outstanding quality record, drug development expertise, willingness to customize, and disciplined project management enable us to deliver real advantage to innovators needing to speed compounds to clinic.
For manufacturing and packaging of powder, the global leader has you covered.

In the world of contract services, no company has more experience in powder-based products than PTI.

Manufacturing and packaging more than 50 million pounds of powder each year, PTI has the unmatched expertise and technology transfer know-how to take on your most challenging projects, including:

- Blending & packaging of Rx & OTC powder formulations
- Formulation, process optimization & commercial scale-up
- Solid dose compression of single & bi-layer tablets

Plus, our award-winning approach to customer service has consistently earned a Number One Contractor Ranking from our pharmaceutical and consumer products clients, year after year.

**Put your trust in the hands of PTI...the powderful global leader.**

[Logo and contact information]
With DPT, development and manufacturing piece together seamlessly.

DPT is the contract development and manufacturing organization (CDMO) that specializes in sterile and non-sterile semi-solid and liquid dosage forms. With unmatched technical expertise and fully integrated drug development and manufacturing services, we can help you successfully develop and commercialize your next product. Partnering with DPT gives you a seamless transition from pre-formulation to clinical supplies to commercial supply. After all, keeping it all together is what sets us apart. To get started, visit us at www.dptlabs.com or call 1.866.CALL.DPT.