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Addressing the increasing demand for single-use technologies and supply chain shortages with future proof systems

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SUPPLY CHAIN CHALLENGES

We began the podcast by talking about the challenges that the industry is facing with respect to single-use systems and increasing demand. Mr. Sanders described how supply issues have become a real problem not only with the single-use assemblies but also with instrument components and sensors.

He went on to explain that end users are facing long delivery times from several of the larger equipment vendors, up to fourteen months for certain consumables. Often vendors can deliver equipment within a couple of months, but without the consumables, it isn't usable. End users are also experiencing slow response times for service request quotes for single-use systems that is impacting many of the smaller companies due to required supplier support for COVID-19 vaccine and therapeutic production.

Furthermore, many equipment vendors have single source supply chains because of their proprietary solutions, this also impacts the ability to increase supply quickly, as does facility and workforce constraints.

IMPACT OF COVID-19 RELATED MANUFACTURING ON SINGLE-USE SUPPLIES

Next, we discussed in more detail how COVID-19 related therapeutic manufacturing has impacted the supply chain and single-use technologies specifically. Phil said that from the customers' perspective, it's hurt their perception of single-use as a solution. With some customers debating whether it's really the right technology to pursue if their deliveries don't allow for faster times to market. This has led some end users to reconsider reusable technology, such as stainless steel.

I followed up by asking which companies are most at risk of experiencing supply chain shortages and delays. Phil shared that in his experience, it is the smaller companies and CDMOs that are not tied to project Warp Speed.

ADDRESSING SUPPLY CHAIN CHALLENGES IN THE NEAR AND LONG TERM

I asked how he thought that supply challenges can be addressed in the near and long term. Phil explained that from his perspective as a vendor, the near-term solution is to be able to provide equipment designs that are less proprietary and more open or agnostic so that multiple vendors can be leveraged to provide a solution, thus permitting quicker deliveries. His recommendation to customers is not to get locked into a proprietary solution that creates a single source of supply, especially for consumables.

BEING BRAND AGNOSTIC AS A SOLUTION

Then we discussed the term brand agnostic and I asked Phil to explain what that term means and the benefits. He said that to him, brand agnostic means Agilitech looks at multiple vendors to provide best-in-class components for specific applications. Not being tied to a specific component or vendor allows Agilitech to create solutions that are best in class and truly fit it for those customers' unique processes. It also enables shorter delivery times for equipment and consumables.

TRULY FIT FOR PURPOSE SOLUTIONS

Next, I asked Phil to clarify what fit for purpose means to Agilitech as it can have different definitions. He stated that Agilitech understands that every customer's application is different in some form, so they work with the customer upfront to understand issues and concerns as well as the short-term and long-term vision. After they have a clear understanding, then they take their standard product design and modify it to meet a customer's exact needs. This eliminates any work on the back end to integrate the equipment into their existing process. Thereby, permitting customers to start runs as soon as the system is installed and tested, equating to faster production and lower overall cost. By being agnostic, Agilitech is not limited to the same supply chain constraints that other vendors are.

In addition, if there is an issue with delivery of a specific component, they can pivot immediately to a different vendor with quicker delivery times without any effect on the design or the delivery of the system. This approach allows customers who have long term relationships with specific vendors to leverage that relationship for better pricing as well as eliminating the need to maintain several different components in their onsite inventory.

Phil then described how Agilitech recently used their fully customizable approach to custom design a chromatography system. He explained that the customer was interested in a single-use chromatography system that included a bubble trap as well as four filters in parallel rather than their standard design of two filters. They designed the system using linking to allow for more filters, but because of facility constraints, they needed to split the skid so the customer was able to fit the equipment through the door to the clean room. To provide full customization, the system was remodeled using 3D software and was designed and approved in less than three weeks.

He went on to say that another customer was using an existing flat sheet tangential flow system, but due to the increased viscosity of the product, they needed to switch to hollow fiber filters. Agilitech modified an existing design to adapt to the hollow fiber filter. Upon review of the 3D model, the customer asked if further modifications could be made to accommodate even the next sized filter for future growth. This is an example of how Agilitech can future proof a system. In this case, Agilitech adapted the design so that the same tubing set could be used for both filters with just a small adaption kit needed when they used the smaller filter and this design process took less than four weeks.

I then asked more about future proofing a manufacturing system to ensure that it evolves with the industry. Phil described that to do this successfully, it is important to understand the customers' short- and long-term goals, as well as what they see as their current constraints. Phil also commented, "Two additional questions that are also helpful are what success looks like and what is your biggest fear. By asking these questions, you learn what their final vision is and what hurdles they face in

implementing the solution. The answers to these questions help to define the features of the system that Agilitech needs to focus on and what kind of flexibility needs to be included in the solution."

Another recent customer example involved providing a system that could be scalable, so the customer didn't need a new skidded solution when they scaled up from a ¼ inch tubing to ½ inch tubing flow path system. Agilitech has designed a single-use technology to accommodate that scale up. By using scalable skid solutions, they can not only streamline and accelerate the scale up process, but ultimately eliminate the need for the customer to have to buy a whole new second skid.

Phil added that it is critical to create solutions based on open architecture control systems. This means the systems are not proprietary and can be supported by the customer's in-house automation team. This also provides customers the flexibility to go from a standalone control capability to a distributed control architecture in the future, which is important as a company grows and begins to scale up. It enables the move from manual to fully automated control. It is also key to reduce capital spending upfront and allows companies to purchase only what they need at the time, but with the building blocks required to grow the system as the company grows.

COST EFFECTIVE SOLUTIONS

I closed the interview by asking Phil if there was anything else that he would like to add. He said that one misconception customers have is that increased flexibility and customization means higher costs, but actually the Agilitech approach is more cost effective than other vendor approaches. Agilitech starts by developing a 3D model upfront as part of that presales process; this allows the proposal to be fully aligned with the customer and provides the most cost-effective solution because there aren't any unnecessary components. The customer ends up with a solution without costly bells and whistles that aren't needed. Since Agilitech knows the long-term and near-term customer goals, they can build in as much capability for that scale up as possible, which reduces that total cost of ownership.

For more information, please see Future Proof Bioprocesses