

Assurance of Supply

Do you know and control all risks that your pharmaceutical value chain is facing from disruptions?



Recent years have confirmed how vulnerable companies are to disruption. Unfortunately, the situation may well deteriorate further as the effects of an unstable political world order as well as geopolitical risks and the consequences of climate change come to define the new normal.

The Suez Canal blockage, various cyber-attacks, COVID and finally Russia's war in Ukraine have reminded us how vulnerable our global supply chains are and made us think about which strategically important products we should manufacture at home, either wholly or in part. With energy in the EU likely to become even more scarce and expensive in this fall, we must urgently re-evaluate country diversity regarding production hubs and supplier selection.

At the same time getting reliable supply throughout the entire value chain has become a complex task, as:

- Manufacturing processes have become more distributed and therefore complex
- Supply chains are globally growing in size and complexity
- Margins continue to get squeezed
- Companies are struggling to define stable supply chain processes that are efficient and repeatable at competitive costs

Besides major disasters quite common problems cause the most frequent supply disruptions:

- Late deliveries (internal & external)
- Volatile demands, respectively disconnect between customer and supplier
- Raw material shortages
- Quality issues or disturbances in the systems
- Unclear processes often caused by department's silo thinking

Every company must review or, where it does not exist, implement a **Business Continuity Management Process** asap. The main focus of this article is to share a summary of principles and measures to ensure seamless supply.

The goal is to:

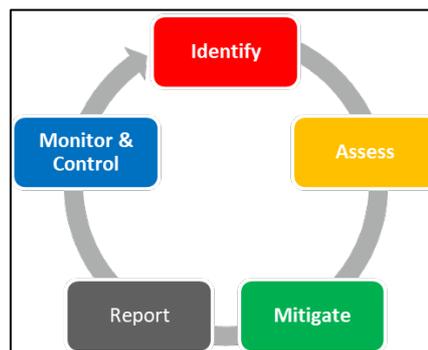
- Manage, minimize, or even eliminate the probability and/or impact of potential product supply risks by establishing a robust governance mechanism
- Establish a set of policies and processes to ensure that critical operations are maintained at a tolerable predefined level, regardless of disruption or timing

- Become pro-active by putting measures into place that safeguard operations and product reputation prior to a disruption
- Coordinate communication between Supply Chain and Production Management for their duty of oversight and transparency to get their involvement and support, for example by allocating required resources

Taking into consideration that companies are measured and scored by profitability, customer satisfaction, revenue and working capital costs, we strongly recommend what we call an "**Assurance of Supply Program**".

It consists of five central process steps and should be designed as a standardized cycle of assessing and mitigating risks across the entire value chain:

- Risk **identification** (detect risks & ensure transparency)
- Risk **assessment** (analyze, evaluate, and prioritize)
- Risk **mitigation** (manage & eliminate risks)
- Risk **reporting and documentation**
- Risk **monitoring & controlling**



The procedure helps to manage and minimize the probability and/or impact of potential product supply risks as well as to coordinate the communication between SC & Production Management.

It is advisable to analyze all risks in detail from a qualitative and quantitative point of view, whether they are economic, technical, legal, political, or environmental and caused internally or externally.

To **identify** the risks and ensure transparency through a structured overview within the company we deploy various methods:

- Extended value stream mapping (End-to-End)
- FMEA (Failure Mode & Effect Analyze)
- Expert survey and cross-functional workshops
- Benchmarking and company comparisons through KPIs (Key Performance Indicators)
- Market analysis and observation

Assessment of all identified risks concerning their individual operational impact to product supply to enable prioritization. The assessment results from three factors:

- Likelihood of occurrence (probability in %)
- Potential severity of monetary impact based on potential loss of revenues and profits
- Degree of unwanted reputational impact on brand and/or employer relations

Once you have recorded and assessed all relevant risks, the most important task is to define **risk mitigation** measures and contingency plans to ensure that you take the right measures to prevent risks from occurring or to minimize their consequences. These measures include for example:

- Dual rather than single sourcing
- Definition and negotiating of new supply contracts
- Building up reserve capacities in production and logistics
- In- or outsourcing, optimized warehouse management
- Improved production planning

Measures requiring substantial investment, must be economically justified through detailed feasibility analyses.

The effectiveness of mitigation actions must be measured, and a respective reporting system and appropriate Key Performance Indicators (KPIs) must be implemented.

Risk reporting and documentation must guarantee that all relevant background information has been made accessible and meets the requirements of the various addressees:

- Directly involved and responsible employees (e.g., product and sub-process owners)
- Extended group of relevant employees
- Management as well as top management

Once the risk management framework is in place, ongoing **monitoring** is critical to continuously identify potential risks that could harm the business. Therefore, it is crucial to:

- Raise awareness of potential risks throughout the company
- Establish an early warning system
- Establish a robust governance mechanism to regularly review supply chain risks and to define mitigation measures to improve supply chain robustness and agility

Our suggestion is to implement a cross-functional Risk Board:

- Designated product owners facilitating the risk management process for a particular group of products
- Line managers representing their sub-process within the entire value chain and having responsibility for risk identification and mitigation related to their processes
- A central risk management function providing general guidance (SOPs) on how to identify & mitigate risks

My years as a SC manager with responsible for tactical and strategic supply chain tasks for major products has shown me that not all risks are avoidable at all times. Nevertheless, it helps enormously to be prepared! We would welcome the opportunity to support you in mastering this challenging and vital task.

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