CASE STUDY: OVERCOMING MATERIALS SUPPLY CHALLENGES

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SITUATION

Supply chain disruptions have occurred many times in my experience i.e. the manufacturing process is ready to run and something happens, it could be material isn't coming on time or material we thought we'd ordered correctly turns out not to be the right material for whatever reason. As a manufacturing team, you either have what you need on the shop floor or you don't, and while a root cause analysis is helpful, it really doesn't matter in that moment – we can't run today is the short story.

A specific situation that occurred recently was that we were unable to get the filter assembly we needed, and our supplier was struggling to meet demand, possibly to due to covid-related orders.

ABOUT

Mark Petrich has worked in biomanufacturing for over 20 years and has navigated many supply chain disruption events. In this case study, Mark shares his experiences and important lessons for mitigating supply chain disruption.

CHALLENGES

The Covid-19 pandemic has caused severe disruption to supply chains, making it difficult to get material. In biopharma there are many constraints, but two possible approaches are: transfer inventory from inside your company or use alternative materials.

Either of these routes can throw up regulatory and change controls hurdles and won't necessarily solve the problem or get the manufacturing process back up and running any quicker. At Merck, we had the same parts in multiple sites but were unable to transfer them between sites because of different inventory systems, different part numbers and, in some cases, quality systems were slightly different so moving inventory from site to site was problematic. Using an alternative was not always welcomed either.

SOLUTIONS

A proactive mindset is key. You need to imagine that these situations are going to happen and plan for them. Fortunately, at Merck, we started this ten years ago, although no one expected the 45 to 55-week lead times we saw last year with Covid. However, we had already planned for a 20-week lead time as well as for the eventuality that procurement colleagues would request a technical alternative to switch suppliers in order to gain leverage or a better price etc.

Establishing what the PDA technical report No. 66 calls functional equivalency was a very important part of the process work and it's something that manufacturing and supply chain personnel should be demanding. Rather than focusing on how quickly a second source can be qualified in response to a crisis, the approach should be the prior qualification of a second source or even alternates from the same source. For example, we received a request for a 100L storage bag, the only item available was a 200L bag from the same company with the same connectors and the same tubing but it couldn't be used. A 200L bag will clearly hold 100L but it would take around six weeks to approve a batch record change.

You can take advantage of these situations to avoid supply disruption if the detail is worked out ahead of time. Particularly the idea of functional equivalency, which is clearly established in the PDA report, and can be simply described as 'doing the same thing with two items that don't appear to be the same'. In the single-use space, this is easier than for raw materials as you're dealing with well characterised single-use plastics. Depending on where you are in your process, you may be able to establish a universe of equivalencies.

In relation to the filter assembly, the model we came up with was unconventional, but it worked. We had a set of qualified components put together in a certain way from a certain supplier that worked in our process, and we investigated a scenario where we took the exact same components at the subcomponent level and had them assembled by a different supplier. This results in fewer changes, but it is still change-control, but the ideal would be to establish standard express lane change control paradigms, otherwise, any adjustments would be slow even if they were technically sound.

So, our supplier graciously allowed us to take their drawings and their list of parts to an alternate supplier, as they couldn't help us in the timeframe we needed. This was not just one quick project; it was in the order of 70-80 assemblies and took many months. So, we had the same parts, a new assembler and the same irradiation conditions, which happened to be gamma radiation. Change controls were needed in our facilities to show the duality of the part number so that the SAP number was lined up with two supplier numbers. The aim was if the parts change was simplified then we could tell our regulatory colleagues that there was no regulatory impact, which in turn made the whole model work. Had a regulatory filing been required, the delays caused that would have meant we might as well have waited for the original supplier to deliver the material.

LESSONS

1) Proactive work pays off, it's like buying insurance, you just need to 'buy' enough

2) If you are well prepared, you'll be able to mitigate some of the effects of these crises, if you're not prepared it's incredibly painful. At Merck, we were both prepared and unprepared; in some areas, we had functional equivalencies laid out and in other areas, we didn't

This case study was presented at a recent virtual event 'Pharma Shifts to Biologics', which included six in depth case studies and networking sessions.

Details of future events can be found here.

You can watch Mark's case study in full and on demand here

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