

Supply Partner network supports biopharmaceutical industry growth

The biopharmaceutical industry is undergoing a rapid expansion in drug discovery, development and approvals. At a recent Supply Partner meeting, industry experts suggested that the growth and diversification of the biopharmaceutical industry will result in a 10–20-fold increase in demand on the supply chain, along with a drive to reduce production costs by a factor of ten. This poses a challenge for the industry as it requires manufacturers and suppliers to work together to manage supply and demand.

Aggregate BioPharma Capacity Analysis workstream

These findings, along with a rise in the use of single-use systems, the emergence of perfusion technology and its impact on batch numbers, sizes and raw materials utilization, prompted the Supply Partners Network Leadership Group to initiate the Aggregate BioPharma Capacity Analysis workstream. Its purpose is to consider the combination of these key factors in a holistic manner to help the industry navigate its way through this exciting period of unprecedented growth and diversification.

At the fifth Supply Partner face-to-face meeting Dave Kolwyck Director of Materials Science at Biogen talked about the trends impacting the industry's supply chain that may have significant consequences. The performance of fermentation is dramatically improving so titers of up to 10gmAb/liter are becoming more common which translates to a 5× intensity and when combined with 2× plant utilization increase, requires 10× raw material. If one considers that the volume is set to double and the consumption per batch is increasing ten-fold then we are heading towards a potential ×20 draw on raw materials and consumables on a global industry scale. This requires a change in the supply chain model to one that is more responsive and less safety stock/ inventory-driven.

Solving problems through collaboration

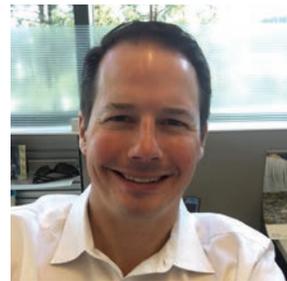
BioPhorum understands that this problem is too large to be solved by any one company or sector alone and that collaboration between biopharmaceutical manufacturers and suppliers is necessary. BioPhorum Supply Partner is one of BioPhorum's fastest growing Phorums with over 35 member companies, half of which are represented by manufacturers and half by their key suppliers. The Phorum's mission is to work together to transform the inbound supply chain for the benefit of end-users, supply partners and patients by improving efficiency and reducing risk to the industry. Two of the Supply Partner workstreams, Forecasting and Demand Planning and Supply Chain Mapping, have made significant progress towards meeting their goals over the past year.



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Forecasting and Demand Planning workstream

The purpose of this workstream is to help implement standardized approaches in the industry and to develop and adapt the supply chain process to meet increasing demand. The workstream held a meeting in 2017 to map out a high-level model of possible future forecasting and demand planning processes and start working on several deliverables. The workstream began by surveying its members and creating an internal position paper to highlight the perspectives and create a vision of best practice.

Cheryl Simmons, Senior Manager of Strategic Sourcing at AstraZeneca, said during this meeting, “The attendees realized that many of the problems facing manufacturers and suppliers were similar; however, there were many differences among them with regards to how they thought about and defined these problems.” Simmons explained that it was necessary to create alignment between manufacturers and suppliers by improving communication. The team first needed to define terms and problems facing the two sectors before they could tackle solutions to the problems.

Following this survey, the workstream began formulating a best practice guide for the industry. “There was

no alignment among the industry, and the best practice guide is a way to create engagement and alignment between suppliers and manufacturers,” said Simmons.

She explained that the guide can be used by any biomanufacturer or supplier to help build a platform leading to excellence within the industry. “The guide is something that will serve as a baseline for the industry for forecasting and demand planning moving forward. It will help suppliers and drug manufacturers to recognize what the blue-sky vision or best practice is for things such as supplier relationship management or performance management. It will give them a way to determine what their current state is and what their future state should look like,” Simmons added.

The guide includes an assessment tool that can be used by any company within the industry to assess their status compared to industry norms and best practice. The goal of the assessment tool is to find strengths and weaknesses within a company in an effort to improve its status. For the tool to be most beneficial, companies should use it annually to assess how the company has performed over the previous year and to focus on continued improvement. Dan Tropea, Director of Supply Chain at NewAge AdvantaPure said, “Some of [the survey] was alarming in that there

was a gap between what best-in-class is and what the reality is. However, where there is alarm, there is an opportunity. It is a challenge to the BioPhorum membership to improve.”

The best practice guide and survey are intended to bring much needed improvement to the industry and enable it to sustain the increasing demand on the supply chain. “The survey results allow us to set new levels of collaboration with our external partners. Our strategic plans are now dedicated to help build relationships that incorporate some of the targets in the survey. Using the survey gap analysis helped AdvantaPure develop a different mindset regarding how to manage our customers’ demands,” said Tropea.

The Forecasting and Demand Planning workstream recently published the best practice guide. The group is excited to have an impact throughout the industry and are thankful for the efforts of the BioPhorum leadership that helped it accomplish its goals. “Many thanks for leading this workstream toward this great accomplishment,” said Thomas Paust, Vice President of Commercial Operations at Sartorius Stedim Biotech.

Level 1	Level 2	Level 3	Level 4	Level 5
<ul style="list-style-type: none"> no accessible or basic supply chain information/documentation which can be manually retrieved upon request 	<ul style="list-style-type: none"> systematic supply chain mapping process with a standardized set of questions (questionnaire) enabling full visibility to tier 1 suppliers 	<ul style="list-style-type: none"> company defined critical materials successfully mapped for tier 1 and some beyond (refreshed on a time period, typically once a year) discrete monitoring of SC events for mapped materials 	<ul style="list-style-type: none"> SCM: fully integrated SCM into business processes monitoring: implemented multi-tier monitoring including analysis and regular reviews risk assessment: output of SCM/monitoring integrated into your risk assessment process BCM 	<ul style="list-style-type: none"> SCM: multi-tier for critical items. Known common sub-tier conflicts/commonalities. Systematically refreshed 100 percentage of materials mapped tier 1 and high percentage mapped to a conclusion monitoring: automated event notification. KPI for response time. Real time data feeds. Dedicated owners for each supplier and/or material risk assessment: closed loop of the mapping/monitoring. Standardized approach. Documented risk mitigation/treatment strategies BCM: embedded in governance framework (BC). Support/oversight of senior executive team. Input for supplier reviews (KPIs)

Figure 3: Supply Chain Mapping Maturity Model: business capabilities – characteristics

Supply Chain Mapping workstream

This workstream has also made progress towards its goal of increasing transparency and visibility of the supply chain, from raw materials to the final product and all touch points in between. The workstream began as a response to the pressure felt across the industry to ensure the continuity, security and safety of the supply chain

Regulatory bodies expect companies to understand all aspects of their supply chain, and in extreme cases, there can be tens of thousands of supply chains so mapping these offers a way for companies to chart the flow of supplies throughout and within the production process.

It became evident to the workstream that there were inconsistencies across the industry regarding supply chain mapping. It realized that companies needed guidance to improve their ability to map the supply chain in an industry-wide accepted manner. The Supply Chain Mapping workstream discussed these issues and developed a consensus. Throughout the past year, the workstream has been drafting a best practice guide to emphasize the importance of supply chain mapping, outline underlying principles and describe methods to implement supply chain mapping.

It is important for companies to understand the importance of supply chain mapping. The supply chain can have a tremendous impact on product quality and patient safety, and it also has financial and reputational implications. Hanna Edstrom-Valsinger, Sourcing Program Leader at GE Healthcare Life Sciences explained, "It is our responsibility to communicate the message and importance of supply chain mapping because it can really impact patients and their lives. It is crucial for companies to have a good understanding of the supply chain to be able to avoid or mitigate

risks ensuring patient safety," said Edstrom-Valsinger.

The guidance also includes a maturity model that allows a company to perform a gap analysis to understand how they align to supply chain mapping expectations and where they should be. The best practice guide is now available. According to Edstrom-Valsinger, the next step for the workstream is to move beyond supply chain mapping and into risk management and business continuity.

Involvement in the Supply Chain Mapping workstream has been a tremendous benefit to Edstrom-Valsinger and her company. "Being involved in the Supply Chain Mapping workstream has been a great learning experience. It has been good to discuss supply chain mapping issues with other companies because they are having the same challenges as us. This workstream has also allowed us to understand what our customer wants and needs and what their expectations are. As a result, we have been able to set realistic goals for our future," said Edstrom-Valsinger.



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