Hochschule Worms
University of Applied Sciences

Worms 2024

# SGR-Chain: Resilient Pharma Supply Chains – Supply Chain Resilience and Mitigation of Drug Shortages

Prof. Dr. David Francas

# Objectives

- **What are the key objectives of this module?**

- After this module, you will be able to:
  - Understand the **impact of drug shortages** on global health systems
  - Get to know **strategies** for **increasing supply chain resilience** and **mitigating the impact of disruptions**.
  - Study supply chain resilience and drug shortages in the simulation of a **biotech supply chain**.

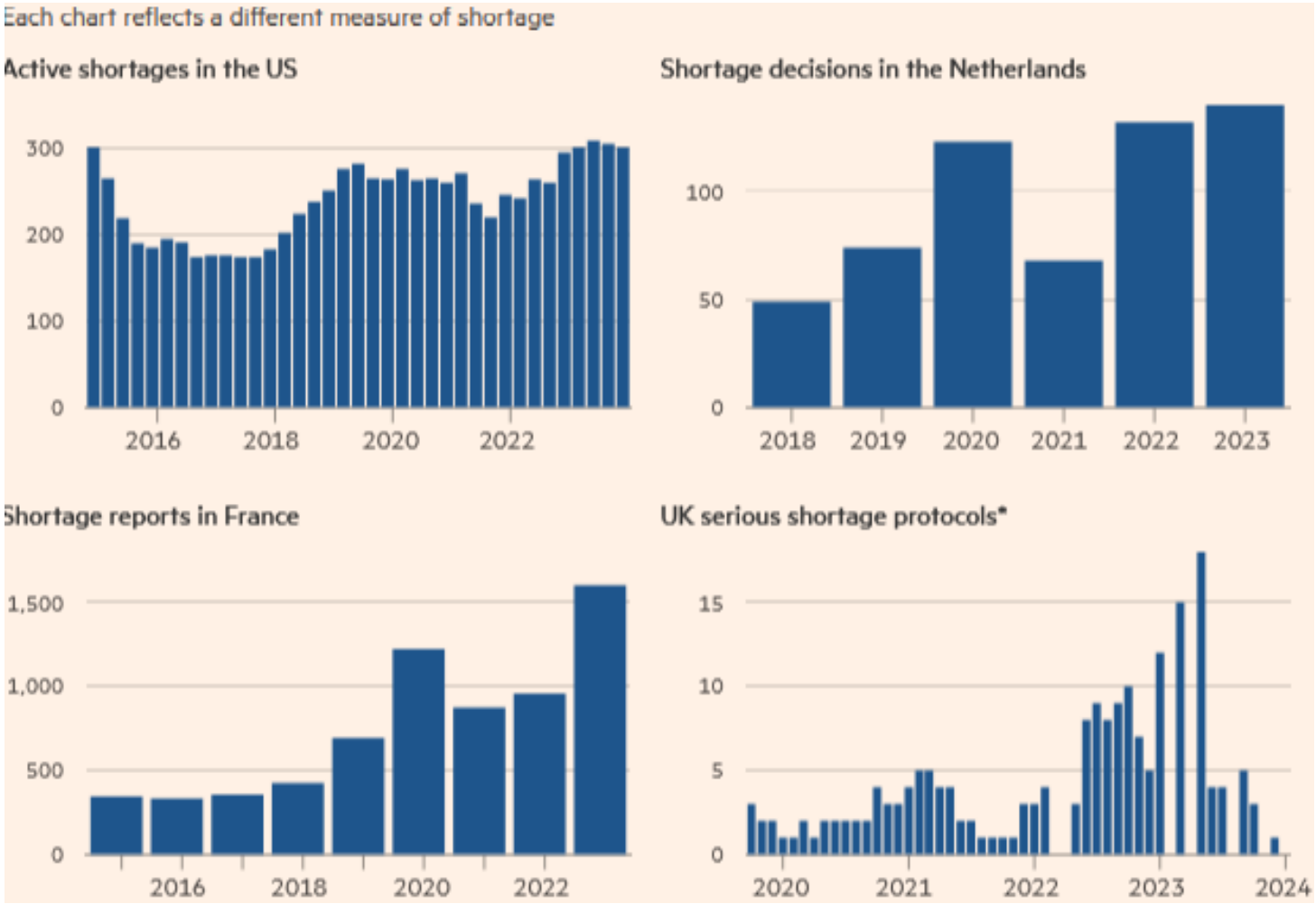
# Agenda

| | |
|---|---|
| 1 | Drug shortages: A global challenge for health systems |
| 2 | Building resilience in supply chains |
| 3 | Case study: E2E risk app pharma |

# Global calls for strengthening drug supply chains

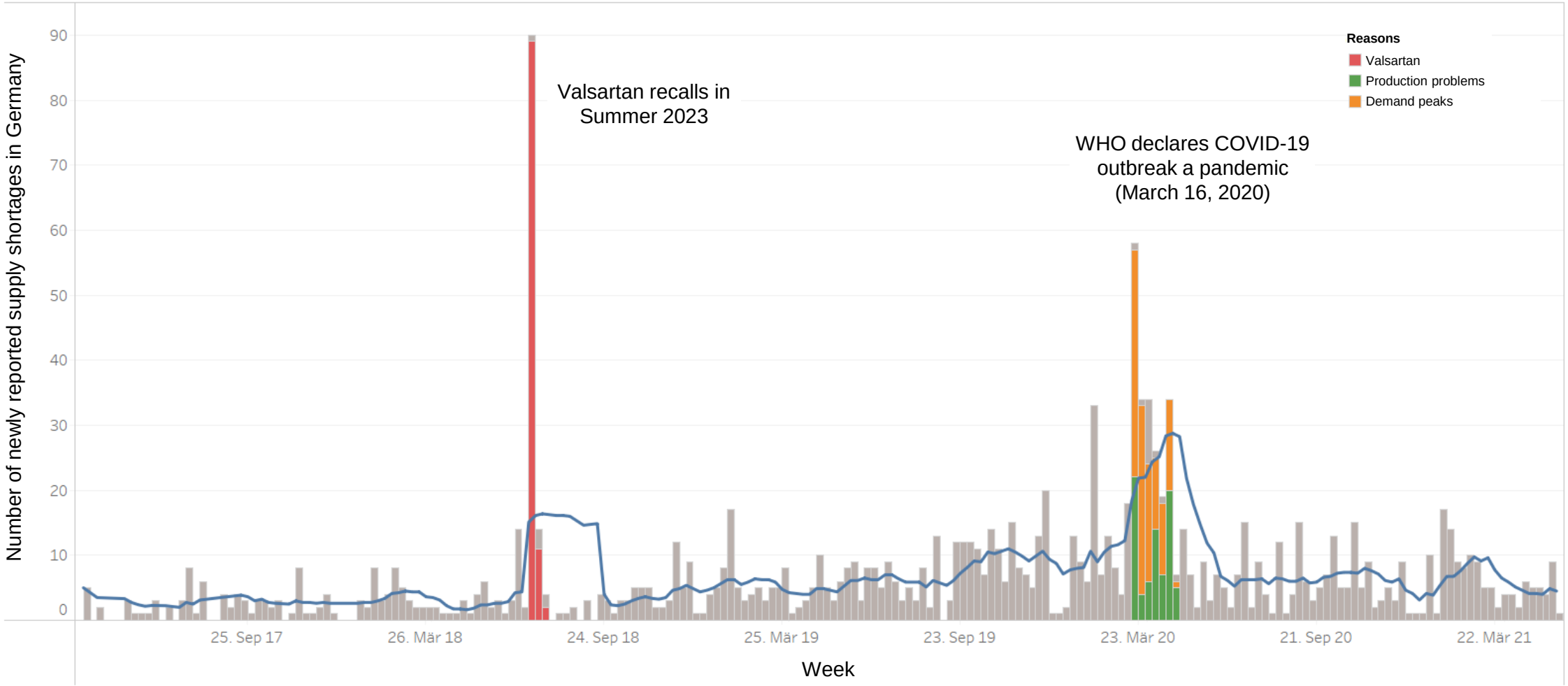
- **Drug shortages** present an ongoing challenge for global healthcare systems.
- The COVID-19 pandemic has highlighted the issue of **high dependence** on suppliers from Asia.
- The Ukraine war also shows how **resource dependencies** can be exploited as a political leverage and a tool of **hybrid warfare**.

# Drug shortages reached a 10-year high in the US in 2023




Source: https://www.ft.com/content/6143300d-d11a-4b2f-898c-87c5dd0ff6ce (Data from University of Utah Drug Information Service, national authorities)

# Shortages during the Corona-Pandemic in Germany




- Between March and April 2020, a temporary increase in reported drug shortages was observed, which, however, remained below the peak numbers of the Valsartan recalls in June 2018.

Source: Francas et al. (2022)



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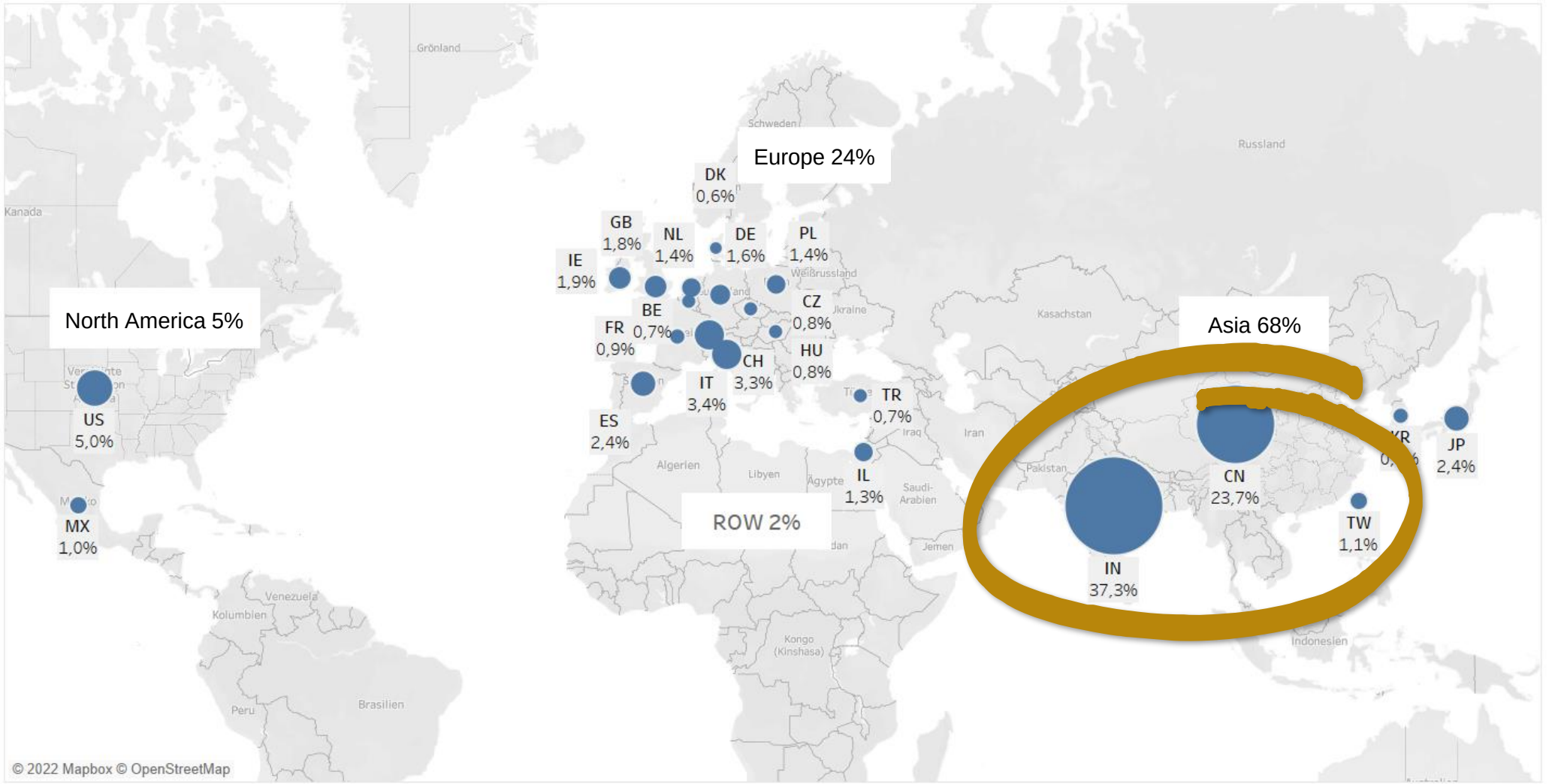
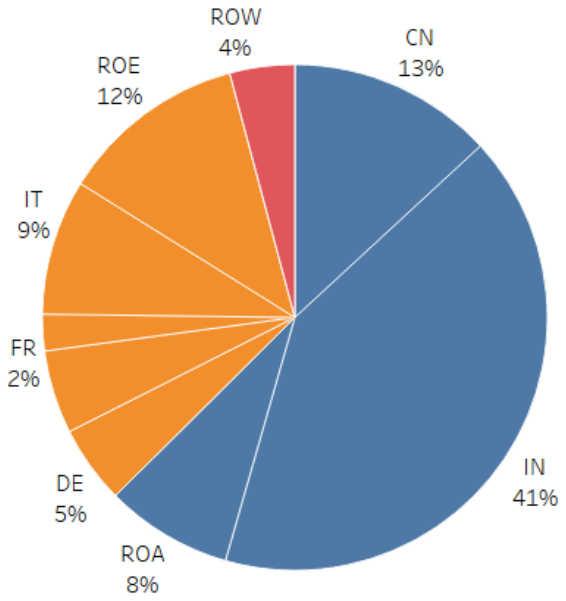
# Europe sources most active pharmaceutical ingredients (API) from India and China




Source: Francas et al. (2022). The data is based on API registrations in the EU and third countries by EU member states (EU incl. UK) in EudraGMP, as of 01.04.2019

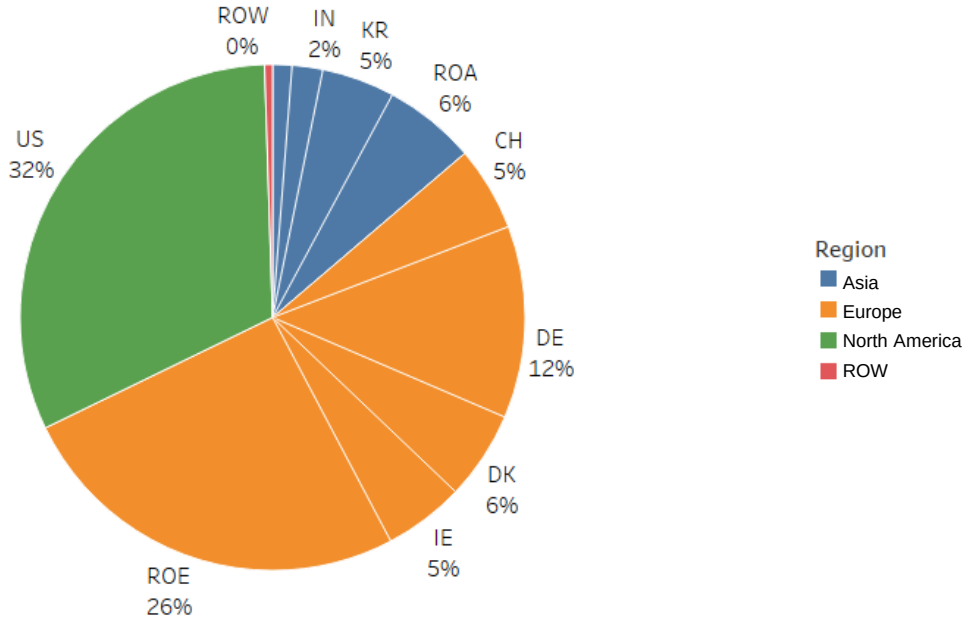
# Differentiation necessary: Biopharmaceutical APIs are primarily manufactured in Europe and the USA

## Chemical APIs used in Generics




Note: The basis for the calculation of the shares is the number of certified approvals (CEPs: 'Certificate of Suitability of Monographs of the European Pharmacopoeia') in the countries. Source: Pro Generika, own calculations.

## Biopharmaceutical APIs




Note: Europe includes the EU, Great Britain, and Switzerland. Considered are biopharmaceutical original products and biosimilars minus no longer approved medicinal products. Active ingredients are counted per location. Figures show cumulative approvals since 2000. Source: European public assessment reports (EPARs) of the EMA, own calculations.

Source: Francas et al. (2022)

# Strengthening drug supply: Selected political initiatives

- **USA**: The Biden administration considers strengthening pharmaceutical supply chains as one of the four most critical areas for ensuring the security of supply in the USA.
- **France**: The French government is targeting reshoring in pharmaceutical production, starting with paracetamol.
- **Netherlands**: As early as 2019, the establishment of a national drug reserve for all medicines was decided.
- **India**: The government plans to reduce dependence on imports of pharmaceutical raw materials by 25% by 2024.
- **Germany**: Drug supply shortage combat and supply improvement act (ALBVVG) in 2023.

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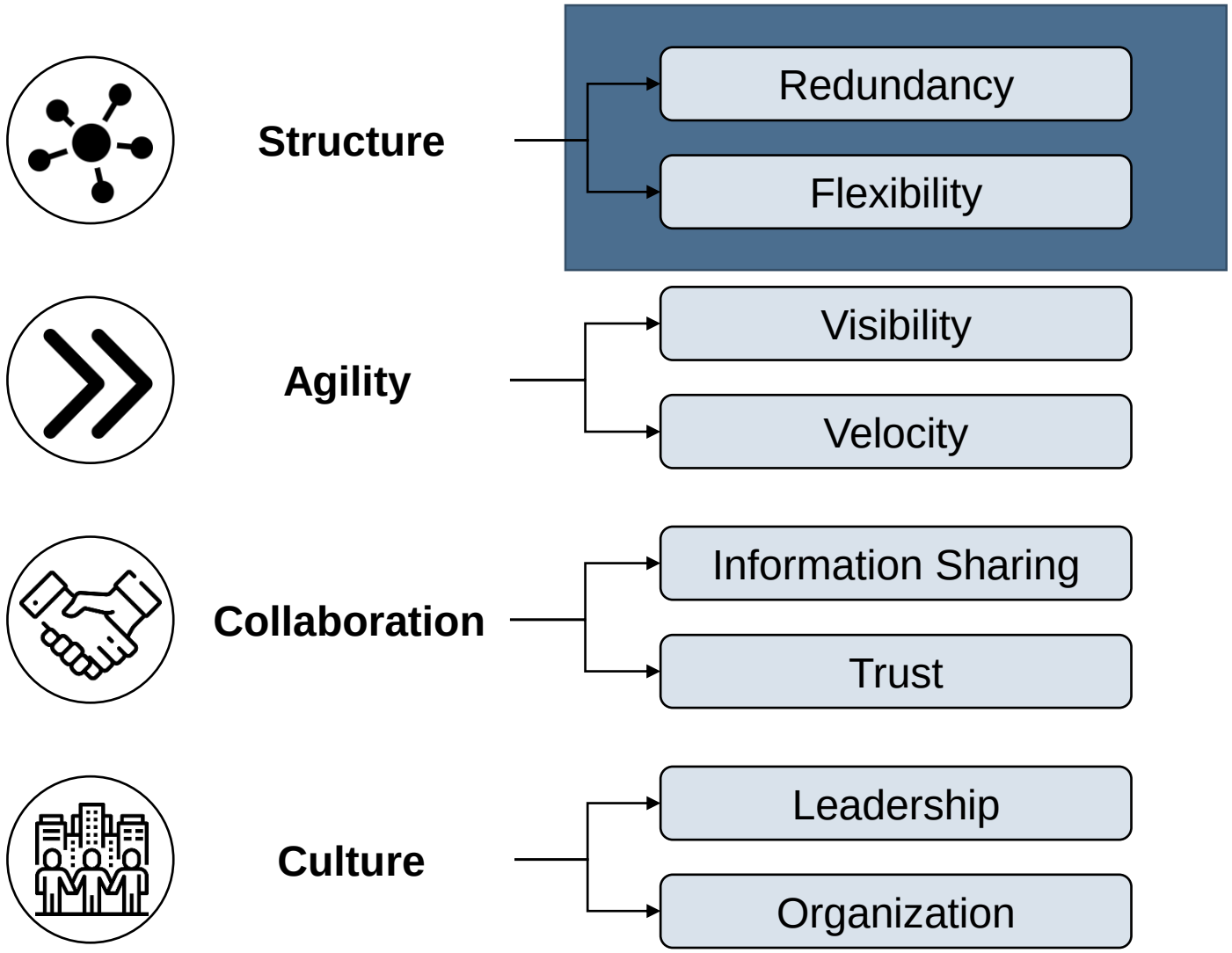
# Supply chain resilience and robustness

- **Supply chain resilience** is “the ability of a supply chain to return to normal operating performance, within an acceptable period of time, after being disturbed”,

- and **supply chain robustness** is “the ability of the supply chain to maintain its function despite internal or external disruptions” (Brandon-Jones, 2014).

# Dimensions of supply chain resilience and improvement strategies




- Reactive (back-up) capacity
- Risk inventory
- Dual sourcing & geographical diversification

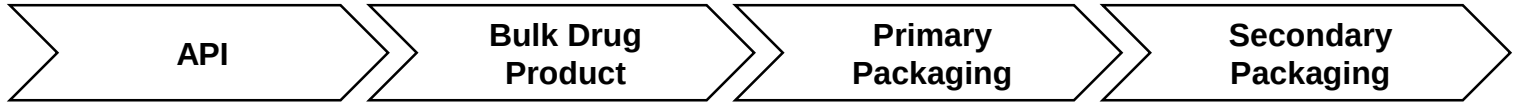
Source: Francas et al. (2021)

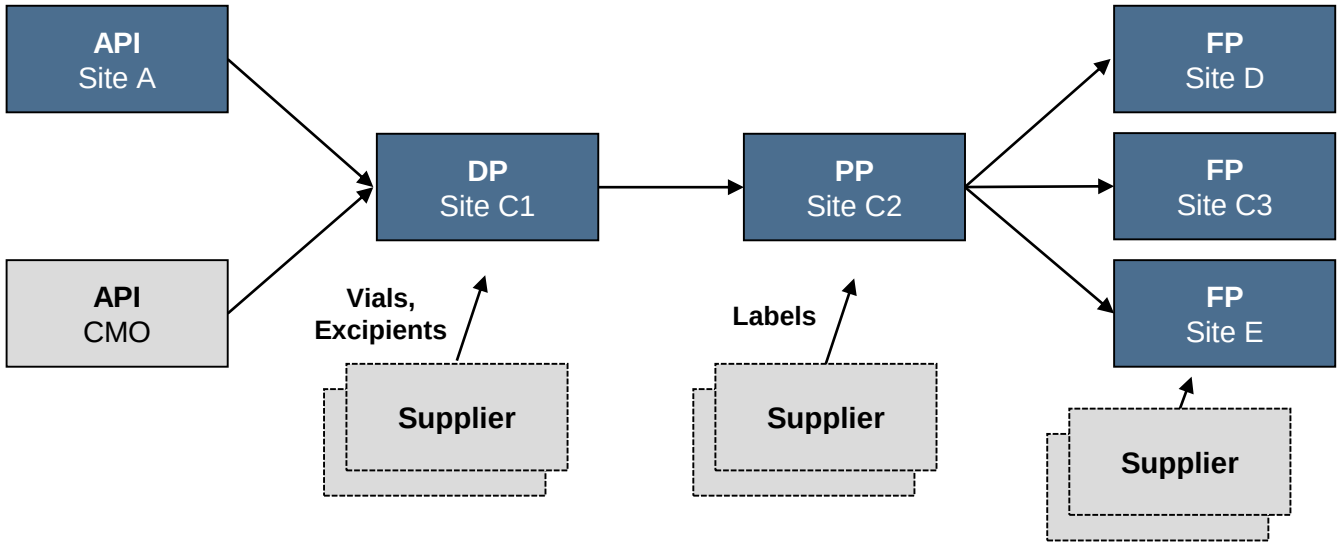
# Measures for supply chain resilience by Simchi-Levi et al. (2015)

- **Time-to-recover (TTR):** The time it takes for a particular node in the supply chain (plant or product location) to restore full functionality after a disruption.

- **Time-to-survive (TTS):** The maximum duration that the supply chain can match supply with demand after a disruption of a particular node, i.e., the time until the first shortages occur.

# A pharmaceutical supply chain




Source: Francas et al. (2021)

# A possible way forward

| Create transparency | Identify and evaluate risks | Optimize resilience |
| --- | --- | --- |
| • Collect data<br>• Supply chain mapping<br>• Build digital twin | • Calculate time-to-shortage metrics and risk exposure in a digital twin<br>• Identify weak links<br>• Prioritize and segment risks | • Reactive (back-up) capacity<br>• Risk inventory<br>• Dual sourcing & geographical diversification<br>(use prescriptive analytics) |

# Allocating inventory in case of supply-demand mismatches

- A supply chain disruption can lead to situations where available inventory and production output is **not sufficient to meet demand**.

- Supply chains have to employ **allocation rules** to allocate scarce inventory to customers. Inventory allocation may be driven by:
  - **Legal** and **regulatory** considerations (contracts, laws)
  - **Fairness** and **ethical** considerations
  - **Profits** (allocating inventory to the most profitable customers).

# Illustrating the impact of allocations rules

- We consider a small disruption scenario and investigate the impact of three different allocation rules:
  - Maximize average service level (SL: Satisfied demand / demand)
  - Maximize worst-case service level (across all markets)
  - Minimize lost sales (minimize financial loss)
- Example data (capacity (150 units) is not sufficient to meet all demands):

| | Demand | Price |
|---|---|---|
| **Market 1** | 100 | 10 |
| **Market 2** | 60 | 7 |
| **Market 3** | 40 | 8 |
| **Capacity** | 150 | |

| | Rules | | |
|---|---|---|---|
| **Metrics** | **max avg. SL** | **max min SL** | **min lost sales** |
| **Avg. SL** | 83% | 75% | 72% |
| **Min. SL** | 50% | 75% | 17% |
| **Lost sales** | 500 | 435 | 350 |

- **Conflict: All metrics (avg. SL, min SL, lost sales) are reasonable objectives for a supply chain. Unfortunately, there is no rule that maximizes all of them.**

# References


- Brandon-Jones, E., Squire, B., Autry, C. W., and Petersen, K. J. (2014). A contingent resource-based perspective of supply chain resilience and robustness. Journal of Supply Chain Management, 50(3), 55-73.
- Francas, D., Fritsch, M., and Kirchhoff, J. (2022). Resilienz pharmazeutischer Lieferketten. Study for the Association of Research-Based Pharmaceutical Companies.
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- Simchi-Levi, D., Schmidt, W., Wei, Y., Zhang, P. Y., Combs, K. and et al. (2015). Identifying risks and mitigating disruptions in the automotive supply chain. Interfaces, 45(5), 375-390.

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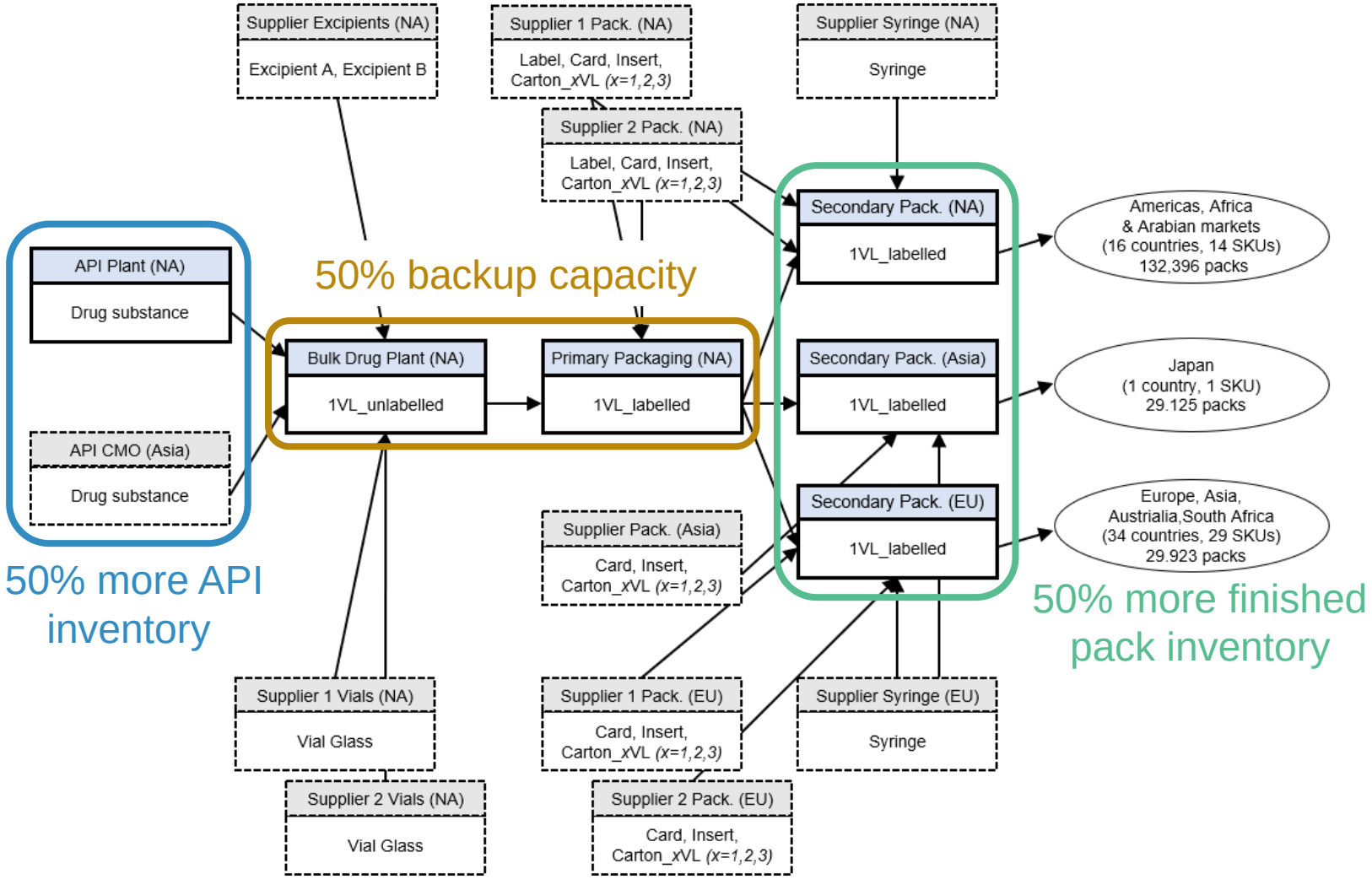
# Interactive case study 1: Evaluating risk improvement measures in a global pharmaceutical supply chain

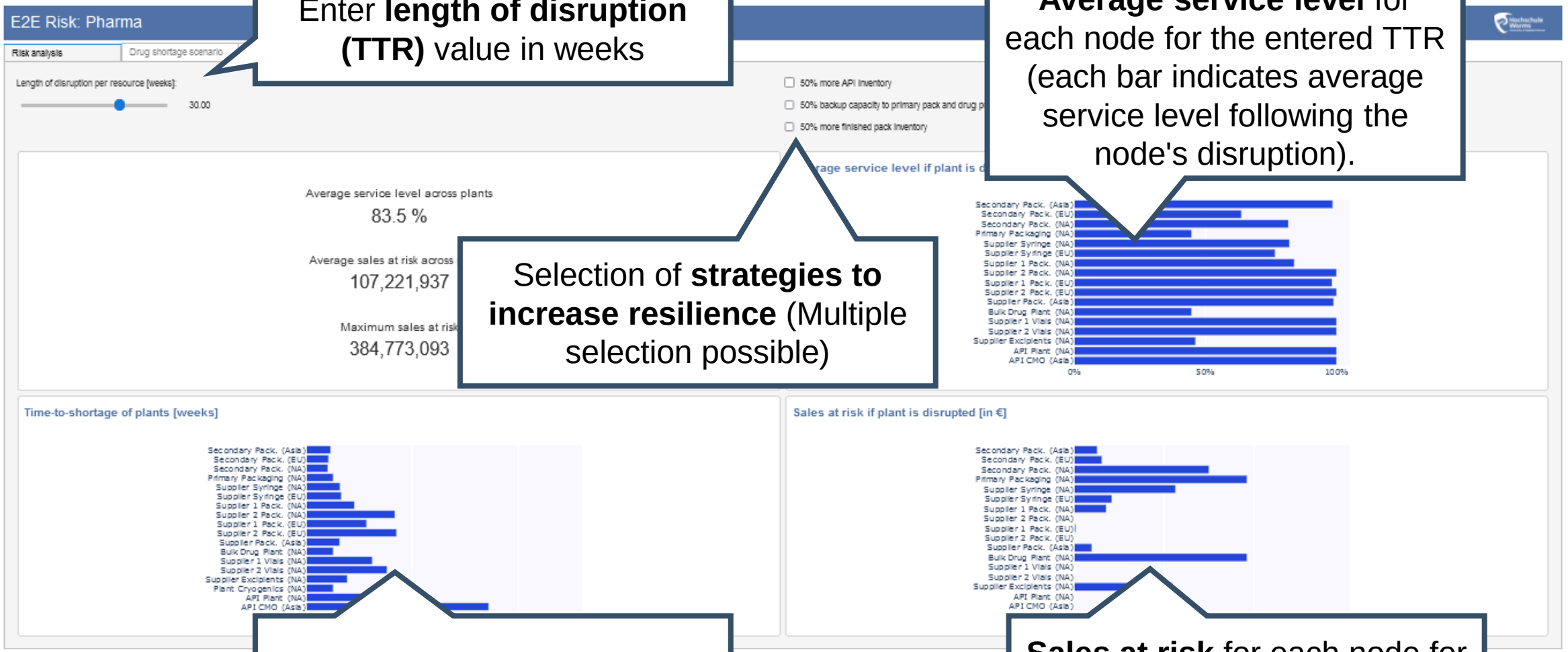
## Case Background

- The data for this case is based on Francas (2021) and is inspired by a real-world biotech supply chain. The supply chain encompasses four main stages: API, drug product manufacturing, primary and secondary packaging. The supply chain model includes own facilities, contract manufacturers, and key suppliers (excipients, primary and secondary packaging) for 44 final SKUs sold in more than 50 markets. The drugs are filled into vials, with packs containing between one and three vials. Sales prices and demand vary considerably across markets.
- For each node (own plant, facility of a contract manufacturer, supplier) in the network, key risk metrics are calculated that follow from a disruption at this particular node and the respective duration of a disruption. In this case, you can investigate the effectiveness of three strategies to increase resilience: (1) 50% more API inventory, (2) 50% backup capacity for primary packaging and drug product, and (3) 50% more finished pack inventory.

# Interactive case study 1: Structure of the biotech supply chain



# The E2E risk app: Pharma (risk analysis)




Enter **length of disruption (TTR)** value in weeks

**Average service level** for each node for the entered TTR (each bar indicates average service level following the node's disruption).

Selection of **strategies to increase resilience** (Multiple selection possible)

**TTS** for each node

**Sales at risk** for each node for the entered TTR



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# Risk analysis and strategies to increase resilience for a biotech supply chain: Tasks

Supply chain leadership wants to conduct a stress test for all manufacturing sites, major suppliers, and contract manufacturers within the supply chain. Management has agreed to investigate the impact of a 20-week disruption on any of the supply chain nodes. Furthermore, they want to understand which node failures would lead to the earliest drug shortages for patients.

You have agreed on the following approach for this stress test:

- Identify the nodes that would be most affected by a 20-week disruption and assess the impact on patients and financials.
- Identify which node failures would lead to the earliest drug shortages for patients.

In addition, the company seeks your advice on appropriate measures to mitigate a 20-week disruption. Which would you recommend? There is an ongoing discussion in the industry about whether risk inventory should be positioned more upstream (API) or downstream (finished goods). How would you respond to this, considering the case at hand?

# Interactive case study 2: Evaluating the impact of a global drug shortage after a disruption

## Case Background

- In this scenario, you can evaluate the impact of a 24-week simultaneous disruption of both API supply sources (a supply shock) and a 35% increase in global demand (a demand shock).
- You can investigate the impact of such a severe disruption on the availability of drugs as well as study the operational and financial impact. Due to the disruption, total inventory and production cannot meet all global demands. Consequently, scarce supply must be allocated to markets. You can apply three different allocation rules: (1) Maximize average service level, (2) Maximize maximum average service level, and (3) Minimize lost revenues.

# The E2E risk app: Pharma (shortage scenario)


Enter **length of disruption (TTR)** value in weeks

**Select allocation rule**

Summary **metrics** for **operational and financial impact**

**Detail metrics** for each market and SKU



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# Evaluating the impact of a global drug shortage after a disruption: Tasks

Consider a 24-week disruption. You are in charge of deciding how to allocate scarce drug supply to patients across the globe.

You should analyze the impact of three different allocation rules. You can, for example, evaluate these rules based on:

- Financial impact
- Availability of drugs for patients (ethical obligations)
- Impact on individual markets (fairness)

If you had to make a decision, which allocation would you prefer, and why?