Automating regulatory compliance with connected supply chain data

Neo4j GraphTalk Boston



Jonathan W. Lowe - *amalgo.ai* - 15 October 2026

For Halloween, let’s meet at the movie theater for a regulatory horror show…

Today’s nightmare includes:

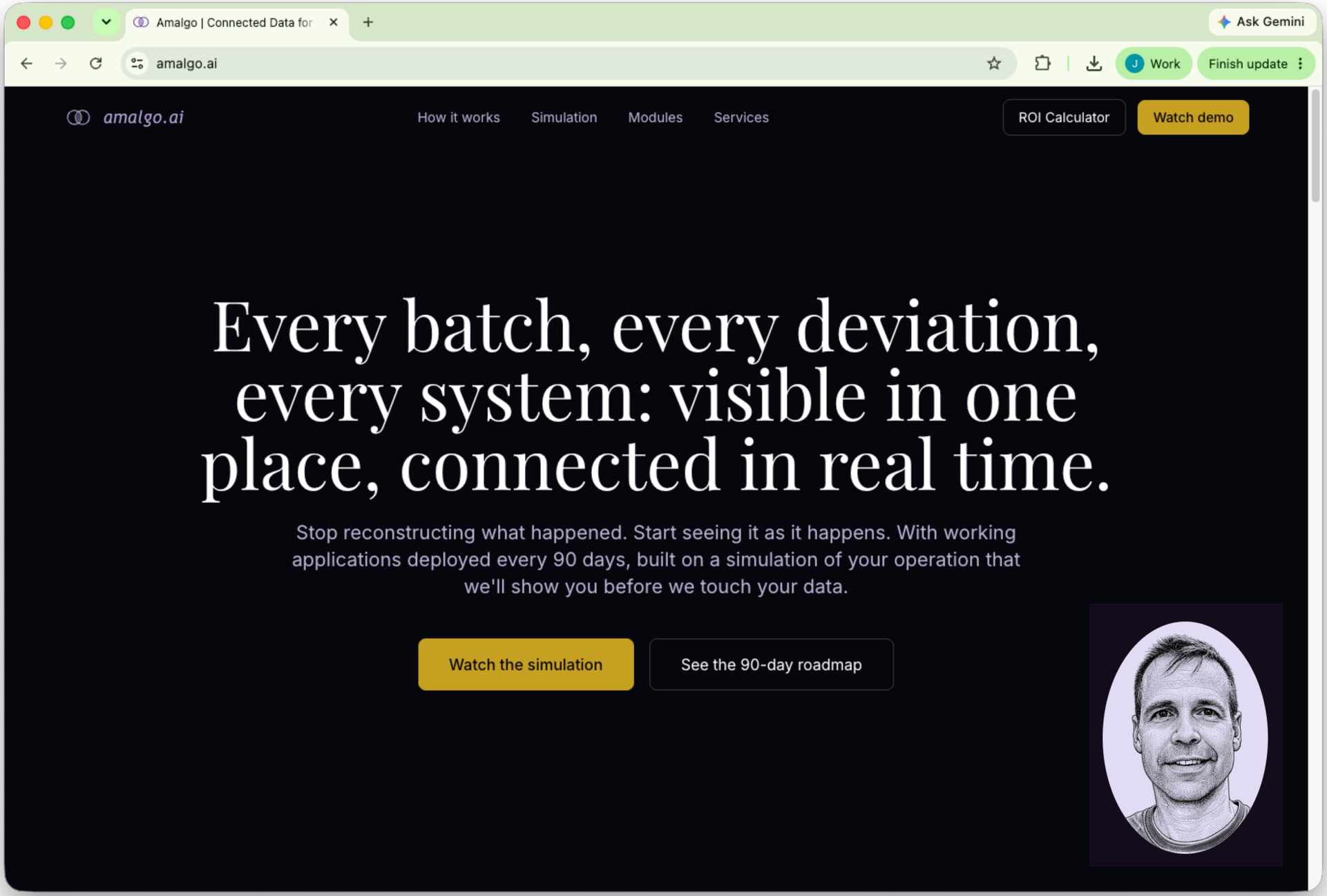
- **Nitrosamines** (NDMA) regulations that have haunted the biopharma industry for nearly a decade
- How to find Nitrosamines skeletons buried in biopharma **supply chains**
- How **connected data** can exorcise Nitrosamines, measure the damage and reduce financial fallout
- How AI **automates compliance** with spooky PFAS, heavy metal and packaging regulations by joining legal graphs to operations graphs

While our tale begins with a nightmare, the take-home comfort is that ***regulation is an accelerator to innovation***.



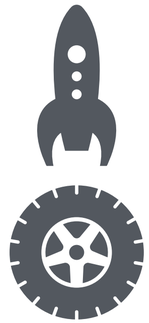
Hi, I'm **Jonathan Lowe!**

- Analytic solution developer for 30 years
- Biopharma industry colleague for 7 years
- At Pfizer, I led a team of 200 data scientists and developers that:
  - Increased efficiency of manufacturing, quality and supply chain operations
  - Consolidated data, built tools and revealed insights to operators
  - Got medicines to patients faster
- Today, I run a software and services company called **amalgo.ai** that:
  - Helps clients connect operations across departmental gaps and siloed systems
  - Guides mission-critical end-to-end decisions





What regulations for Nitrosamines (NDMA) have haunted the biopharma industry for nearly a decade?



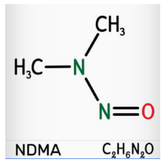
Discovery: From dry cleaning to deadly tumors

Nitrosamines are first synthesized and described by chemist **Otto Witt**



1878

British scientists **John Barnes and Peter Magee** conduct routine toxicity screening on **N-nitrosodimethylamine (NDMA)**, a proposed new solvent for dry-cleaning.



1956

Screening reveals that NDMA is **profoundly hepatotoxic** and causes aggressive, malignant liver tumors in rats

1956

Magee, Hermann Druckrey, and others test across multiple animal models

1957

90% of all tested nitrosamines prove to be potent **carcinogens**

1957

Compounds are dangerous when **metabolized by enzymes in the liver** (specifically Cytochrome P450)



1958

Compounds break down into highly reactive diazonium ions that bind to and **permanently mutate DNA**

1958



1959-1969

But… public is largely unaffected because Nitrosamines are restricted to **specialized industrial manufacturing** like rocket fuel or rubber vulcanization

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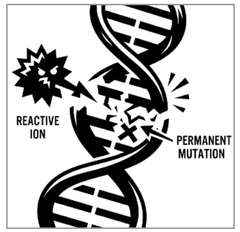
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1970's: The food and consumer scare



1970

Crisis in Norway: mysterious wave of **lethal liver disease** strikes farm animals and mink



1970

Investigators trace source to herring meal (fish food) **preserved using sodium nitrite**

1970's

Scientists realize **nitrites** (common preservatives) easily react with **amines** (abundant in meat) under heat or acidic conditions to spontaneously generate NDMA

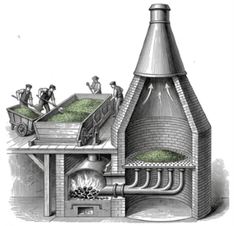
1970's

Researchers find nitrosamines in:
Cured meats
Beverages
Tobacco



1970's

Food science quickly pivots and regulators lower allowable nitrite levels



1970's

Manufacturers add **Vitamin C (ascorbic acid)** or erythorbic acid to cured meats to chemically block conversion of nitrites into nitrosamines

1970's

Breweries change kilning methods to dramatically reduce nitrosamines in beer

2000's

Nitrosamines come to be considered a **controlled, historic problem**

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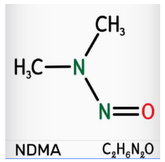
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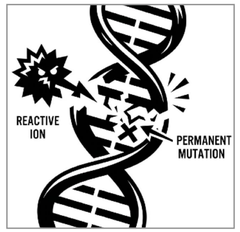
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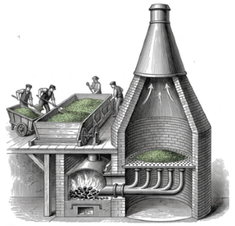
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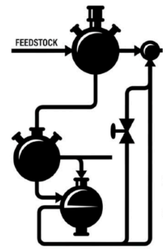
2000's

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2018-present: The pharmaceutical crisis

June 2018

US FDA and European regulators find massive, unacceptable levels of NDMA in **Valsartan**, a widely prescribed blood pressure medication



2018

Investigation reveals a change in chemical synthesis of the **active ingredient** at a manufacturing plant accidentally creates amines and nitrites in the factory solvents



2018-2022

Nitrosamine impurities discovered in several blockbuster drugs



2018-2022

Massive **global recalls** of:
Sartans (Losartan)
Ranitidine (Zantac)
Metformin (Glucophage)
Varenicline (Chantix)

2023-Today

Regulators require drug companies to complete **exhaustive risk assessments** of their chemical pathways to guarantee nitrosamines stay below **strict daily intake thresholds**

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For drug manufacturers, the financial fallout of Nitrosamine recalls unfolded in a devastating, multi-layered timeline

1

Immediate Operational Shock

When a manufacturer detects a Nitrosamine impurity exceeding the ultra-strict (often nanogram level) regulatory threshold, they face a sudden and costly operational halt.

- **Logistics and Destruction:** Companies must physically retrieve, quarantine, and certify hazardous waste destruction of millions of tablets through rapid, voluntary nationwide recalls, which can easily cost **$10 million to $100 million** in direct loss per event.
- **Generic Margin Crush:** For producers of low-margin generic commodities, the cost of developing specialized testing methods, validating equipment, and filing new regulatory paperwork often **exceeds an entire year's profit** for that medicine.

2

Supply Chain Paralyzation

Unlike typical contamination cases caused by a dirty factory or single bad batch, Nitrosamine formation often happens when specific chemical solvents unexpectedly interact with the drug's active ingredients during storage…

- **The Sourcing Domino Effect:** When an active pharmaceutical ingredient (API) from a supplier is flagged, a cascade occurs. Every downstream brand, packager, and distributor utilizing that API must immediately **freeze their supply chains**.
- **Market Share Forfeiture:** While a manufacturer halts production to reformulate their drug or find a new supplier, the market moves on. Competitors who avoided the impurity quickly step in, permanently eating away the affected manufacturer's **market share**.

3

Multi-Year Litigation Tail

The ultimate financial reckoning hits years after the physical recall, when class-action lawsuits and corporate settlements mature.

- **Billions in Legal Charges:** The litigation tail is heavily documented among industry giants. UK pharma leader GSK agreed to pay up to **$2.2 billion** to settle roughly 80,000 U.S. state court lawsuits tied to Nitrosamines in the heartburn drug Zantac.
- **Widespread Settlements:** Similarly, Sanofi recorded a **$100 million** settlement for thousands of related claims, while Pfizer settled 10,000 cases under confidential terms.
- **Reputational Damage:** These corporate payouts do not even include the invisible damage to a brand's reputation and subsequent **drops in stock equity**.

With strict global regulatory implementation deadlines, manufacturers continue to pour massive capital into real-time monitoring and chemical redesigns to avoid the next catastrophic recall.



How to find Nitrosamine skeletons buried in biopharma supply chains?

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C-Suite: “Trace our genealogy for NDMA origins, impacts & remedies!”

Isolate and test every possible point of origin where nitrites could react with amines across our entire **recipe genealogy**!

Measure the Nitrosamine levels downstream of the origin points and identify all impacted finished goods batches!

Never say “recall”

Hurry up.

Inventory all batches we are shipping to all markets, find any we can reroute to other markets and report on the monetary costs and savings!

The lofty C-Suite



As you wish…

How will I do all this?!

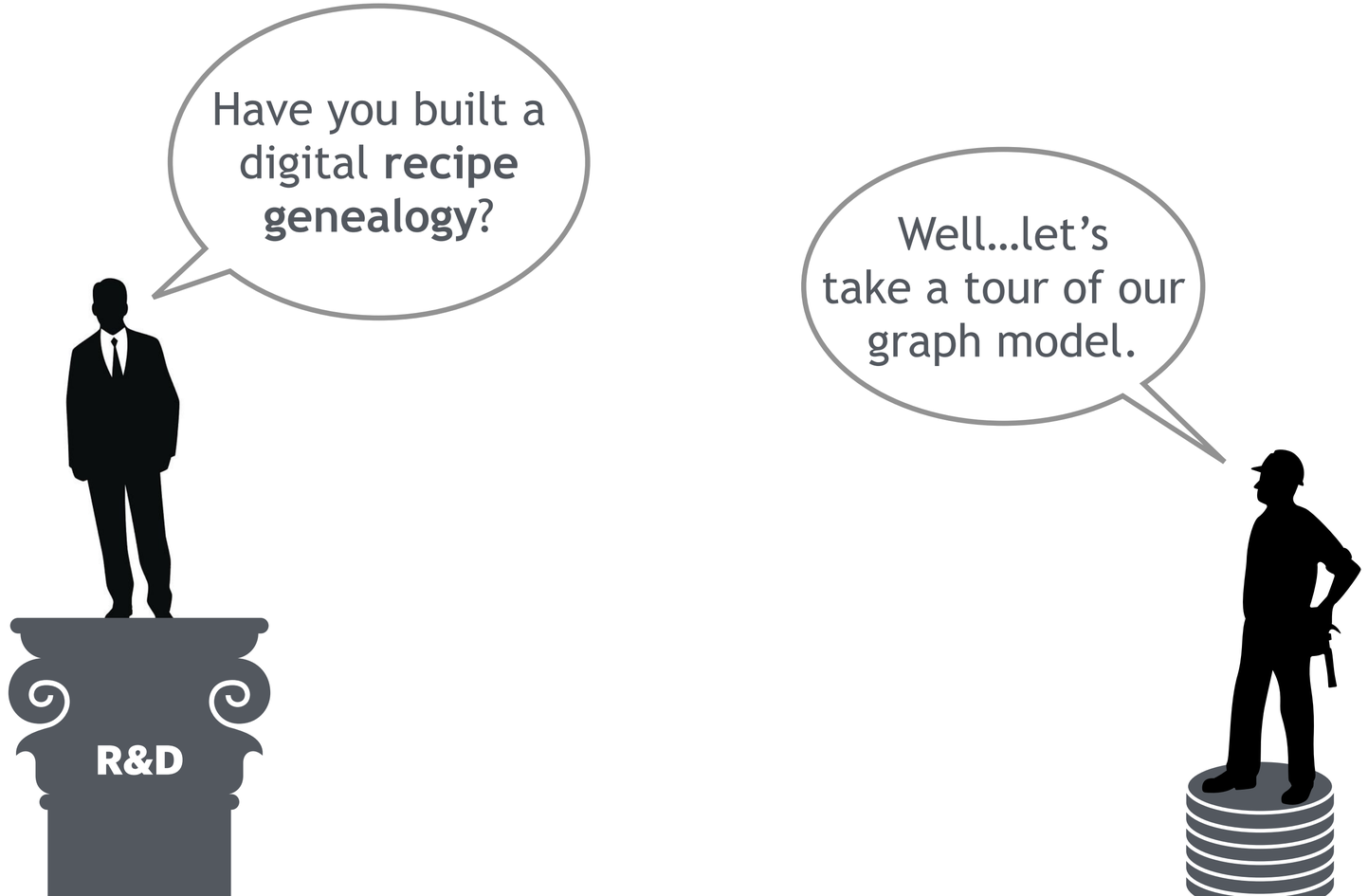


The humble Builder

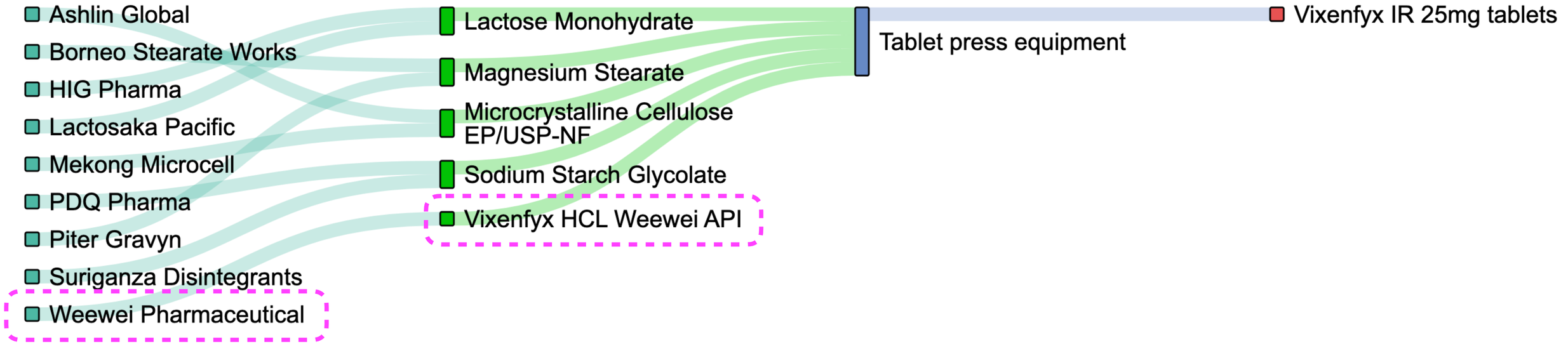
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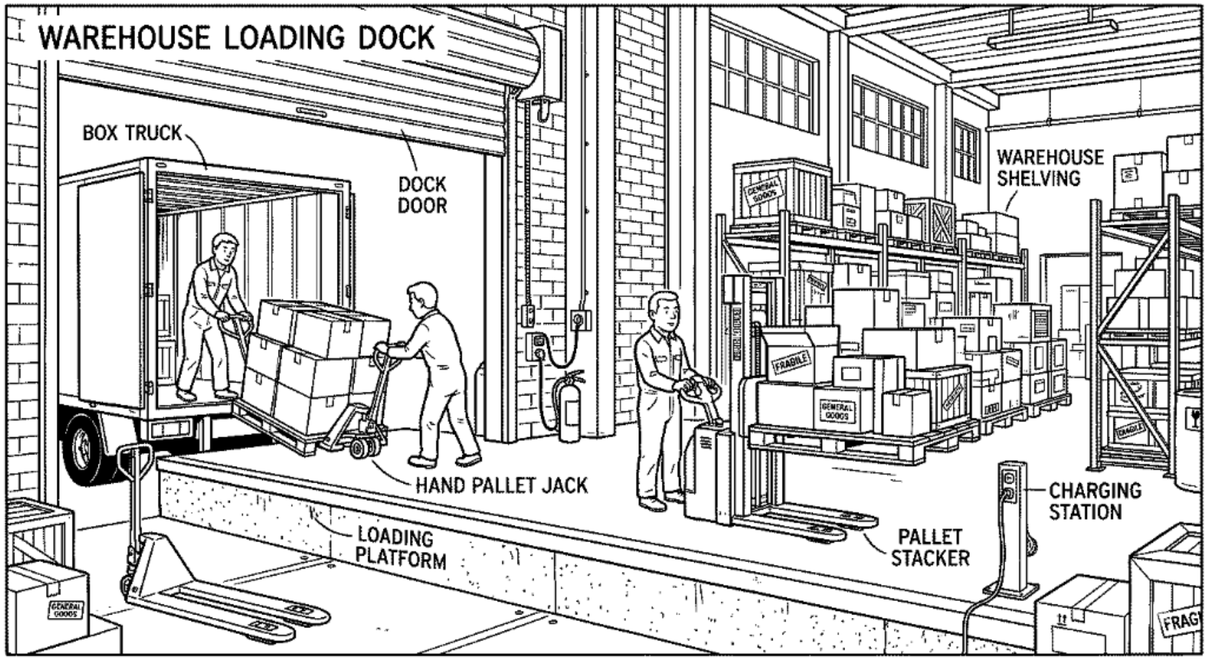
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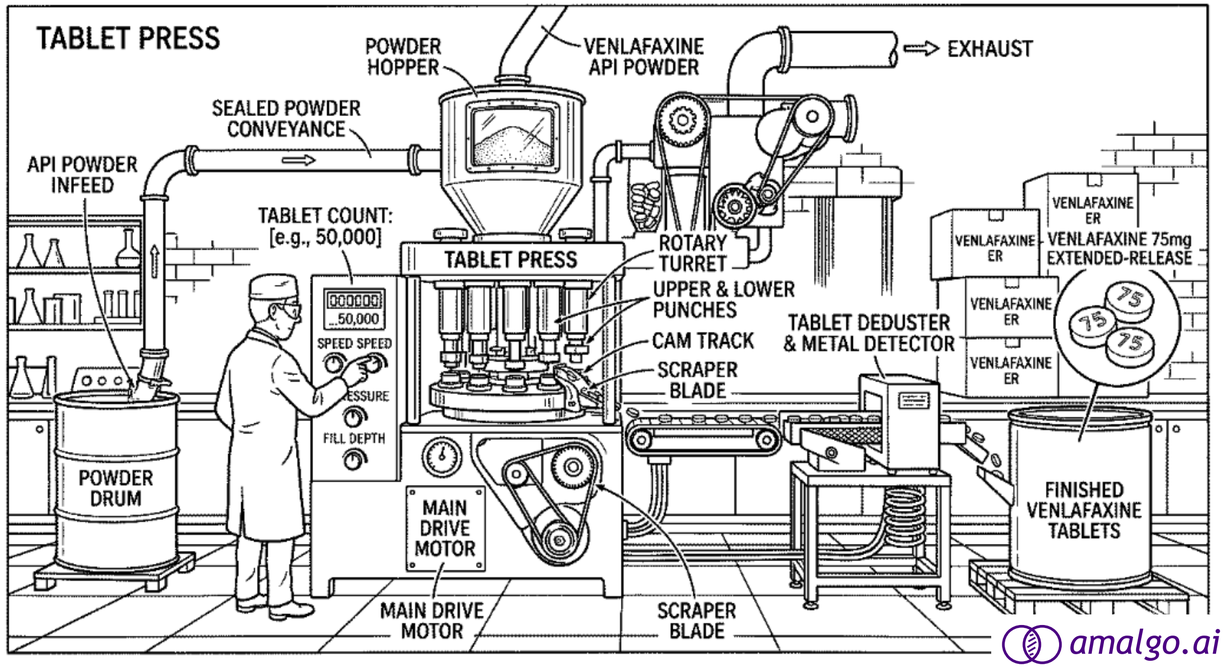
Maybe you’re wondering: What exactly *is* a recipe genealogy in the first place?



Vendors, raw materials & drug substance (API) —> drug product

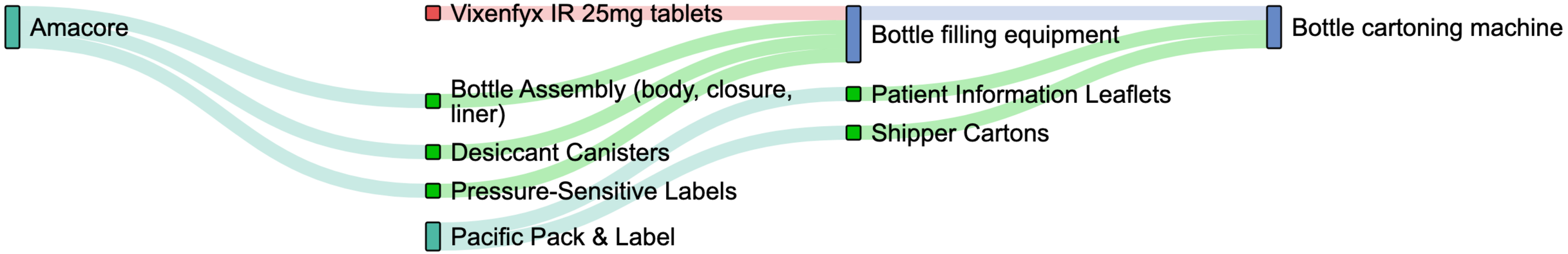


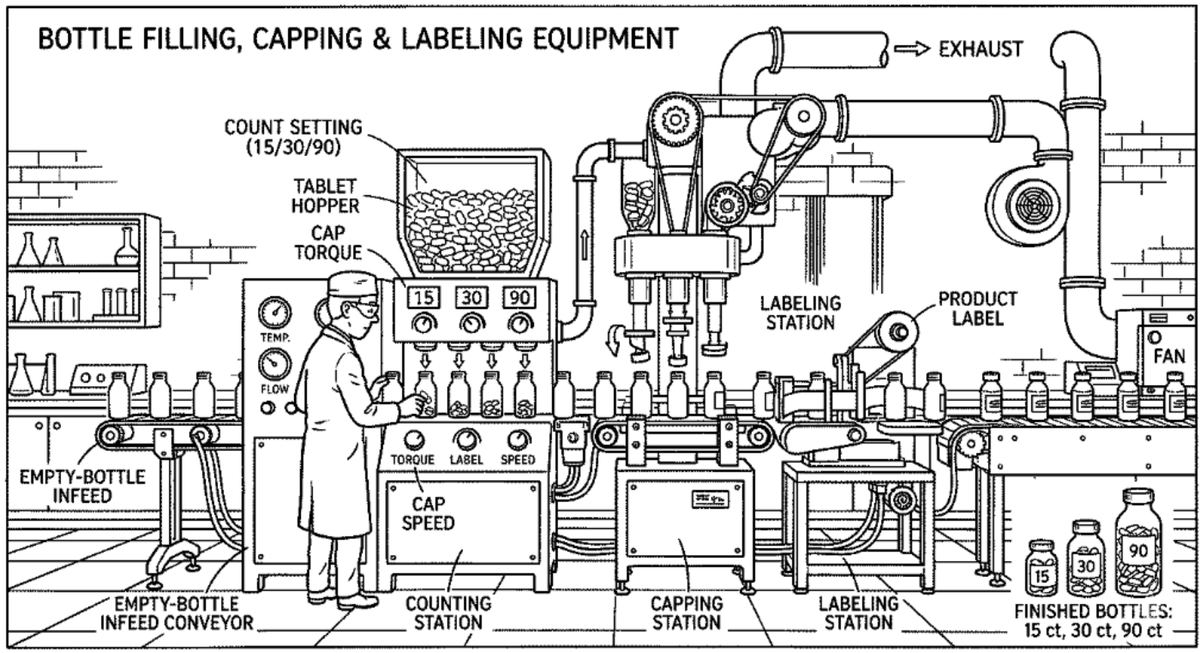


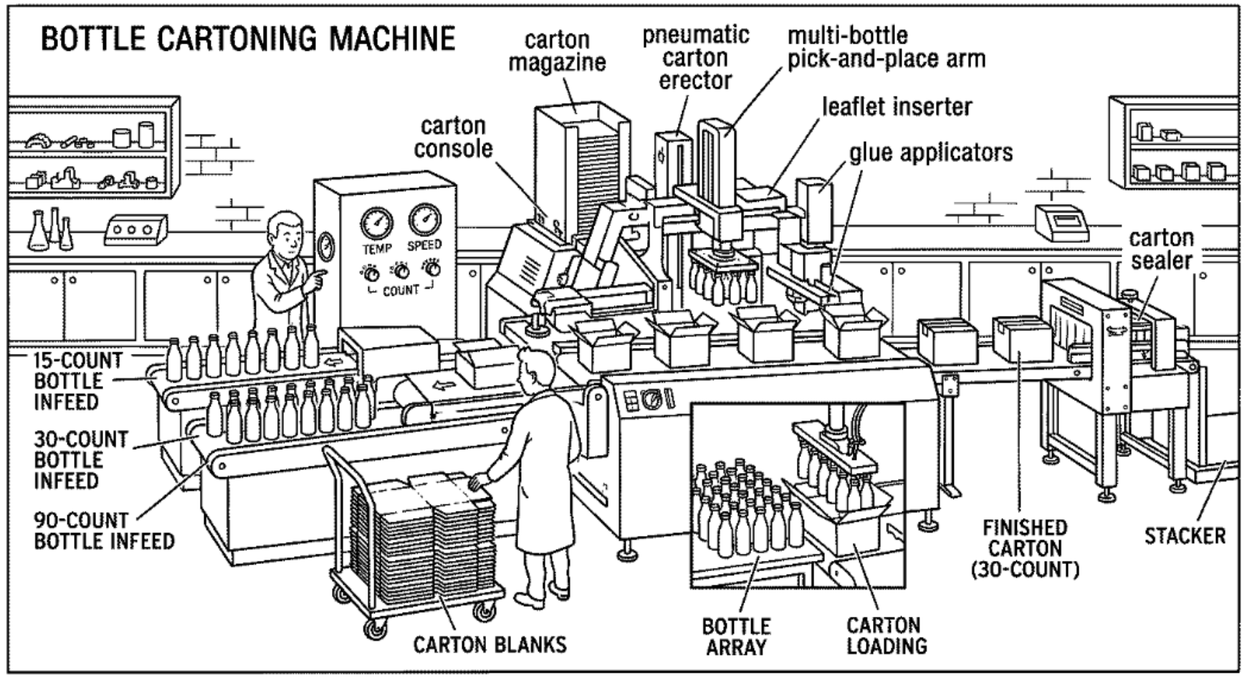


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Drug product —> (primary) packaged product

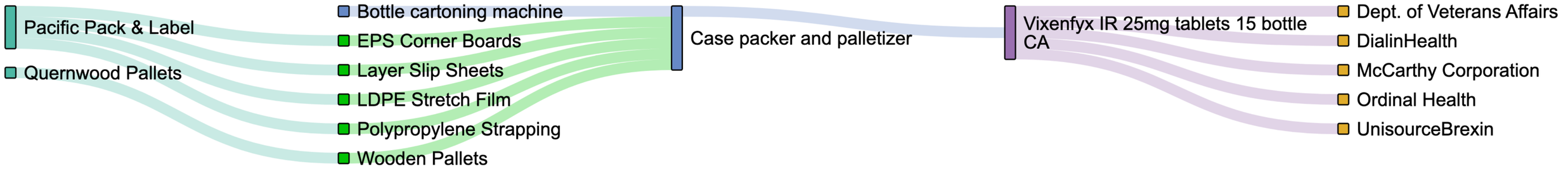


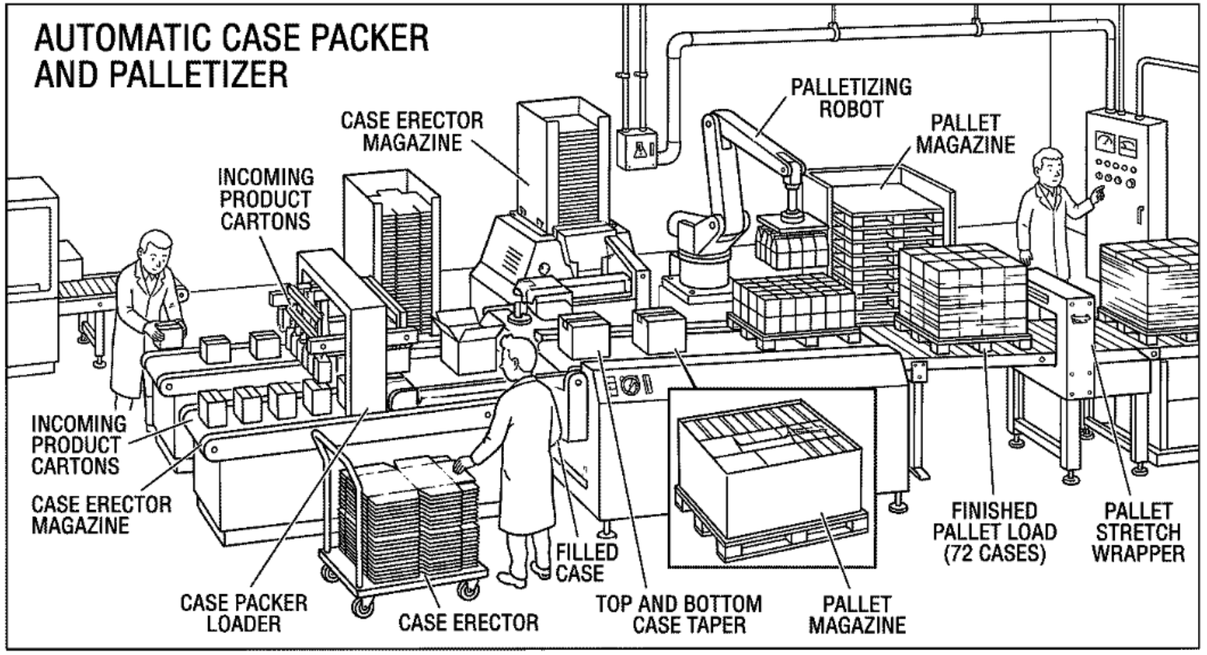


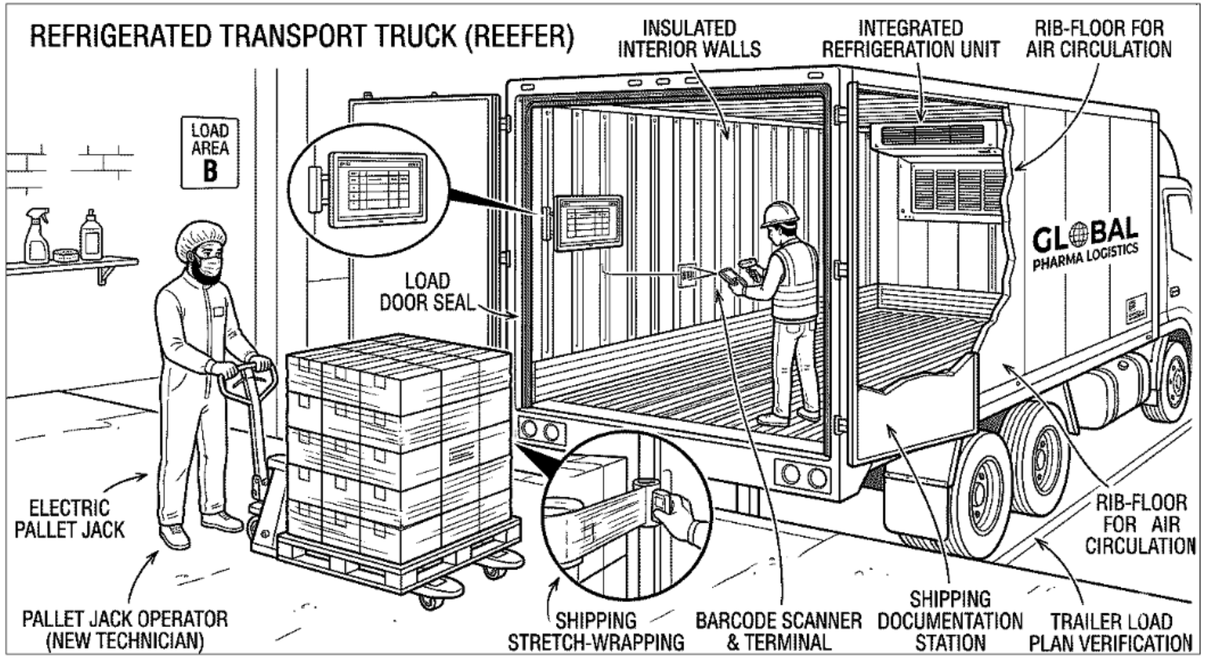


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Primary packaged product —> finished packaged product

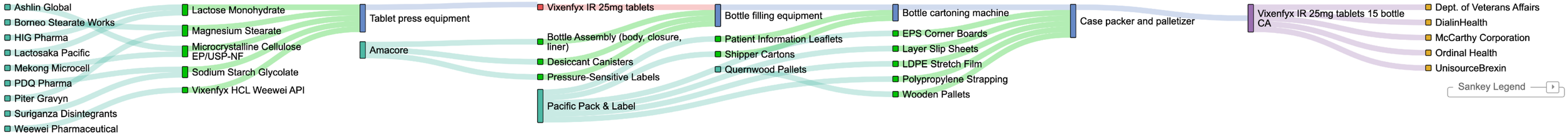


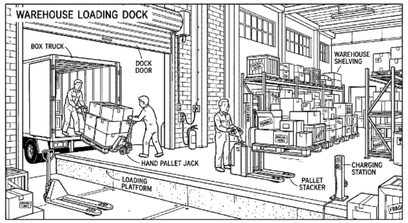




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Sankey Factory: Site | **Material** | Batch | Scroll — Vixenfyx IR 25mg tablets 15 bottle CA — Batches: **25**





Receiving Clerks:
- Caitlin Martin
- Clare Johnson
- Corey Macmillan
- Glen Fraser
- Kathleen Pritchard
- Peadar Cairns
- Rachelle O'Hehir
- ராஜலட்சுமி தங்கம்மாள்

Vendors:
- Weewei Pharmaceutical
- Ashlin Global
- Amacore
- Capsugrill (Linzo)
- Collocarn
- Olloy Corporation
- Medanex
- HIG Pharma
- PDQ Pharma
- Piter Gravyn

Raw Materials: $921,470

Lead Time: 25-30d

API (Vixenfyx HCl): $80/kg

MCC: $3.50/kg

HPMC: $8/kg

HPMC 6CPS: $10/kg

Ethylcellulose: $6/kg

DCM: $1.10/kg

Methanol: $0.70/kg

Lactose: $2.50/kg

SSG: $6/kg

MgSt: $3.50/kg

Packaging: $0.25/ea

Labels: $0.05/ea

Gelatin Capsules: $0.012/ea

API/MCC ROP: 300M / Qty: 500M

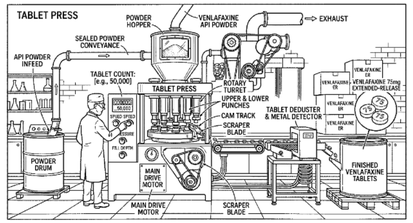
HPMC/EC/DCM/Methanol ROP: 75M / Qty: 100M

Lactose ROP: 300M / Qty: 500M

SSG ROP: 60M / Qty: 100M

MgSt ROP: 25M / Qty: 50M

Packaging/Labels/Caps ROP: 75M / Qty: 100M



Production Shift Leads:
- Arran Dermody
- Ayesha McCool
- Bronagh O'Kieve
- Ciaran Marren
- Clara Meldon
- Colin Lloyd
- Daliono Manullang
- Enya Phayre
- Gillian Courtney
- Ian Hussain
- Maurice White
- Paula Harvey
- Samantha Quinn
- நன்மணி வுபீர்
- வசுமதி பச்சையம்மாள்
- 雪梅 梁

Cost: $18,456

Time: 153.8 hrs

Capacity: 1,000,000 tablets

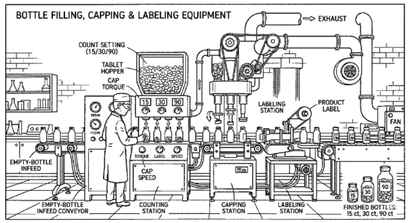
Cycle: 60 min

Throughput: 250M/batch

Rate: $120/hr

Changeover: 0.15 hrs

Batch: 100M units



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Cost: $1,992

Time: 24.9 hrs

Packaging: $3,068/batch

Bottle assy: $2,050

Desiccant: $85.96

Labels: $932.15

Capacity: 400 bottles

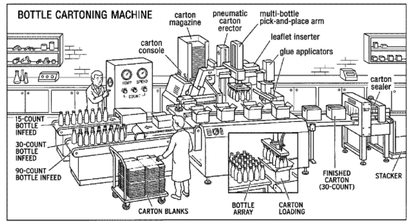
Cycle: 1 min

Throughput: 6.9M-41.5M/batch

Rate: $80/hr

Changeover: 0.1 hrs

Batch: 25-40 units



Production Shift Leads:
- Ayesha McCool
- Bronagh O'Kieve
- Clara Meldon
- Maurice White
- 雪梅 梁

Cost: $507.00

Time: 7.8 hrs

Packaging: $706.29/batch

Leaflets: $669.29

Shipper cartons: $37.00

Capacity: 2 cartons

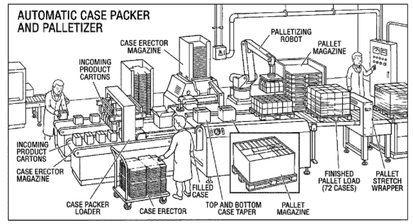
Cycle: 1 min

Throughput: 72 cartons/batch

Rate: $65/hr

Changeover: 0.25 hrs

Batch: 18 units



Production Shift Leads:
- Arran Dermody
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- Enya Phayre
- Paula Harvey

Cost: $286.00

Time: 5.2 hrs

Packaging: $105.94/batch

Slip sheets: $8.64

Pallets: $84.48

Stretch film: $7.20

Corner boards: $4.32

Strapping: $1.30

Capacity: 1 pallet

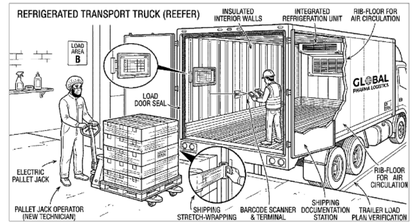
Cycle: 4 min

Throughput: 6 pallets/batch

Rate: $55/hr

Changeover: 0.15 hrs

Batch: 18 units



Shipping Coordinators:
- John King
- Levi Marques
- Maria Helena Moura
- Orfhlaith McTernan

Warehouse Operators:
- Ana Vitória Guerra
- Bernard MacGurk
- Christine O'Donnell
- Danielle Jones
- Guy Hudson
- Hamish Fitzsimons
- Hannah Clarke
- Irene Edwards
- Janet Pritchard
- Joanna Long
- Jodie Stewart
- Joseph Davies
- Joshua Creedon
- João Lucas da Cruz
- Kirk Durkin
- Martin Bishop
- Nicole Monteiro
- Rosemary Long
- Seanan O'Callaghan
- Sophie Siqueira
- Tamara Birmingham
- Trevor Gaynor
- Trevor Kelly
- Trevor O'Loughlin
- Tristan McLaughlin
- ஸ்தியா எழிற்குமரி
- ஸ்ரீகாந்த் வுரணி
- 娟 顾
- 玉华 高
- 玉梅 李

OTIF: 99%

Transit: 13.9d

Domestic: $800.00/shipment

EU: $1,500/shipment

Near Intl: $2,500/shipment

Long-haul: $5,500/shipment

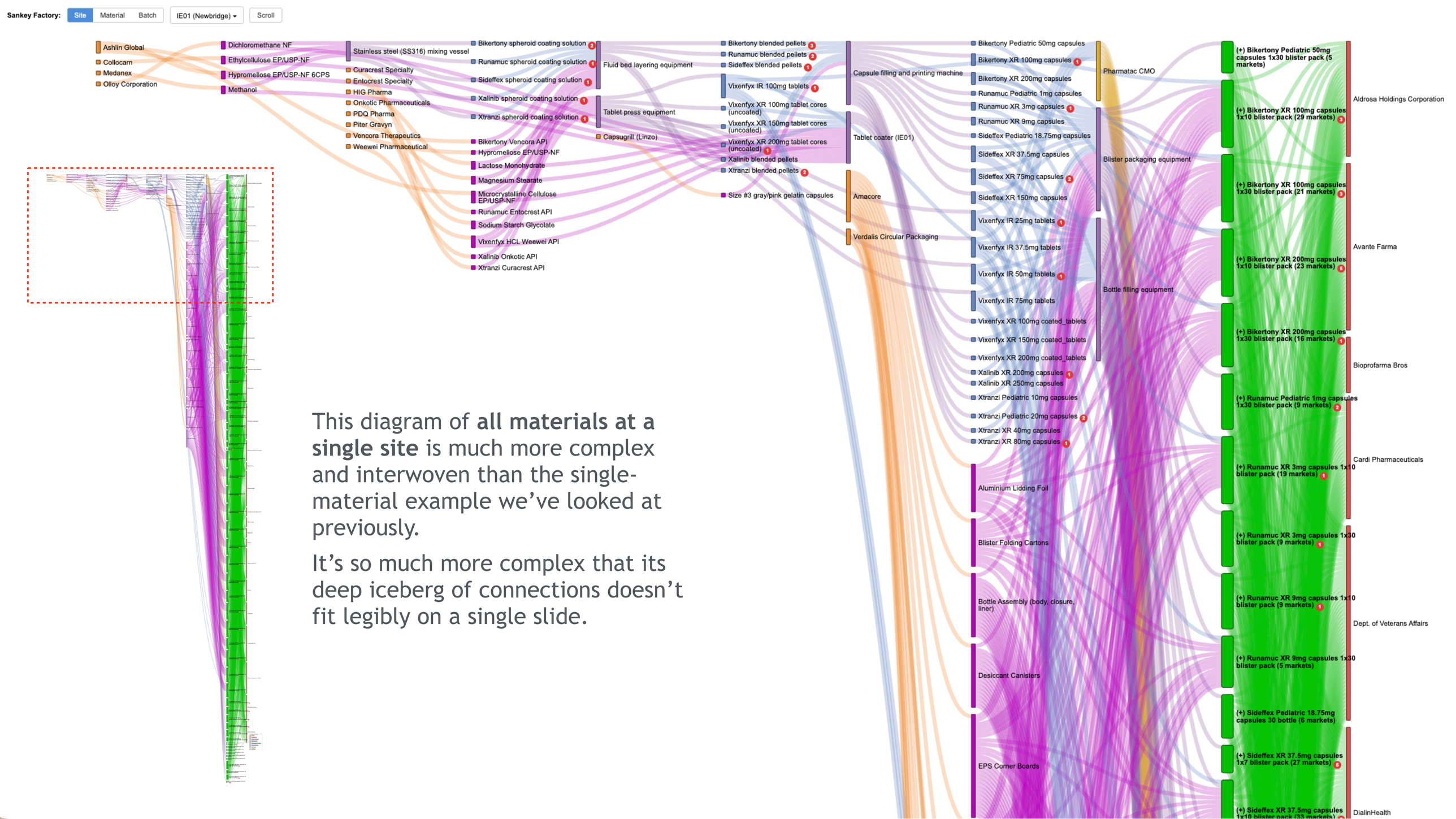
Customs: $350.00/shipment

Demand: NA 48%, EMEA 34.5%, APAC 15%, SA 2.5%

Pallets/Truck: 26

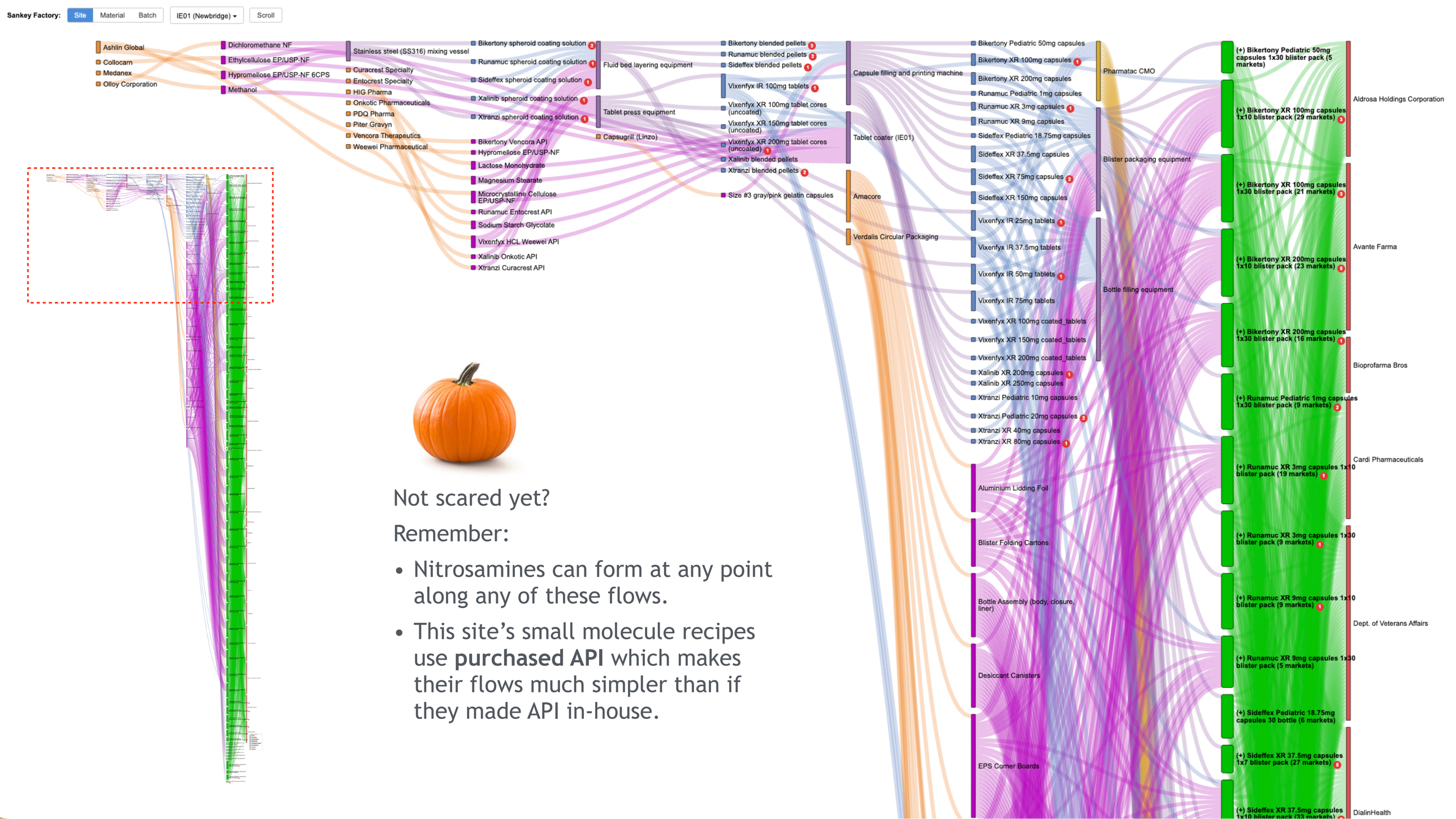
The detailed inventory shown here covers only **one material's** operations...

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This diagram of **all materials at a single site** is much more complex and interwoven than the single-material example we've looked at previously.

It's so much more complex that its deep iceberg of connections doesn't fit legibly on a single slide.

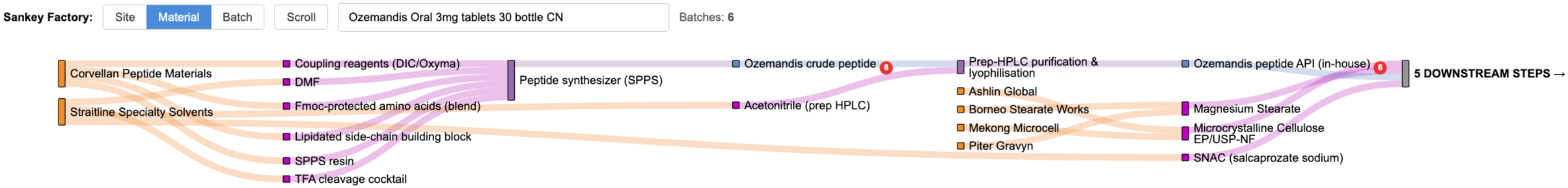


Not scared yet?

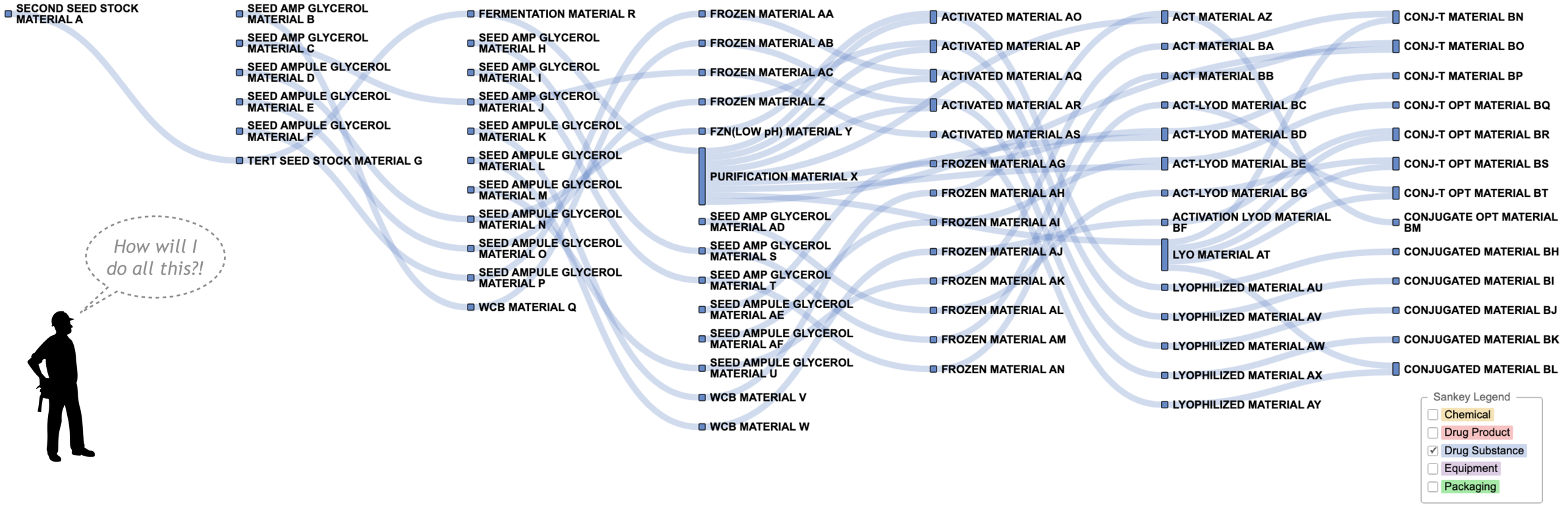
Remember:

- Nitrosamines can form at any point along any of these flows.
- This site's small molecule recipes use **purchased API** which makes their flows much simpler than if they made API in-house.

In-house API production for synthetic peptides



In-house API production for biologics such as 10-25 serotype vaccines

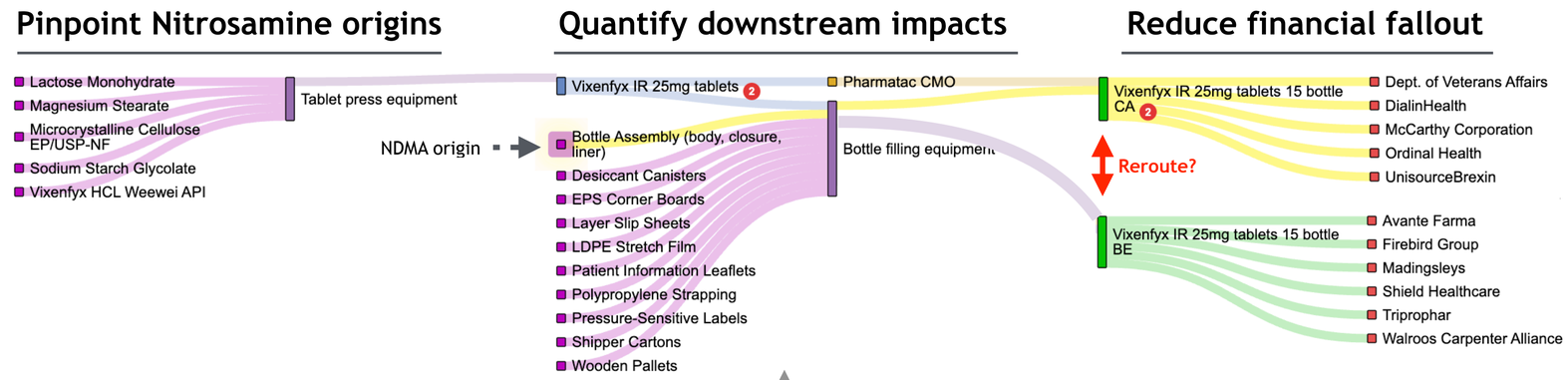




How connected data can exorcise Nitrosamines, measure the damage and reduce financial fallout

System-of-record data remains as-is — graph persists connections

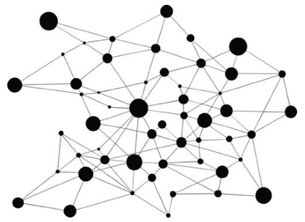
User-facing web-based applications and insights



GraphQL API (read-write)

Neo4j database of real-time connected genealogy

Knowledge Graph



Bulk & queued Extract-Transform-Load (ETL) processes

System-of-record source data



amalgo.ai

ERP

+

MES

+

LIMS

+

PLM

+

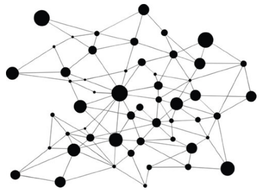
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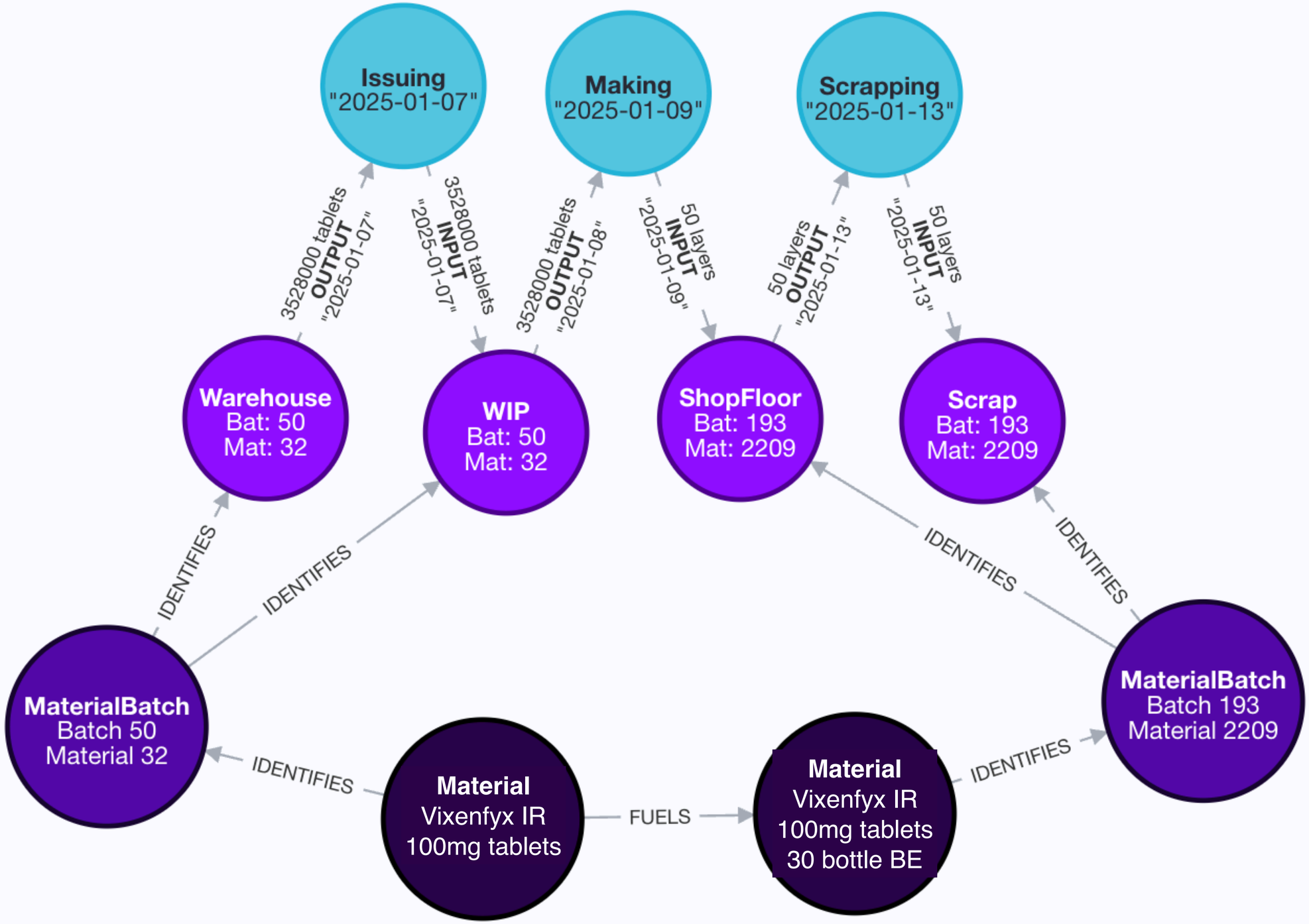
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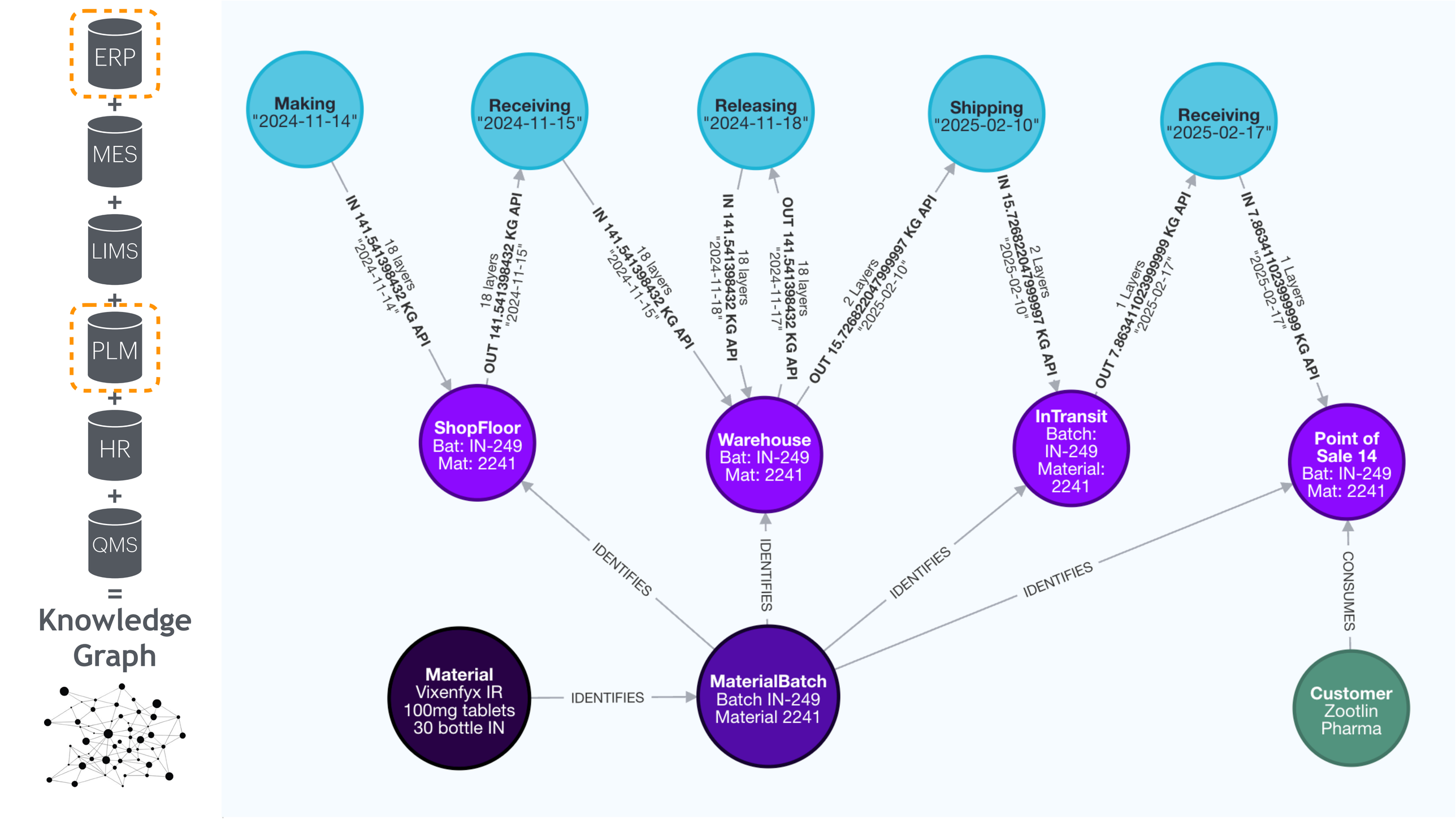
QMS

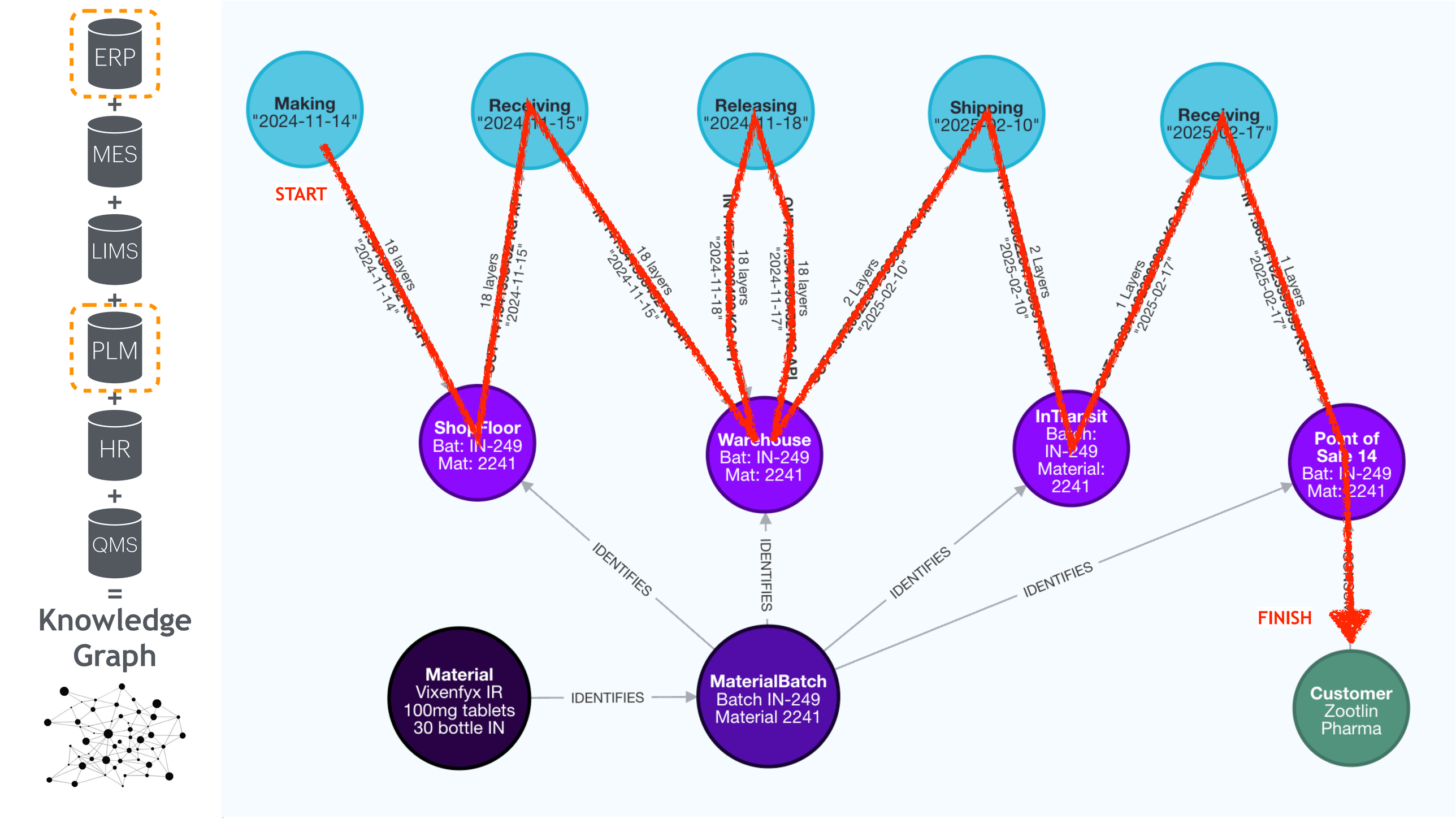
=

Knowledge Graph






ERP
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MES
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LIMS
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PLM
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HR
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QMS
=
Knowledge Graph
Making "2024-11-14"
Receiving "2024-11-15"
Releasing "2024-11-18"
Shipping "2025-02-10"
Receiving "2025-02-17"
IN 141.541398432 KG API
18 layers "2024-11-14"
OUT 141.541398432 KG API
18 layers "2024-11-15"
IN 141.541398432 KG API
18 layers "2024-11-15"
IN 141.541398432 KG API
18 layers "2024-11-18"
OUT 141.541398432 KG API
18 layers "2024-11-17"
OUT 15.726822047999997 KG API
2 Layers "2025-02-10"
IN 15.726822047999997 KG API
2 Layers "2025-02-10"
OUT 7.8634110239999999 KG API
1 Layers "2025-02-17"
IN 7.8634110239999999 KG API
1 Layers "2025-02-17"
ShopFloor
Bat: IN-249
Mat: 2241
Warehouse
Bat: IN-249
Mat: 2241
InTransit
Batch:
IN-249
Material:
2241
Point of Sale 14
Bat: IN-249
Mat: 2241
IDENTIFIES
IDENTIFIES
IDENTIFIES
IDENTIFIES
CONSUMES
Material
Vixenfyx IR
100mg tablets
30 bottle IN
IDENTIFIES
MaterialBatch
Batch IN-249
Material 2241
Customer
Zootlin
Pharma


ERP
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MES
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LIMS
+
PLM
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HR
+
QMS
=
Knowledge Graph
Making
"2024-11-14"
START
Receiving
"2024-11-15"
Releasing
"2024-11-18"
Shipping
"2025-02-10"
Receiving
"2025-02-17"
18 layers
"2024-11-14"
18 layers
"2024-11-15"
18 layers
"2024-11-15"
18 layers
"2024-11-18"
18 layers
"2024-11-17"
2 Layers
"2025-02-10"
2 Layers
"2025-02-10"
1 Layers
"2025-02-17"
1 Layers
"2025-02-17"
Shop Floor
Bat: IN-249
Mat: 2241
Warehouse
Bat: IN-249
Mat: 2241
InTransit
Batch:
IN-249
Material:
2241
Point of
Sale 14
Bat: IN-249
Mat: 2241
FINISH
IDENTIFIES
IDENTIFIES
IDENTIFIES
IDENTIFIES
Material
Vixenfyx IR
100mg tablets
30 bottle IN
IDENTIFIES
MaterialBatch
Batch IN-249
Material 2241
Customer
Zootlin
Pharma

ERP

+

MES

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LIMS

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PLM

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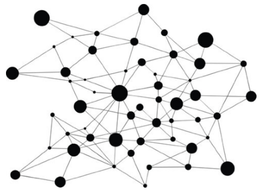
HR

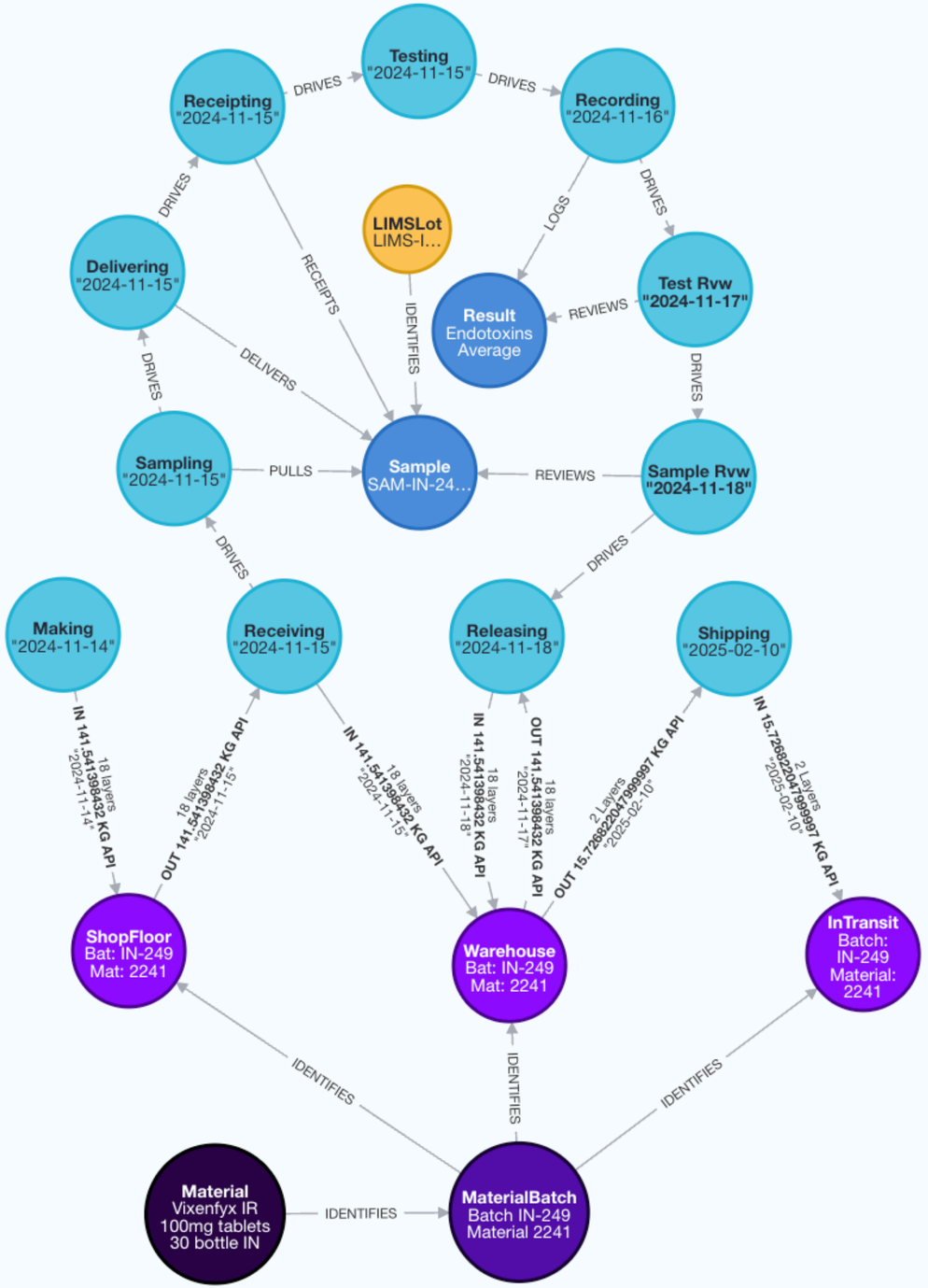
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QMS

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Knowledge Graph





ERP

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MES

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LIMS

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PLM

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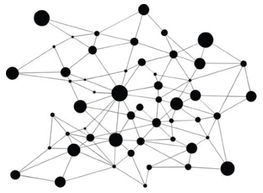
HR

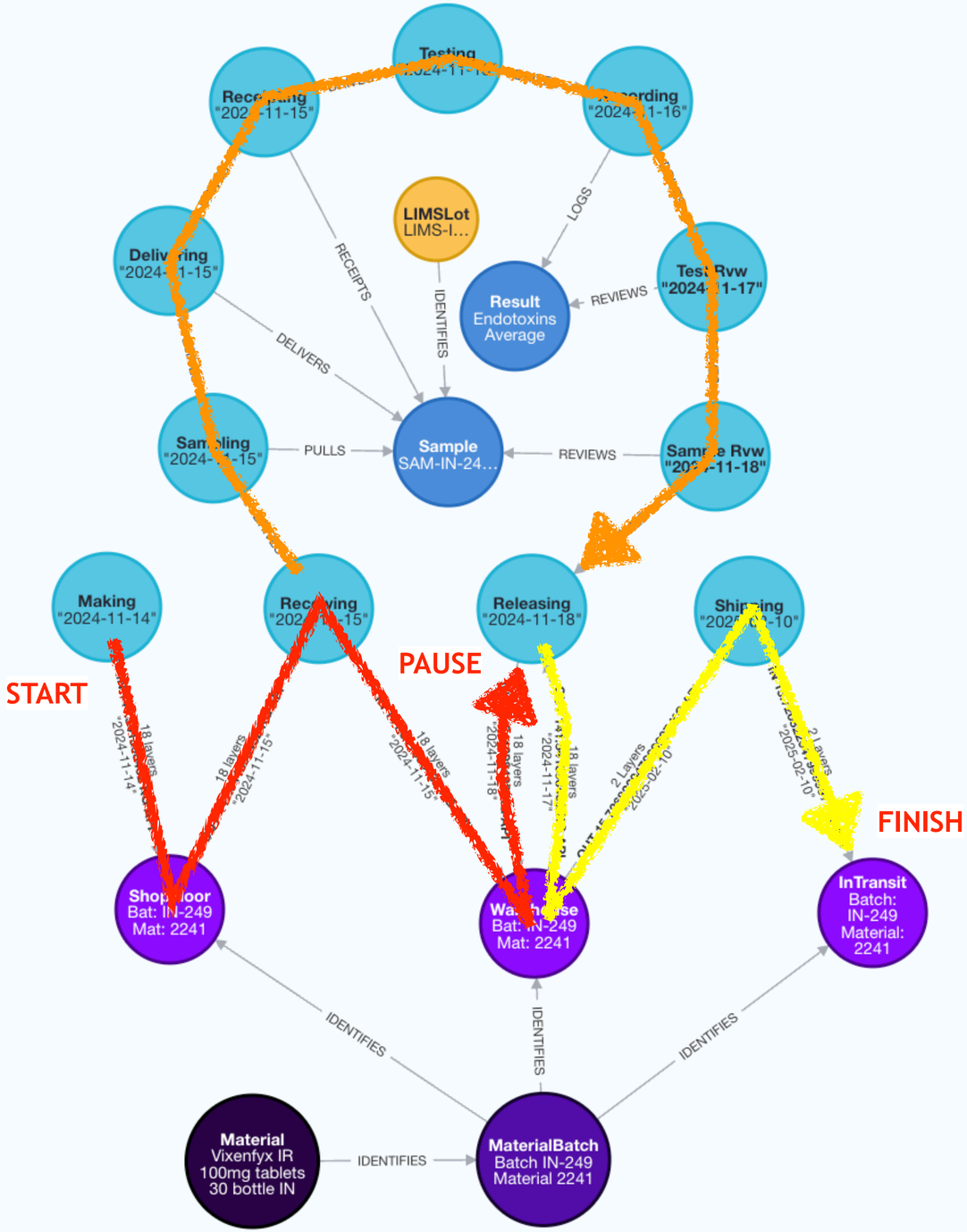
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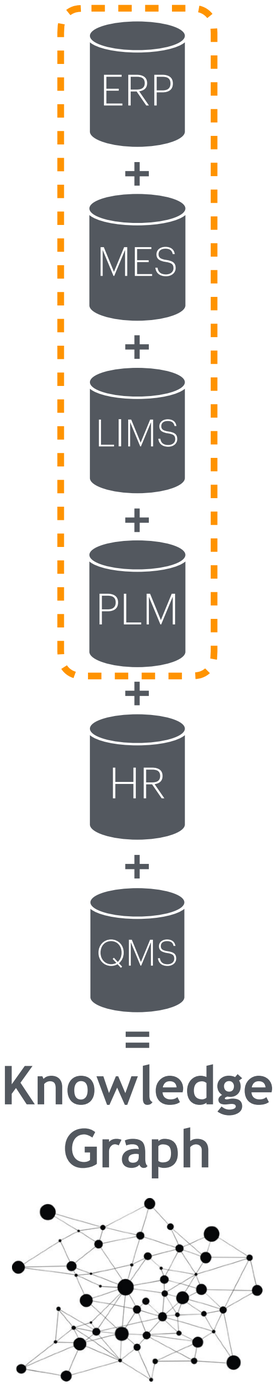
QMS

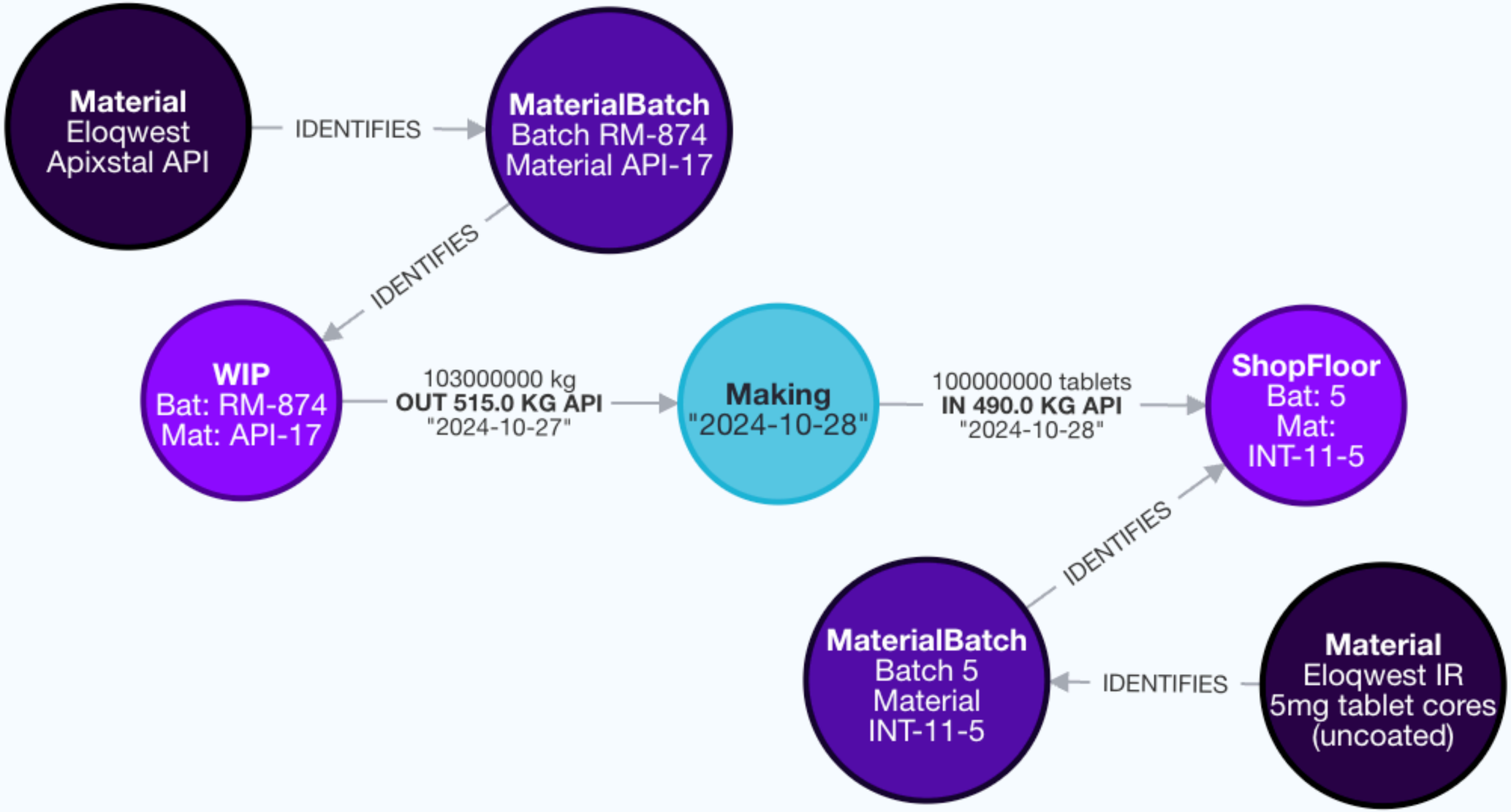
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Knowledge Graph






ERP
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MES
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LIMS
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PLM
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HR
+
QMS
=
Knowledge
Graph


Material
Eloqwest
Apixstal API
IDENTIFIES
MaterialBatch
Batch RM-874
Material API-17
IDENTIFIES
WIP
Bat: RM-874
Mat: API-17
103000000 kg
OUT 515.0 KG API
"2024-10-27"
Making
"2024-10-28"
100000000 tablets
IN 490.0 KG API
"2024-10-28"
ShopFloor
Bat: 5
Mat:
INT-11-5
IDENTIFIES
MaterialBatch
Batch 5
Material
INT-11-5
IDENTIFIES
Material
Eloqwest IR
5mg tablet cores
(uncoated)

ERP

+

MES

+

LIMS

+

PLM

+

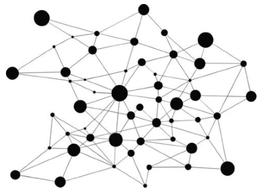
HR

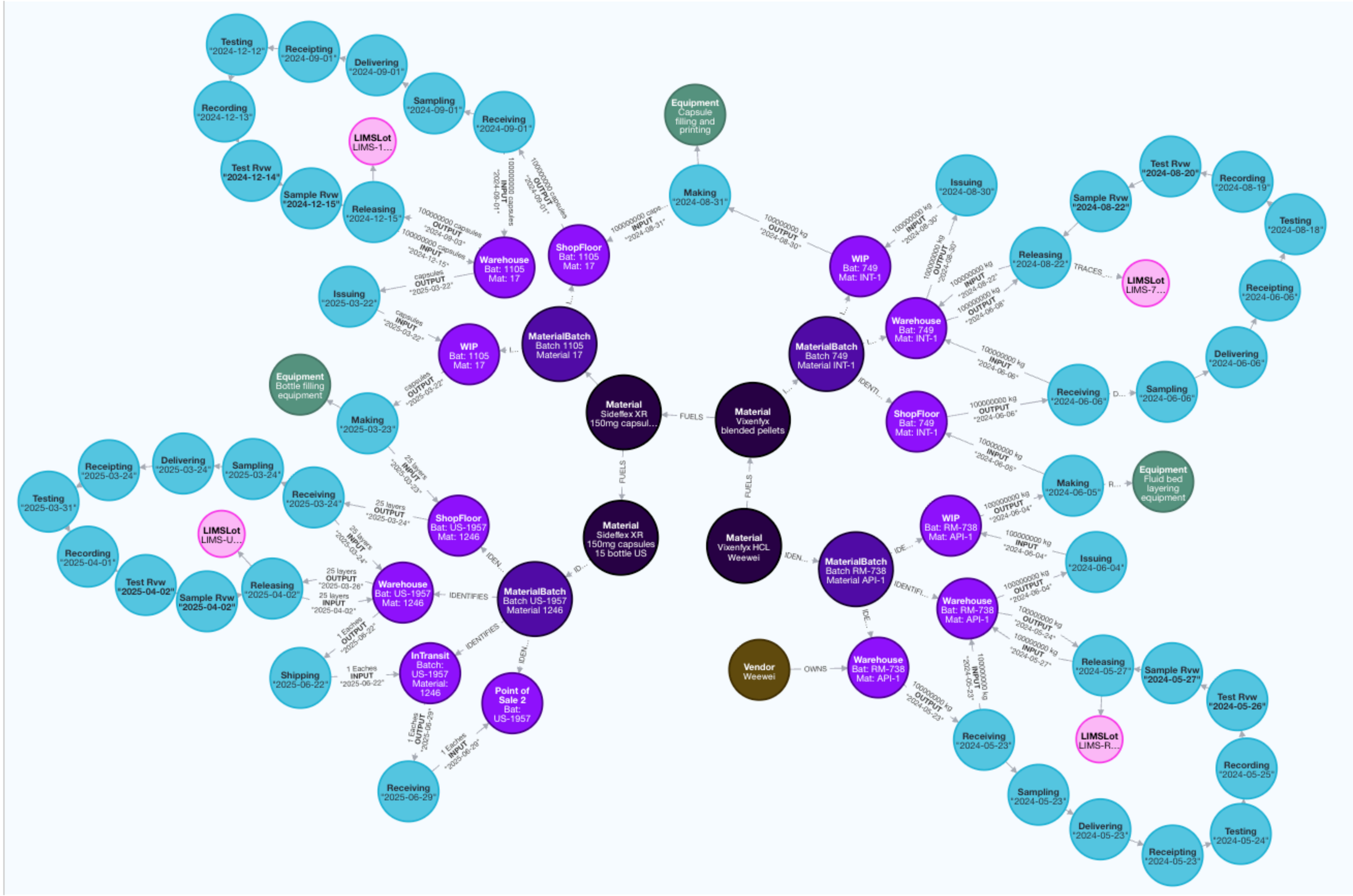
+

QMS

=

Knowledge Graph





ERP

+

MES

+

LIMS

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PLM

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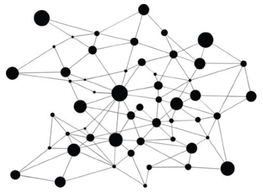
HR

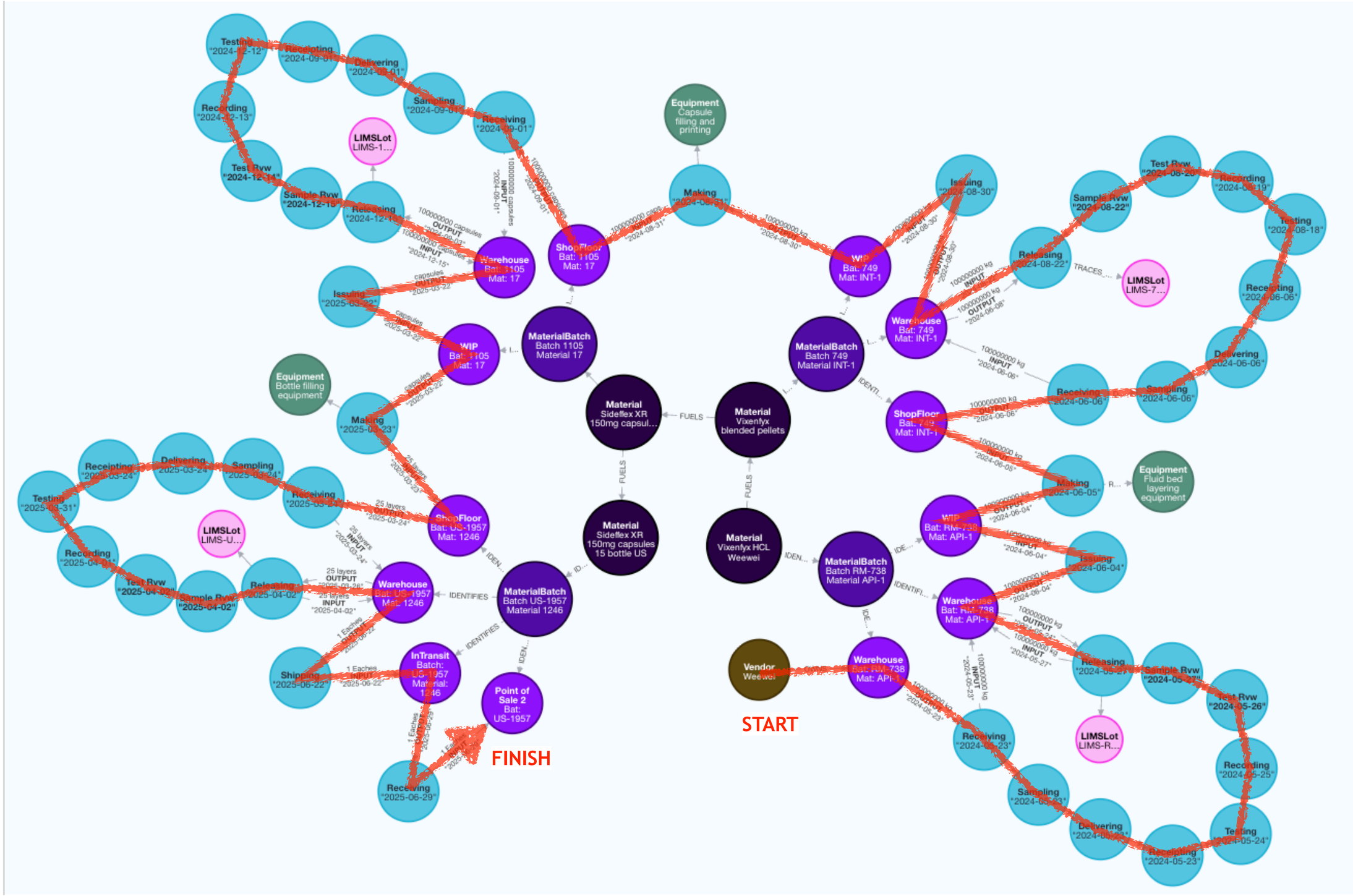
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QMS

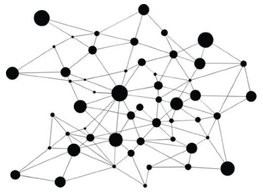
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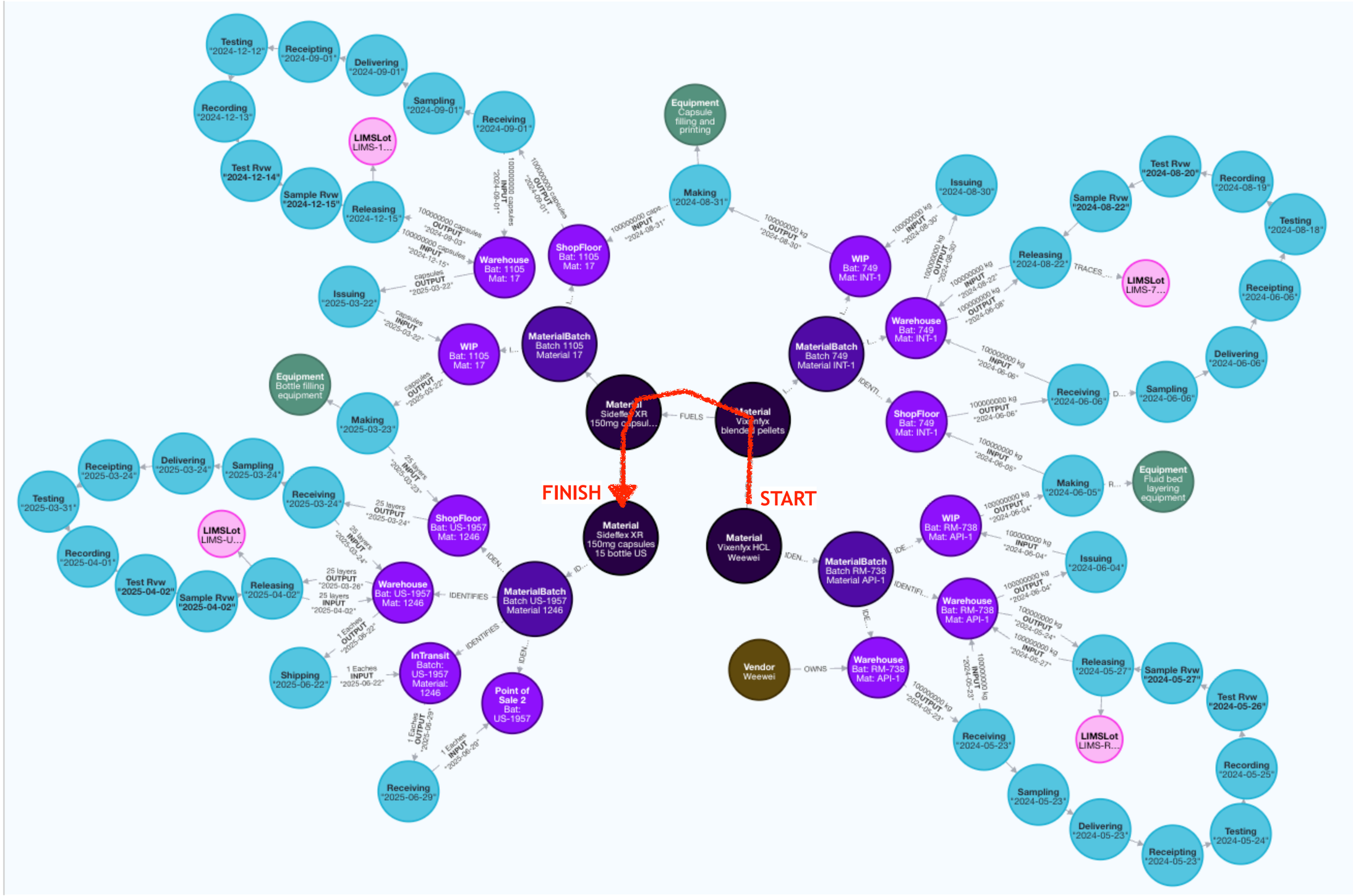
Knowledge Graph



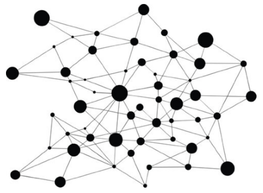


ERP + MES + LIMS + PLM + HR + QMS = Knowledge Graph





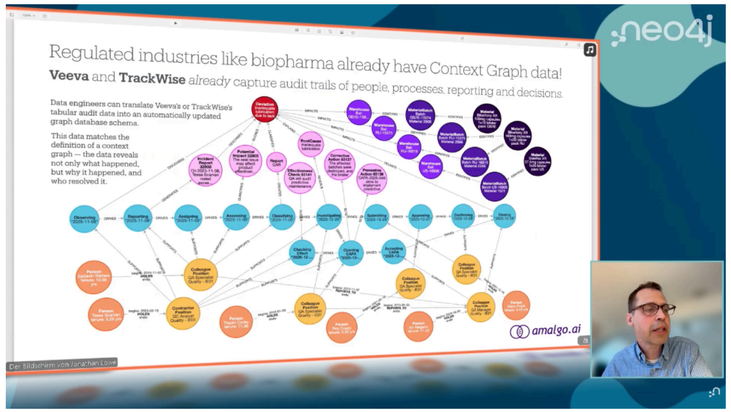
ERP + MES + LIMS + PLM + HR + QMS = **Knowledge Graph**

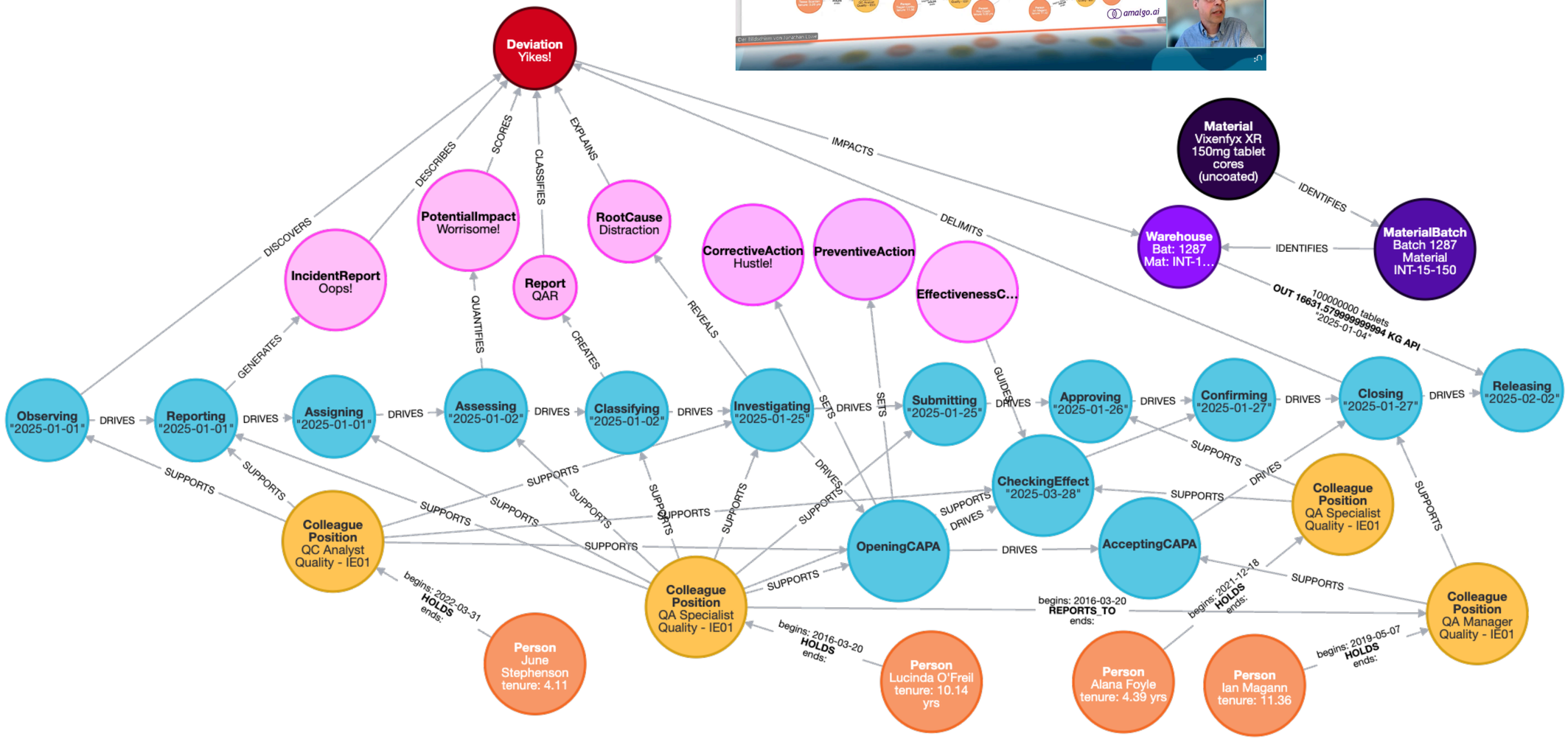


Financial returns from Context Graph & AI that reduces QA investigation durations

Neo4j - GraphTalk Munich - 2 July 2026

(https://www.youtube.com/watch?v=wvEFvWytIvw)

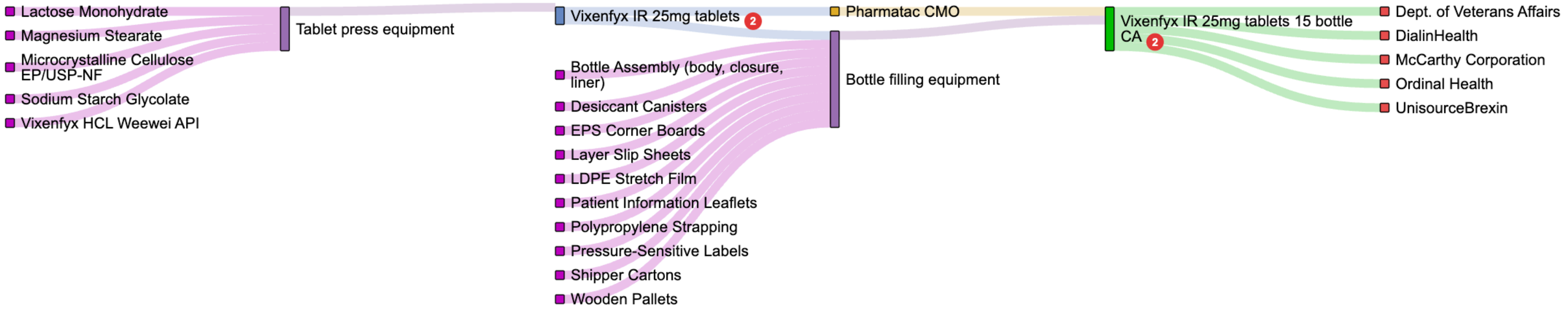




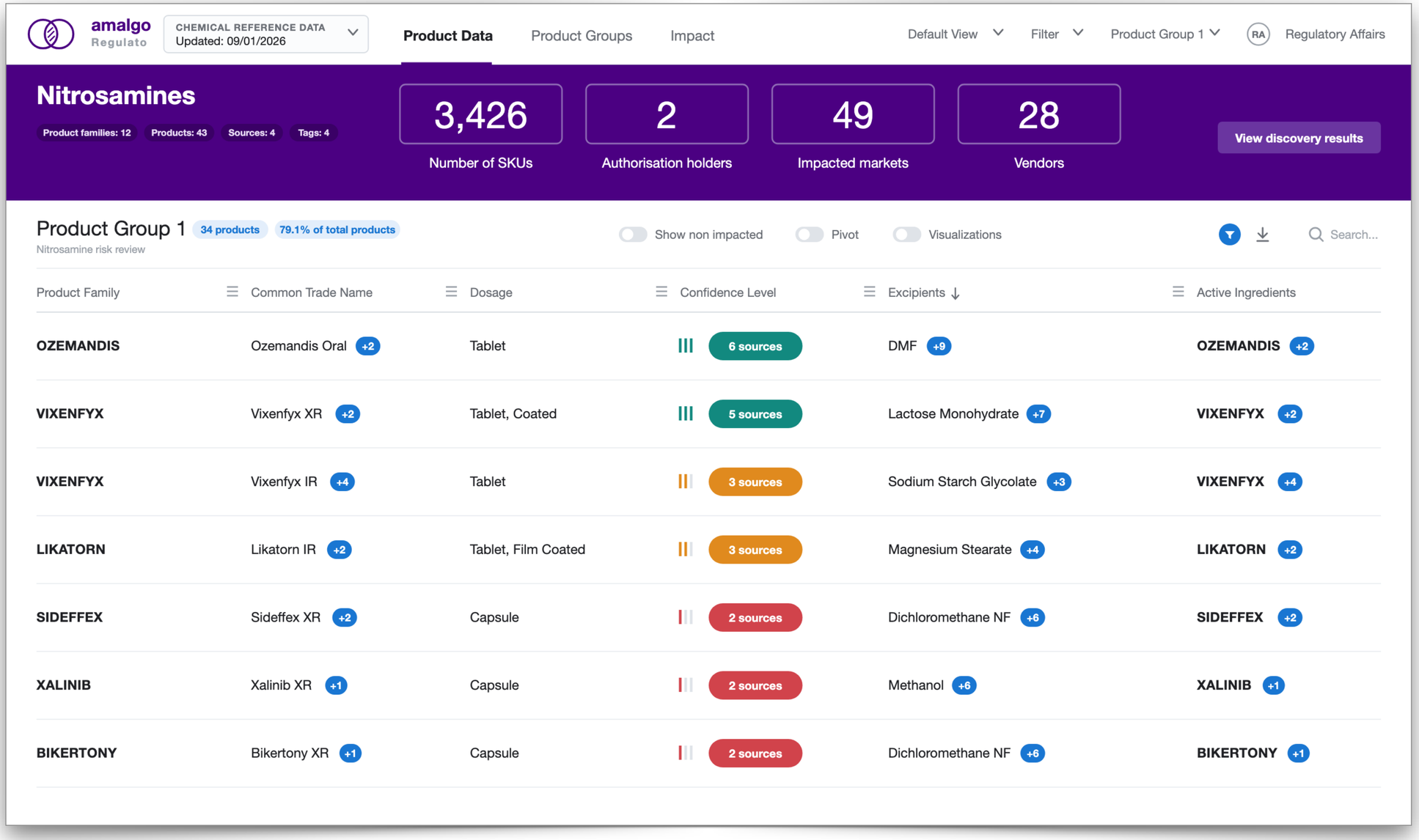
amalgo.ai

C-Suite: “Trace our genealogy for NDMA origins, impacts & remedies”

Maybe you’re wondering: What exactly *is* a recipe genealogy in the first place?

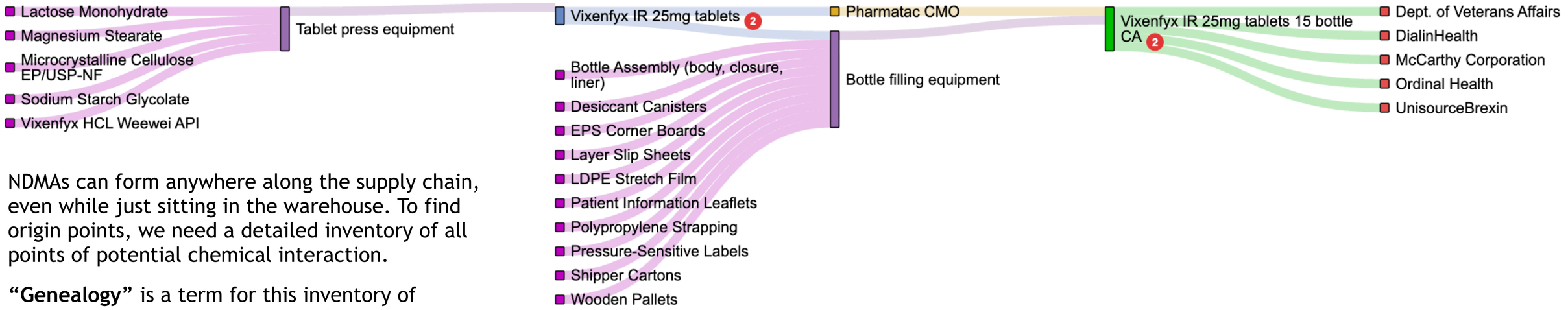


Apps built on top of a knowledge graph search for existence of Nitrosamines in all products and analyze impacts across the portfolio



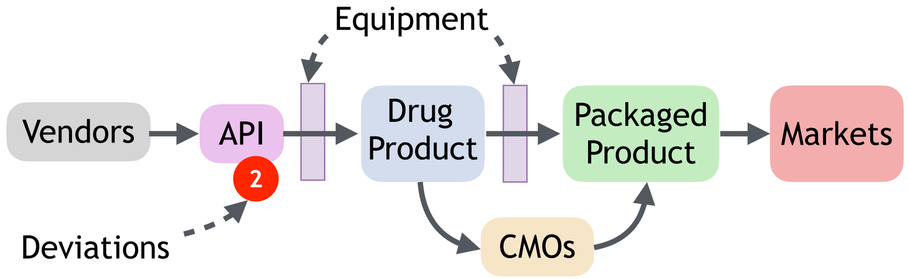
C-Suite: “Trace our genealogy for NDMA origins, impacts & remedies”

Pinpoint Nitrosamine origins



NDMAs can form anywhere along the supply chain, even while just sitting in the warehouse. To find origin points, we need a detailed inventory of all points of potential chemical interaction.

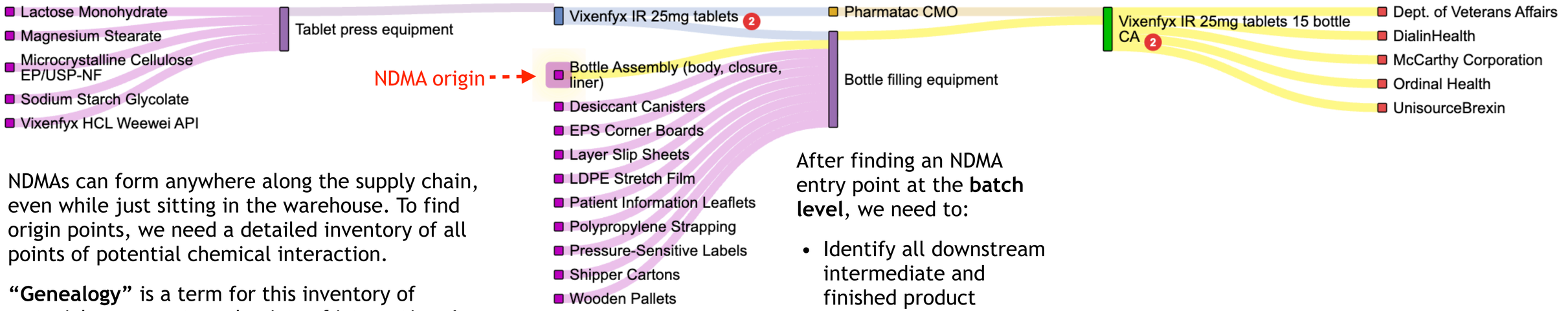
“Genealogy” is a term for this inventory of material movements and points of interaction. It includes:



C-Suite: “Trace our genealogy for NDMA origins, impacts & remedies”

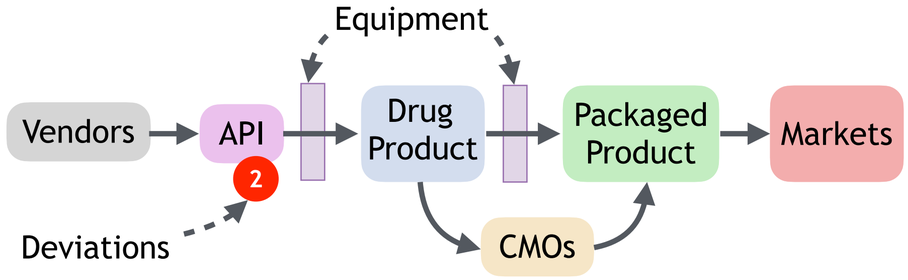
Pinpoint Nitrosamine origins

Quantify downstream impacts



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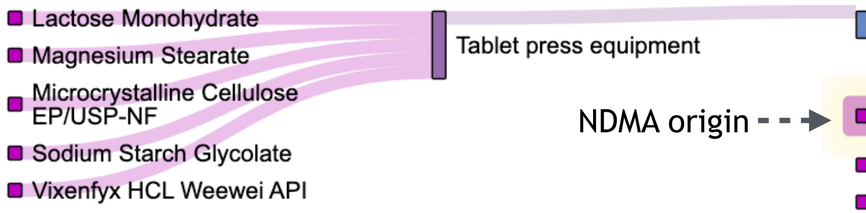


After finding an NDMA entry point at the **batch level**, we need to:

- Identify all downstream intermediate and finished product batches the NDMA has contaminated
- Test NDMA levels in finished product batches for comparison to allowable levels in their specific destination markets
- Calculate the cost of the recalls

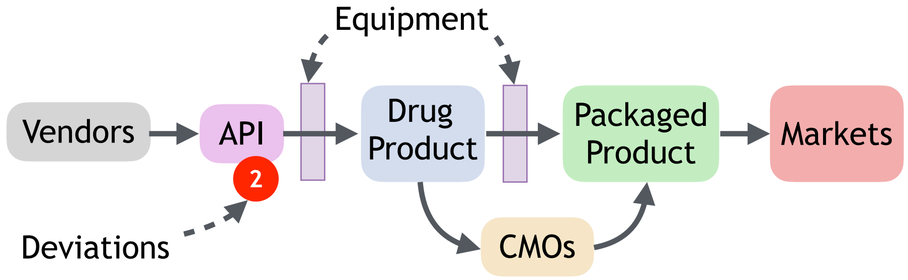
C-Suite: “Trace our genealogy for NDMA origins, impacts & remedies”

Pinpoint Nitrosamine origins

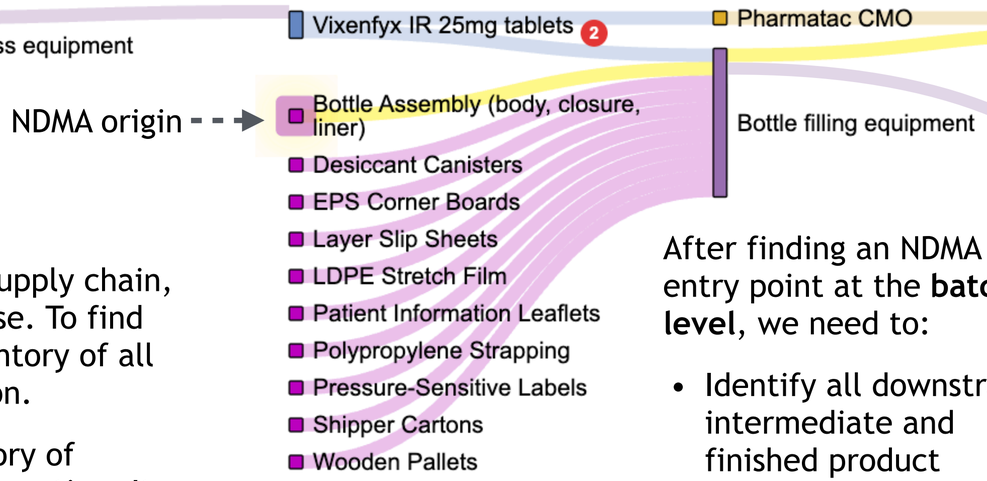


NDMAs can form anywhere along the supply chain, even while just sitting in the warehouse. To find origin points, we need a detailed inventory of all points of potential chemical interaction.

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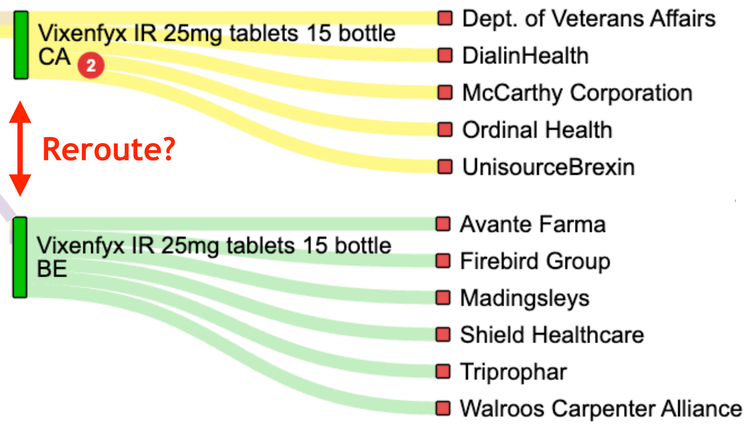
Quantify downstream impacts



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- Identify all downstream intermediate and finished product batches the NDMA has contaminated
- Test NDMA levels in finished product batches for comparison to allowable levels in their specific destination markets
- Calculate the cost of the recalls

Reduce financial fallout



Different markets set different regulatory constraints over time. Rather than simply recalling all tainted goods…

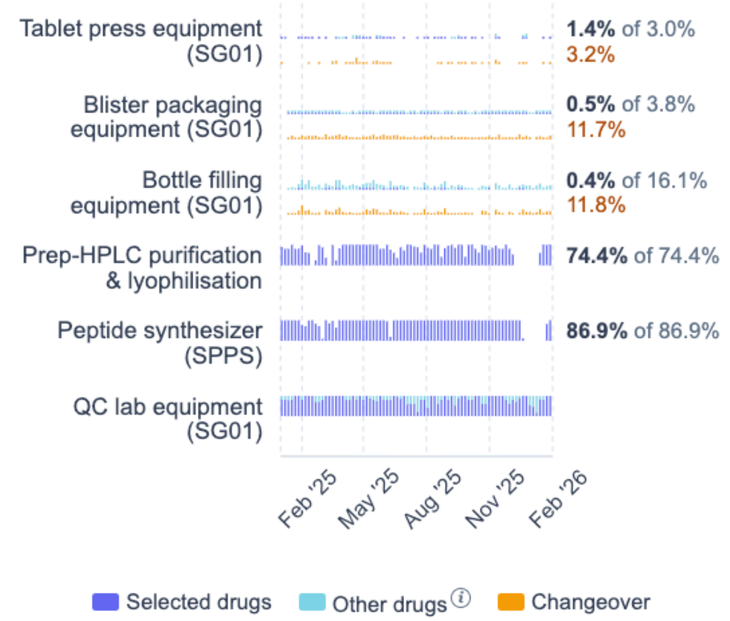
- Can in-transit stock with zero or low levels of NDMAs be **rerouted** to markets with the most strict regulatory limits?
- Can in-transit stock with higher levels of NDMAs be **rerouted** to markets where it still fits within the (less strict) regulatory limits?

Our horror movie has a romantic sub-plot, with treats not tricks!

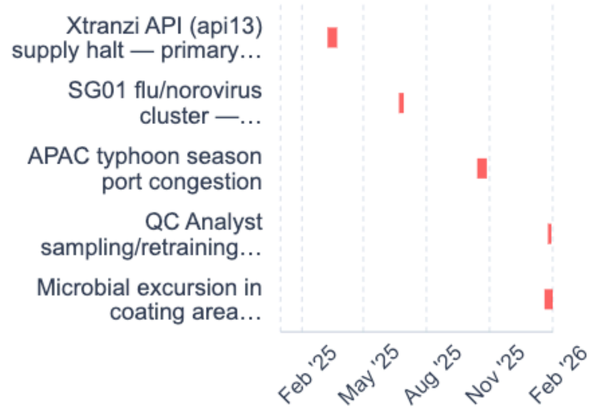


Equipment Utilization

Percentages are machine run time. Each row is cut into 80 time slices of 5 days; a slice's height is the share of it the machine ran (full height = ran throughout).

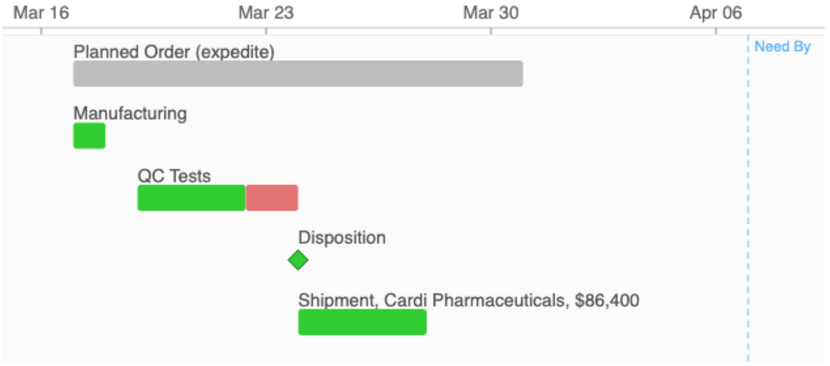


Disruptions

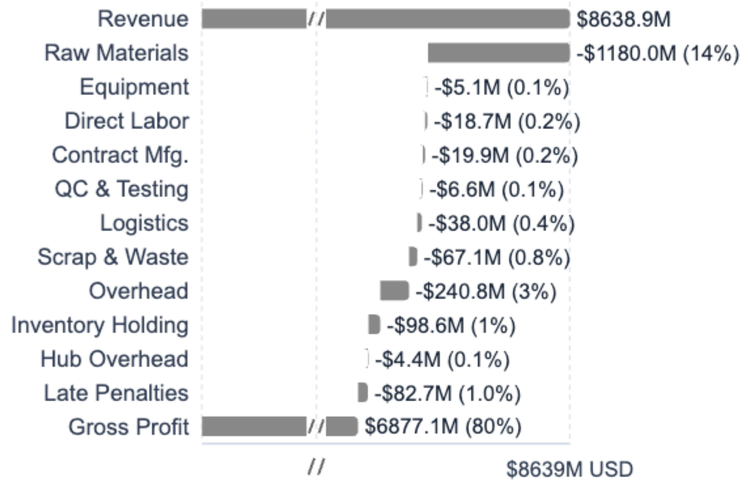


Key Metrics

Metric	Value
On Time In Full	94.7% (43,958 orders, 2,316 late)
Cost of Goods Sold	$1761.8M (20% of revenue)
Overall Equipment Effectiveness	23.12% quality 95.82% performance 99.78% availability 24.18%
Internal Throughput Time	avg 7d, median 5d, p90 10d
Internal Process Lead Time	avg 17.7d, median 13d, p90 26d
Batches and Scrap	14,924 produced, 624 scrapped (4.2%)
Percent Yield	94.6% (1,228 products)
Inventory Days of Supply	41.2d (2,195 batches on hand, 1,600 shipped in last 30d)
Deviations	565 total, 401 closed on time (71%)
QC Utilization	24.2% – 100.4% (73 analysts)
AI Observations	Analyze these metrics



Revenue - COGS = Gross Profit

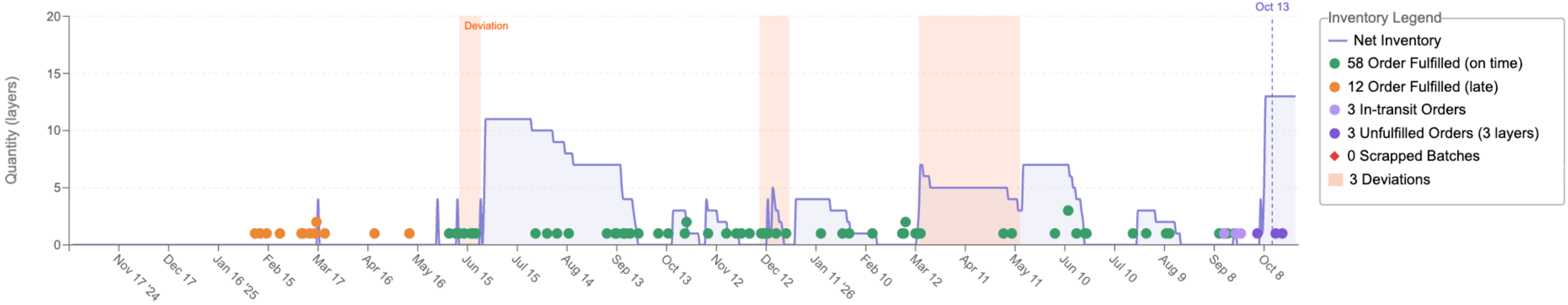


Investigations -- 30-day closure target



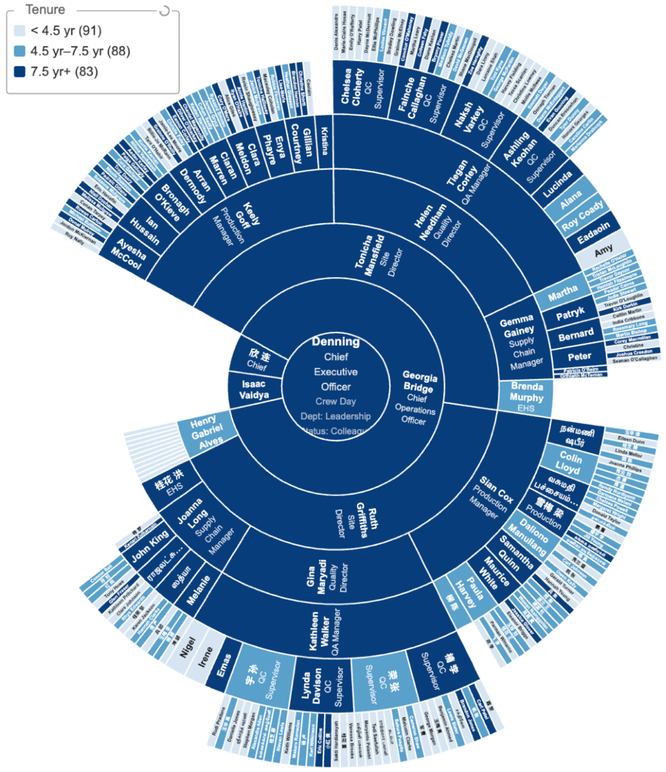
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Warehouse Inventory — Munjinga SC 10mg syringes 4 pen carton ES/PT

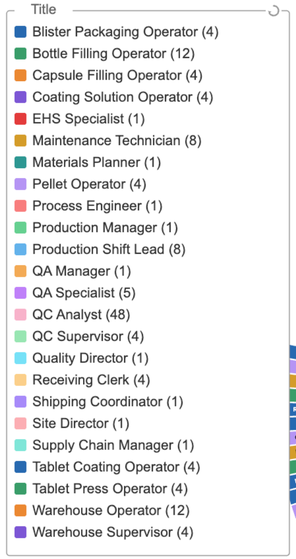


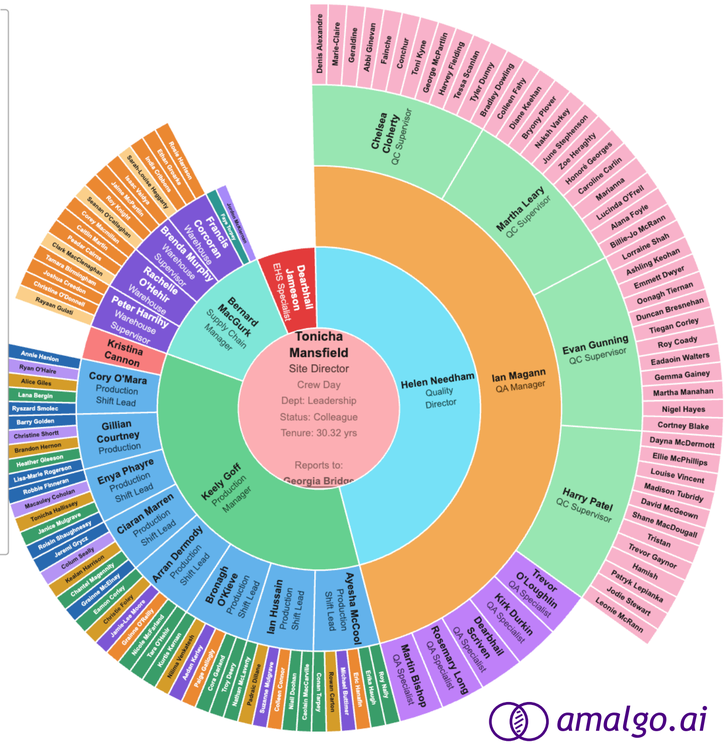
Org Chart

As of 10/08/2026 · Color by Tenure · Levels 7 · 262 active







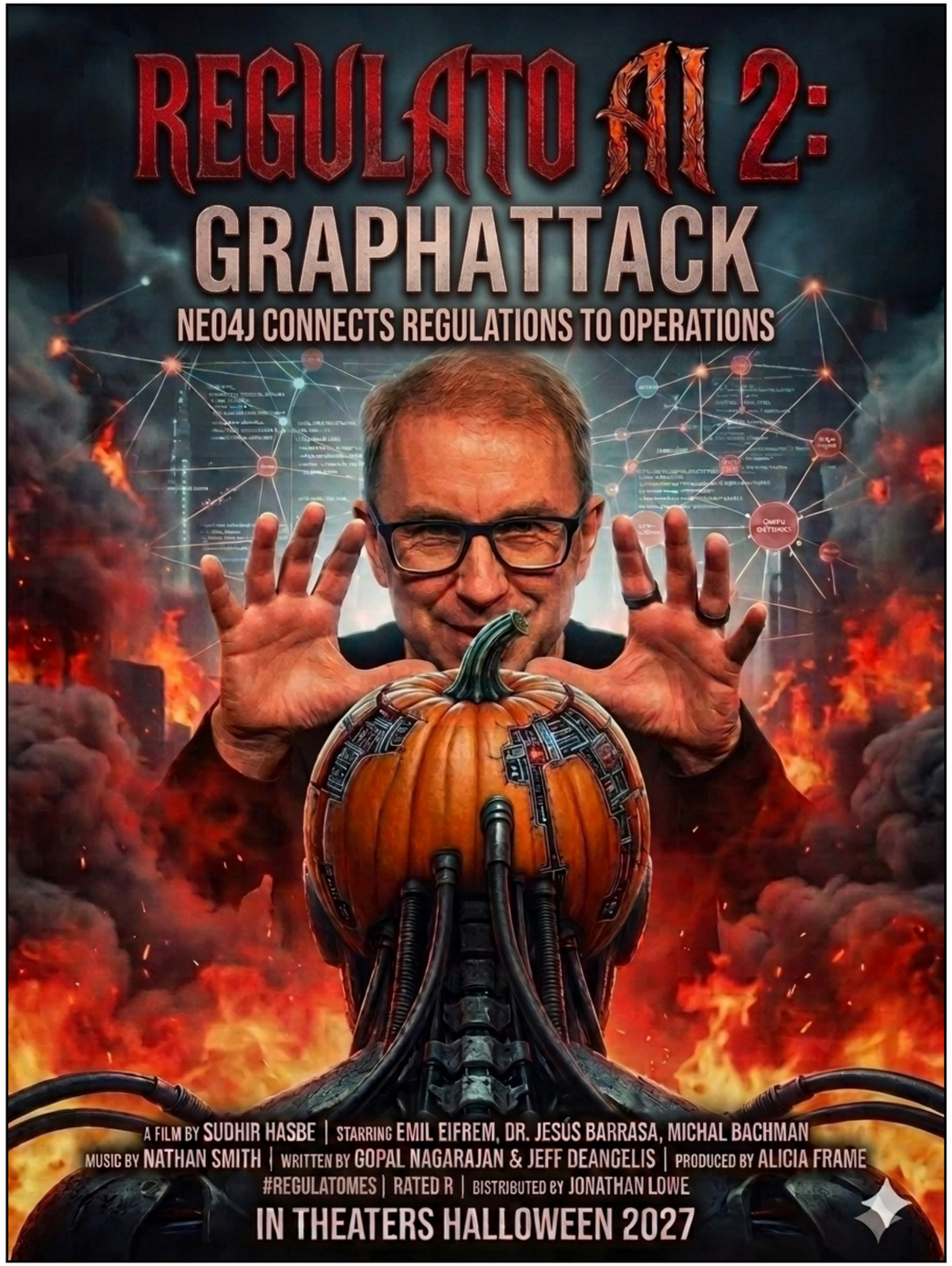


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Thanks to science, our day-to-day exposure has become incredibly low compared to generations past.

So, we can all get back to business as usual, right…?



Wrong! There's a spooky sequel about compliance with heavy metals, PFAS and packaging regulations…

What happens in the sequel?

- There are **new threats** to human health in our medicines, food, cosmetics and packaging.
- **Heavy metals** and **PFAS** ("forever chemicals") are now targets for regulatory compliance, along with regulations designed to improve **package safety & recycling**.
- Thankfully, that knowledge graph you built to manage Nitrosamines is **reusable** for all of these new regulatory concerns.
- Unlike in the era of Nitrosamines, modern **AI is enabling partnerships** to automate regulatory compliance in ways not previously possible…

PPWR regs drive economically viable recycling networks

Polluter pays: The Packaging and Packaging Waste Regulation (PPWR) Extended Producer Responsibility (EPR) framework is designed so that the industry collectively funds 100% of the physical waste management network.

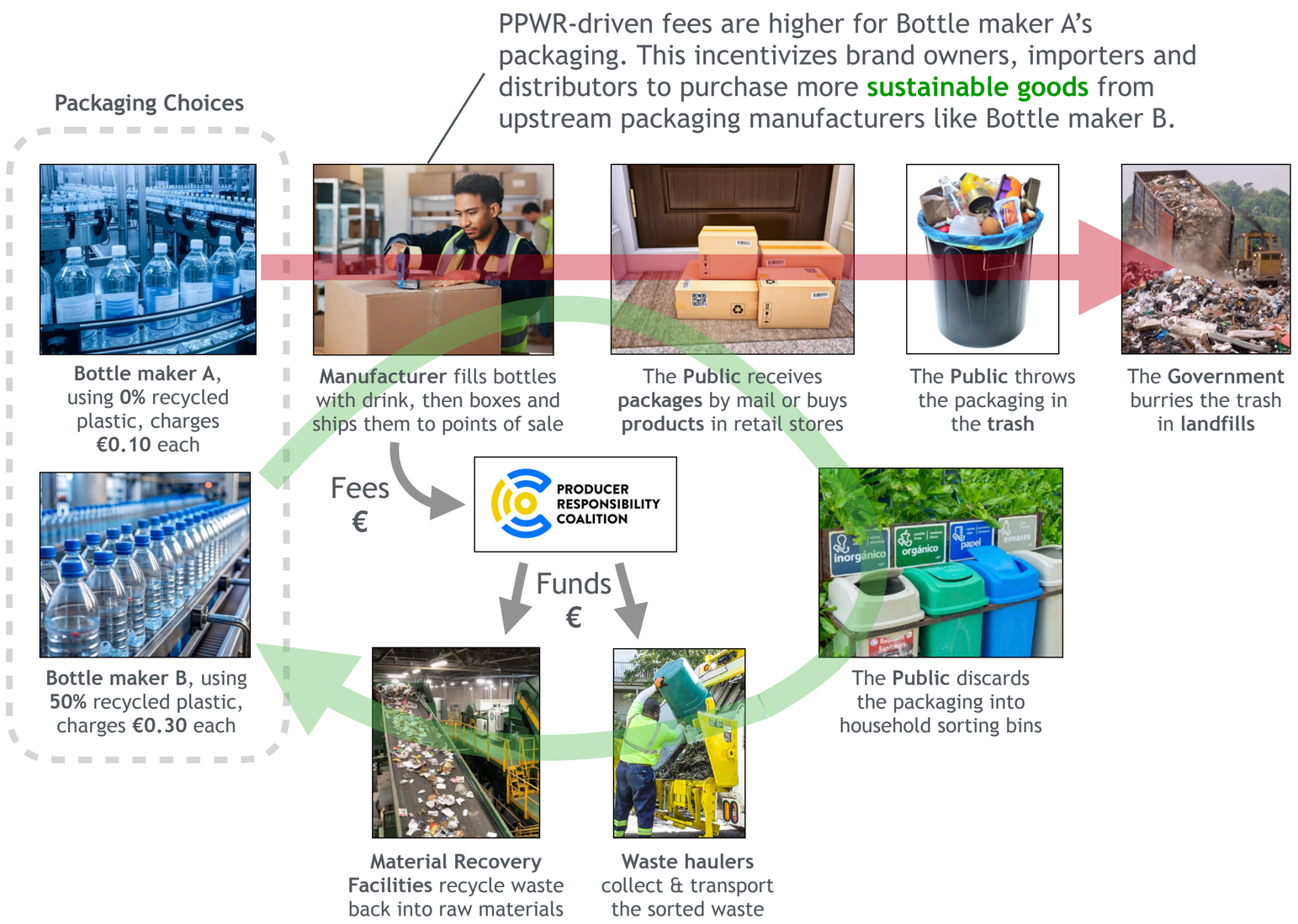
Who is charged? Through the PPWR law, Governments charge brand owners, importers, or distributors — the consumer goods companies that choose the packaging and introduce the finished products into the market.

Who collects fees? Rather than direct government billing, companies pay fees to Producer Responsibility Organizations (PROs) like Belgium's Fost Plus or France's CITEO.

What do fees fund? The PRO uses the pool of producer fees to **reimburse municipal governments and recycling operators** for the net costs of collecting, sorting, and processing that specific packaging.

EPR fees also **actively fund the infrastructure and management** of the recycling economy, including building recycling facilities, scaling up local collection programs, educating the public and finding viable end markets for recyclable materials.

Why bother? The goal is for every EU state to have an economically viable recycling network by 2030.



Regulations are typically long documents, heavily cross-referenced and written in confusing “legalese” language (example: EU PPWR)

Example: 2024 EU recycling regulations

This half-page excerpt comes from the main Packaging and Packaging Waste Regulations (PPWR) document, which is **120 pages** long.

REGULATION (EU) 2024/... OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 24 April 2024

on packaging and packaging waste, amending Regulation (EU) 2019/1020 and Directive (EU) 2019/904, and repealing Directive 94/62/EC

CHAPTER II — SUSTAINABILITY REQUIREMENTS

Article 6
Recyclable packaging

1. All packaging placed on the market shall be recyclable.
2. Packaging shall be considered recyclable where it complies with the following:
   (a) it is designed for recycling, as established in delegated acts adopted by the Commission pursuant to paragraph 4;
   (b) it is effectively and efficiently collected separately in accordance with Article 43(3) and Article 44;
   (c) it is sorted into defined waste streams without affecting the recyclability of other waste streams, and in line with the sorting criteria established under Article 12(4);
   (d) it can be recycled so that the resulting secondary raw materials are of sufficient quality to substitute the primary raw materials, subject to the conditions laid down in Annex II, Table 1.
3. By way of derogation from paragraph 1, innovative packaging may be placed on the market for a maximum period of 5 years from the date of its first introduction, provided that it fulfills the reporting requirements laid down in Article 39(2) and is accompanied by the technical documentation specified in Annex VII.
4. The Commission is empowered to adopt delegated acts in accordance with Article 58 to supplement this Regulation by establishing:
   (a) design for recycling criteria and performance grades based on the parameters listed in Table 2 of Annex II;

This sentence refers to two other Articles. The half-page shown here references **12 other information sources** (articles, annexes, tables, paragraphs) found either in this or other documents.

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Supplier's Certificate of Analysis

PHARMA-PAC SOLUTIONS

Pharma: Solutions
T: + (122) AS6-7B9O
E-mail :@pacsolutions.com
B: pharma-pacsolutions.com

CERTIFICATE OF ANALYSIS

Product Name: High-Density Polyethylene (HDPE) Bottles Batch Number: B-2026-904
Manufacturing Date: August 12, 2026 Expiry Date: N/A

TEST PARAMETER	SPECIFICATION	ACTUAL RESULT
Appearance	Translucent molded shape	Conforms
Dimensions	Matches Drawing Rev. C	Conforms
Wall Thickness	Min 0.85 mm	0.92 mm
Extractable Residue	Max 0.05 mg/dm²	0.01 mg/dm²

ADDITIONAL REGULATORY DECLARATIONS:

Surface Treatment: These containers undergo a post-molding, in-line *fluorination process utilizing a fluorine/nitrogen gas mixture* to *enhance barrier properties and reduce chemical permeation.*

Processing Additives: Internal mold release agents used contain *synthetic fluoropolymer-based processing aids (PPA)* to ensure surface *uniformity and eliminate melt fracture during extrusion.*

QA/QC sign-off

Quality Assurance Manager

QA NON-COMPLIANCE DETECTED
UNACCEPTABLE PFCA LEVEL
NCR No: 2026-B904-01



Danger: Direct gas reactions can yield byproducts like perfluoroalkyl carboxylic acids (PFAS) that can leach straight into liquid medicines over time.

Neo4j offers a solution for automatically converting free-text from one or more documents into a structured knowledge graph

Text representation of information

Document 1

The financial contributions to be paid by producers to fulfill their extended producer responsibility obligations as referred to in Article 45 shall be modulated based on the recyclability performance grades achieved by the packaging, in accordance with the criteria set out in Article 46(3) and without prejudice to the requirements of Article 5(2) regarding substances of concern.

Document 2

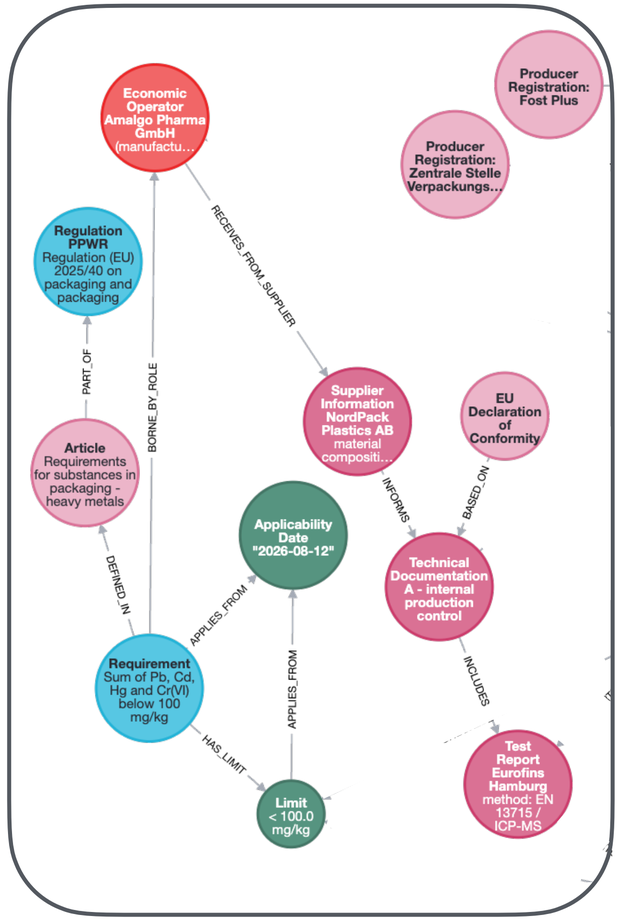
4. The Commission is empowered to adopt delegated acts in accordance with Article 58 to supplement this Regulation by establishing: (a) design for recycling criteria and performance grades based on the parameters listed in Table 2 of Annex II; (b) the methodology for the assessment of the recyclability at scale, which shall incorporate the criteria established in Article 47(2) and the reporting metrics provided under Article 50(5).

Document 3

Surface Treatment: These containers undergo a post-molding, in-line flourination process utilizing a flourine/ nitrogen gas mixture to enhance barrier properties and reduce barrier permeation.

AI information extraction pipeline

Knowledge graph representation of information



Legal Review of knowledge graph

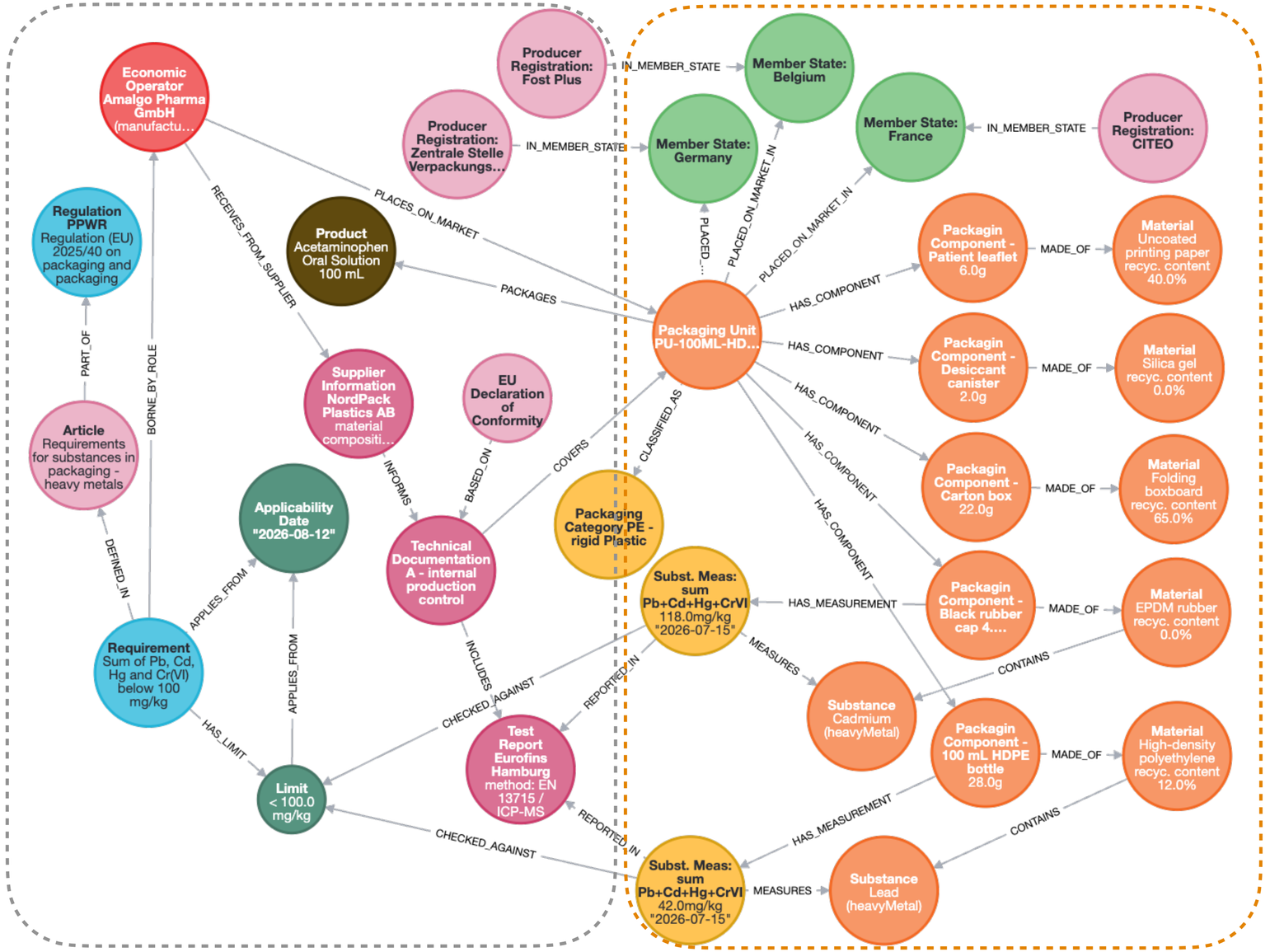


Expert human lawyers validate and update the knowledge graph manually for accuracy, completeness and consistency with laws.

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Using deterministic logic, Amalgo connects regulatory and operations graphs to automatically check for non-compliance

Regulatory graph & Supplier Analysis graph

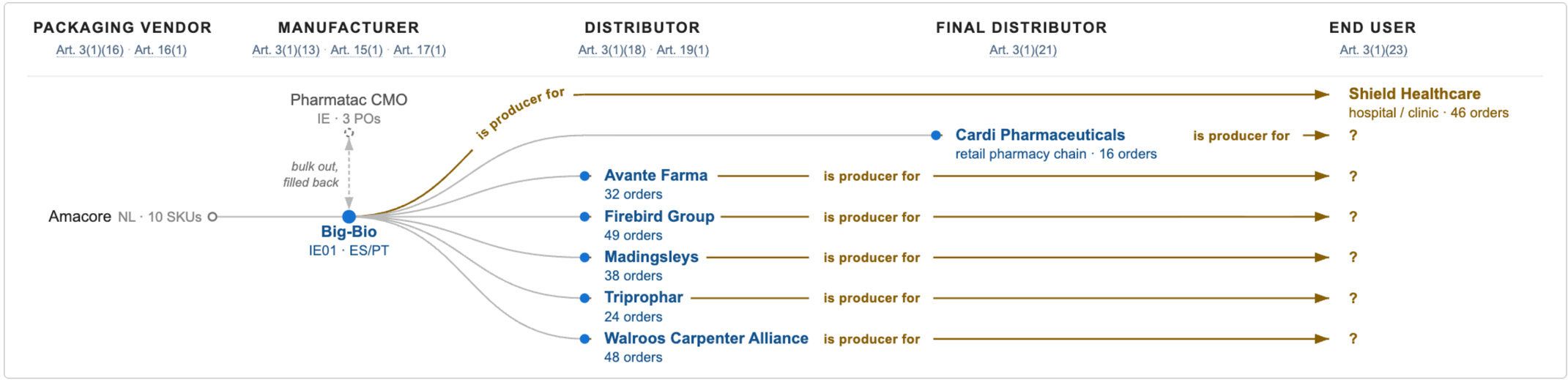


Operations graph

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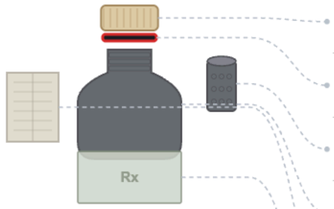
Apps visualize connected regulatory and operations data to automatically guide biopharma clients on the path to compliance

PPWR fees and obligations depend on who first places packaging in a nation state. Operations knowledge graphs provide the supply chain data needed to confirm the PPWR roles.



If any component in a packaging unit fails to meet a regulatory requirement for heavy metals, the whole unit can't be shipped. Amalgo's solution spots compliance failures early.

This pack



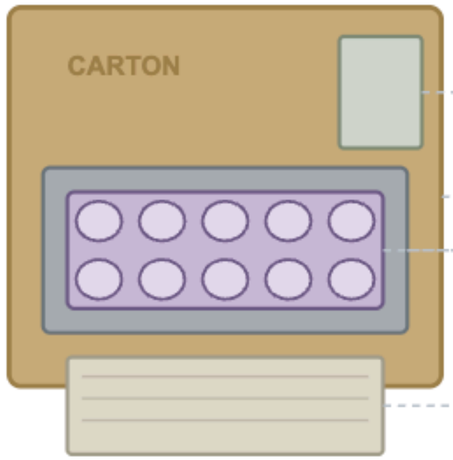
Highlighted: the part over the limit.

Component	Material	Pb	Cd	Hg	Cr(VI)	Sum	vs 100 mg/kg	Report	Method
closure	Polypropylene closure resin PMAT–PP	1.9	0.4	0.1	0.6	**3**	PASS	HM-2026-002 *Ardennes Analytical Services, Liege (BE) · 2026-02-18*	Microwave-assisted acid digestion with **ICP-MS** for Pb, Cd and Hg; **ion chromatography** with post-column derivatisation for Cr(VI) speciation. Per **CEN/TR 13695-1**. The limit is on the sum, but each element is shown too, so you can see which one drives it. Lab, date and the full analyte list are on each row's report.
liner	EPDM closure liner PMAT–EPDM	74	4	2	38	**118**	FAIL	HM-2026-003 *Ardennes Analytical Services, Liege (BE) · 2026-02-25*	
desiccant	Pigmented HDPE (carbon black) PMAT–HDPE_BLACK	5.1	0.9	0.1	1.9	**8**	PASS	HM-2026-001 *Ardennes Analytical Services, Liege (BE) · 2026-02-11*	
body	Pigmented HDPE (carbon black) PMAT–HDPE_BLACK	5.1	0.9	0.1	1.9	**8**	PASS	HM-2026-001 *Ardennes Analytical Services, Liege (BE) · 2026-02-11*	
leaflet	Uncoated paper (leaflet / label facestock) PMAT–PAPER	10.6	1.9	0.4	5.1	**18**	PASS	HM-2026-009 *Ardennes Analytical Services, Liege (BE) · 2026-04-08*	
label	PVC pressure-sensitive label, non-washable adhesive PMAT–PVC_LABEL	13.5	2.6	0.3	5.6	**22**	PASS	HM-2026-005 *Ardennes Analytical Services, Liege (BE) · 2026-03-11*	

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Adding graph data about alternate packaging materials enables not only compliance and improved recyclability, but reduction of fees

Legacy pack



Feature	Legacy pack
Components	5
Weight per unit	11.6 g
PCR recycled content	**Excluded** — Art. 7(4)(a) no fee relief

	Before	After
label	Self-adhesive label stock MAT–LABELSTOCK 0.3 g · sortability tier **€42**	→ ⭐ Paper facestock, washable adhesive (saves €79) Uncoated printing paper MAT–PAPER 0.2 g · material rate **€2** **–€40**
body	Folding boxboard MAT–CARTONBOARD 5.5 g · material rate **€54**	→ ⭐ Lighter-grammage folding boxboard (saves €16) Folding boxboard MAT–CARTONBOARD 4.7 g · material rate **€46** **–€8**
barrier	PVC / PVdC (thermoformed) MAT–PVC 3.4 g · sortability tier **€475**	→ ⭐ Alu-alu cold-form laminate (saves €842) Aluminium MAT–ALUMINIUM 4.6 g · material rate **€54** **–€421**

Our tale began with a nightmare, but is ending with hope driven by ***regulation as an accelerator to innovation***.

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From regulatory complexity to continuous compliance confidence.

Stay tuned... legal and regulatory expertise, combined with amalgo.ai's connected operational data and AI platform, helps manufacturers achieve and maintain compliance with the EU Packaging and Packaging Waste Regulation (PPWR).

Announcement pending...

LEGAL & REGULATORY INTELLIGENCE

- Deep expertise in PPWR and wider packaging regulation
- Practical interpretation and guidance for application
- Ongoing insight as requirements evolve

+

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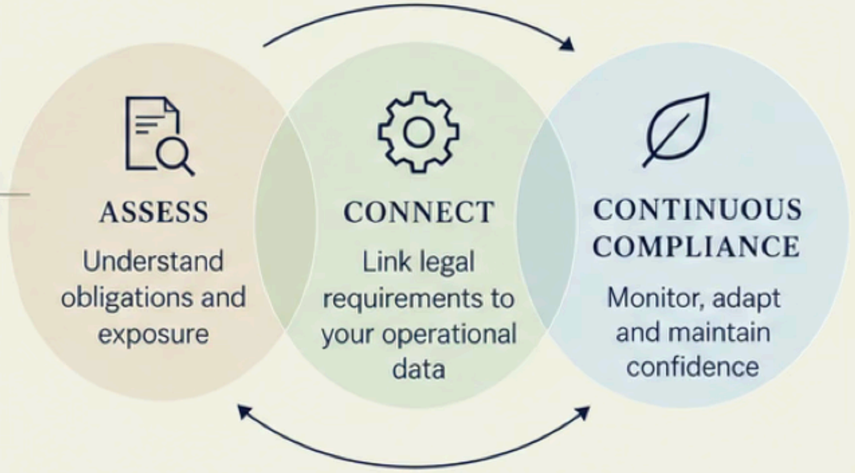
CONNECTED OPERATIONAL INTELLIGENCE

- Connects packaging, product and supply chain data
- AI-driven assessment and scenario modelling
- Evidence-backed recommendations and reporting

=

A JOINT SOLUTION FOR PPWR

EVIDENCE-BACKED COMPLIANCE THROUGHOUT THE LIFECYCLE



Automating regulatory compliance with connected supply chain data

Neo4j GraphTalk Boston

Let’s talk about connected data and defensible decisions. Thank you and Happy Halloween!



Jonathan W. Lowe - *amalgo.ai* - 15 October 2026