Case Study

Advance Planning: Developing Supply Risk Mitigation Strategy

Service Areas: Commercial Launch, Manufacturing, Quality, Supply Chain
Lifecycle Stage: Clinical, Commercial

Converge conducts a Manufacturing Supplier Risk Assessment and uses the results to build a Supplier Risk Management Plan.

A commercial biopharmaceutical company was preparing for their second product launch when senior leadership acknowledged the need to prioritize the supply chain and manufacturing mandates and provisions of the CARES Act. These included regulations specific to required biopharmaceutical supplier risk management and visibility. Supply chain leadership saw the new risk management requirements as an opportunity to improve their capabilities and build the required supplier redundancy plans.

Furthermore, the company did not have an official clinical or commercial supply chain and manufacturing risk mitigation strategy aligned to their diverse set of global suppliers of raw materials, drug substance, drug product, and packaging and labeling. Scenarios like this are frequent in the industry, especially with newly established commercial companies.

Therefore, the Head of Supply Chain called for creating a formal clinical and commercial supply chain and manufacturing supplier risk assessment and subsequent mitigation plan. This would ensure that the company could respond quickly if a future shortage impacted their supply chain, while also complying with the CARES Act requirements.

Given that all internal employees were focused on upcoming launch efforts, the company decided to collaborate with an external partner. This also ensured objective evaluation of cGMP clinical and commercial supplier risk because the partner did not have the working relationship with each supplier.

Risk Assessment Results Lead to Supplier Risk Management Plan

Converge Consulting was already partnering with this company on a variety of critical supply chain initiatives (sales & operations planning, long range manufacturing & capacity planning), so we were familiar with their manufacturing supply lines and suppliers in general. This allowed for a speedy and smooth project onboarding and ramp up.

We conducted a formal Clinical and Commercial Manufacturing Supplier Risk Assessment. We evaluated each supplier using a methodology based on weighted scoring dimensions within defined supplier and quality risk categories.

Then, a Clinical and Commercial Manufacturing Supplier Risk Management Plan was developed based on the assessment findings. It included a phased approach to mitigating each supplier's identified risk. Also, the plan aligned with both the company's Quality Risk Management Policy and CARES Act Sec. 3112: Additional manufacturer reporting requirements in response to drug shortages.

The completed plan now identifies and evaluates supply risks for each supplier location. It also includes options for mitigating a potential shortage or other interruption, as well as an individual redundancy plan for each supplier.

Status Today

Today, our client has both a process and methodology for conducting future risk assessments. They also have a robust risk management plan for their entire supply network. They are meeting the CARES Act requirements and should pass a supply chain risk audit easily, if required.

This effort also helped the Supply Chain team determine how to manage their supply risks on a day-to-day basis. They are now considering the development of a full Supplier Relationship Management process that includes incorporating and documenting governance for the entire plan.

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