Mitigating Raw-Material Risks During a Pandemic

Novo Nordisk Pharmatech A/S

The COVID-19 crisis has reinforced the importance of having a strong supply chain and a risk-management and business-continuity plan. How can you mitigate your raw-material risk, especially during a pandemic?

Risks When Choosing a Raw Material Supplier: How do you select your critical raw-material suppliers? What selection criteria and which risks have you identified? To understand risks related to supply, demand, material supplier capacities, and so on, you need information that can come only from communicating with your supplier about the stability of supply, production capacity, and transportation and distribution chain.

A large organization such as Novo Nordisk can secure a continued source of raw materials. We have experienced significantly increased freight fees and limited availability of transportation for both our human insulin and our quaternary ammonium compounds ("quats") active pharmaceutical ingredients (APIs). Despite that, and thanks to close cooperation with our customers, we are delivering our products as promised and without disrupting planned manufacturing processes.

Working Together: Transparent communication is essential. To best manage unforeseen situations such as a pandemic, we perform contingency planning based on our customers' needs. Furthermore, we secure our supply chain by building partnerships, exchanging forecasts and discussing foreseen changes, and performing joint planning.Sometimes, doing so is easier said than done. One way to facilitate those processes is by creating supply agreements. We have entered into numerous supply agreements and quality assurance agreements (QAAs) with our customers, which help maintain clear expectations from both sides and provide peace of mind.

Minimizing Raw Material Variability: Our customers want to source materials from reliable sites that deliver as agreed on quality, purity, and consistency between batches and shipments. The cornerstone of our organization is an effective quality management system, which helps us to achieve that goal.

Novo Nordisk is monitored stringently by international regulatory authorities and customers. We have an outstanding track record of compliance and customer satisfaction because we learn from each audit, monitor compliance requirements, and strive for continuous improvement.

One-Stop Regulatory Compliance: Audits can cover the good manufacturing practice (GMP) level of a supplier, but supplier qualification consists of many aspects. Those include regulatory requirements and available risk assessments as well as a supplier's overall compliance, noncompliance, and recall history.

We take pride in providing a simple, hassle-free, "one-stop" compliance and regulatory package. All Novo Nordisk activities are gathered at one site in Europe, making supply chain audits easy. Our customers are issued up-front access to a full package of certificates from authorities (e.g., current GMP as well as International Organization for Standardization (ISO) 9001, 14001, and 45001); qualification dossiers, statements, and declarations; change notifications, questionnaires, stability and analysis documents; and more.

For us, being qualified as a supplier is only the beginning of a journey. We support our customers throughout the whole product life cycle, with premium service and documentation. That is part of our ambition to remain a preferred supplier and contribute to improving pharma and biopharma processes.

For more information, visit novonordiskpharmatech.com, follow us on LinkedIn, or contact us at nnprinfo@novonordiskpharmatech.com.

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