

3M Science.
Applied to Life.™

**2017 Global Biologics Downstream
Processing Technologies
Product Leadership Award**

FROST & SULLIVAN

BEST
2017 PRACTICES
AWARD

GLOBAL BIOLOGICS DOWNSTREAM
PROCESSING TECHNOLOGIES
PRODUCT LEADERSHIP AWARD

Contents

Background and Company Performance	3
<i>Industry Challenges</i>	3
<i>Product Family Attributes and Business Impact</i>	4
<i>Conclusion</i>	5
Significance of Product Leadership.....	7
.....	7
Understanding Product Leadership.....	7
<i>Key Benchmarking Criteria</i>	8
Best Practices Award Analysis for 3M	8
<i>Decision Support Scorecard</i>	8
<i>Product Family Attributes</i>	9
<i>Business Impact</i>	9
<i>Decision Support Matrix</i>	10
Best Practices Recognition: 10 Steps to Researching, Identifying, and Recognizing Best Practices.....	11
The Intersection between 360-Degree Research and Best Practices Awards.....	12
<i>Research Methodology</i>	12
About Frost & Sullivan	12

Background and Company Performance

Industry Challenges

Biologics manufacturing downstream processing is complex and involves removal and separation of therapeutic protein compounds from cell cultures and other extract medium. The protein separation process is followed by an extensive series of downstream purification steps that must yield products suitable for human therapeutics use with a high level of efficiency and reliability. Impurities such as host cell protein, DNA, adventitious and endogenous viruses, endotoxins, aggregates, and other species must be removed, and, at the same time, an acceptable yield should be maintained.

Traditionally, companies have used centrifugation methods to remove impurities; however, these processes are not reliable, sometimes unable to remove host cell DNA and other associated impurities efficiently. Also, it is difficult to scale up when using a centrifugation approach.

Another major challenge is that biologics is an evolving product class, with substantial variations in compositions. Due to these variations, the centrifugation process requires adjustments according to variations, thus complicating the task and incurring additional costs.

Once the solution is purified, it is then loaded on the 'Protein A' column for chromatography, but if the solution is contaminated, these impurities bind to the column and reduce the effectiveness of both the chromatography process and the column life.

Over the past two decades, there have been significant developments in the upstream manufacturing processes due to technology developments in the cell lines, bioreactors, and culture media formulations. Although these developments have translated into a significant increase in production output, technology innovation for filters and chromatography columns in the downstream production process has not occurred at the same rate.

Frost & Sullivan research estimates the global biologics API market (monoclonal antibodies, vaccines, recombinant proteins, and other cell therapies products) to have reached about \$32.3 billion in 2016, and it is expected to grow at a compound annual growth rate (CAGR) of 12% from 2016 to 2020. This strong market growth indicates an increase in associated opportunities and thereby a high demand for related, higher-performing purification techniques.

Product Family Attributes and Business Impact

Match to Needs, Reliability, and Quality

Considering the existing process challenges and expected rise in market demand, 3M introduced its Emphaze™ AEX Hybrid Purifier product, which eliminates the problems hampering existing purification techniques in the biologics downstream manufacturing sector. The platform addresses the purification challenges by reducing both particulates and soluble contaminants (such as DNA and HCPs) and is designed for use at the end of the primary clarification stage of mammalian cell cultures.

The Emphaze™ AEX Hybrid Purifier is constructed from polypropylene scaffold and fine fibre nonwovens, where nonwoven is hyper functionalized with a quaternary anion exchange ligand, and fine particle, and a bioburden reduction membrane with a defined 0.2 µm pore qualifying zone. The product is an all-synthetic material construction.

Emphaze™ AEX Hybrid Purifier is able to reduce host cell DNA by 99.99%. In addition, HCP reduction of 20 to 40% is often achieved with Centrate or harvest fluids. This level of processing purification standards at clarification has never been achieved by any other existing system, which highlights the innovation standards of 3M's Emphaze™ AEX Hybrid Purifier.

A majority of host cell DNA is removed prior to protein-A column, and this allows the protein-A column to perform its core function: capture mAbs. After purification using the novel 3M platform, the volume of DNA/chromatin attached to the protein column is largely reduced, meaning fewer chemicals required for protein-A column cleaning. This results in an extended life for protein-A columns.

In various industrial-scale manufacturing applications, the product has shown consistent process improvement and economic outcomes, indicating its strength in quality management.

Further, 3M Emphaze™ AEX Hybrid Purifier can be applied to a wide range of applications including recombinant protein expression cell-culture, bacterial recombinant protein expression, indicating the company's focus on meeting specific customer needs. Meeting the critical industry needs through disruptive innovation and strong quality standards help 3M outclass both existing technologies available in the market and competitors' products.

Product/Service Value and Positioning

Frost & Sullivan appreciates the fact that 3M is the only company to offer this type of comprehensive purification platform, which has helped it position itself as an industry leader and disruptive innovator. The product is able to replace centrifugation or the second stage of depth filtration entirely, resulting in less complicated and more streamlined execution complemented by significant cost savings.

The company has adopted a developmental and production process-specific approach, which requires it to work closely with each client's production planning team to design the whole downstream purification process and customize functions to meet purification requirements specific to planned biologics product portfolios. Frost & Sullivan recognizes

the success of this best practice in setting 3M up to make appropriate changes/upgradation in technology that will enhance outcomes, help clients achieve higher economic efficiency, and improve their production process. Prioritizing customer success over all other outcomes is considered a best practice by Frost & Sullivan because it differentiates leading companies dedicated to building relationships with their customers from those whose bottom line remains revenue-driven alone. Without a doubt, customized product offerings and first-mover advantage have boosted the company's success in gaining strong traction from clients across the world.

Product Design Flexibility and Easy Integration with Existing Systems

Emphaze™ AEX Hybrid Purifier is based on 3M's core technologies—advanced polymer materials, fine fibre nonwovens, and porous membranes—which combined make a unique purification media that can be deployed in any production environment and is suitable for the production process of a wide range of biologics. To enable easy integration into existing production processes, Emphaze™ AEX Hybrid Purifier is designed to provide loading capacity similar to fine grades of highly-charged conventional depth filters, and hence it can be easily integrated with existing manufacturing processes where these filters are used. Also, the product is encapsulated in 3M's standard single-use capsule design to enable seamless integration with a 3M matched component solution, which includes high capacity 3m™ Zeta Plus™ depth filtration and 3M™ LifeASSURE™ sterilizing grade membranes for harvest and clarification process. This considerably reduces the initial capital investment requirement. By adopting this approach, 3M looks to offer end-to-end processing solutions to its clients with an aim to become a strategic partner with leading biologics companies.

Further to serve application-specific requirements, the company offers three different sizes of filter capsules: laboratory, scale up, and production scale. Application-specific designs and sizes help the company better meet client needs. Frost & Sullivan believes that offering different capacity of filter products is critical for product success in biologics business, wherein clients' requirements are quite dynamic and sometimes production process planning and set-up take years. This approach is a clear testament to the client-focused thought process of 3M when it comes to product design.

With the biologics and biosimilar market slated for double-digit growth over the next 5 to 7 years, 3M's demonstration of innovation leadership in the downstream purification process space positions the company advantageously, and Frost & Sullivan expects it to witness strong revenue growth in this product segment.

Conclusion

With downstream processes becoming a key challenge for biologics manufacturing, innovations and process improvements represent critical forces driving growth for the biologics industry. Frost & Sullivan has always believed that sound manufacturing and bioprocessing capabilities are crucial for success and finds 3M's Emphaze™ platform as an exceptional innovation designed to overcome purification issues, which help companies in improving the quality standards of their products. The platform works extremely well for

the removal of insoluble particles like HCP, DNA thus improving efficiency in the production of mAb drugs, bacterial or mammalian cell culture-based recombinant proteins. By leveraging its engineering and innovation expertise, the company has successfully reinforced its leading position in the biologics process development, manufacturing, and process monitoring solutions space.

With its strong overall performance, innovative filtration and purification platform, and operational excellence 3M has earned Frost & Sullivan's 2017 Global Product Leadership Award.

Significance of Product Leadership

Ultimately, growth in any organization depends upon customers purchasing from a company and then making the decision to return time and again. A comprehensive product line, filled with high-quality, value-driven options, is the key to building an engaged customer base. To achieve and maintain product excellence, an organization must strive to be best-in-class in three key areas: understanding demand, nurturing the brand, and differentiating from the competition.



Understanding Product Leadership

Demand forecasting, branding, and differentiating all play a critical role in finding growth opportunities for your product line. This three-fold focus, however, must be complemented by an equally rigorous focus on pursuing those opportunities to a best-in-class standard. Customer communications, customer feedback, pricing, and competitor actions must all be managed and monitored for ongoing success. If an organization can successfully parlay

product excellence into positive business impact, increased market share will inevitably follow over time.

Key Benchmarking Criteria

For the Product Leadership Award, Frost & Sullivan analysts independently evaluated two key factors—Product Family Attributes and Business Impact—according to the criteria identified below.

Product Family Attributes

- Criterion 1: Match to Needs
- Criterion 2: Reliability and Quality
- Criterion 3: Product/Service Value
- Criterion 4: Positioning
- Criterion 5: Design

Business Impact

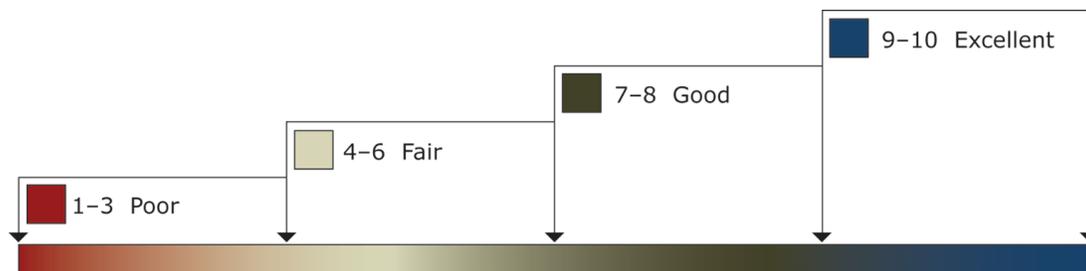
- Criterion 1: Financial Performance
- Criterion 2: Customer Acquisition
- Criterion 3: Operational Efficiency
- Criterion 4: Growth Potential
- Criterion 5: Human Capital

Best Practices Award Analysis for 3M

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 Product Family Attributes and Business Impact (i.e., These are 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, we have chosen to refer to the other key participants as Competitor 2 and Competitor 3.

<i>Measurement of 1-10 (1 = poor; 10 = excellent)</i>			
Product Leadership	Product Family Attributes	Business Impact	Average Rating
3M	10	8	9
Competitor 2	5	5	5
Competitor 3	5	5	5

Product Family Attributes

Criterion 1: Match to Needs

Requirement: Customer needs directly influence and inspire the design and positioning of the product family.

Criterion 2: Reliability and Quality

Requirement: Products consistently meet or exceed customer expectations for performance and length of service.

Criterion 3: Product/Service Value

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

Criterion 4: Positioning

Requirement: Products or services address unique, unmet need that competitors cannot easily replicate or replace.

Criterion 5: Design

Requirement: The product features an innovative design, enhancing both visual appeal and ease of use.

Business Impact

Criterion 1: Financial Performance

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

Criterion 2: Customer Acquisition

Requirement: Product strength enables 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

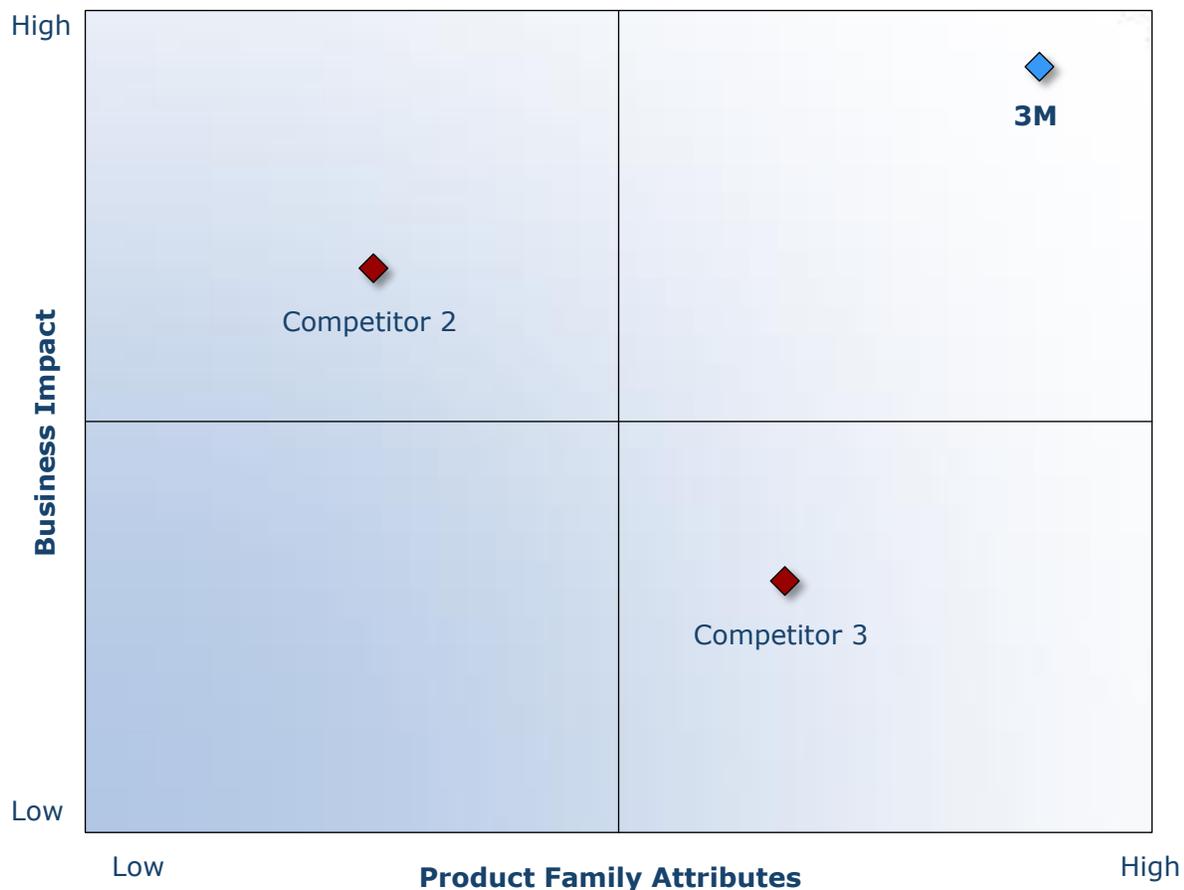
Requirements: Product quality strengthens brand, reinforces customer loyalty, and enhances growth potential.

Criterion 5: Human Capital

Requirement: Company culture is characterized by a strong commitment to product quality and customer impact, 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 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Interview thought leaders and industry practitioners • Assess candidates' fit with best-practice 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-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	<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-practice 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-practice 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-practice criteria
9 Communicate recognition	Inform Award recipient of Award recognition	<ul style="list-style-type: none"> • 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 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 future 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 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>.