Pharma Supply Chain Resilience

How modelling, simulation and AI can help to safeguard future supply chain reliability and resilience of pharmaceutical companies!

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Need for action

Since the COVID-19 pandemic, the problem of frequent drug shortages has become clearly visible. Not only vaccines are affected, but also antibiotics, cancer drugs and drugs for children. And it's not just about innovative drugs, but also often about generic drugs.

How could this happen? The search for minimal CoGS led in the pharmaceutical industry to globally optimized, largely redundancy-free production networks with the lowest possible inventories in the supply chain itself.

Of course, such lean networks are complex and therefore more susceptible to the failure of individual components. If these networks are now put under stress by an increasingly protectionist attitude on the part of the states, which is materializing through tariff and non-tariff trade barriers, then this endangers a secure supply of goods.

In 2020, the European Commission developed a new pharmaceutical strategy for Europe, which includes an initiative to secure the supply of medicines across the EU and avoid shortages.

In this context, pharmaceutical companies are encouraged to shift their production back to the European continent. Onshoring or nearshoring of API and critical materials or process steps in connection with dual source solutions should increase the resilience of supply chains.

In addition, when a new drug is approved, the regulatory authorities require proof of the reliability and resilience of the corresponding supply chain. In return, the EU promises longer exclusivity for new drugs if the reliability of the supply chain can be guaranteed.

For the FDA, too, the topic of secure market supply has long been an integral part of their pre-approval, pre-market or pre-license inspections.

This applies in particular to products classified as Received Breakthrough Therapy or Regenerative Medicine Advanced Therapy and products used to treat a serious illness or medical condition for which there is no substitute.

Supply chain simulation in response

For a quick identification of effective / correct measures to increase the reliability and resilience of a supply chain, a simulation of the supply chain itself is the right choice - however, the following must be observed:

- The correct delimitation of the E2E process: on the one hand, all processes and resources (e.g. work center, personnel, material) as well as the partners must be part of the simulation, which can have a decisive influence - on the other hand, the "whole world" must not be evaluated, but it must be meaningful be defined and focused.

  The core of the model are usually the processes from production and logistics, QC/QA and engineering. However, if initial indications indicate that raw materials / services from upstream suppliers are critical, the simulation model must be expanded accordingly. The same applies to the media or energy supply or the provision of transport capacity.

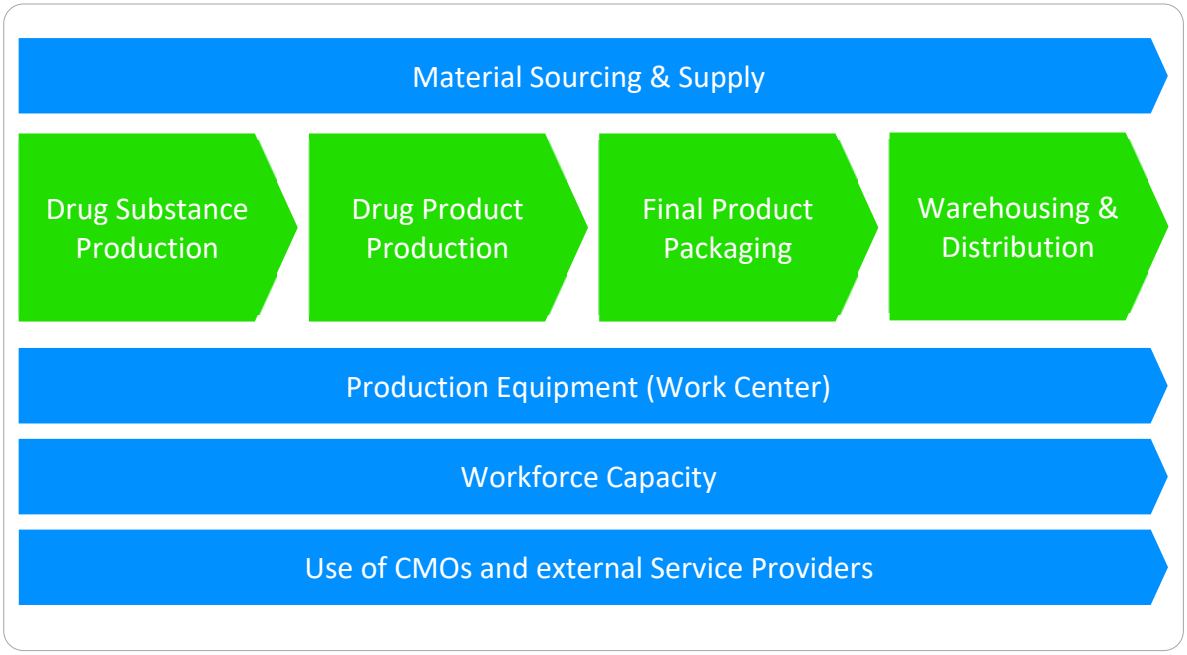

Fig. 1: Pharma Supply Chain – Model Elements

- The right level of abstraction: due to the computer capacity available today, one is easily tempted to map everything in detail 1:1 in a model and then have it calculated. However, this makes neither economic sense nor is it advisable in terms of the objective, it often blocks the view of the essentials – an example may make it clearer: for the question of whether personnel represents my bottleneck resource in production, not every individual employee has to be shown, but a role-based consideration is sufficient.

- The simulation model must be dynamic, i.e. the time factor is an integral part of a simulation. Appropriate information must be mapped in the model components for

both processes (running times, downtimes, transport times) and resources (availability times, replacement times). This is the only way to simulate realistically.

- Scenarios of how the model reacts to events must be run against the simulation model. A distinction can be made between goal- and risk-oriented scenarios.

- In the former, the degree of target attainment of sales and capacity scenarios is simulated and analyzed. On the sales side, three scenarios are usually distinguished: base, maximum and minimum sales volumes over a 5 to 10 year time horizon . On the capacity side, on the other hand, it is about scenarios that can map / take into account different shift models, degrees of yield, equipment expansion stages or the additional use of external service providers.

  Considering supply chain reliability and resilience, the risk-based scenarios ask what happens if a risk materializes. The risks can be of a very different nature, e.g. reduction in yield in production process A, increase in the batch failure rate by N%, increase in sick leave in the workforce, failure of a sub-supplier, extension of customs clearance in country A, failure of the power supply in building X.

  Over time, this creates a library of scenarios. In the future, it will allow new questions to be formalized very quickly by adapting existing scenarios and fed into the simulation process.

After creating transparency and identifying the consequences of a risk, suitable counter measures must be identified. The simulation itself can (still) not do it automatically. For this purpose, solution approaches are to be discussed with the cooperation of internal and external experts, their implications / effects are to be simulated in the model and finally prioritized.

An "automatic" and thus AI-based derivation of corresponding proposals requires historical data and already verified causal chains (cause / effect relationships). The latter are often still a future dream for most companies. Despite all the euphoria regarding the possibilities of AI, it must be accepted that this will take time.

Project approach and procedure

The approach of artistratis is value-based and pragmatic:

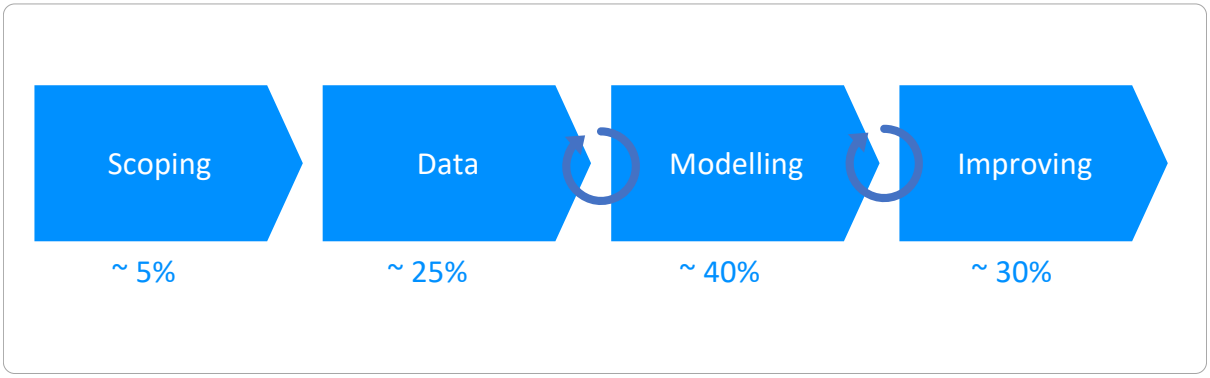

Fig. 2: Approach and Procedure

At the beginning of a project there is the correct delimitation and objective of the simulation project itself: is only one product / one national market affected or an entire product category and possibly also several markets?

Is the focus on the initial presentation of the available capacity or on answering questions regarding the ability of the supply chain to react quickly to risks? After this phase, artistratis submits a high-level proposal for the model.

artistratis recommends starting with a simple model, following the KISS principle and gradually refine it, using the knowledge already gained about the process and the model dynamics.

The gathering and quality assurance of the data required for the modeling follows. artistratis only uses double-checked data in the actual modeling in order to prevent the danger of garbage in / garbage out at an early stage.

The construction of the model is supported by a corresponding standard simulation software - already available at the customer or provided by artistratis. artistratis is not tied to a specific supplier but masters various standard software applications. artistratis sees itself as an expert for the “right modeling”.

The scenarios resulting from the project objectives are formalized, fed into the model, simulated and documented. artistratis hands over the model, the input data and the graphically prepared scenario results to the client.

The process concludes with a targeted search for improvements. For this purpose, artistratis conducts workshops and individual discussions. artistratis can also provide supporting AI-based analysis for this. The results are summarized in an implementation program, explained and handed over.

If requested by the client, this one-time, project-oriented process can be established as a routine process in the client's organization. This makes simulation the core competence of your own organization.

Depending on the complexity of the simulation objects and corresponding data availability, the project duration is usually between 1 and 3 months.

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