2017 European Bioanalytical Contract Testing Services Customer Service Leadership Award
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Background and Company Performance

Industry Challenges

Biosimilars: The Promise

Biologics, such as monoclonal antibodies and recombinant proteins, continue to drive the biopharmaceutical sector due to their targeted therapeutic focus and potent action. With a growing aging population worldwide, precision medicine for cancer, autoimmune and metabolic disorders, and cardiovascular diseases is central to nearly all biopharmaceutical companies’ discovery and development efforts, as these are the most prevalent and costly chronic conditions. However, these life-saving therapies are often out of reach for patients due to the high treatment costs associated with biologics.

Biosimilars, a lower-cost version of the original branded biologicals, represent the next frontier in drug development. Biosimilar agents provide an opportunity to extend patient access to lower-cost, high-quality biologic treatment options. Factors fueling this market include:

- Increased global efforts towards affordable therapeutic alternatives to contain escalating healthcare expenditures and a slew of impending patent expirations—$70 to $80 billion worth of blockbuster biologics—by 2020.
- More defined regulatory pathways for biologics alongside innovations in recombinant DNA and low-cost manufacturing technologies that support flexible and cost-efficient processes, meeting the growing global demand for affordable products while satisfying increasingly stringent regulations that are essential for the safe and effective use of biosimilars.

Europe: Paving the Way

With over a decade of experience with biosimilar drugs, Europe (EU) has 21 approved products and more authorizations pending, holding the lion’s share of the total market—approximately 47%. Despite a slow initial uptake, biosimilar adoption is currently rising across EU, expanding patient access by more than 40% between 2006 and 2014 in Germany, Spain, France, the United Kingdom, and Italy. Frost & Sullivan estimates the European biosimilars market will reach nearly $29 billion by 2025, increasing at an astounding compound annual growth rate (CAGR) of 30.4% from 2016 to 2025.¹

Notwithstanding its distinct advantages, biological (functional) characterization poses unique challenges. These complex macromolecules require bioanalytical equivalency, i.e., demonstrable safety and efficacy similarity between the innovator molecule and the biosimilar, to achieve approval. Per EU regulatory guidelines, manufacturers must deliver extensive, robust, head-to-head analytical evidence—both structural and functional—supporting the products’ biosimilarity. However, unlike generics—its small molecule counterpart—biosimilars are not identical copies of the regulatory-approved biological product, i.e., the biological reference drug or innovator product.

¹ Biosimilars Market, Europe, Forecast to 2025 (Frost & Sullivan, March 2017)
Biosimilar development is product-specific, requiring technologically complex, sophisticated, and lengthy biological processes, from batch to batch, that must ultimately demonstrate fingerprint-like similarity to the innovator product. Also, albeit creating sizable revenue generating opportunities, biosimilars’ faster approval rates and reduced time to market as compared to biologics widen existing gaps between available and needed capacity. Very few market participants currently have both the technical expertise and capabilities to fulfill the burgeoning demand.

**Bioanalytical Testing Services: The Linchpin to Regulatory Approval**

Over the last several years, biopharmaceutical companies increasingly outsource services intrinsic to drug research and development (R&D)—preclinical and clinical—to contract research organizations (CROs) to lower costs, mitigate risks, and gain efficiencies. Drug safety and efficacy are still the main bottlenecks for advancing safe, cost-effective therapeutics. Bioanalytical testing is a core activity across the drug development value chain, identifying potential safety and efficacy risks at both the preclinical and clinical stages. Thus, CROs in this space occupy a significant, if not prominent, position within the framework of drug development.

With major biopharmaceutical companies progressively moving towards novel biologics and biosimilars, the bioanalytical testing services segment will witness a tremendous surge in the next five to six years. Testing must comply with Good Laboratory Practice (GLP) standards to ensure data quality, reliability, and validity as, ultimately, the results from all of these studies determine a drug’s application approval or rejection. Biomarker testing, potency assays, drug absorption, distribution, metabolism, and excretion (ADME), and metabolic profiling, and pharmacokinetic testing are key services under GLP principles.

According to Frost & Sullivan, the global bioanalytical testing services market generated $780 million in 2016, growing at a CAGR of 12.9% from 2016 to 2021; potency testing represented the largest segment accounting for 32% of the total market. As with the broader ‘one-stop-shop’ global trend, CROs offering cutting-edge, integrated bioanalytical approaches that reduce downstream risks will capture substantial share in this fast-growing segment.

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Quality of Customer Service and Customer Impact of Sartorius Stedim BioOutsource

Founded in 2007, Glasgow-based BioOutsource, now called Sartorius Stedim BioOutsource is a leading global contract testing services provider to the biopharmaceutical industry. A small, privately-held CRO in its beginnings, BioOutsource harnessed a strong reputation as a biosimilar specialist. The company was the first to develop validated, off-the-shelf cell-based potency assays (bioassays) to substantiate product safety and efficacy similarity per the European Medicines Agency (EMA) guidelines. After reporting 40% year-over-year growth in 2015, the company became part of the Sartorius Stedim Biotech (SSB) group. A world-renowned biopharmaceutical supplier of products and services, SSB enables its customers to develop and manufacture medical drugs safely and efficiently. As a total solutions provider, the company offers a portfolio covering nearly all steps of biopharmaceutical manufacturing. SSB focuses on single-use technologies and value-added services to meet the rapidly changing technology requirements of the industry it serves.

Sartorius Stedim BioOutsource: Future-Focused, Innovation Led, Trusted Service Provider

Early in its history, BioOutsource identified biosimilars as a growing sector and invested in the upfront development of a suite of in vitro bioassays based on the first wave of innovator products set to go off patent. Positioned to execute readily, the company gained an early-mover advantage in the nascent market.

BioOutsource continued to strengthen its expertise, expanding its industry-leading, off-the-shelf bioassay portfolio, and thereby, reinforcing its global thought leadership standing as it grew alongside the biosimilars market. Over the years, the pioneering company engaged in more than 200 biosimilar development programs with over 50 developers worldwide. In the last four years, Sartorius Stedim BioOutsource achieved preferred vendor status, leading most customers to proactively seek its readily available, reliable, accurate, and high-quality in vitro potency assays for biosimilar development. Moreover, the company reduces its customers R&D costs—eliminating the time and money required for assay development—and speeds time-to-market which, in the intensely competitive biosimilar space, provides a huge strategic advantage for its partners. Through continuous investments in its R&D program, the company is well-positioned to capture the second and third wave of biosimilar agents as these progresses into the market.

“Customers certainly see Sartorius Stedim BioOutsource as the go-to place to test their biosimilar molecules for comparability. They have confidence that we have developed readily available assays for first wave biosimilars and that we continue to invest to ensure a similar suite of assays are available to meet the demand of the second wave.”

-Sandy Bulloch, Director of Technical Field Marketing, Sartorius Stedim BioOutsource
Frost & Sullivan believes that Sartorius Stedim BioOutsource’s biosimilar expertise and customer-centric innovation allows it to anticipate the rising market demands and bolster its commitment to biopharmaceutical partners—develop a deeper understanding and knowledge of biosimilars than competitors, offer comprehensive off-the-shelf bioassays readily available to a range of innovator products, and maintain a faster time-to-market at lower overall costs.

**Foresight with Insight: Knowledge Breadth, Strategic Depth**

The changing competitive landscape forces CROs to adopt strategies that expand their service portfolio and geographical footprint—through either capital expenditures or merger and acquisition activities—to enhance their value proposition and support end-to-end biopharmaceutical services. Despite the industry-wide consolidation trend, bioanalytical testing is a relatively new segment; fragmented and largely comprised of niche players. While critical, extensive biological characterization is not the only assessment required for drug approval. EMA’s “totality of evidence” guidelines recommend an orthogonal approach to regulatory approval—a full quality dossier garners information from physicochemical and functional analyses as well as binding kinetic determinations and data from animal and clinical studies.

While not losing sight of its core expertise (bioassays), BioOutsource is tapping available growth opportunities by leveraging SSB’s extensive bioprocessing technology platforms, global presence, and wide customer reach. The company combined its deep biosimilar understanding and leading-edge expertise in bioassays with the group’s broader capabilities and expanded geographical footprint to offer a complete product and service combo. For instance, the company utilizes Sartorius Stedim Cellca’s cell line CHO Expression Platform to optimize biosimilar cell line development and SSB’s single-use technologies and value-added services to respond rapidly to changing technology capabilities and market needs. It also expanded its biological safety testing and chemistry portfolio. With the additional capabilities, BioOutsource can piece together a fuller picture to its customers, providing complete structural and functional analyses to ensure that their product is, in fact, demonstrating fingerprint-like similarities to the biological reference product at all stages.

Through SSB’s global network, BioOutsource is in the process of extending biosimilar access to emerging Asian and South American countries. Furthermore, the company opened a bioanalytical and biosafety testing laboratory in Cambridge, Massachusetts in November 2016. With its first two biosimilars—filgrastim and insulin glargine—reaching the market in 2015\(^1\), the United States is emerging as a game-changer on the global stage, and BioOutsource is, again, ideally positioned to gain substantial market share.
The company is also widening its market scope, developing best practices to customize bioanalytical approaches in support of biologics, vaccines, and biosimilars—with future sights on gene and cell therapies—development and production.

"Sartorius Stedim BioOutsource has significant expertise in the development of potency and binding assays for biosimilar molecules, and by understanding the mode of action of monoclonal antibodies, this expertise can be easily extended to provide biological assay development for innovator molecules."

- Sandy Bulloch, Director of Technical Field Marketing, Sartorius Stedim BioOutsource

**Long-lasting Framework: Knowing the Customer’s Needs**

An experienced team with strong scientific capabilities, leading technologies, and regulatory compliant processes in place are crucial to project success, but service excellence is key to long-term sustainability. CROs must develop strong relationships with their customers for continuous growth.

Sartorius Stedim BioOutsource cultivates transparent relationships with the sponsors to enhance the overall service experience and customer satisfaction. The company understands the pathways and specific milestones in their customers’ biosimilar development programs and sets aggressive timelines to ensure regulatory approval is on track. Since its incorporation with SSB, BioOutsource implemented additional best practices to fine-tune its management operations. A client management team engages directly with the customers throughout the course of the program—fostering smooth, two-way communication channels at all stages. With a single touchpoint to convey updates and drive services, the company coordinates its multi-site, plethora of testing offerings to provide customers seamless, systematic, and timely relevant bioanalytical information for the quality dossier. Through its Voice of the Customer system, BioOutsource captures customers’ feedback to evaluate its performance and maintain best-in-class products and services.

"It is very easy to lose the concept of service and get wrapped up in the science and experimentation. At the end of the day, we [BioOutsource] are a contract service organization where ‘Service’ is the key word."

- Sandy Bulloch, Director of Technical Field Marketing, Sartorius Stedim BioOutsource
Conclusion

With major biopharmaceutical companies progressively moving towards novel biologics and biosimilars, the bioanalytical testing services segment will witness a tremendous surge in the next five to six years.

Frost & Sullivan’s research identifies Sartorius Stedim BioOutsource as a trusted biopharmaceutical partner with an impeccable reputation and unique, expertise on biosimilars—supporting development for a range of innovator products, with faster time-to-market and lower overall costs. The company leverages Sartorius Stedim Biotech group’s broader capabilities and expanded geographical footprint to offer comprehensive, integrated bioanalytical approaches, poising the company for exponential growth in coming years.

For its pioneering, industry-leading, off-the-shelf bioassay portfolio, thought leadership on biosimilars, and unique product and service combination for enhanced customer satisfaction, Sartorius Stedim BioOutsource earns Frost & Sullivan’s 2017 Customer Service Leadership Award in the bioanalytical contract testing services market.
Significance of Customer Service Leadership

Ultimately, growth in any organization depends upon customers purchasing from a company and then making the decision to return time and again. The service experience is, therefore, 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 the competition.

Understanding Customer Service Leadership

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

For the Customer Service Leadership Award, Frost & Sullivan analysts independently evaluated two key factors—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 practice 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 globe</td>
<td>Pipeline of candidates who potentially meet all best-practice 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>
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<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-practice 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-practice Award recipient</td>
<td>Decision on which company performs best against all best-practice criteria</td>
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<tr>
<td>9</td>
<td>Communicate recognition</td>
<td>Inform Award recipient of Award recognition</td>
<td>Announcement of Award and plan for how recipient can use the Award</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 our 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, leading to 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, enables clients to 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 practice models to drive the generation, evaluation and implementation of powerful growth strategies. Frost & Sullivan leverages more than 50 years of experience in partnering with Global 1000 companies, emerging businesses, and the investment community from 45 offices on six continents. To join our Growth Partnership, please visit http://www.frost.com.