A SUCCESFUL SUPPLY CHAIN STRATEGY BEGINS DURING PROCESS DEVELOPMENT

A conversation with Parrish Galliher

ABOUT

Parrish Galliher has been in bioprocessing for over 40 years, primarily working in manufacturing and supply chain planning. He founded a single-use manufacturing technology company that was acquired by GE Healthcare. He currently works as an independent bioprocess consultant. Moderator Ben Locwin is a healthcare executive with quantitative and qualitative analytics expertise. He works with senior managers at biopharmaceutical, vaccine, and medical device companies to market at higher velocity and with higher quality.

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BL: Data veracity, quality and breadth are vital for effective supply chain management – particularly when it comes to responding to disruption. With this in mind what is the best way to ensure the accuracy of information at all key points in a supply chain?

PG: I think it starts with the recognition that supply chain management falls upon many different departments within a drug company - from process development to manufacturing to validation to quality assurance quality control as well as, obviously, logistics, warehousing and ultimately regulatory.

So the key is to engage decision makers in those departments, to sit down and recognize the importance of supply chain management and putting in place risk assessment to actually work through all those different departments. The idea is to walk down the supply chain and identify weak points in the chain and bringing that assessment back to the team.

BL: How important is it that the people involved understand the importance of effective supply chain management and how do you go about ensuring an appropriate level of engagement?

PG: I think it's a question of how much you can impress upon them the negative impact of a supply chain disruption. For example, you give them the scenario where manufacturing is held up because you cannot get a particular component or raw material and then get them to think through the full impact.

For example, if you're in clinical supply chain, manufacturing disruption could mean running out of trial supplies which means your trials are going to come to an end or go on hold and that is going to obviously have a big impact on the company's overall performance.

So the key is to point out to the team members the potential risks and the very substantial likely cost impact of any supply chain disruption and once you do that, in my experience, most people begin to take the risk assessment more seriously.

BL: Where and when in the drug development process should a company begin analysing its supply chain for potential weaknesses?

PG: It begins with the process development organization, which is responsible for developing the process used to make the product. It is incumbent upon them to look through the entire process and make their own risk assessment. What's the probability of the process running into disruptions down the line?

It requires a step-by-step analysis so you do not leave any stone unturned. It should include not only raw materials but components like disposables – connectors, tubing, bags, equipment etc. - and any other components used in the manufacturing process.

So I think the process development group should do that analysis very thoroughly to uncover any weaknesses in the process and to bring that to the team.

BL: Would you embed somebody in process development group so they know exactly what you're looking to get out of that work?

PG: Well that would be the best case scenario but that costs resources. But you don't always have the luxury of hiring an individual to do this.

Really I think it should be up to the management team in process development to do a thorough analysis and make sure nothing is overlooked and to bring that analysis forward to the supply chain management team

BL: Moving on to the wider supply chain and the topic of external disruptions. What is the best way of developing a strategy to identify and counter any disruptions?

PG: Well certainly with regard to the manufacturing process, the obvious thing is to develop alternative steps so that if there is a disruption in any one step, the process has an alternative to switch over to.

Now that may sound easy on paper but in fact it could trigger a lot of extra work across a number of departments, certainly if you're talking about an alternative to a primary production step.

For example when there is a disruption and you switch over to the new step you have to go through getting the equipment validated, training the operators and then looking at the data. So it's not an easy task to pre-engineer alternative steps into the process. It takes it takes a lot of work.

The alternative to that is to work with suppliers to put the onus on them to develop alternative steps. So for instance some companies outsource development of chromatography steps and in the process of doing that you can ask the contractor to develop an alternative step to the primary step. So that way you're putting the resource demand or burden on the outsourced organization and that reduces the workload internally.

BL: How important is it to make clear to any contractor that it is a part in a wider supply chain and is expected to work to mitigate potential disruptions?

PG: I've been working with a company that is outsourcing their manufacturing to a CMO and they outsourced all process development and manufacturing. And the CMO had developed a step in the purification scheme that used a resin that was in poor supply. It was an old legacy resin and the manufacturer was only producing like one batch a year.

So, what was the response? Well the client decided to pay for the CMO to develop alternative steps and they're in the middle of doing that right now and they're look at alternatives including affinity chromatography, which is a big change to the process.

In that case the drug firm chose a CMO that was not very sensitive to the potential for supply chain disruption. It picked a resin that was a weak choice and now they're paying for it after the fact in terms of extra work to develop an alternative approach to that step.

The saying invest now or pay later has come back to me many times over the years. A lot of folks hurry to get their drug into the clinic so they rush process development and as a result weak decisions get made and then they get implemented into manufacturing and then that sets up the organization for failure.

The bottom line is that you have to bite the bullet, invest early build a robust process and then watch it as it goes into manufacturing and support it.

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