

F R O S T & S U L L I V A N

BEST PRACTICES

AWARDS

F R O S T & S U L L I V A N

2020 BEST PRACTICES AWARD

 **G-CON**
MANUFACTURING Inc.

**2020 GLOBAL PREFABRICATED CLEANROOM
SYSTEM SOLUTIONS FOR BIOPHARMACEUTICALS
CUSTOMER VALUE LEADERSHIP AWARD**

Contents

Background and Company Performance	3
<i>Industry Challenges</i>	3
<i>Customer Impact and Business Impact</i>	4
<i>Conclusion</i>	8
Significance of Customer Value Leadership	9
Understanding Customer Value Leadership	9
<i>Key Benchmarking Criteria</i>	10
Best Practices Award Analysis	10
<i>Decision Support Scorecard</i>	10
<i>Customer Impact</i>	11
<i>Business Impact</i>	11
<i>Decision Support Matrix</i>	12
Best Practices Recognition: 10 Steps to Researching, Identifying, and Recognizing Best Practices.....	13
The Intersection between 360-Degree Research and Best Practices Awards.....	14
<i>Research Methodology</i>	14
About Frost & Sullivan	14

Background and Company Performance

Industry Challenges

Traditionally, the biopharmaceutical industry has been dominated by large-scale batch processing infrastructure, such as facilities where billions of tablets are produced annually. Frost & Sullivan observes how the rapidly-evolving pharmaceutical landscape, especially in relation to biological and precision drugs, has increased the need for more agile facilities that can treat diverse patient populations.

Large batch processing systems consist of multiple operation units, sizable inventory, and numerous intermittent operation steps. As a result, it requires weeks or even months to manufacture a batch of tablets. At the same time, Frost & Sullivan analysts monitor how the biopharmaceutical industry is experiencing dynamic technological changes with Big Data, additive manufacturing, and robotics now present in key industrial applications. Such advancements allow manufacturers to decrease critical drugs' time-to-market. The biopharmaceutical industry is also witnessing an increased need for facilities and cleanroom structures due to the high demand for a COVID-19 vaccine and other biologic drugs. The facilities and cleanrooms are used to carry out applications such as cell culture and harvesting for cell and gene therapy, purification and compounding for vaccine production, and sterile equipment manufacturing.

The need to expedite drug production is spurring the adoption of technologies such as Big Data and robotics. As such, Frost & Sullivan notes that the ability to seamlessly integrate futuristic technology upgrades is a key concern for customers. However, traditional facility infrastructures have difficulty accommodating such requirements. Conventional facilities, ranging from brick-and-mortar infrastructure to offsite-built container systems and stick-built modular wall panel solutions, are not readily deployable and can take months to be completely functional. As each traditional facility is considered a new project, the design and build aspects are lengthy and unreliable. Project schedules can run up to 12 months or longer, and the high hourly compensation models for designers and contractors do not incentivize a rapid manufacturing process. Furthermore, build budgets are generally exceeded due to numerous unanticipated costs.

In addition, traditional facilities are generally used only for a single product lifecycle and are purpose-built. Hence, a customer cannot immediately configure traditional infrastructure to meet the demands of evolving therapies and applications. Even if a customer is able to invest the time and resources to modify the facility, it cannot be achieved without interrupting existing processes. Furthermore, investment in staff training is often required to handle the tools of the new facility effectively.

Frost & Sullivan finds that the vendor able to provide modular, pre-fabricated cleanroom infrastructures and pharmaceutical facilities that can be set-up with lower lead times will properly meet evolving customer requirements. Such vendors will find themselves positioned to capture market share in the dynamic North American market.

Customer Impact and Business Impact

Performance Value

Texas-based G-CON Manufacturing, Inc. (G-CON) has developed a new approach to designing and constructing cleanroom facilities, called PODs. As the structures are prefabricated and prequalified, the PODs can be quickly deployed at the customer site. Frost & Sullivan notes that other competitors, in contrast, either construct cleanrooms onsite or provide container based system; both require higher lead times and expense (e.g., installing systems such as heating, ventilation, and air conditioning (HVAC)). G-CON's cleanroom PODs are delivered as fully-functional facilities, with internal air handling, duct work, automation, fire suppression, and other HVAC controls already in place. The POD units are designed, fabricated, and assembled off-site at the G-CON facility and are subjected to factory acceptance testing prior to shipping to customers. Such a unique approach, which is not typically pursued by traditional architecture and engineering (A&E) firms, ensures that the PODs meet specifications upon reaching the customer's site.

Another differentiating factor of G-CON's PODs is that aside from being designed and fabricated much faster, they can also be built in parallel to the shell host facility and process equipment. As a result, the PODs significantly reduce construction time. Depending on the client requirements, G-CON can either build a single POD in a standard configuration or as a POD cluster with multiple subPODs assembled together. Thus, customers have the flexibility to run their clinical and commercial processes either separately in single PODs or combined within the same structure. Frost & Sullivan research reveals that G-CON has truly transformed the design and construction of cleanroom facilities by turning them into turnkey platforms that can be built and deployed in a fraction of the time of traditional approaches.



Figure 1. Single POD



Figure 2. POD Cluster with Multiple SubPODs

Image Source: G-CON Manufacturing, Inc.

Customer Ownership Experience: Speeding Deployment through an Autonomous POD Environment

G-CON is committed to delivering a fulfilling ownership experience to customers. To that end, the company encompasses a 3S (speed, scale, and savings) approach to develop an autonomous cleanroom solution. Other competitors take anywhere between 17 and 24 months to build and start up a fully operational facility, creating acute challenges for the

biopharmaceutical industry, which is already facing capacity constraints. G-CON's client-centric approach enables PODs to be built and operational within 6 to 12 months. Furthermore, as G-CON's PODs are entirely designed and built off-site, customers do not have to worry about contaminating work zones or impeding existing clinical processes.

Frost & Sullivan appreciates how G-CON also enhances the customer ownership experience by pre-configuring the construction site, utility components, and connection points to the PODs. As a result, connections are expedited once the PODs are installed at the site. To illustrate the company's best practice, G-CON delivered a portable, continuous, miniature, and modular (PCMM) POD to Pfizer Inc., a leading multinational pharmaceutical corporation, to be used as an oral solid dosage facility. The POD, which is about 700 square feet, was pre-configured with GEA's ConsiGma oral solid dosage line which included wet granulation, fluid bed drying and tablet compression and integrated into the PODs. The entire set-up was installed at the customer site and operational within weeks. Frost & Sullivan finds this case study to be a true testament to G-CON's commitment to developing industry-leading manufacturing capabilities and deploying best-in-class cleanroom facilities within the shortest time possible.

Customer Purchase Experience: Cost Savings and Budget Reliability

Customers in the life sciences industry rely on precise delivery times and accurate budgets, as these elements influence their critical activities, from vaccine development to cell and gene therapies. The construction of cleanroom facilities by traditional A&E firms and other competitors are commonly delayed by months, with cost increases typically accounting for 30 to 50% more than the planned budget. Furthermore, indirect costs (e.g., purchasing temporary material, material storage, safety gear, and insurance) make traditional construction approaches cost-prohibitive. G-CON's off-site construction approach eliminates indirect costs and is subject to neither bad weather conditions nor worker union disputes. Moreover, in contrast to other competitors who do not compensate for project delays, G-CON compensates for any potential delay by either working overtime or through multiple shifts.

Customers using PODs immediately realize financial benefits when they save operational costs spent on energy and do not experience any business interruption. Moreover, G-CON accelerates the manufacturing cycle time even more by offering a standard POD product portfolio with off-the-shelf designs. The designs can be built, delivered, and ready for operations in less than 3 months. This standardized product portfolio enables G-CON to offer the PODs at a competitive price point. While other competitors' cleanrooms (e.g., an 8.5' x 50' facility), might cost anywhere between \$1.2 and \$1.5 million, G-CON's standard POD starts at \$300,000 and goes up to \$1 million to meet higher-capacity requirements. It is also critical to note that while competitors' cleanrooms are just an empty facility, G-CON's price point includes all necessary cleanroom components (such as automation controls and fire suppression equipment). As such, customers do not have worry about lengthy post-build bill of materials reviews.

Finally, the order process is streamlined as customers can simply select the type of POD they need and immediately place an order with G-CON. Such features illustrate G-CON's

unmatched ability to offer the best purchase experience to customers.

Achieving Operational Efficiency via smartPODs

As biopharmaceutical manufacturers move toward greater emphasis on quality programs based on standardization to reduce costs and increase reliability, their ability to provide customized packages has diminished. They expect engineering contractors to reduce man-hours in the design and construction phases of projects. Hence, G-CON collaborates with system integrators to provide modular skid/package units, which enables customers to save time and money.

G-CON's focus on operational efficiency is best illustrated by its endeavor to deliver integrated digital solutions along with its cleanroom PODs. In general, cell/gene therapy and bioprocessing involves several steps that are manually-driven, increasing the cost and risk of quality issues. Biopharmaceutical companies either rely on the in-house information technology team or third-party software providers to automate certain aspects of bioprocessing. Whereas competitors in the cleanroom construction space only design and build facilities, G-CON helps customers streamline their internal processes. In 2019, the company forged a strategic collaboration with L7 Informatics, a leading provider of life science process automation software. G-CON subsequently integrated L7's Enterprise Science Platform software into its PODs, positioning the enhanced offering as its smartPOD solution.

This first-of-its-kind integrated solution provides traceability, key performance indicators (KPIs), process, and production trending statistics on a single interface, enabling customers to access all data generated from the equipment. Furthermore, the smartPOD provides enhanced intelligence and predictive analytics to help customers address issues in advance - rather than waiting for the equipment to break down. For example, end users can use G-CON's onboard controls and integrated software platform to obtain real-time notifications about arising issues. Actionable insights, such as replacement needs or maintenance cycles, are also generated. As a result, smartPOD customers can reduce process downtime, enhance cycle time, improve throughput, and lower capital costs. Moreover, by enabling customers to make the best use of their bioprocess data, G-CON drives the production of personalized medicine and accelerates time-to-market.

Growth Potential and Customer Acquisition

As the prefabricated cleanrooms market is expected to witness a steep compound annual growth rate (CAGR) of 20 to 25% over the next 5 years, G-CON's modular, flexible bio-manufacturing solutions and rapidly deployable facilities are poised to gain greater traction amidst peers that are currently focused solely on modular panel systems and traditional stick-built structures. G-CON is one of the fastest organically growing life sciences businesses, and it has witnessed 186% year-on-year (YoY) growth from 2018 to 2019 while maintaining positive cash flow. With several large projects currently in backlog and a strong project pipeline driven mainly by the race to deliver a COVID-19 vaccine, the company is well-positioned to maintain its strong financial performance.

G-CON follows two key approaches to effectively acquire new customers: global expansion, especially across Europe and the Middle East, and strategic collaboration with pharmaceutical and biopharmaceutical equipment builders and technology developers.

In 2019, G-CON opened its first international facility in Ireland to cater to the needs of customers across Europe and the Middle East. Customers in those regions face the challenge of low-quality cleanroom facilities, especially from China-based competitors who charge higher prices and require considerable project delivery lead times. With more than 11 years of experience in the North American life sciences market, Frost & Sullivan agrees that G-CON is best positioned to understand the needs of multinational enterprises in Europe and the Middle East and provide them with enhanced value-delivery solutions.

That same year, G-CON forged a strategic collaboration with GE Healthcare, a leading multinational conglomerate that manufactures diagnostic imaging agents and radiopharmaceuticals, to integrate its FlexFactory offering into G-CON PODs. FlexFactory, a modular manufacturing platform, helps digitize and speed-up processes for cell therapy clinical trials. In contrast to competitors that do not provide assistance in the implementation of technological solutions within the cleanroom facilities, this integrated solution enables a fully functional production line that can support end-to-end cell therapy and viral vector technologies for drug developers. In addition, G-CON is partnering with Vanrx Pharmsystems Inc., a Canada-based manufacturer of automated drug filling systems. Through this collaboration, customers can purchase the G-CON POD pre-installed with Vanrx Microcell Vial Filler, which helps end users immediately start their own filling facility, develop clinical trial supplies, and bring new drugs to market faster.

Customer Service Experience: GMP Project Management Services

In general, Current Good Manufacturing Practice (cGMP) construction projects involve critical aspects such as meeting regulatory requirements, gaining regional government approvals, securing design permits, and procuring vetted contractors and vendors. Understanding and implementing these aspects gets very complicated for customers, especially for start-ups who do not understand the intricacies of construction projects. To help customers overcome this challenge, the company launched G-CON Building Services, through which it provides facility project management services - from initiation to completion of the entire project.

While other competitors offer such services, they generally hire third-party professionals or companies to do so, which increases the cost of services. G-CON leverages its 20 years of cGMP facility experience and technical know-how of the life sciences cleanroom manufacturing industry to provide uniquely specialized and cost-effective construction project management services. A key differentiating factor is that G-CON Building Services is a one-stop-shop for customers. For example, the company can help customers during any stage of the project, including facility layout, order-of-magnitude estimates, site selection assistance, schedule development, compliance review, project construction tracking, and reporting. Furthermore, G-CON Building Services has expertise in facilities project management for varied applications, such as biologics, pharmaceutical, research and development, and clinical labs.

Conclusion

Frost & Sullivan recognizes how G-CON Manufacturing is poised to revolutionize the construction and deployment of cleanroom facilities through its prefabricated and prequalified POD offering. In contrast to other competitors, G-CON's PODs can be built and installed 3-times faster and are more economical. The PODs are completely built off-site and pre-configured with HVAC, automation, and fire suppression systems, eliminating the need for third parties.

Frost & Sullivan is quite impressed with G-CON's approach to standardizing the PODs product portfolio with off-the-shelf designs that allow for the mass production of cleanroom facilities. PODs can also be rapidly configured as per customer requirements. The company's unique approach allows it to deliver a fully built and operational POD in less than 3 months. Moreover, G-CON's strategic collaboration with leading process automation software providers, pharmaceutical and biopharmaceutical equipment builders, and technology developers has helped it become a one-stop-shop for all of the relevant cleanroom facility requirements of biopharmaceutical customers.

With its strong overall performance, G-CON earns the 2020 Frost & Sullivan Global Customer Value Leadership Award.

Significance of Customer Value Leadership

Ultimately, growth in any organization depends on customers purchasing from a company and then making the decision to return time and again. Satisfying customers is the cornerstone of any successful growth strategy. To achieve this, an organization must be best in class in 3 key areas: understanding demand, nurturing the brand, and differentiating from the competition.



Understanding Customer Value Leadership

Customer Value Leadership is defined and measured by 2 macro-level categories: Customer Impact and Business 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 Value Leadership Award, Frost & Sullivan analysts independently evaluated Customer Impact and Business Impact according to the criteria identified below.

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

Business Impact

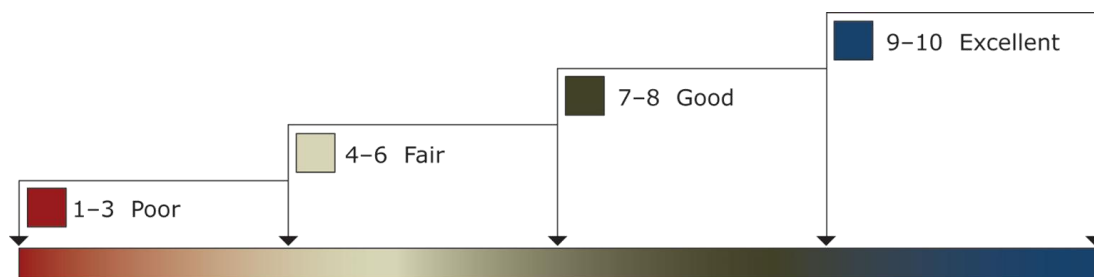
- Criterion 1: Financial Performance
- Criterion 2: Customer Acquisition
- Criterion 3: Operational Efficiency
- Criterion 4: Growth Potential
- Criterion 5: Human Capital

Best Practices Award Analysis for G-CON Manufacturing

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 Customer Impact and Business 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 2 and Competitor 3.

<i>Measurement of 1–10 (1 = poor; 10 = excellent)</i>			
Customer Value Leadership	Customer Impact	Business Impact	Average Rating
G-CON Manufacturing, Inc.	9.5	9.0	9.25
Competitor 2	7.5	8.5	8.00
Competitor 3	7.0	7.0	7.00

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.

Business Impact

Criterion 1: Financial Performance

Requirement: Overall financial performance is strong in terms of revenue, revenue growth, operating margin, and other key financial metrics.

Criterion 2: Customer Acquisition

Requirement: Customer-facing processes support the efficient and consistent acquisition of new customers, even as it enhances retention of current customers.

Criterion 3: Operational Efficiency

Requirement: Staff is able to perform assigned tasks productively, quickly, and to a high quality standard.

Criterion 4: Growth Potential

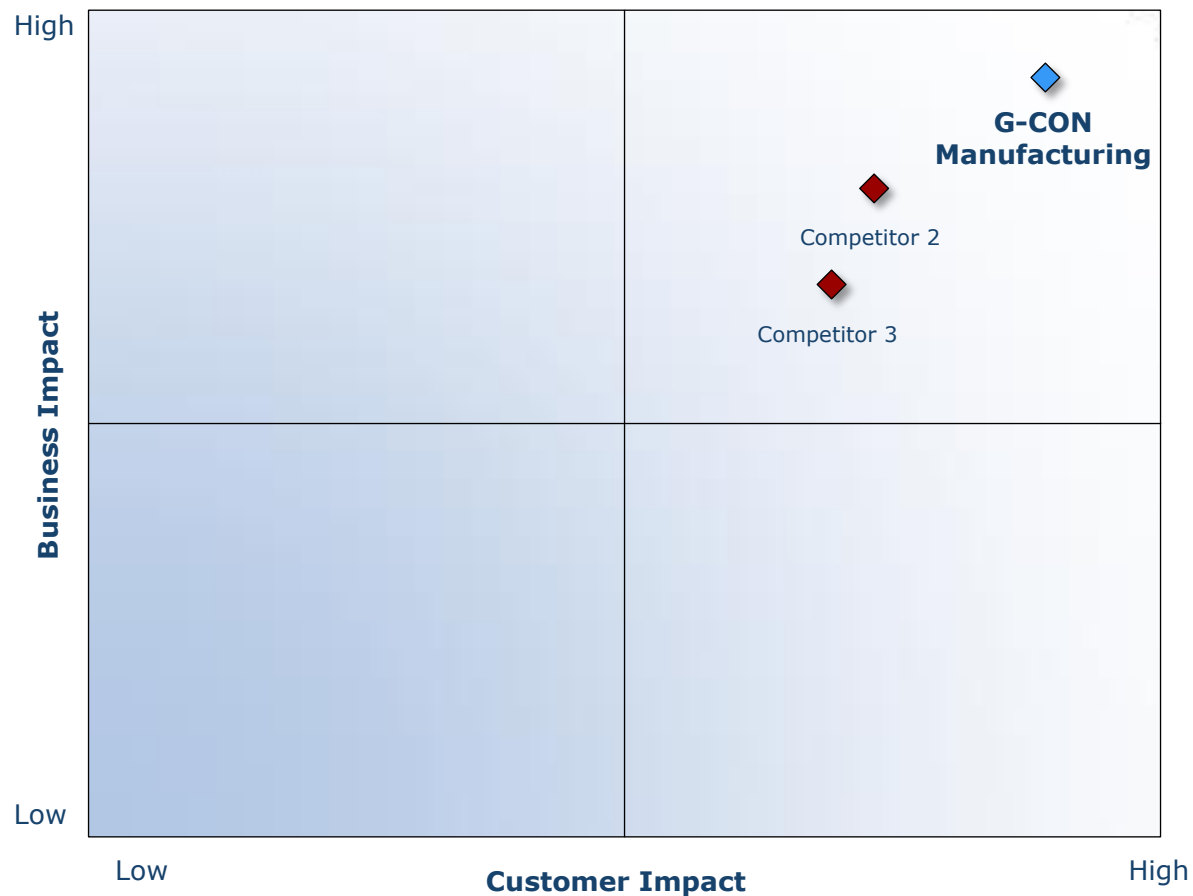
Requirements: Customer focus strengthens brand, reinforces customer loyalty, and enhances growth potential.

Criterion 5: Human Capital

Requirement: Company culture is characterized by a strong commitment to quality and customers, which in turn enhances employee morale and retention.

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 practices 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Review analysis with panel Build consensus Select recipient 	Decision on which company performs best against all best practices criteria
9 Communicate recognition	Inform Award recipient of Award recognition	<ul style="list-style-type: none"> Announce Award to the CEO 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 is able to share Award news with stakeholders and customers	<ul style="list-style-type: none"> 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>.