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Managing risk and minimising the complexity of your global single-use supply chain

With the rapid growth of single-use systems (SUS} for drug production, especially by drug manufacturers with multiple locations across the globe, there are many risks associated with underestimating the regulatory compliance, manufacturing and quality requirements of these systems. For example, using SUS introduces new logistics challenges that, if not properly understood and planned for, can leave biopharma manufacturers vulnerable to supply chain complexities.

To minimise these risks, biopharma manufacturers can benefit by adopting a global single-use supply chain strategy early in the drug development life cycle and carefully evaluating their chosen single-use equipment and materials suppliers. When reviewing a prospective supplier, there are two primary considerations for biopharma manufacturers to keep in mind: Regulatory and quality compliance, and supply chain operational excellence of the supplier.

REGULATORY & QUALITY COMPLIANCE

There are four main categories to review when evaluating a single-use provider's regulatory and quality compliance initiatives.

First, the environment where single-use equipment and materials are being manufactured should be checked to ensure proper controls are in place to monitor and track environmental conditions where the materials are produced. The production facility should have documented evidence of annual cleanroom recertification and a validated process showing a rotational cleaning regimen, as well as air/surface viable and non viable particulate testing being carried out on a scheduled basis.

Cleanrooms should also be monitored for 'real time' temperature, humidity and differential pressure monitoring. Second, product sterility validation that follows a well defined, recognised reference standard identified by regulations such as ANSI/AAMI/ISO 11137 should be investigated. There should be documented evidence this validation is performed on a routine basis. The single-use supplier's ability to perform lot-release testing on finished products, to verify that the product meets certain requirements after sterilisation, should be the third item reviewed. Most requests for this testing include USP<85> for bacterial endotoxins and USP <788> for particulate contamination.

The fourth, and potentially most important item for reducing risk in the single-use supply chain, is to fully understand a supplier's quality risk management (ORM} programme. A key element of ISO 9001 and cGMP related to quality is risk-based decision making, and a qualified single-use supplier will have developed quality metrics to control the risks associated with the manufacturing of their products.

Essential steps in risk management generally include risk assessment (identification, analysis and evaluation}; risk control (mitigation, reduction and acceptance}; and risk review. The ORM programme should have a risk register to identify and review where the greatest risks may occur, and quality metrics and monitoring should be used. This will help track important quality indicators and improvement of those indicators, including: 'On time' delivery, turnaround time for engineer's drawings, turnaround time for quality documentation, and tracking of manufacturing defects.

The single-use provider's ORM programme should also include quality management for their suppliers, with risk-based audits of their raw material supply chain. Risk-based classifications for raw material suppliers should be included along with routine audits of high risk suppliers, established quality agreements and performance reports from suppliers, and performance metrics that can be tracked and evaluated over time with suppliers.

Evidence of a business continuity plan should also be in place. This will ensure that the single-use supplier is ready to respond in case of a serious event that has the potential to disrupt operations.

SUPPLY CHAIN OPERATIONAL EXCELLENCE (OPEX)

Biopharma manufacturers should conduct an ongoing evaluation of a single-use supplier's supply chain OpEx capabilities. Aligning these capabilities with the manufacturer's own quality practices is important as biopharma manufacturers design their facilities entirely with SUS and expand globally.

These supply chain OpEx capabilities should be built around a collaborative planning, forecasting and replenishment (CPFR) programme that includes:

- Understanding customer requirements, such as important product/order attributes of dating, documentation, order frequency, lot control and storage material handling requirements
- Effectively transferring documented requirements to internal systems to 'operationalise' things such as customer care instructions, warehouse instructions, and set-up of customer-specific inventory reserves
- Regularly engaging in customer planning meetings to obtain updated forecasts
- Engaging with customers and suppliers to manage changes in key factors such as required components and lead times

Supply chain assurance can also be achieved through a customer-centric approach with flexibility and solutions that decrease complexity around storage and delivery. Integrated sales and operations planning (S&OP) is an integrated business management process that helps ensure the executive or leadership team of an organisation is continually focused and aligned across all functions. The S&OP process includes an updated forecast that leads to a sales plan, production plan, inventory plan, customer lead time (backlog) plan, new product development plan, strategic initiative plan, and resulting financial plan. Done well, the S&OP process enables effective supply chain management.

One of the more challenging supply chain issues is faster lead times for finished goods. Stocking more finished goods has inherent risks related to proper warehousing and storage. Many biopharma manufacturers lack adequate warehousing infrastructure to store large volumes of single-use products. For this reason, it's beneficial to work with single-use equipment and materials suppliers that can provide local storage and quick delivery.

READY TO MANAGE & MITIGATE RISK

Biopharma manufacturers can help ensure their single-use production operations remain secure by working with single-use suppliers who combine ingenuity and product leadership with powerful channel and supply chain operations. Ultimately, this should include superior single-use expertise with a collaborative approach in designing solutions; access to a broad product portfolio with components sourced from multiple suppliers; unique capabilities, such as expedited system design and delivery of drawings; and, ultimately, supply chain OpEx capabilities that are fully supported by regulatory and quality compliance.

ABOUT THE AUTHOR

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Tim has 20+ years of experience as an engineer and business development with VWR, PAW BioScience Products, and Biopure Corporation where he has designed single-use products, components, and systems that are used by the global drug and vaccine manufacturing industry.

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