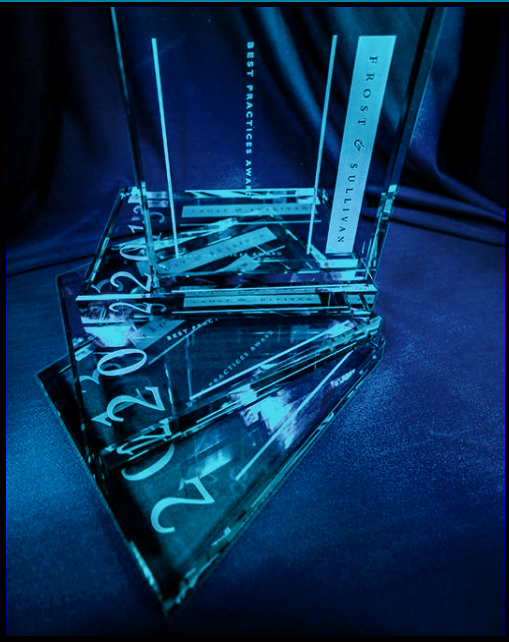# FROST & SULLIVAN

sölabs Passionate about Quality Automation

2016 North American Enterprise Quality Management Solution for Mid-Size Biotechnology Customer Value Leadership Award

2016
BEST PRACTICES
AWARDS

Contents

Background and Company Performance

Industry Challenges

Biotechnology companies seek to consistently produce high-quality products and services; comply with global industry and regulatory quality standards; reduce process risks and operational/ownership costs; improve financial performance, profitability and operational efficiency; increase productivity; and transform and accelerate their businesses as customer demands change and competition increases. Meeting these goals is a challenge as many of the established quality processes and requirements change and new requirements rapidly take effect. The challenge is intensified by the lack of flexible, app-based quality processes and an integrated, flexible, scalable, and adaptable quality management solution. Part of the problem stems from quality management software vendors' lack of understanding of customer requirements.

Vendors that can offer a reliable enterprise quality management solution that allows for growth and can manage all quality processes with one user interface are best positioned to provide an enhanced value proposition to their customers and secure a competitive edge.

Customer Impact and Business Impact

Price/Performance Value

SOLABS maximizes the value proposition for its customers in the quality management domain through SOLABS QM10, one of the most collaborative enterprise quality management systems (EQMS) with functionalities in line with the latest technological advances. Unique and perfectly designed to address the requirements of customers from different industry backgrounds, this fully integrated EQMS software solution — the result of 50,000 research and development hours — is in its 6th iteration and is geared toward the needs of life science organizations. It is broken down into 3 sections: document, training, and process. Fully expandable and scalable, SOLABS QM10 ensures faster adaptation to rapid technological advancements than competing solutions. Customers can begin by leveraging the specific functional areas of SOLABS QM10 and then scale easily, grow quickly, and update their model to a completely integrated EQMS as their businesses evolve in tandem with emerging market trends. Document and training management are built into the solution and come with the core software. What sets SOLABS QM10 apart is that SOLABS has developed apps for all types of quality processes in the biotechnology, medical device and life sciences industry, where processes are interoperable and can integrate with each other. The 3 sections can be linked together as 1 system and can communicate with each other. Designed to provide "one version of the truth," SOLABS QM10 helps its users manage corrective and preventive action (CAPA) and investigations, non-conformances, deviations, complaints, controlled documents, change control, audits, and employee training records on a single user interface that is intuitive and standardized across all functional areas.

SOLABS QM10 comes with advanced analytics, as well as extensive, integrated, and ready-to-use reporting capabilities for users to create and distribute reports that enable the right decision to be made at the right time. SOLABS' flexible user license serves different categories, such as standard, train ID, and external users, with no concurrent user limitation.

The substantial increase in the volume of real-time actionable insights available with SOLABS QM10 provides customers with better visibility, control, coordination, and execution to reduce cycle times in quality processes. This improves response time for audits, required changes, and product releases, which reduces the risk of non-compliance, and ultimately maximizes return on investment. The company provides its customers with comprehensive capabilities to address all needs and constraints with a single solution. SOLABS has effectively used its experience of more than 15 years and thorough understanding of quality management to address major industry challenges and secure a competitive advantage.

Customer Ownership Experience

With an aim to enrich its customers' ownership experience, SOLABS designed its SOLABS QM10 with innovative features and functionalities that rapidly adapt to technological advances. SOLABS understands that different organizations have different structures and processes, and has designed an app-based system that can be customized to end-user requirements. SOLABS can identify which processes are most important to a customer, and its Best Practices unit can develop apps that can be quickly and easily deployed. The Best Practices unit, over its years of collaborating with biotech, pharmaceutical, medical device, and contract manufacturers, has developed and continues to develop quality process apps with different flavors, which are templates with subtle but significant distinctions geared toward specific vertical needs and company sizes. These internally developed process apps eliminate the need for its customers to reach out to a third party. There are different flavors to meet the different needs of each of its customers for CAPA, Non-Conformance, Complaint, Audit, Investigation, Calibration& Maintenance, Out-of-Specification, Change Control, and Deviation. A catalog of all flavors including an overview and flowchart for each flavor is available on their website.

SOLABS enables flexible enterprise integration between its solution and other systems and software: ERP such as SAP, CRM such as Salesforce.com, LIMS such as StarLims, LMS such as SkillPad, EDMS such as Documentum and MS SharePoint and ECTD such as DocuBridge as well as legacy solutions or third-party software. The small installation footprint of SOLABS QM10's core software and related components allows organizations to easily set it up in virtual environments.

SOLABS provides a dedicated hosting option in which each customer has its own and dedicated cloud environment. SOLABS offers these in partnership with Iron Mountain, using it's physically and environmentally secure, fully validated and qualified national data center in Western Pennsylvania. Unparalleled product attributes, such as apps model for

quality process, enterprise integration, cloud offering and virtualization, have helped SOLABS instill a sense of ownership pride in its customers on adoption of its offering.

Customer Service Experience

SOLABS works closely with its customers to ensure an optimal service experience. Its Best Practices unit conducts on-site workshops to understand an organization's needs and ensure that apps meet all requirements out of the box. Its developers and quality assurance team work together on what is normally a 3-cycle deployment process. After the customer tests the process in a sandbox and provides feedback, SOLABS makes adjustments for further testing. At the end of the 3rd test cycle, SOLABS fully validates and deploys it. Because SOLABS offers template flavors and directly oversees development through several lines of configuration, it can get a process up and running in a matter of a few weeks.

The company regularly contacts its customers to ensure that they are up to date with the latest EQMS version and other advances, as well as additions to its product suite. An annual user group meeting brings together users from various industries to exchange ideas on quality management, attend interactive presentations and workshops, and network. The meeting gives SOLABS a platform to enhance its solutions and address specific customer problems.

SOLABS' Professional Services group works closely with customers on project management, installation, quality process deployment, training, and data migration. The company's competitive advantage includes its ability to ensure the speedy development of an accurate and stable model. SOLABS QM10 can be implemented as a turnkey solution or as a shared system. For instance, SOLABS can work with its customers and take over the implementation activities in case its customers either are strapped for resources or do not have as many people dedicated to implementation. Currently available in 4 languages (English, French, Spanish and Japanese), SOLABS provides unlimited support packages built to work with its customers. As long as its customers are subscribed to the support and maintenance agreement, they will enjoy the benefits of its support structure and package.

Customer Acquisition

SOLABS' strategy to accurately analyze customer requirements and design optimal quality management solutions has resulted in the successful deployment of its SOLABS QM10 across the North American biotechnology industry, especially in small and medium-sized companies. SOLABS is witnessing more demand from virtual biotech companies that have a strong need for control over functionalities such as CAPA and deal with numerous suppliers and vendors. SOLABS' highly efficient resource pool with unmatched industry expertise and understanding of every aspect of a customer's business enables the company to devise and quickly implement a 100%-fit model.

SOLABS has remarkably scaled up its services in the dynamic biotechnology industry, helping companies improve their operational efficiency and audit response times. It maintains GxP, GCP & GMP compliance by automating quality operations with respect to US Food and Drug Administration 21 CFR Part 11 and Annex 11, and keeps pace with consumer demands to improve productivity and reduce operational costs. Improving such directly measurable key performance indicators strengthens SOLABS' potential to further expand the scope of applications for its solution.

SOLABS has a 100% client renewal rate of its support and maintenance agreement. The company offers an initial 3-year agreement for software support and maintenance with no upfront license fee regardless of whether software is hosted or installed on premise. Customers only pay an annual fee depending on the number of users in the system. SOLABS caters to customers with multiple sites around the world or single sites, whether fully integrated, contract manufacturer, or virtual. Most of its 40 clients are based in the based in the United States with offices in Canada, Europe, and Asia.

Leading companies that have reaped huge benefits by deploying SOLABS QM10 include Sunovion Pharmaceuticals, Sandoz, Pharmascience, Ironwood Pharmaceuticals, EndoCeutics Inc. and Hoya Surgical Optics. Given the high level of customer satisfaction with its solutions and boasting one of the highest customer retention rates and a robust (and continuously expanding) customer base, SOLABS is expected to further strengthen its position in the North American market in the coming years.

Growth Potential

After 15 years of automating quality operations, SOLABS is a private and well-funded by successful entrepreneurs in the life sciences industry. It has over 5,000 active users worldwide, handles over 2,000 transactions daily, and completes 95% of its projects within/on budget. Its positive cash flow, double-digit growth for the past 5 years, 100% turnkey project management and 100% renewal rate, and high customer satisfaction boosts its growth potential in this market.

SOLABS QM10 has been successful in promoting customer value leadership and drawing the attention of leading companies from the medical device, pharmaceutical, clinical trial, and research and development verticals. The company caters to niche participants as well as market leaders such as Wockhardt, Purdue Pharma, Ropack, Alphora Research, Bio Agri Mix, Vita Health Products, Mattek Corporation, Microline, WellSpring Pharmaceutical, Chembio Diagnostics Vetoquinol, and AVON.

Conclusion

Known for its unmatched industry expertise and understanding of every aspect of customers' businesses, SOLABS has ramped up its capabilities to provide unmatched customer value and solidify its position in the North American EQMS market for the mid-size biotechnology industry. Leveraging its 3-section design of document, process, and training, SOLABS has secured a competitive edge by providing an integrated solution that is configurable according to its customers' processes and terminologies. This flexible and scalable solution enables a phased implementation approach. An app-based model for quality processes enhances its value proposition to meet all customer requirements out of the box and allow for integration and interoperability of processes. With its strong overall performance, SOLABS has earned Frost & Sullivan's 2016 Customer Value Leadership Award.

Significance of Customer Value Leadership

Ultimately, growth in any organization depends upon customers purchasing from your company, and then making the decision to return time and again. Delighting customers is therefore the cornerstone of any successful growth strategy. To achieve these dual goals (growth and customer delight), an organization must be best-in-class in three key areas: understanding demand, nurturing the brand, and differentiating from the competition.

Understanding Customer Value Leadership

Customer Value Leadership is defined and measured by two macro-level categories: customer impact and business 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 customer value.

Key Benchmarking Criteria

For the Customer Value Leadership Award, Frost & Sullivan analysts independently evaluated two key factors—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 Practice Award Analysis for SOLABS

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 our 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
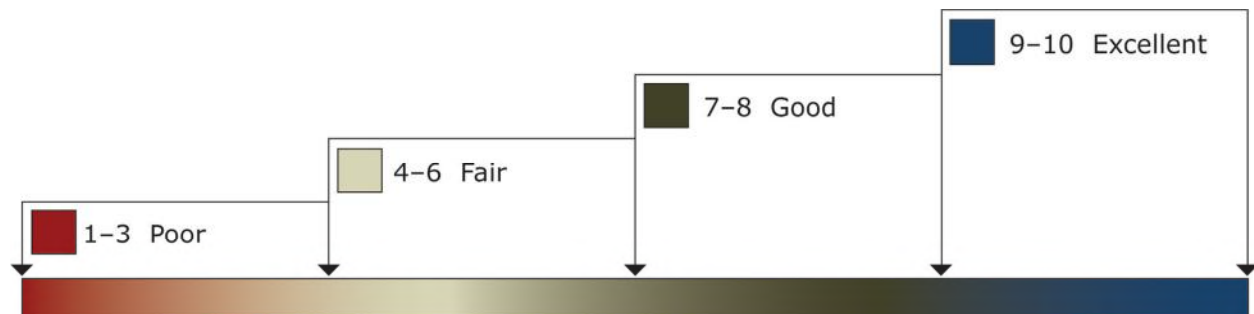
The Decision Support Scorecard is organized by Customer Impact and Business Impact (i.e., the overarching categories for all 10 benchmarking criteria; the definitions for each criteria are provided beneath the scorecard). The research team confirms the veracity of this weighted scorecard through sensitivity 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, we have chosen to refer to the other key players as Competitor 2 and Competitor 3.

DECISION SUPPORT SCORECARD FOR CUSTOMER VALUE LEADERSHIP AWARD

Measurement of 1–10 (1 = poor; 10 = excellent)			
Customer Value Leadership	Customer Impact	Business Impact	**Average Rating**
SOLABS	**9.5**	**9.5**	**9.5**
Competitor 2	8.0	8.0	8.0
Competitor 3	7.0	7.0	7.0

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 like they are buying the most 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: Strong overall financial performance in terms of revenues, 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 can 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.

DECISION SUPPORT MATRIX FOR CUSTOMER VALUE LEADERSHIP AWARD
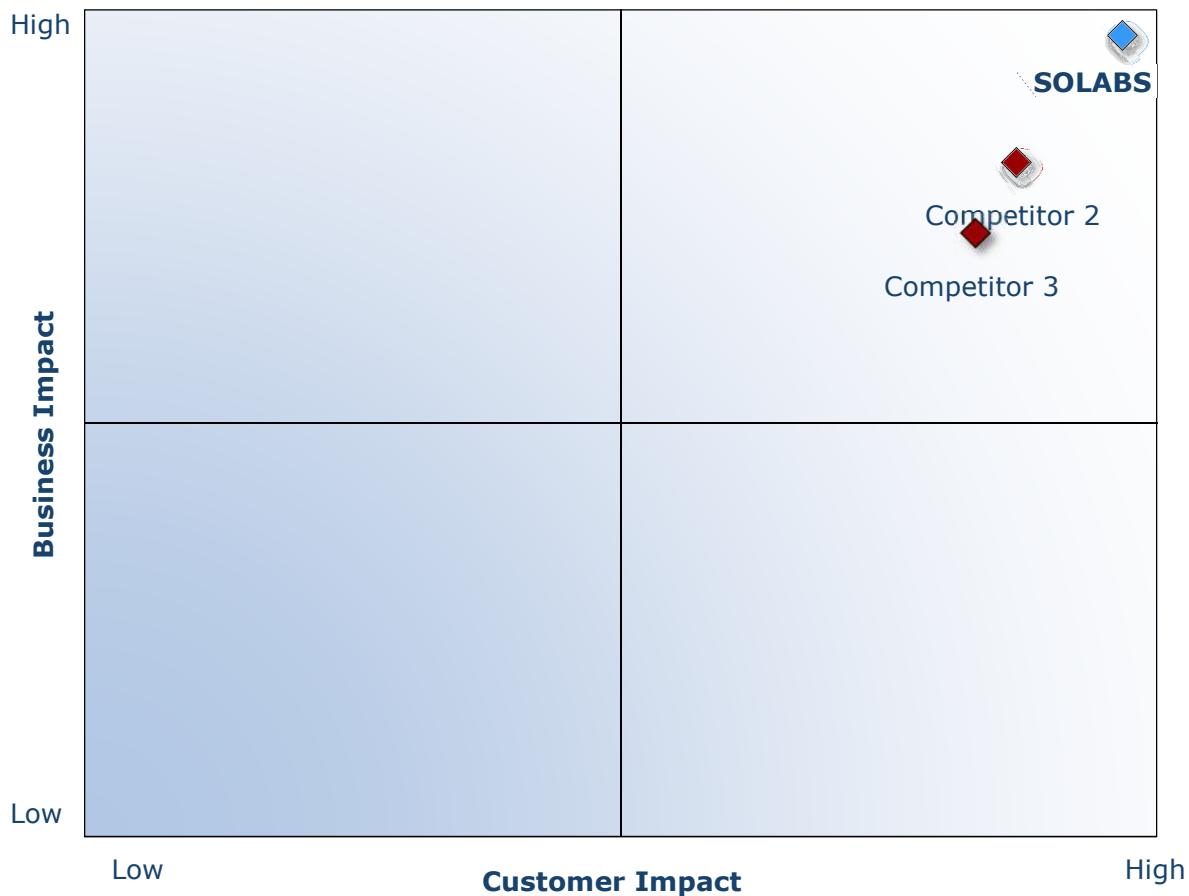
The Intersection between 360-Degree Research and Best Practices Awards

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 players and for identifying those performing at best-in-class levels.

360-DEGREE RESEARCH: SEEING ORDER IN THE CHAOS

Best Practices Recognition: 10 Steps to Researching, Identifying, and Recognizing Best Practices

Frost & Sullivan Awards 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 globe	• Conduct in-depth industry research • Identify emerging sectors • Scan multiple geographies	Pipeline of candidates who potentially meet all best-practice 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-practice criteria • Rank all candidates	Matrix positioning all candidates' performance relative to one another
3 **Invite thought leadership in best practices**	Perform in-depth examination of all candidates	• Confirm best-practice 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-practice 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-practice award recipient	• Review analysis with panel • Build consensus • Select winner	Decision on which company performs best against all best-practice criteria
9 **Communicate recognition**	Inform award recipient of award recognition	• Present 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 may share award news with stakeholders and customers	• Coordinate media outreach • Design a marketing plan • Assess award's role in future strategic planning	Widespread awareness of recipient's award status among investors, media personnel, and employees

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 almost 50 years of experience in partnering with Global 1000 companies, emerging businesses and the investment community from 31 offices on six continents. To join our Growth Partnership, please visit http://www.frost.com.