SUS—an Acronym for "Single-Use Systems" or "Supply Under Shortage?"

It is the bottleneck in pharmaceutical manufacturing: lead times. What approaches can secure business continuity? What are ways to overcome dependencies on vendors' supply?

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BIOPHARM INTERNATIONAL: What is the strategic outlook for the usage of single-use systems, especially consumables, in the pharmaceutical industry?
FISCHER: Ninety percent of medicines don't work for 30% of people. So, in the future, we will see more treatment programs and drugs tailor-made for specific groups such as different genders and ages, and even individualized medicine. With this prediction, technology will focus on cell and gene therapies and oncological therapies. Almost all biopharmaceutical manufacturers are starting to embrace single-use technology. Additionally, there is continued success and subsequent expansion of biologics and vaccines. Aging is also a megatrend—a positive trend—that will have an enormous influence on healthcare as people live longer. Life expectancy is 100+ years in the future in many countries, and the supply of medication for a growing population needs to be fulfilled. Therefore, the industry needs production platforms that are at a lower cost, flexible, and able to meet these rapidly changing demands. Hence, the adoption of single-use technology is expected to increase rapidly in clinical settings, production, and manufacturing.

BIOPHARM INTERNATIONAL: What are some reasons for the increased implementation of single-use systems?
FISCHER: Single-use technology can provide a simpler, faster, and lower-cost route to production capacity when compared to conventional stainless-steel equipment and facility design. It has universal applicability, be it large-scale manufacturing of vaccines, antibody-drug conjugates, or emerging regenerative medicine such as cell and gene therapy. Single-use systems provide solutions for every pharmaceutical manufacturing facility and every batch size. The use of sterilized single-use consumables eliminates the need for clean and steam-in place operations while supporting sustainability. This simplifies both the design of a facility's infrastructure and the complexity of each unit's operation equipment. Additionally, it is cost-efficient. The engineering and construction costs are reduced, and the time from project start to production readiness can shrink up to 50% with pre-designed modular facility layouts. So, single-use systems facilitate cost-competitive production processes in the biopharma industry by massively reducing resources needed for cleaning. Also, there is a reduced risk of cross-contamination leading to fewer batch rejections. To sum it up, single-use systems are more agile, faster, cheaper, and safer.

BIOPHARM INTERNATIONAL: What are some of the challenges with supplying single-use systems and components globally?
FISCHER: One challenge is finding the right partners, as you can't do it alone as a manufacturer. Pharmaceutical industries are dependent on reliable suppliers for single-use systems, consumables, and corresponding equipment. A trustful relationship with a single-use supplier needs to be established, which also includes documentation and audits. This process takes time. Lead times are generally several months for consumables at up to 12 months or longer for single-use-related

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equipment. But the question is why? Following the trends addressed in the beginning, more manufacturers utilize single-use systems. This is leading to a general shortage of raw materials, especially plastics, so suppliers need to ramp up their production capacities to fulfill the demands of the market. But this chain continues to the suppliers of the suppliers for delivery of raw materials, so the situation currently is tense. We need to develop and deploy new strategies in production planning, not only at the manufacturers' plants but also at the suppliers' end.

BIOPHARM INTERNATIONAL: How did the pandemic contribute to the supply shortage?

FISCHER: COVID contributed a lot to the current situation, as a lightning-fast ramp up for producing a tremendous number and quantities of vaccines overwhelmed the market. In some cases, contracts were taken over by COVID programs, and materials were prioritized for COVID. It is the so-called "triage of single-use systems," which is leading to an even more tense shortage of materials on the market. Quarantined staff is another point: It has a major impact on all industries, as human resources are stretched too thin, and overstaffing or having backup employees is rarely possible or realized. Also, transportation is a limiting factor: online shopping, rising demands from quarantine, etc. This all led to limitations resulting in unpredictable shipping delays.

BIOPHARM INTERNATIONAL: What are the mitigations and strategies that can be implemented by pharmaceutical manufacturers?

FISCHER: One major point is to plan ahead and establish reliable forecasts, which manufacturers should clearly communicate to suppliers. Another factor is building stock and procuring it early and procuring extra. But as an inventory reduction was part of the business strategy, especially for bigger pharmaceutical companies, this may not be possible, However, manufacturers should make sure their suppliers have enough material in their warehouse to compensate for production peaks or other unforeseen events. Manufacturers should also consider alternative sources. Single sourcing should never be part of your business continuity plan; always develop a contingency plan B or even C and D, and manufacturers should prioritize their projects. Keep suppliers focused on the most critical items, which can only be identified by manufacturers.

BIOPHARM INTERNATIONAL: What mitigations and strategies can suppliers implement?

FISCHER: Again, suppliers should ask themselves: Is supply-chain management planning ahead, building stock, procuring extra and early? Suppliers should implement dedicated project managers to speed up the process from the start of a project until the equipment is utilized. Specialization and experience build knowledge that facilitates accurate and efficient planning and implementation. Suppliers should internally establish a solid quality management system and formal procedures for managing customers and their supplier processes. Clear and transparent standards in processes and documentation are key, and they prevent unnecessary time-consuming discussions, misunderstandings, failing on audits, etc. Suppliers should also make clear project plans and schedules and communicate and stick to them. This can be facilitated by regular governance meetings internally with manufacturers and with the raw material suppliers, which is also a major point.

BIOPHARM INTERNATIONAL: Which strategies do you recommend to create a reliable long-term end-to-end plan for manufacturers and suppliers?

FISCHER: There's a clear necessity to set realistic timelines and adhere to the planned schedule for both sides. This might mean open and frank communication about production plans, capacities, and so on to keep expectations realistic. Forecasts and common agreements between manufacturers and suppliers make production planning easier and reliable. Also, for both sides, it's necessary to create a common understanding and common standards across the industry with respect to equipment and consumable design. This enhances the delivery speed, as the design phase is extremely time-consuming. Good education and well-funded knowledge on both sides increase the efficiency and communication of the experts and in finding alternative solutions together if necessary. This can be supported by platforms, for example, BioPhorum, bringing suppliers and manufacturers together in a neutral area, working together on hot potatoes, and developing strategies feasible and advantageous for both sides. To sum up, when it's about the supply of medication to the patient, it's not a competition. Hence, only teamwork makes the dream work.