FROST & SULLIVAN

BEST PRACTICES AWARDS

cytiva

2020 GLOBAL FLEXIBLE BIOPHARMACEUTICAL MANUFACTURING PLATFORM FOR LIFE SCIENCES COMPANY OF THE YEAR AWARD

Contents

Background and Company Performance

Industry Challenges

Frost & Sullivan expects the global biologic drug market to reach approximately $390 billion in the next two years, and the requirement for faster and more consistent drug delivery is increasing at a rate the industry finds hard to match. For instance, the increasing demand for personalized medicine requires producing smaller batch sizes, whereas new drug modalities and new manufacturing technologies require adaptable and flexible production environments. Biopharmaceutical manufacturing companies are looking for dynamic processing environments that have made the transition from established, large-batch production setups to smaller-scale production facilities. Today, more than 70% of all clinical trials planned in the United States are in phase I and II, with more than 50% of companies outsourcing certain bioprocessing tasks; about 19% have outsourced more than half of their tasks. These numbers reflect the increasing demand for bioprocessing solutions which address the needs of small and mid-sized biotechnology companies.

The biomanufacturing industry is complex and faces unique issues, such as an ever increasing need to reduce costs, development of international bio-manufacturing centers, and the nuances of managing a cell and gene therapy pipeline. These challenges are impacting various aspects of the industry. For instance, current facility capacity and production is further strained by the ability to sufficiently hire and train a workforce. More than 50% of bio-manufacturing facilities around the globe are dealing with capacity problems this year due to the urgent demand for vaccines and therapeutics used to combat COVID-19.

In response, the bioprocess and pharmaceutical manufacturing industries are rapidly assessing options to support manufacturing in geographies where healthcare needs are most critical today and into the future. Flexibility within a standard configurable platform approach will help to address training concerns and adaptability when producing unknown drug modalities in new geographies. Options to quickly deploy and qualify personnel, equipment, control systems and facilities are at the forefront of most business decisions today. Decision makers are evaluating companies, products and technologies based on investments that will offer flexibility, efficiency and speed. Proven technologies of today will need to flex with biopharmaceutical business needs over time and offer plug and play configurability for manufacturing in the future.

Biomanufacturing's requirement for flexibility stretches beyond equipment, into the plant infrastructure. Automation platforms that can control equipment, processes and even facilities are a critical component of an efficient biomanufacturing ecosystem. They play a key role in streamlining transfer of production from one facility to another, reducing manual interventions and assuring regulatory compliance.

Additionally, the complexities of cell therapy products create unique logistical challenges in addition to new approaches to manufacturing. Cell therapy manufacturing starts with the collection of cell samples from patients in a clinical facility and concludes with the

administration of the final drug to the patient. This entire supply chain process requires careful control of multiple hand-off points and procedures. A complete understanding of the entirety of the cell therapy workflow is required to generate the best value from a supply chain perspective.

Visionary Innovation and Performance/Customer Impact

Cytiva is a global provider of technologies and services that help advance and accelerate the development and manufacture of vaccines and therapeutics. Previously part of GE Healthcare Life Sciences, Cytiva was formed in April 2020 following the acquisition by Danaher Corporation. Cytiva caters to key applications, including monoclonal antibodies, vaccines, cell and gene therapies, cellular analysis, diagnostics, genomics, lab filtration, and protein research. This best practice award is focused on the Cytiva FlexFactory single-use biomanufacturing platform.

Addressing Unmet Needs

The Cytiva FlexFactory single-use platform is designed to address the increasing need for a connected and flexible manufacturing solution for biologics. The FlexFactory combines production equipment (cell culture, filtration, purification), automation (hardware and software), connectivity solutions (single-use tube sets, sensors, aseptic connectors, bags), as well as project management, installation, commissioning and calibration, training, process development, and maintenance services into an integrated one-stop-shop offering. The core differentiating feature is Cytiva's ability to offer integrated monitoring and control in a single-use processing platform. In contrast to the top competitors' offerings, where it can be cumbersome to integrate hybrid manufacturing lines, FlexFactory is a comprehensive, single point of contact, solution designed to be completely flexible, allowing changes that support evolving bio-manufacturing requirements.

In the FlexFactory platform, all process equipment can be integrated with the Cytiva Figurate automation platform that includes central control capability, data acquisition, user management, and recipe control. Centralized automation helps decrease user error, process variation, and risk related to manual processing. A FlexFactory platform can record data from all equipment and display it graphically on one of the several mobile workstations for real-time monitoring of the entire process. Navigation between screens allows the user to monitor and control one or many pieces of equipment at once. Automation enables monitoring and control of every process unit operation including cell culture, harvesting operations, mixing, purification and filtration.

In essence, the FlexFactory is provided as a complete and integrated turn-key solution that can be configured to manufacture a growing list of modalities including monoclonal antibodies, viral vectors, plasmid DNA, and vaccines.

For added convenience, all of this is managed through a single point of contact within Cytiva. Frost & Sullivan finds that no other competitor in the market provides a comparable end-to-end biomanufacturing capability. Cytiva's approach improves speed, reduces risk and complexity and delivers flexibility that is needed in this evolving and diverse biomanufacturing industry.

Cytiva's experts drive value creation even further by providing strategic guidance on all aspects of the project, from process development and design to equipment installation automation integration and testing. Whatever the production needs, Cytiva will work with bio-manufacturers to turn their vision into reality in less than 10 months of approving the process design. In contrast, the competitors in this space generally take longer to realize a project because they have to collaborate with third party vendors to develop and deliver an end-to-end bio-manufacturing solution.

Performance Value: Configurable Platform with Batch Control and Recipe

The FlexFactory platform provides the functionality and flexibility needed to support a wide range of bio-manufacturing and processing initiatives. The platform enables easy implementation of batch control based on control recipes for specific unit operations.

Figure 1. Typical Automation Architecture in a FlexFactory with a PLC Solution

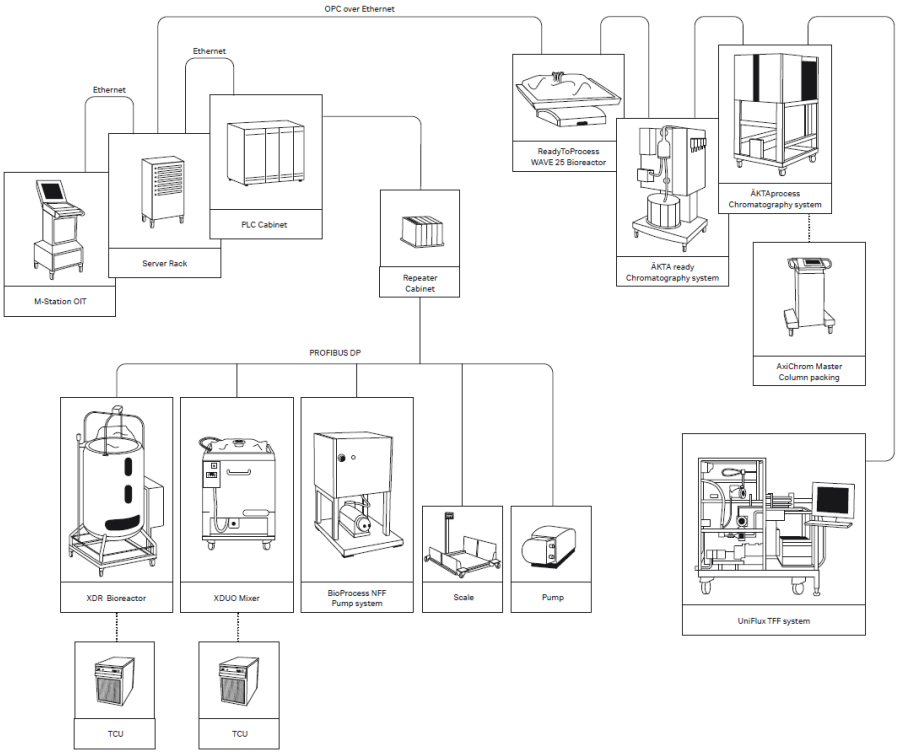


Image Source: Cytiva

Batch control software is crucial to realize the value of automation systems in bio-manufacturing. Through batch control, biomanufacturers can operate the same process consistently with high quality and adherence to process parameters specified in the recipe, thereby decreasing the risk of human error. To facilitate this process, Cytiva provides the Figurate automation platform, featuring control and communication capabilities that convert data insights into productive results for both upstream and downstream production efficiency gains.

Cytiva's platform approach, integrates disparate systems to control all equipment. Both the batch management software and equipment operations can be accessed seamlessly through a single human machine interface (HMI). To illustrate a best practice example, Bayer AG, a leading Germany-based pharmaceutical company, adopted FlexFactory integrated with the Figurate automation platform powered by DeltaV to setup two single-use XDR bioreactors and a purification train. FlexFactory has benefitted the company by providing the flexibility to add two more single-use bioreactors when the need arises.

Visionary Scenarios through Mega Trends: Using AI to Digitize Bioprocessing

Bio-manufacturers will realize the value of digital solutions depending on how they leverage big data to predict and optimize process parameters, resulting in better product yields. Cytiva has demonstrated how to utilize raw material characterization to evaluate yield-efficiencies in bio-manufacturing facilities. With advanced analytics, data from batch performance and raw materials can be mapped to batch characteristics from high performing batches. Critical process-parameters can be identified and optimized to maximize the yield of every production batch, to drive efficiency, quality and purity.

Implementation Best Practices: KUBio Facility Integrated with FlexFactory

Cytiva has further enhanced the flexibility and speed to deliver biomanufacturing capacity with a predesigned standard modular biomanufacturing facility solution, called KUBio. The FlexFactory platform is integrated into the KUBio facilities, to meet customer requirements, and delivered as one comprehensive offering. The structures are prefabricated and prequalified for quick deployment at the customer site. Conversely, biomanufacturers can either construct a brick-and-mortar facility onsite, or retrofit an existing faciality. Whereas traditional stick built biomanufacturing facilities can take anywhere from 24 to 36 months, KUBio facilities can be built and deployed in less than 18 months, enabling speed to market for biologics around the world. KUBio facilities are also 25% to 50% lower in cost when compared to traditional facilities because they are pre-designed, built offsite and utilize a smaller, more efficient footprint. Furthermore, KUBio facilities consume approximately 25% less water and energy than facilities that use traditional stainless steel technologies.

Best Practice Example 1: BeiGene Biotech, a leading China-based biopharmaceutical manufacturer, was planning to set up a facility to manufacture monoclonal antibody therapies targeted to fight cancer. With six internally developed biologics in clinical trials and three marketed therapeutics, they were looking for an innovative manufacturing solution. Their goal was to be innovative and impactful and have the highest quality. They realized the KUBio facility was faster alternative than whatever local companies were capable of building with a higher standard of quality. The KUBio facility was up and running in 18 months.

Since the solution utilized a standard approach, BeiGene can efficiently and rapidly transfer process to new manufacturing sites wherever capacity is needed.

Best Practice Example 2: Pfizer Inc., a leading US-based drug maker, was looking to set up a biotechnology facility in China to manufacture biopharmaceuticals for ailments such

as autoimmune disorders, diabetes, and cancer. Pfizer chose the Cytiva KUBio modular facility integrated with the FlexFactory single-use platform because it enabled the manufacturing of biologics in multiple 2,000-liter single-use bioreactors. Manufacturing biologics in single-use disposable plastic units enabled Pfizer to eliminate expensive cleaning and sterilization, making the operation more efficient. The FlexFactory platform also provided the capability to quickly switch between drugs, allowing the company to make new biopharma drugs as needed without major overhaul and expense.

Brand Equity and Financial Performance

As the surge in production of COVID-19 related products and race towards vaccine development are expected to provide an approximate $14 billion opportunity for bioprocess equipment vendors. Cytiva's cutting-edge solutions, which includes cell biology and protein research equipment, chromatography resins, cell culture media, single-use technologies, diagnostic tests and service, is poised to gain greater traction amidst peers that lack end-to-end capabilities for bioprocess solutions. Acquired by Danaher for $21.4 billion in March 2020, Cytiva is already focused on ramping up the business, with plans to invest $500 million, employ more than 1,000 people over the next five years, and expand its global manufacturing capacity. In 2019, Cytiva reported $3.3 billion in revenue. The company is supported by more than 7,000 employees around the globe.

The world is experiencing accelerated capacity expansion in the biopharmaceutical manufacturing industry due to the massive focus on COVID-19 vaccine development, which leaves an immediate need for single-use biomanufacturing platforms. Today, Cytiva has partnered with more than 100 companies dedicated to the development of COVID-19 drugs and vaccines, such as Takara Bio, Avacta, and University of Queensland. In addition to COVID-19 vaccine, Cytiva has invested in strengthening its presence in industries that develop monoclonal antibodies and cell and gene therapies. Committed to delivering a fulfilling service experience to customers, Cytiva is strengthening the supply of its solutions by increasing the overall capacity in key product areas and encompassing 'dual manufacturing' practices. Thus, if Cytiva's customers encounter capacity constraints in one location, they can readily activate the other back-up sites.

Conclusion

Demand is increasing for dynamic manufacturing environments that will enable biomanufacturers to transition from large-batch production to smaller scale, multiproduct and multimodality manufacturing facilities that offer reduced timelines and cost commitments. The Cytiva FlexFactory platform enables efficient design of manufacturing platforms for the development and production of biopharmaceuticals. This platform serves as the foundation for flexible, configurable, and scalable bio-manufacturing. A key competitive advantage is that the FlexFactory platform provides a comprehensive solution from a single point of contact that includes equipment, automation, consumables and services from an experienced and proven provider.

For its strong overall performance, Cytiva has earned Frost & Sullivan's 2020 Company of the Year Award.

Significance of Company of the Year

To receive the Company of the Year Award (i.e., to be recognized as a leader not only in your industry, but among non-industry peers) requires a company to demonstrate excellence in growth, innovation, and leadership. This excellence typically translates into superior performance in three key areas—demand generation, brand development, and competitive positioning—that serve as the foundation of a company's future success and prepare it to deliver on the 2 factors that define the Company of the Year Award: Visionary Innovation and Performance, and Customer Impact).

Understanding Company of the Year

Driving demand, brand strength, and competitive differentiation all play critical roles in delivering unique value to customers. This three-fold focus, however, must ideally be complemented by an equally rigorous focus on Visionary Innovation and Performance to enhance Customer Impact.

Key Benchmarking Criteria

For the Company of the Year Award, Frost & Sullivan analysts independently evaluated each factor according to the criteria identified below.

Visionary Innovation and Performance

Criterion 1: Addressing Unmet Needs
Criterion 2: Visionary Scenarios through Mega Trends
Criterion 3: Implementation of Best Practices
Criterion 4: Blue Ocean Strategy
Criterion 5: Financial Performance

Customer Impact

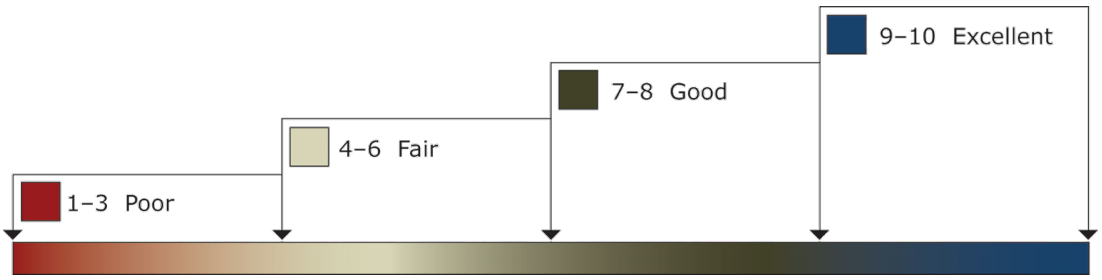
Criterion 1: Price/Performance Value
Criterion 2: Customer Purchase Experience
Criterion 3: Customer Ownership Experience
Criterion 4: Customer Service Experience
Criterion 5: Brand Equity

Best Practices Award Analysis for Cytiva

Decision Support Scorecard

To support its evaluation of best practices across multiple business performance categories, Frost & Sullivan employs a customized Decision Support Scorecard. This tool allows research and consulting teams to objectively analyze performance according to the key benchmarking criteria listed in the previous section, and to assign ratings on that basis. The tool follows a 10-point scale that allows for nuances in performance evaluation. Ratings guidelines are illustrated below.

RATINGS GUIDELINES



The Decision Support Scorecard considers Visionary Innovation and Performance and Customer Impact (i.e., the overarching categories for all 10 benchmarking criteria; the definitions for each criterion are provided beneath the scorecard). The research team confirms the veracity of this weighted scorecard through sensitivity analysis, which confirms that small changes to the ratings for a specific criterion do not lead to a significant change in the overall relative rankings of the companies.

The results of this analysis are shown below. To remain unbiased and to protect the interests of all organizations reviewed, Frost & Sullivan has chosen to refer to the other key participants as Competitor 1 and Competitor 2.

Measurement of 1–10 (1 = poor; 10 = excellent)			
Company of the Year	Visionary Innovation & Performance	Customer Impact	**Average Rating**
Cytiva	**10**	**10**	**10**
Competitor 1	8	8	8
Competitor 2	7	7	7

Visionary Innovation & Performance

Criterion 1: Addressing Unmet Needs

Requirement: Implementing a robust process to continuously unearth customers' unmet or underserved needs, and creating the products or solutions to address them effectively.

Criterion 2: Visionary Scenarios through Mega Trends

Requirement: Incorporating long-range, macro-level scenarios into the innovation strategy, thereby enabling first-to-market growth opportunity solutions.

Criterion 3: Implementation of Best Practices

Requirement: Best-in-class strategy implementation characterized by processes, tools, or activities that generate a consistent and repeatable level of success.

Criterion 4: Blue Ocean Strategy

Requirement: Strategic focus on creating a leadership position in a potentially uncontested market space, manifested by stiff barriers to entry for competitors.

Criterion 5: Financial Performance

Requirement: Strong overall business performance in terms of revenue, revenue growth, operating margin, and other key financial metrics.

Customer Impact

Criterion 1: Price/Performance Value

Requirement: Products or services offer the best value for the price compared to similar offerings in the market.

Criterion 2: Customer Purchase Experience

Requirement: Customers feel they are buying the optimal solution that addresses both their unique needs and their unique constraints.

Criterion 3: Customer Ownership Experience

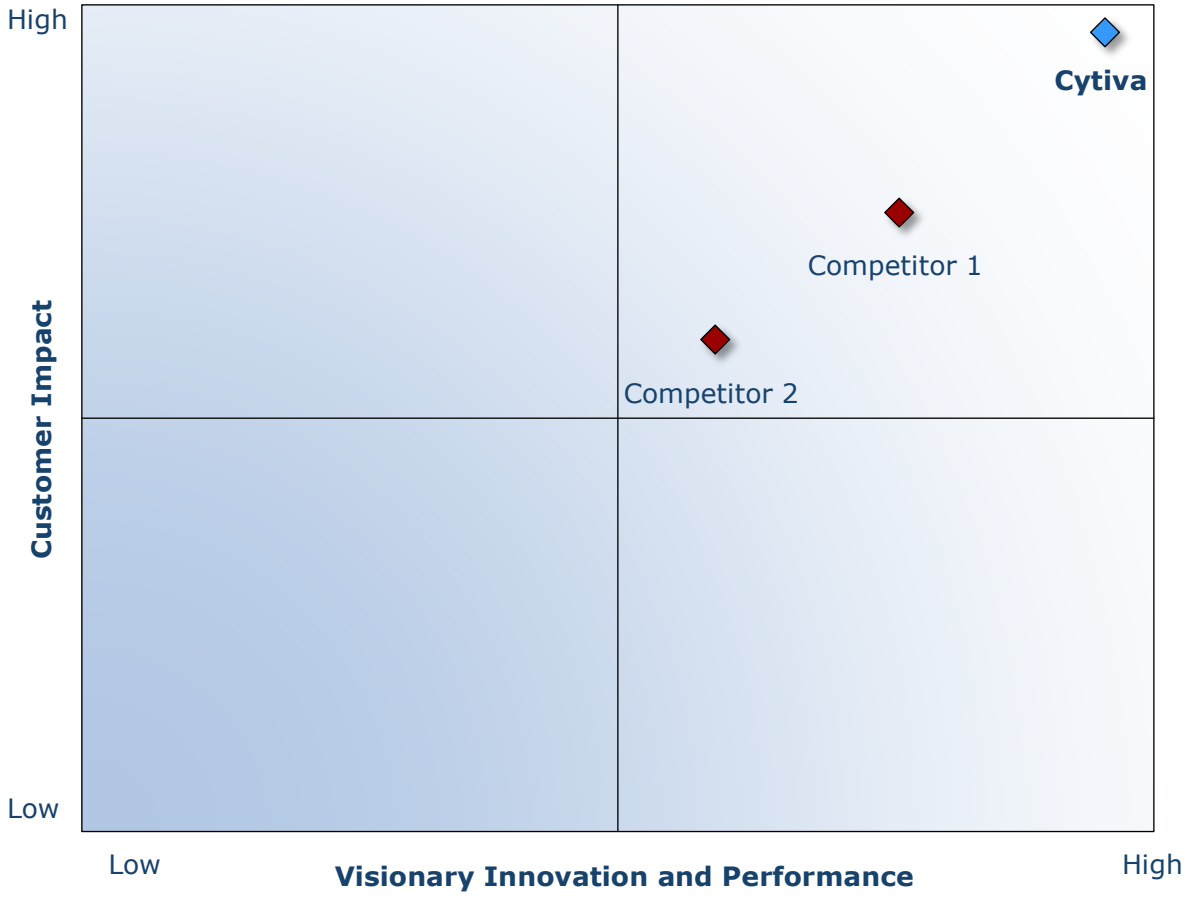
Requirement: Customers are proud to own the company's product or service and have a positive experience throughout the life of the product or service.

Criterion 4: Customer Service Experience
Requirement: Customer service is accessible, fast, stress-free, and of high quality.

Criterion 5: Brand Equity
Requirement: Customers have a positive view of the brand and exhibit high brand loyalty.

Decision Support Matrix

Once all companies have been evaluated according to the Decision Support Scorecard, analysts then position the candidates on the matrix shown below, enabling them to visualize which companies are truly breakthrough and which ones are not yet operating at best-in-class levels.



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.

	STEP	OBJECTIVE	KEY ACTIVITIES	OUTPUT
1	**Monitor, target, and screen**	Identify award recipient candidates from around the world	• Conduct in-depth industry research • Identify emerging industries • Scan multiple regions	Pipeline of candidates that potentially meet all best practices criteria
2	**Perform 360-degree research**	Perform comprehensive, 360-degree research on all candidates in the pipeline	• Interview thought leaders and industry practitioners • Assess candidates' fit with best practices criteria • Rank all candidates	Matrix positioning of all candidates' performance relative to one another
3	**Invite thought leadership in best practices**	Perform in-depth examination of all candidates	• Confirm best practices criteria • Examine eligibility of all candidates • Identify any information gaps	Detailed profiles of all ranked candidates
4	**Initiate research director review**	Conduct an unbiased evaluation of all candidate profiles	• Brainstorm ranking options • Invite multiple perspectives on candidates' performance • Update candidate profiles	Final prioritization of all eligible candidates and companion best practices positioning paper
5	**Assemble panel of industry experts**	Present findings to an expert panel of industry thought leaders	• Share findings • Strengthen cases for candidate eligibility • Prioritize candidates	Refined list of prioritized award candidates
6	**Conduct global industry review**	Build consensus on Award candidates' eligibility	• Hold global team meeting to review all candidates • Pressure-test fit with criteria • Confirm inclusion of all eligible candidates	Final list of eligible award candidates, representing success stories worldwide
7	**Perform quality check**	Develop official award consideration materials	• Perform final performance benchmarking activities • Write nominations • Perform quality review	High-quality, accurate, and creative presentation of nominees' successes
8	**Reconnect with panel of industry experts**	Finalize the selection of the best practices award recipient	• Review analysis with panel • Build consensus • Select winner	Decision on which company performs best against all best practices criteria
9	**Communicate recognition**	Inform award recipient of recognition	• Inspire the organization for continued success • Celebrate the recipient's performance	Announcement of award and plan for how recipient can use the award to enhance the brand
10	**Take strategic action**	Upon licensing, company able to share award news with stakeholders and customers	• Coordinate media outreach • Design a marketing plan • Assess award's role in strategic planning	Widespread awareness of recipient's award status among investors, media personnel, and employees

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.

360-DEGREE RESEARCH: SEEING ORDER IN THE CHAOS

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.