FROST & SULLIVAN BEST PRACTICES AWARD

CONTRACT DEVELOPMENT AND MANUFACTURING ORGANIZATION - GLOBAL

Customer Service Leadership
2019

Piramal Pharma Solutions
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Background and Company Performance

Industry Challenges

The pharmaceutical industry is evolving towards personalized medicines, niche therapies, fast-track programs and novel delivery systems. Frost & Sullivan observes how intense competition mandates companies to update their drug pipeline with high-efficacy, novel, and complex therapeutics to stay ahead in the market. Hence, globally, companies strive to expedite discovery, development, and time-to-market (TTM) of the drugs, while handling drug development cost pressures — leading to outsourcing to contract development manufacturing organizations (CDMOs). Outsourcing enables pharma and biopharma companies to optimize costs and leverage integrated service capabilities — improving both efficiency and drug’s TTM.

Developing Complex Molecules Requires Extensive Capabilities and Experience

Manufacturing complex molecules with niche targets is massively capital-intensive and requires extensive development capabilities. Though high in demand, molecules with novel modalities and complex structures struggle with developmental constraints. Feeble protein expression, solubility issues, low–yield purification processes, and inadequate analytical testing methodologies compel pharma and biopharma companies to give up promising, yet difficult to develop molecules, which could potentially advance exceptionally novel therapies for patients. In addition, Frost & Sullivan notes that traditional development technologies have high turnaround times (TATs), stretching delivery time and TTM. Alternatively, CDMOs invest in unique developmental technologies, expertise, and specialized manufacturing platforms such as single-use/disposable bioreactors, lean operations, and continuous manufacturing processes that deliver safe and high-quality products on time to accelerate a drug’s TTM quite significantly — motivating pharma companies to outsource to CDMOs. Pharma companies receive an assurance of long-term, end-to-end supply chain security from CDMOs, thus, limiting effort and cost of handling inventory, logistics, and rescheduling due to delays.¹

Frost & Sullivan points out that high research and development (R&D) expenditure and technical and manufacturing set-up complexities are other limiting factors that propel biopharma and pharma companies to outsource clinical and commercial-stage manufacturing profitably to CDMOs. Integrated solution offerings assist on various verticals and eliminate supply chain issues due to sourcing from multiple suppliers in the drug development life cycle. Additionally, small and mid-sized pharma and biotech companies lack captive manufacturing capacities to drive R&D and diversify product portfolio; as such, engaging a CDMO in early-lifecycle stage projects and forging a long-term relationship with them is generally profitable. Outsourcing allows concentrating on core competencies, and not investing resources on expertise, manufacturing, and high-

end, scalable technologies - such as injectables, highly potent active pharmaceutical ingredients (HPAPIs), and medicine dosage formulations.  

Focus on Specialty Care Drugs and Expanding Opportunities

The contract manufacturing ecosystem is shifting its focus on novel drug development for specialty care, both for niche and prevalent diseases (e.g., cancer). Chemotherapy is the predominant method for cancer treatment; however, there is an urgent need to meet the evolving requirements for personalized cancer therapies that require highly potent APIs, such as antibody drug conjugates (ADCs).

Developing specialty care drugs can be cost prohibitive without outsourcing to CDMOs. Thus, Frost & Sullivan feels that this shift to specialty care drugs presents immense opportunities for CDMOs that offer custom, innovative chemistries (e.g., ADCs). 3 Within these current opportunities, CDMOs are consolidating, expanding geographic presence, and penetrating niche markets to improve profitability. A rise in unique business models, end-to-end service offerings, and one-stop-shops provide value-added services (including regulatory and financial support to customers); apart from drug development, the emergence of virtual biotech, out-licensing, and risk sharing between pharma and CDMOs are disrupting the traditional business models. 4 Additionally, globalization necessitates CDMOs to have global manufacturing facilities to rapidly serve global customers; this in turn demands CDMOs to have high-end experience in handling different regulatory and manufacturing requirements, per country. As regulatory bodies become increasingly stringent over quality and compliance, they follow risk-based, high-focus inspection that covers industry benchmarks. Frost & Sullivan’s research concludes that CDMOs that align themselves with industry quality standards and incorporate rigorous monitoring and continuous improvement will lead the CDMO industry.

Quality of Customer Service and Customer Impact

Piramal Pharma Solutions (PPS) is the global CDMO arm of Piramal Enterprises Ltd., led by a global management team based out of North America and Europe.

PPS offers end-to-end integrated services across the spectrum of the entire drug development life cycle including drug discovery, drug development, and commercial manufacturing of drug substances and drug products. With approvals from regulatory authorities in the United States (US), Europe, Canada, Brazil and Japan among others; the company’s development centers and manufacturing sites, operate globally across North America, Europe, and Asia. With unparalleled R&D focus, the company employs a pool of over 700+ world-class scientists to propel development programs for global

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pharmaceutical customers. PPS strives to re-engineer its internal capabilities, programs, and new technologies to quicken a drug’s TTM, when discovering, developing, and manufacturing innovative novel drugs.

**Leveraging Global Operations for On-time Delivery, Reducing Time-to-Market**

Frost & Sullivan notes that PPS clearly differentiates itself from its competitors by having half of its manufacturing sites in the East and the other half in the West — in North America, Europe, and Asia; all key sites are periodically inspected by the US Food and Drug Administration (FDA), UK Medicines and Healthcare products Regulatory Agency (MHRA) and Pharmaceuticals and Medical Devices Agency (PMDA) Japan among others. In line with its concept of ‘Global Vision, Local Execution’, the company leverages its diverse geographic presence (large presence in the US, Europe and India) to remain agnostic to its customers’ outsourcing requirements - irrespective of their location. The company uniformly blends global operations (its 12 different sites operate together as a single entity) with flexible scheduling that lower delivery timelines and raise product quality to ensure on-time delivery to customers, locally. For example, a North American customer gets a delivery of the API from a US FDA inspected North American facility; using starting materials manufactured at the Indian facility, thereby, optimizing cost and time and achieving operational efficiencies through their internally controlled supply chain. Frost & Sullivan appreciates how PPS properly simplifies the supply chain, allowing flexible movement of products across the drug development life cycle. With its integrated services (e.g. integrated oral solid dosages, integrated ADC services), the company accelerates TTM, optimizes cost, and lowers developmental complexity.

**The Partner of Choice: Patient Focus, Customer Centricity, and One-Stop-Shop Model for Integrated Service Offering**

"Piramal Pharma Solutions continues to be the 'Partner of Choice' for global pharmaceutical companies as we work alongside, to mutually serve patients. We continue to invest in capacities and capabilities across our sites, gearing up for future demand from our customers’ development pipeline and commercial portfolio. I strongly believe that our integrated platform of services, passion to delight customers, robust quality track record, and a committed team will continue to positively impact shareholders and create more value for our investors, in the years to come.”

- Vivek Sharma, CEO, Piramal Pharma Solutions

The fulcrum of PPS’ focused offerings is customer centricity — ensuring that customers succeed in serving patients with novel, efficacious, and cost-effective therapeutics, in a timely manner. The company emphasizes its unique requirements, converting cost proposition into a value proposition, by focusing on a customers’ unique positioning in the market to help overcome the customers’ cost challenges. Understanding the customer’s focus, needs, observations, and goals, helps design strategic plans that enables them to
meet their goals quickly and efficiently. Ensuring customer success manifests PPS’s vision to be a trusted partner in the journey towards reducing the burden of disease.

Working with global pharma companies, PPS provides exceptional customer experience and regularly measures it through customer satisfaction index (CSI) surveys, internal partner surveys, customer communication (interviews, call, and feedback), and workshops.

- Using NPS (Net Promoter Score) metrics, PPS has introduced a robust feedback mechanism which assists it in calculating customer loyalty. It is distinctive and is the first of its kind in the Contract Development and Manufacturing Organization (CDMO) business.

- The Customer Effort Score (CES) is recorded which acts as an indicator of the effort taken by the customer in order to push the matter through for resolution. A high CES score signifies that we have simplified the process for our customers to employ the services.

- Using the AQSCI (Assurance, Quality, Service, Value, Innovation and People) model for all businesses on the Qualtrics platform, we have implemented a system to generate Customer Experience (CX) Insights via Voice of Customer (VOC) which was designed & rolled out as a centralised automated customer satisfaction survey in accordance to the needs of the customer. A platform to improve CSI (such as Customer Satisfaction Index Score & reporting gaps, area ownership, action planning, etc.) was configured and put into practice. We involve the customer in every phase of the customer satisfaction process including corroborating the survey responses, developing a roadmap strategy and completing the feedback loop.

- In addition to the above, we conduct a comprehensive site-wise analysis by an internal partner satisfaction survey that is utilised for internal purposes i.e. for internal stakeholders or cross-functional customers.

- To resolve customer problems on call, technical issues such as understanding of customer grievance, usage of correct language, listening to the grievance attentively, are assessed to enhance the quality of the call. Workshops on customer centricity are organized for customer facing teams to embellish their capabilities in managing an efficient grievance cell.

The company assesses the results and creates an action plan to improve on the following critical areas that result in PPS having high CSI metrics — an average score of 88.8%, with a growth of 1.5% from 2018.

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• “Voice of business” employs predictive modelling, customer account mapping, and key account management

• “Voice of customers” revolves around CSI analysis, net promoter score, Customer Effort Score (CES) and qualitative assessment

• “Voice of process” maps the customer’s journey and audits customer experiences across all our sites.

• “Voice of employees” includes workshops and assessment of core competency, rewards and recognition and Internal Partner Satisfaction Survey (IPSAT) for various functions like Supply Chain, IT and Shared Services

PPS has proven expertise in injectable capabilities and provides end-to-end contract development and manufacturing capabilities across active pharmaceutical ingredients (API) and formulations, including niche capabilities in handling cytotoxic injectable, hormonal formulations, and high potency APIs (HPAPI). PPS is also one of the biggest ADC providers globally and also conducts robust R&D on their auditing capabilities. PPS offers integrated services — a one-stop-shop model with comprehensive solutions right from discovery, intermediate, API, dosage formulation, R&D, and commercial manufacturing across multiple continents. In October 2018, PPS announced the launch of its Xcelerate Integrated Solutions™ platform addressing the growing industry need for preferred partner relationships. This platform enables the company to offer customized solutions for both large volume indications and niche fast-track medicines.

Frost & Sullivan firmly believes that PPS’s proficiency in drug substance and drug product development and manufacturing, and customer centric focus enables it to invest time and effort in building long-term, rewarding relationships with customers. The company’s philosophy and strategies provide a solution that fits the need of each customer uniquely, and it is the “Partner of Choice” for both pharma and biopharma clients to complete 70+ successful integrated projects, over the last three to four years.

**Optimizing Customer’s Production Economies with Supply Chain and Distribution Efficiencies**

PPS’ R&D team resolves complex process development and formulation challenges, optimizes processes and develops robust processes (for customers) that minimize the cost of their products - with subsequent cost advantage to patients. The company continually calibrates with customers to explore new technologies, and locate competitively priced intermediates and starting material to optimize production economies. The distinct footprint of PPS, with around half its sites in the East and the other half in the West, allows customers to manufacture the final API or Drug product out of the West, while back integrating into starting materials and intermediates out of its sites based in the East. The integrated approach reduces delivery timelines and improves
TTM, allowing customers to monetize time savings and reap the value of early and on-time product launches.

As one of the world leaders in the ADC segment, PPS provides integrated ADC manufacturing solutions from development through clinical and commercial (GMP) batch manufacturing and ADC fill/finish. The company offers end-to-end solutions through the ADC conjugation and the fill-finish service (between Europe and North America sites). The cytotoxic payload can be supplied from the high potency drug substance development and manufacturing facility in Michigan, thereby, completing the end-to-end solution. PPS has an excellent track record - manufacturing 850 ADC batches, 440 GMP batches and has experience with 180 different ADCs and more than 55 toxin/toxin-linker systems. PPS is involved in the supply of commercial ADCs on the market and is working with several Phase II and Phase III clinical trials on breakthrough drugs with multiple pharmaceutical companies.

PPS continues to solidify its distribution network by employing a best-in-class global sales team. This in turn allows the company to explore new markets and customers and expand the company’s reach.

Delivering High-quality and Operational Excellence with Organic and Inorganic Growth

With a high focus on compliance, quality standards, and reliability since 2011, the company cleared 33 US FDA inspections, 143 other regulatory inspections, and 971 customer audits across all its facilities, without closing production. With an ongoing focus on quality, the company designs an innovative quality framework that deploys across global operations and manufacturing sites and reports to the company’s board.

The company is growing both inorganically and organically through acquisitions and capital investments to cater to the evolving customer needs and to serve as a one-stop-shop. Strengthening its value proposition for big pharma companies, PPS is building new capabilities in outsourcing, as well as strengthening partnership initiatives with customers. PPS’ acquisitions in the last three years consolidate its offering profile. For instance, the US-based Coldstream Laboratories Inc. acquisition builds capabilities in cytotoxic manufacturing injectable products, while Ash Stevens added the expertise in specialty manufacturing of HPAPIs in North America. Furthermore, PPS is investing over US$85 million to expand and build capabilities throughout its facilities. In response to customer requirements, the acquired HPAPI facility in Michigan has recently undergone expansion to be able to safely handle compounds down to 20ng/m³. Additionally, the company is adding new technologies and operations, best practices to automate, improve operations’ scale and yield, lower cycle times, and reduce costs.
Conclusion

High research and development cost, capital-intensive complex manufacturing set-up, long-term end-to-end supply chain security, and developmental constraints challenge pharmaceutical and biopharmaceutical companies to discover, develop, and manufacture drugs commercially. Outsourcing to a contract development and manufacturing organization (CDMO) is a viable financial option for pharma and biopharma companies, allowing them to focus on core competency. At the same time, CDMOs’ integrated service offerings lower overall production costs, limit supply chain issues, provide high-end expertise, and reduce delivery timelines to quicken a drug’s time-to-market.

Piramal Pharma Solutions guided by its core values of Knowledge, Action, Care and Impact provides end-to-end capabilities to its pharmaceutical customers across the entire drug development lifecycle. A customer-centric organization, PPS combines its global operational capabilities and uniform scheduling to minimize supply chain constraints and lower delivery timelines for customers. Integrated service offerings allow the company to ensure a seamless transition of products across the drug development lifecycle to optimize customer's production economies, simplify developmental complexity, and improve time-to-market of new product launches. In its effort to serve patients, PPS focuses on its customer’s unique market positioning, customizes its offering, and strives to make them successful in the market.

With excellent customer service as its primary endeavour, Piramal Pharma Solutions earns the 2019 Frost & Sullivan ‘Global Customer Service Leadership’ Award.
Significance of Customer Service Leadership

Ultimately, growth in any organization depends on customers purchasing from a company and then making the decision to return time and again. The service experience is a critical component of a company’s efforts to retain customers, over the long term. Through successful retention, companies enhance their brand, increase demand for their products, and differentiate themselves from competition.

Understanding Customer Service Leadership

Customer Service Leadership is defined and measured by 2 macro-level categories: Quality of Customer Service and Customer Impact. These two sides work together to make customers feel both valued and confident in their products’ quality and performance. This dual satisfaction translates into repeat purchases and a lifetime of customer value.
Key Benchmarking Criteria

For the Customer Service Leadership Award, Frost & Sullivan analysts independently evaluated Quality of Customer Service and Customer Impact according to the criteria identified below.

Quality of Customer Service
- Criterion 1: Empowerment
- Criterion 2: Leverage of Customer Feedback
- Criterion 3: Speed/Timeliness
- Criterion 4: Frictionless Interaction
- Criterion 5: Technological Investment

Customer Impact
- Criterion 1: Price/Performance Value
- Criterion 2: Customer Purchase Experience
- Criterion 3: Customer Ownership Experience
- Criterion 4: Customer Service Experience
- Criterion 5: Brand Equity
Best Practices Recognition: 10 Steps to Researching, Identifying, and Recognizing Best Practices

Frost & Sullivan analysts follow a 10-step process to evaluate Award candidates and assess their fit with select best practices criteria. The reputation and integrity of the Awards are based on close adherence to this process.

<table>
<thead>
<tr>
<th>STEP</th>
<th>OBJECTIVE</th>
<th>KEY ACTIVITIES</th>
<th>OUTPUT</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Monitor, target, and screen</td>
<td>Identify Award recipient candidates from around the world</td>
<td>Pipeline of candidates that potentially meet all best practices criteria</td>
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<tr>
<td>2</td>
<td>Perform 360-degree research</td>
<td>Perform comprehensive, 360-degree research on all candidates in the pipeline</td>
<td>Matrix positioning of all candidates’ performance relative to one another</td>
</tr>
<tr>
<td>3</td>
<td>Invite thought leadership in best practices</td>
<td>Perform in-depth examination of all candidates</td>
<td>Detailed profiles of all ranked candidates</td>
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<tr>
<td>4</td>
<td>Initiate research director review</td>
<td>Conduct an unbiased evaluation of all candidate profiles</td>
<td>Final prioritization of all eligible candidates and companion best practices positioning paper</td>
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<tr>
<td>5</td>
<td>Assemble panel of industry experts</td>
<td>Present findings to an expert panel of industry thought leaders</td>
<td>Refined list of prioritized Award candidates</td>
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<tr>
<td>6</td>
<td>Conduct global industry review</td>
<td>Build consensus on Award candidates’ eligibility</td>
<td>Final list of eligible Award candidates, representing success stories worldwide</td>
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<tr>
<td>7</td>
<td>Perform quality check</td>
<td>Develop official Award consideration materials</td>
<td>High-quality, accurate, and creative presentation of nominees’ successes</td>
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<tr>
<td>8</td>
<td>Reconnect with panel of industry experts</td>
<td>Finalize the selection of the best practices Award recipient</td>
<td>Decision on which company performs best against all best practices criteria</td>
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<tr>
<td>9</td>
<td>Communicate recognition</td>
<td>Inform Award recipient of recognition</td>
<td>Announcement of Award and plan for how recipient can use the Award to enhance the brand</td>
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<tr>
<td>10</td>
<td>Take strategic action</td>
<td>Upon licensing, company is able to share Award news with stakeholders and customers</td>
<td>Widespread awareness of recipient’s Award status among investors, media personnel, and employees</td>
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The Intersection between 360-Degree Research and Best Practices Awards

Research Methodology

Frost & Sullivan’s 360-degree research methodology represents the analytical rigor of the research process. It offers a 360-degree view of industry challenges, trends, and issues by integrating all 7 of Frost & Sullivan’s research methodologies. Too often companies make important growth decisions based on a narrow understanding of their environment, resulting in errors of both omission and commission. Successful growth strategies are founded on a thorough understanding of market, technical, economic, financial, customer, best practices, and demographic analyses. The integration of these research disciplines into the 360-degree research methodology provides an evaluation platform for benchmarking industry participants and for identifying those performing at best-in-class levels.

About Frost & Sullivan

Frost & Sullivan, the Growth Partnership Company, helps clients accelerate growth and achieve best-in-class positions in growth, innovation and leadership. The company's Growth Partnership Service provides the CEO and the CEO's growth team with disciplined research and best practices models to drive the generation, evaluation and implementation of powerful growth strategies. Frost & Sullivan leverages nearly 60 years of experience in partnering with Global 1000 companies, emerging businesses, and the investment community from 45 offices on 6 continents. To join Frost & Sullivan’s Growth Partnership, visit http://www.frost.com.