



BUILDING A RESILIENT PHARMA SUPPLY CHAIN: STRATEGY, RISK & INNOVATION FOR THE FUTURE

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ROADMAP

SATELLITE



API FDF API + FDF

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1 A PHARMA GMBH (INDUSTRIESTRASSE 18, HOLZKIRCHEN)

FDF

Germany

3D IMAGING DRUG DESIGN AND DEVELOPMENT LLC (LITTLE ROCK)

FDF

United States of America (USA)

3M (COLUMBIA)

FDF

United States of America (USA)

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COLLAPSE



Agenda

1. Approach by Governments

- 1.1. Manufacturing Footprint
- 1.2. 86 Essential Medicines (ASPR)
- 1.3. Deep Dive Examples

2. Approach by Companies



Agenda

1. Approach by Governments

1.1. **Manufacturing Footprint**

1.2. 86 Essential Medicines (ASPR)

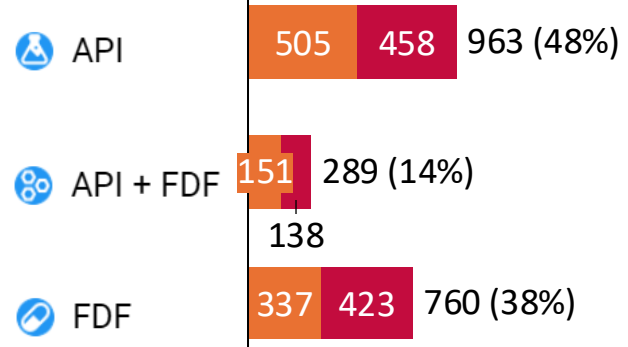
1.3. Deep Dive Examples

2. Approach by Companies

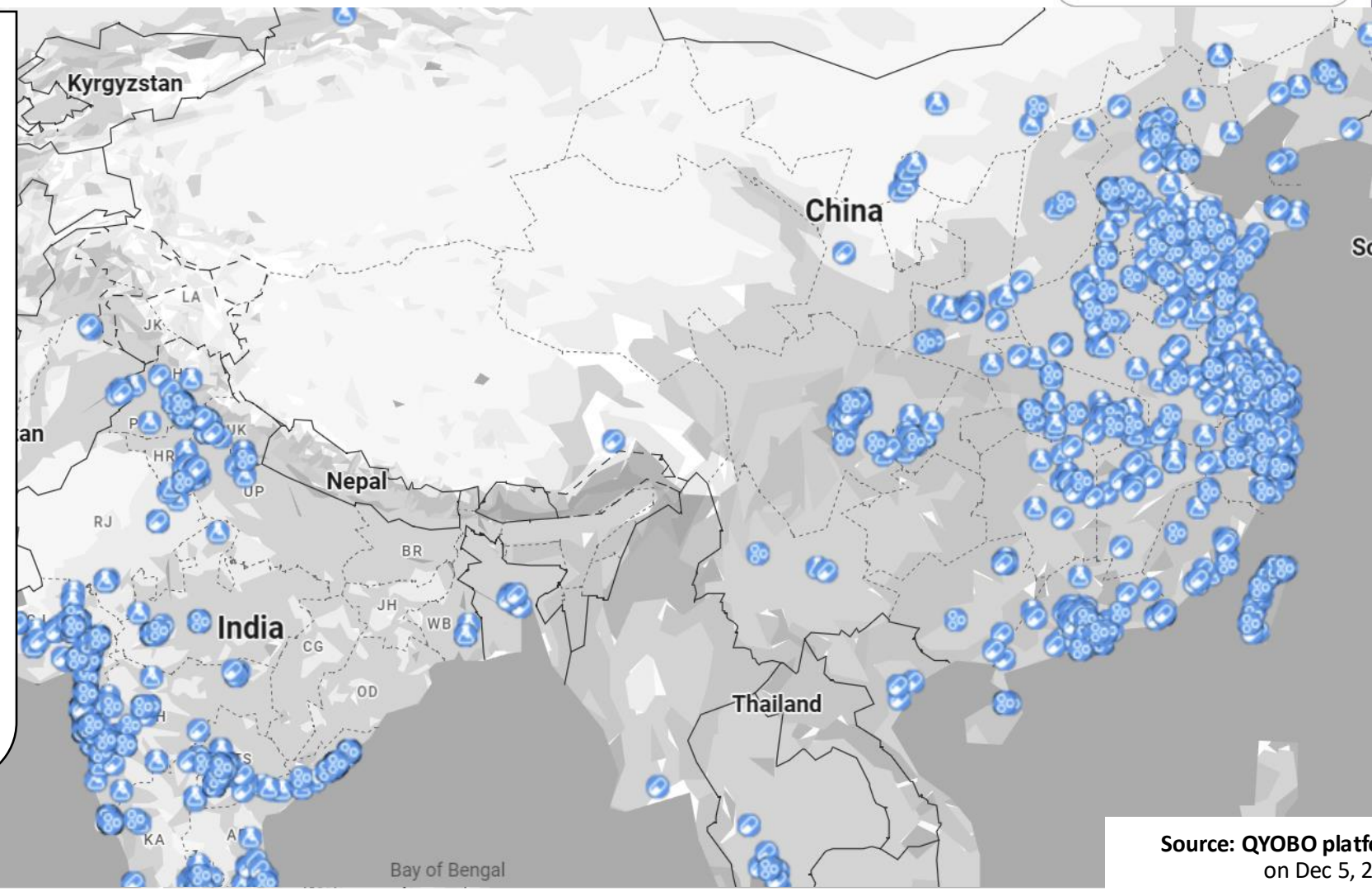
- India and China combined have roughly 1,000 pure API sites, roughly double the number of U.S. and EU combined



India/China Pharma Manufacturing Sites¹



Total = 2,497 sites (API includes IPI, inactive ingredients)

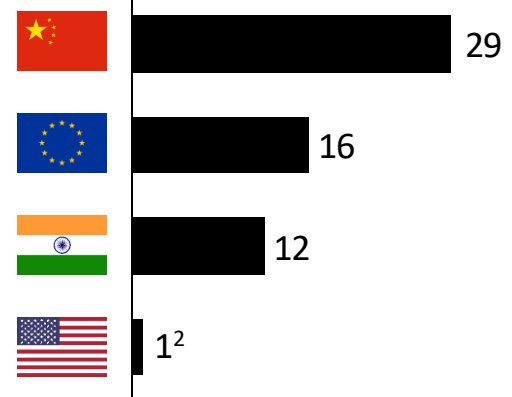


Source: QYOB0 platform
on Dec 5, 2025

- In some therapeutic areas, such as beta-lactam antibacterials, the U.S. is soon 100% dependent on foreign API manufacturing



Beta-lactam API Manufacturing Sites¹



Source: QYBO platform
on Dec 5, 2025

¹ Large, international sites suitable for international, not only domestic, supply
² CHEROKEE PHARMACEUTICALS LLC (RIVERSIDE) which is set to be closed

- In some therapeutic areas, such as beta-lactam antibacterials, the U.S. is soon 100% dependent on foreign API manufacturing



QYOBONews

To: Markus Felgenhauer >

Merck plans phased layoffs starting May as it winds down Cherokee (Riverside) plant

QYOBONews

Site closure

2025-03-15

Merck & Co. confirmed that approximately 163 workers will be laid off by July as part of a gradual shutdown of its Cherokee manufacturing plant in Riverside, Pennsylvania. The full facility closure is expected in 2026. The site is the last active manufacturing site for beta-lactam APIs in the USA.



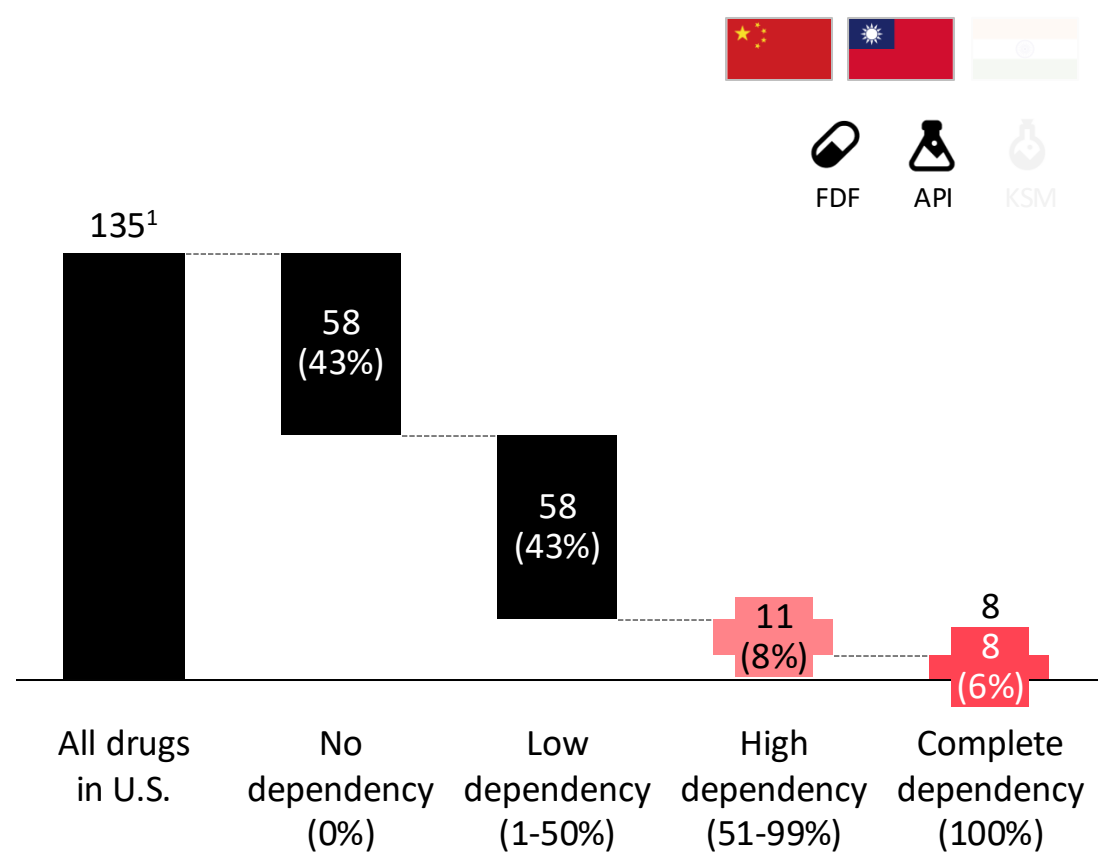
Source: QYOBONews platform
on Dec 5, 2025

Agenda

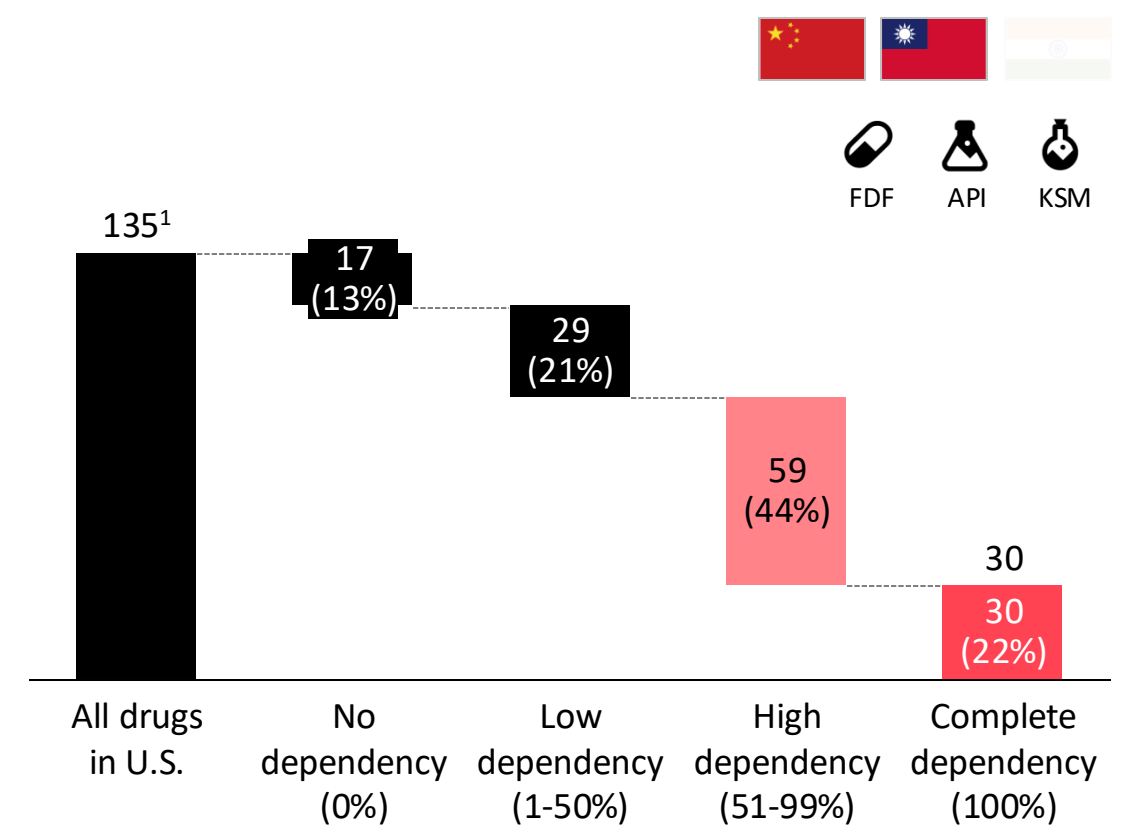
1. Approach by Governments
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2. Approach by Companies

■ **86 Essentials** – 6% depend entirely on FDF/API from China and Taiwan, which increases to 22% if KSMs are considered

All drugs – Supply chain dependency, %



All drugs – Supply chain dependency, %

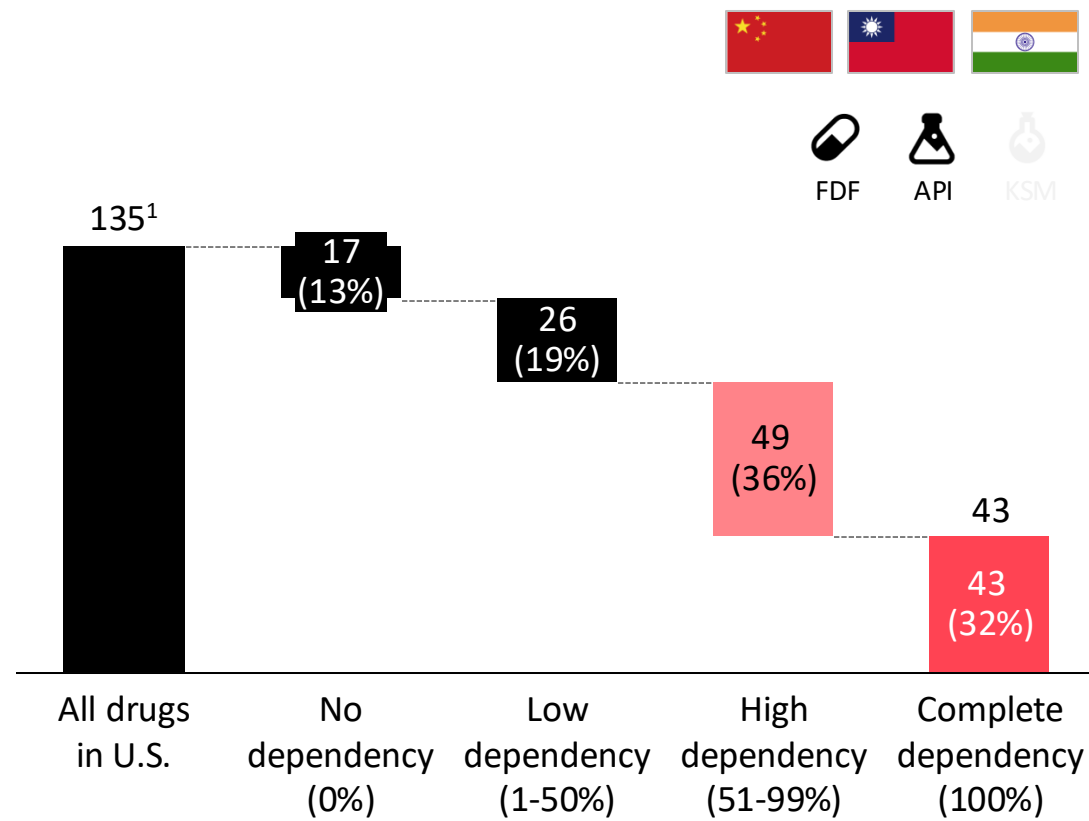


Source: QYOBO Platform as of January 18, 2026

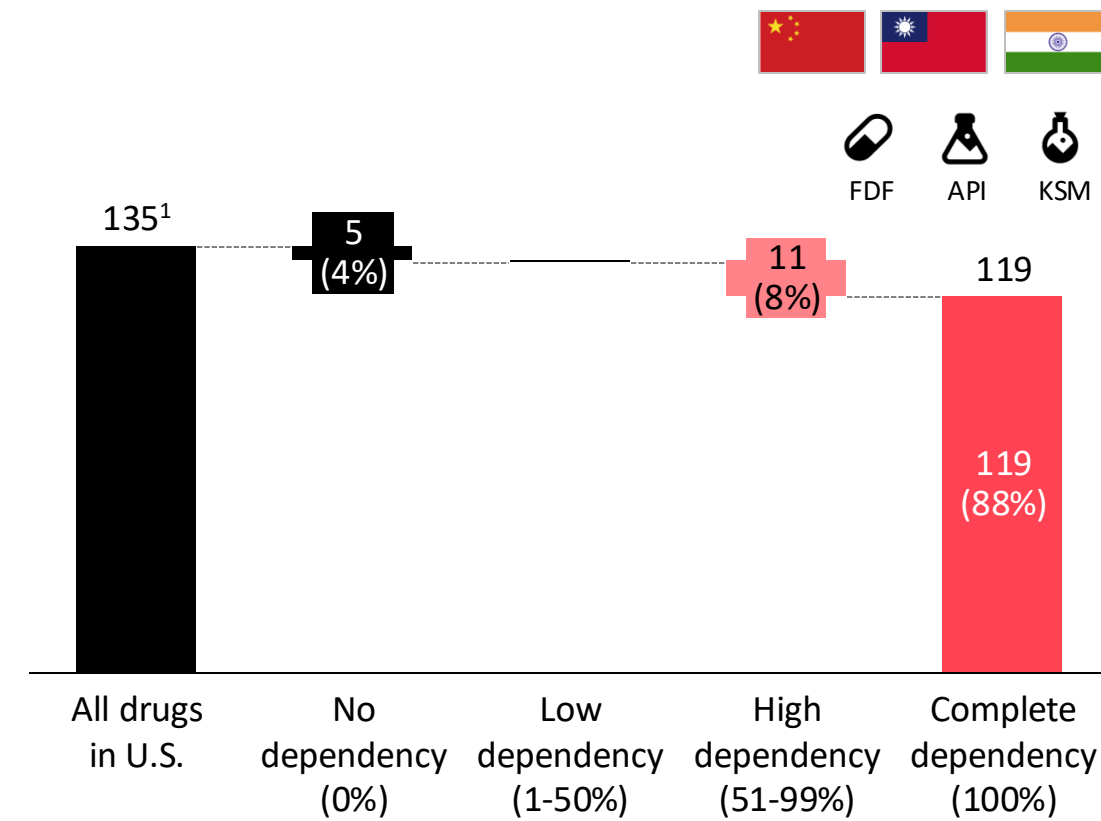
¹ The public list of 86 essential medicines contains API and administration route, but does not specify the dosage. Hence e.g. “Oral” is interpreted as “oral solids and solutions”, resulting in a higher number of drugs overall since capsules, tablets, oral films as well as syrups and solutions are counted separately.

- **86 Essentials** – 32% depend entirely on FDF/API from China, Taiwan and India, which increases to 88% if KSMs are considered

All drugs – Supply chain dependency, %



All drugs – Supply chain dependency, %



Source: QYOBO Platform as of January 18, 2026

¹ The public list of 86 essential medicines contains API and administration route, but does not specify the dosage. Hence e.g. “Oral” is interpreted as “oral solids and solutions”, resulting in a higher number of drugs overall since capsules, tablets, oral films as well as syrups and solutions are counted separately.

- U.S. Government is already taking action and is engaging with friendly nations as well as prioritizing products

 **QYOBO**

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Shionogi wins USD 119M BARDA award to build US antibiotic manufacturing plant

Investments 2026-04-08

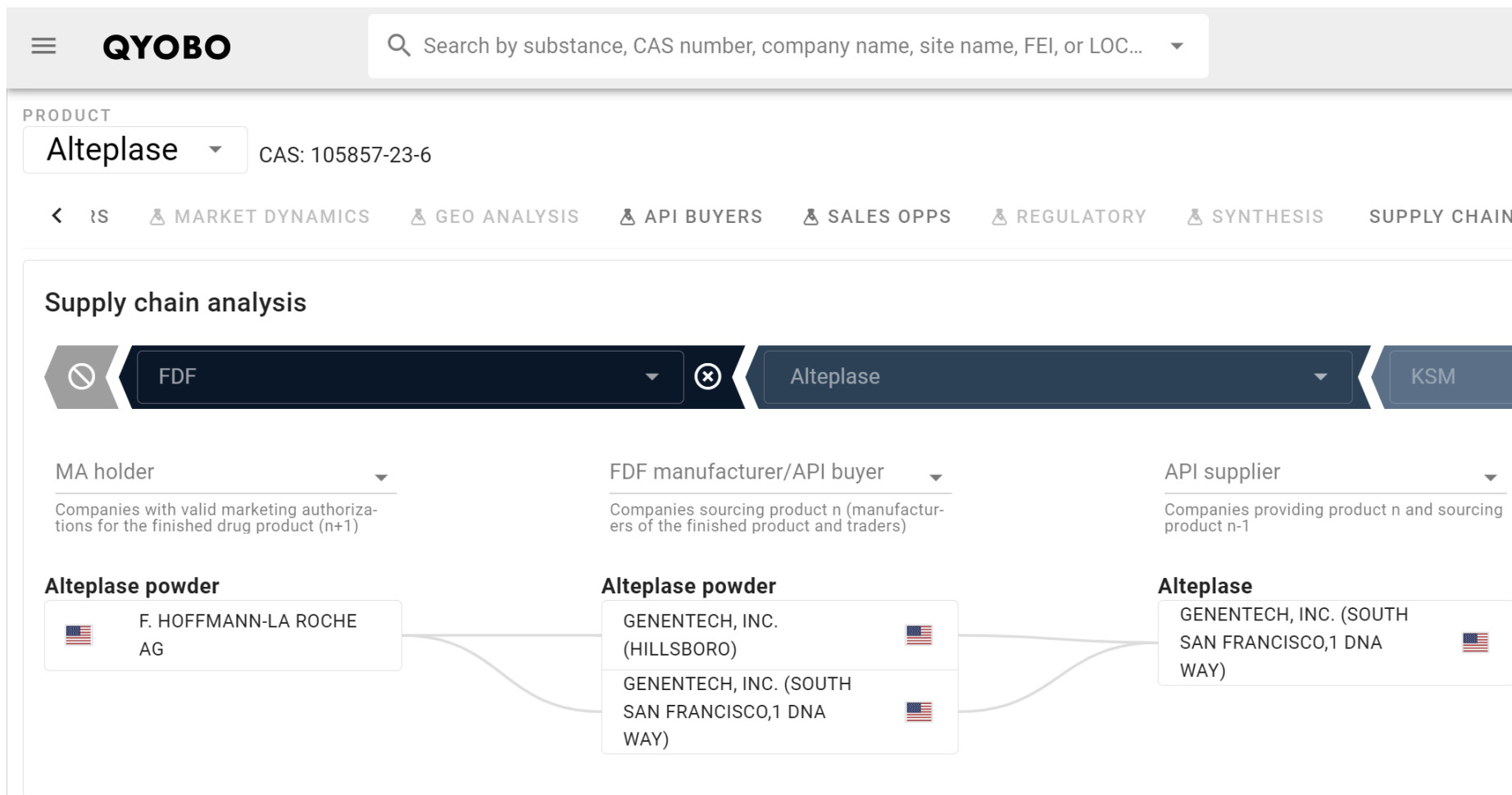
Shionogi has received a contract from BARDA under Project BioShield for its antibiotic Fetroja (**cefiderocol**) as a countermeasure against drug-resistant Gram-negative bacterial infections. The contract starts at USD 119 million with multiyear options totaling up to USD 482 million. Funding will support establishing US drug manufacturing, procurement, and advancing Fetroja for treating infections from high-priority bioterror pathogens including melioidosis and plague, plus expanding into pediatric indications.

Source: [Shionogi](#)

Agenda

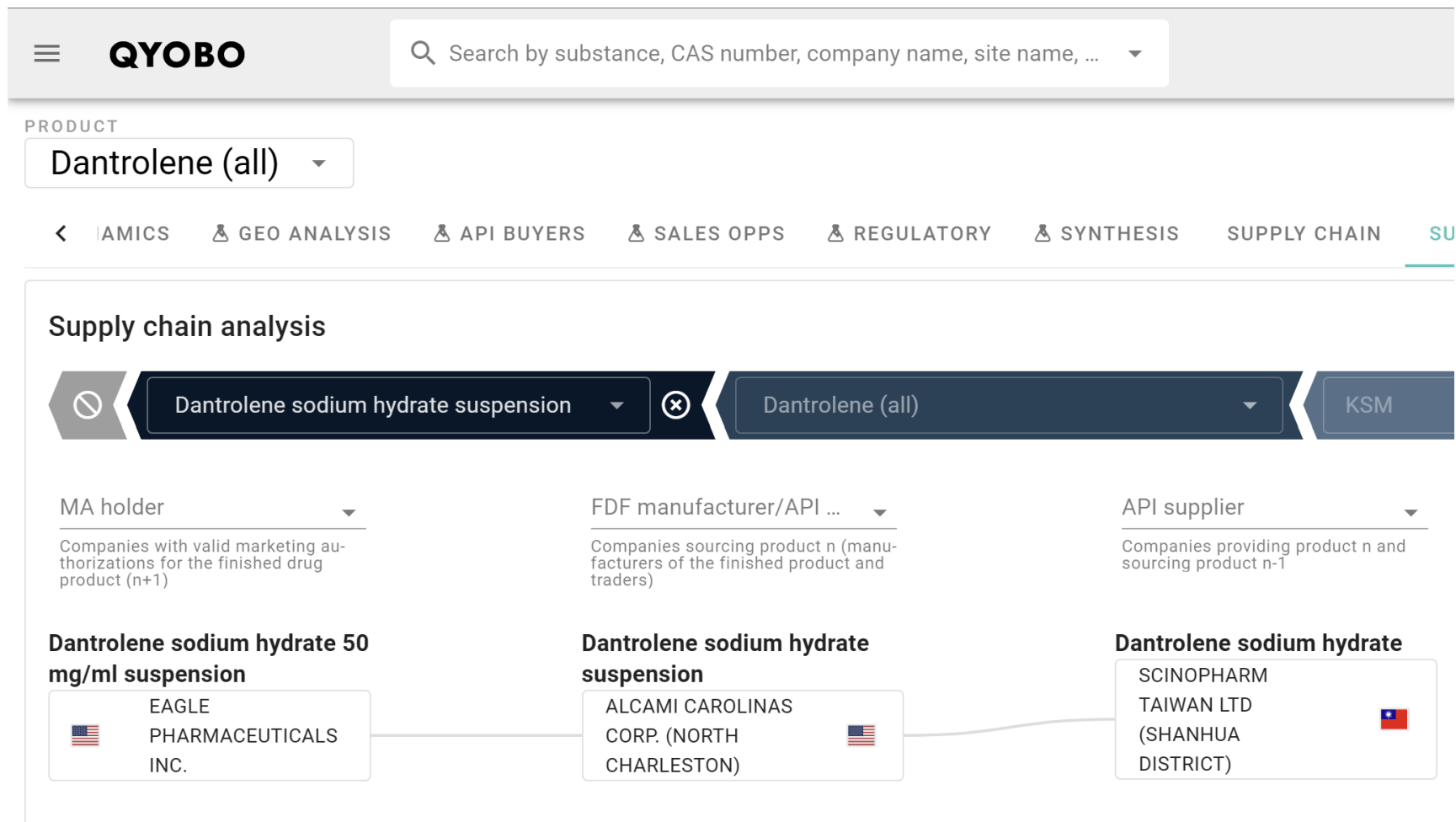
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Example 1 – 0% China/Taiwan dependent supply chain Alteplase powder for injection



Note:
Alteplase is made by CHO cells that are fed with glucose, hence there is no classic KSM

■ Example 2 – 100% China/Taiwan dependent supply chain Dantrolene sodium suspension



- While 21 companies sell Cefdinir capsules in the U.S., all are made at just three sites in India – one is under a warning letter since 2019



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SITE PROFILE

Corporate Group: [Redacted] **Active Warning Letter**

< API DEMAND REGULATORY **COMPLIANCE** SITE INSPECTIONS ESG >

USFDA - Inspection outcome November 23, 2022

Inspection outcome ● Non-compliant (OAI), with Form 483 issued

Form 483 16 observations

Investigators Rajiv R Srivastava, Thomas J Arista

Observations listed in Form 483

1. There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.
2. Appropriate controls are not exercised over computer or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel.
3. Written procedures are not established for evaluations conducted at least annually to review records associated with a representative number of batches, whether approved or rejected.
4. All records of production, control, distribution, components, and labelling associated with a batch of drug products were not maintained at least one (1) year after the expiration date.
5. Equipment used in the manufacture, processing, packing, or holding of a drug product lack appropriate design to facilitate operations for its intended use and for its cleaning and maintenance Specifically.
6. Routine calibration of automatic and mechanical equipment is not performed according to a written program design to assure proper performance.
7. The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed.
8. <censored> dosage forms are manufactured within Grade D (ISO 8) manufacturing areas / environment.

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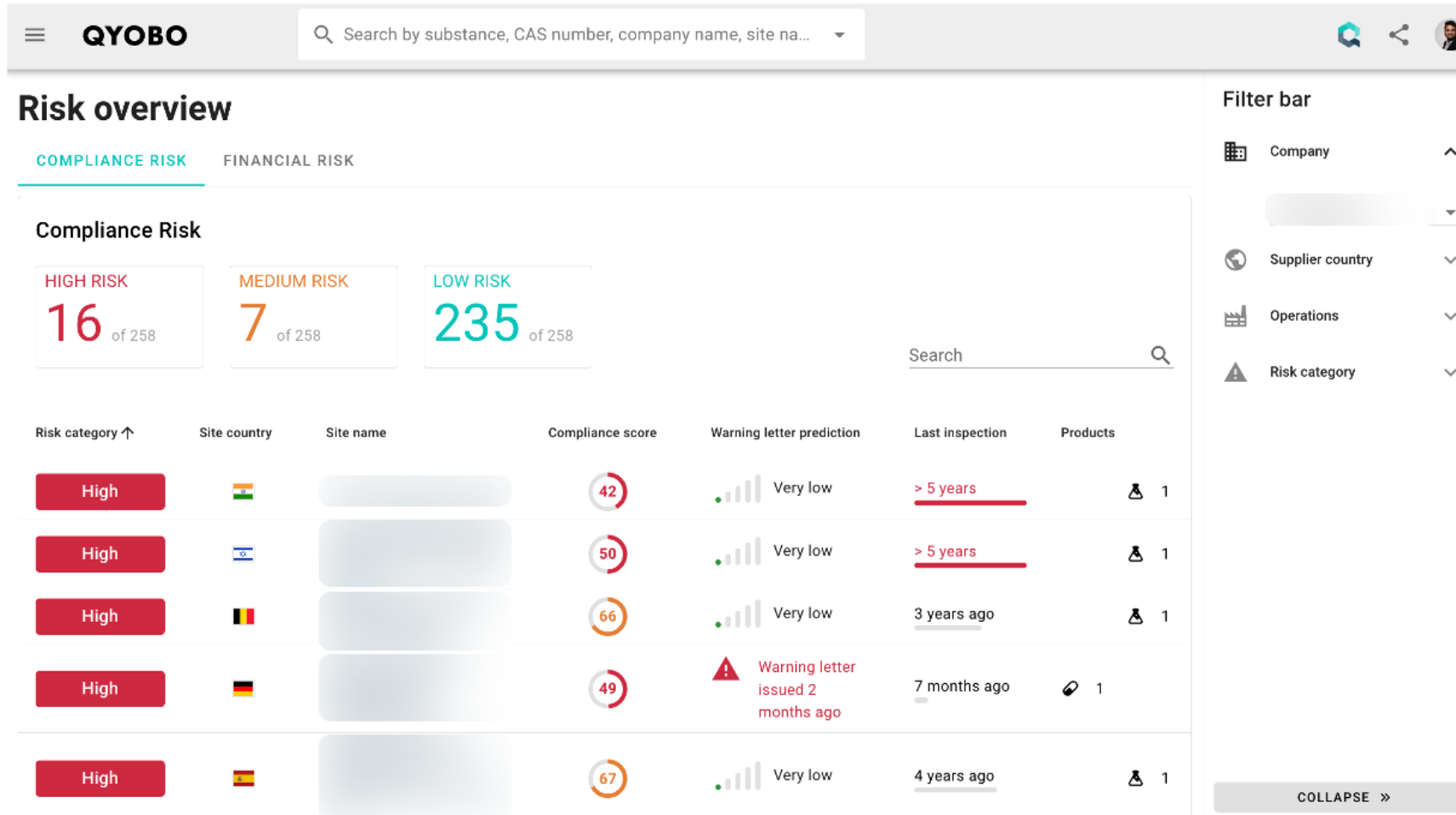
2. Approach by Companies

- A single non-compliance event can easily wipe off millions of business value for a company and their customer

Non-compliance event	Date, country and company	P&L impact, mUSD	Market cap. impact, mUSD
Warning letter	12-24  	-500	
Form 483	02-24  	-20*	-80
Form 483	12-23  		-600
Warning letter	11-23  		-700
OAI inspection	09-23  		-12,000
Warning letter	02-18  	-300	

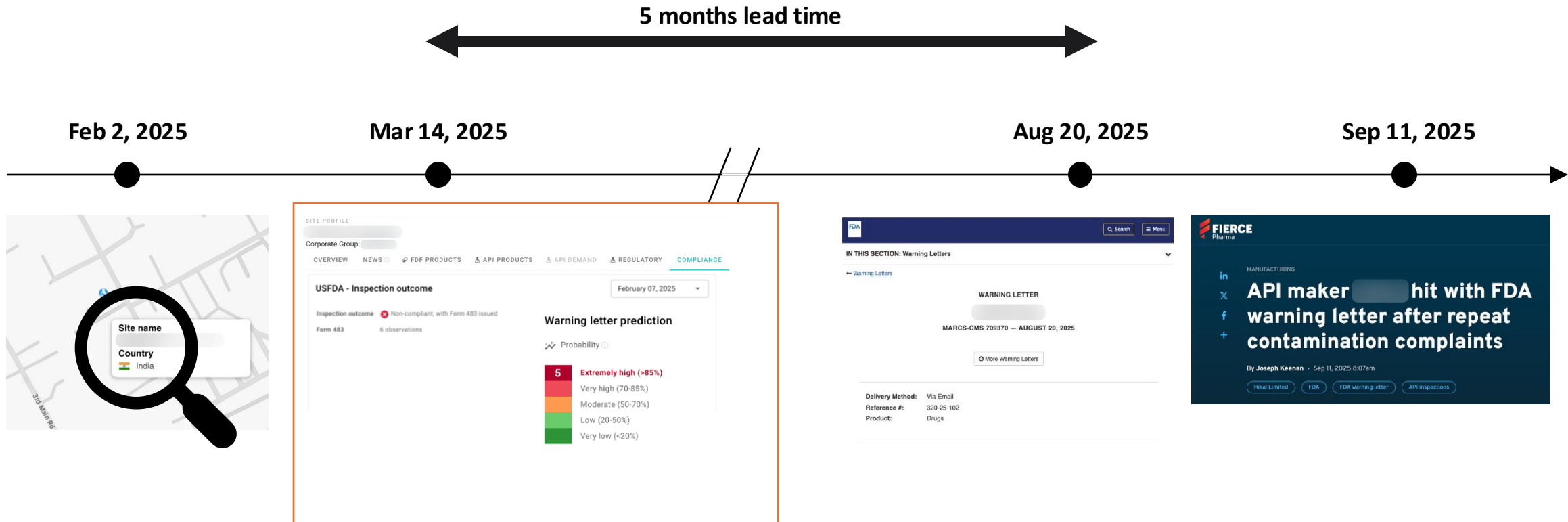
- Companies are “actively tracking” compliance risks for their supplier sites

[Anonymous Example]



- A Client learned about a GMP compliance failure five months ahead of time, and even triggered an internal audit right away

[Anonymous Example]



■ Key Takeaways



Supply chains are more transparent than ever

Mapping each supply chain is (extremely complex but) achievable.



Governments are already using this intelligence

Using intelligence to educate their decision and policy-making.



Pharma companies are going a step further

Leveraging geopolitical shifts to identify opportunities and safeguarding their supply chains by eliminating risks ahead of time.