

US DSCSA Insights (Post-Stabilisation, Exception Mgmt., WEE Transactions, Expanded NDC)



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Excellis Health Solutions, an NNIT group company: Overview

NNIT

NNIT is Global business and technology consultancy, with a focus on advisory, development, implementation and operation services for the international life sciences market.



Excellis Health Solutions

Excellis Health Solutions is an industry leading consulting firm in the supply chain and serialization space helping clients implement technologies and processes to comply with global track and trace requirements and to achieve a value-added digitalization of the supply chain



Enterprise Serialization & Traceability

- Strategy – Healthchecks
- Regulatory Services, Compliance
- Vendor integration,
- Validation Services
- Managed Services (SB, Radar, Alert Management)

Supply Chain Digitalization

- Strategy – Healthcheck
- Partners integration
- Systems integration, IDMP
- Migration, M&A

Brand Protection

NNIT – Global Presence, Strategic Business Services



Strategic Business Areas

- Clinical
- Regulatory Affairs
- Quality Management
- Manufacturing & Supply Chain
- Safety

Service Offerings

- Business Advisory Consulting
- Implementation
- Managed Services
- Migration
- Center of Excellence



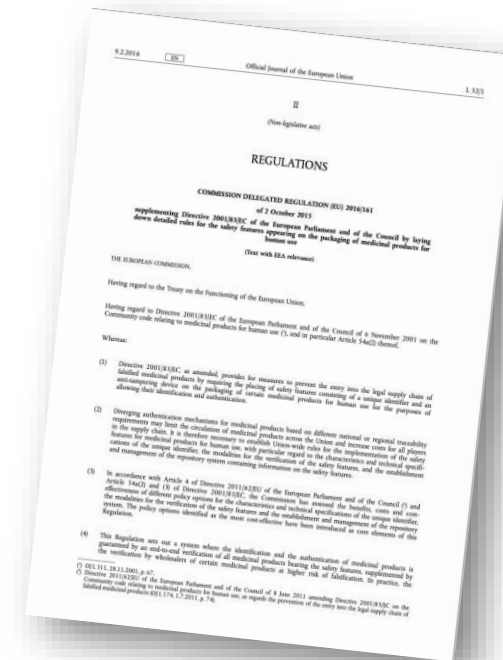
Revenue \$206M+ USD	Revenue Growth 9.6%+
Annual Growth 15%+ last 3 years	Market Cap \$2.7B+
Employees 1700+ employees	Customers 120+ customers

EHS Service Bureau Alert Management : Background

Why do we receive alerts?

DR Article 36 “Operations of the repositories system”: The repositories system shall provide for at least the following operations:

- (b) the triggering of an alert in the system and in the terminal where the verification of the authenticity of a unique identifier is taking place when such verification fails to confirm that the unique identifier is authentic



- When medicinal packs cannot be authenticated, Alerts are raised according to specific rules.
- Alert indicate there are products or packs with quality issues or a suspicion of falsification

EHS Service Bureau Alert Management : Background

What do to do when alerts happen?

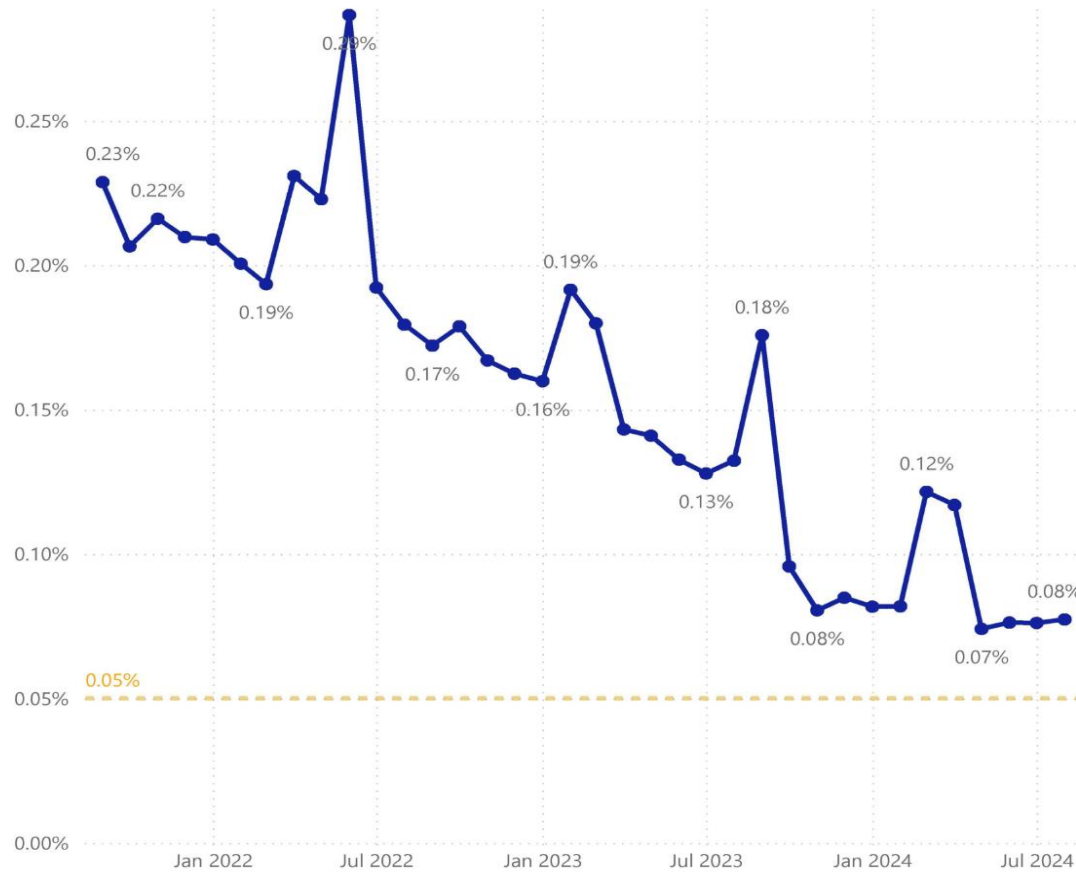
- The Delegated Regulation (EU) 2016/161 stipulates that “Any legal entity establishing and managing a repository which is part of the repositories system shall (...) provide for the **immediate investigation** of all potential incidents of falsification.”
- EU Commission Q&A on Safety Features
 - “The purpose of the investigation in Article 37(d)is to rule out that alerts triggered in the system have been caused for technical reasons, such as issues with the repository system, data upload, data quality, incorrect end-user scanning or other similar technical issues.”

EMVO Report Sept 2024



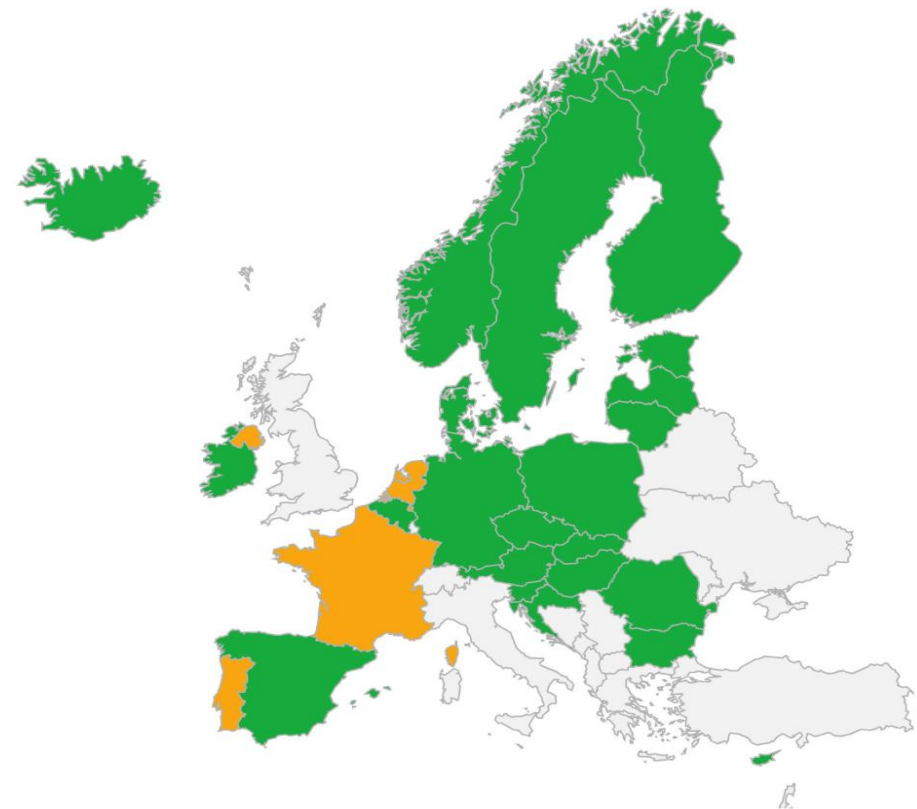
Key Figures

EMVS Overview - Total number of alerts in relation to the total number of scans



Country Overview - Alert Rate - Last calendar month

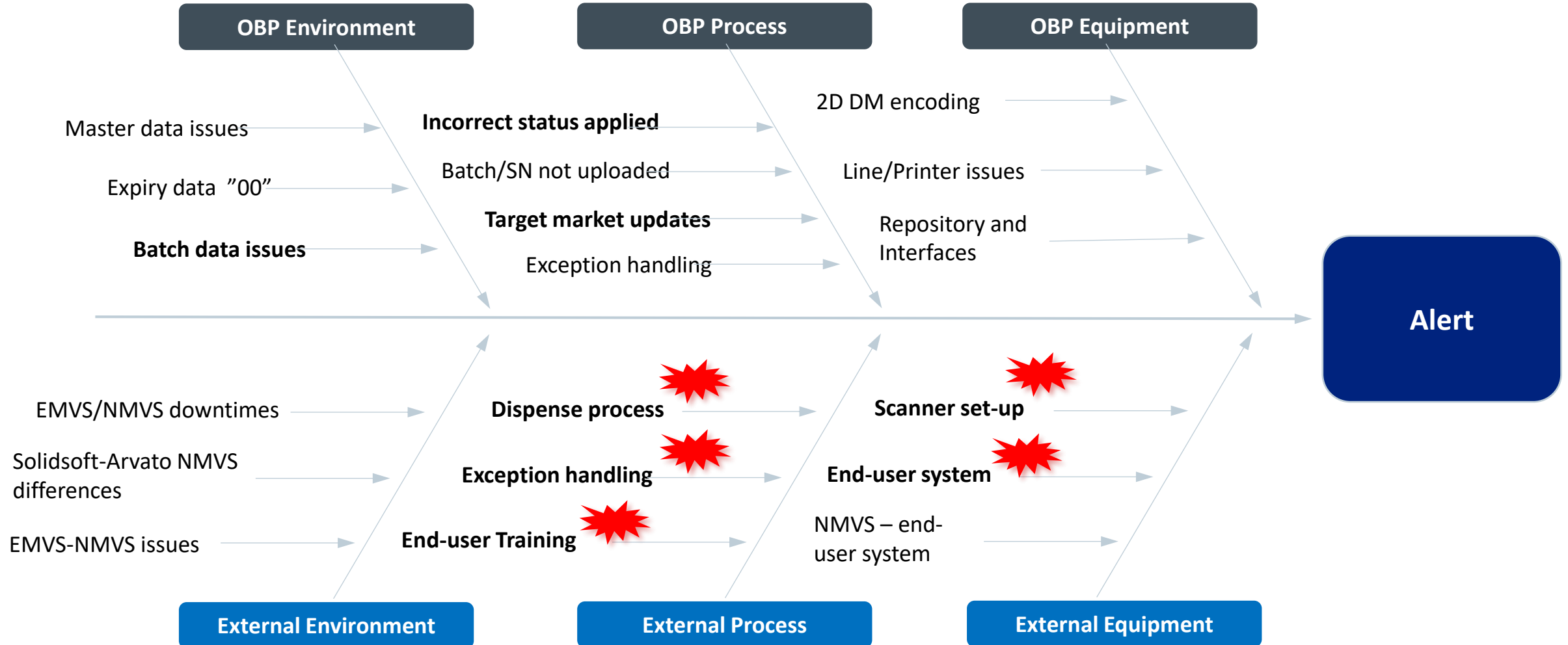
Rate Readiness ● Between 0,1% and 1% ● Higher or equal 1% ● Lower or equal to 0,1%



EHS Service Bureau Alert Management : Root causes of Alerts – Resolutions

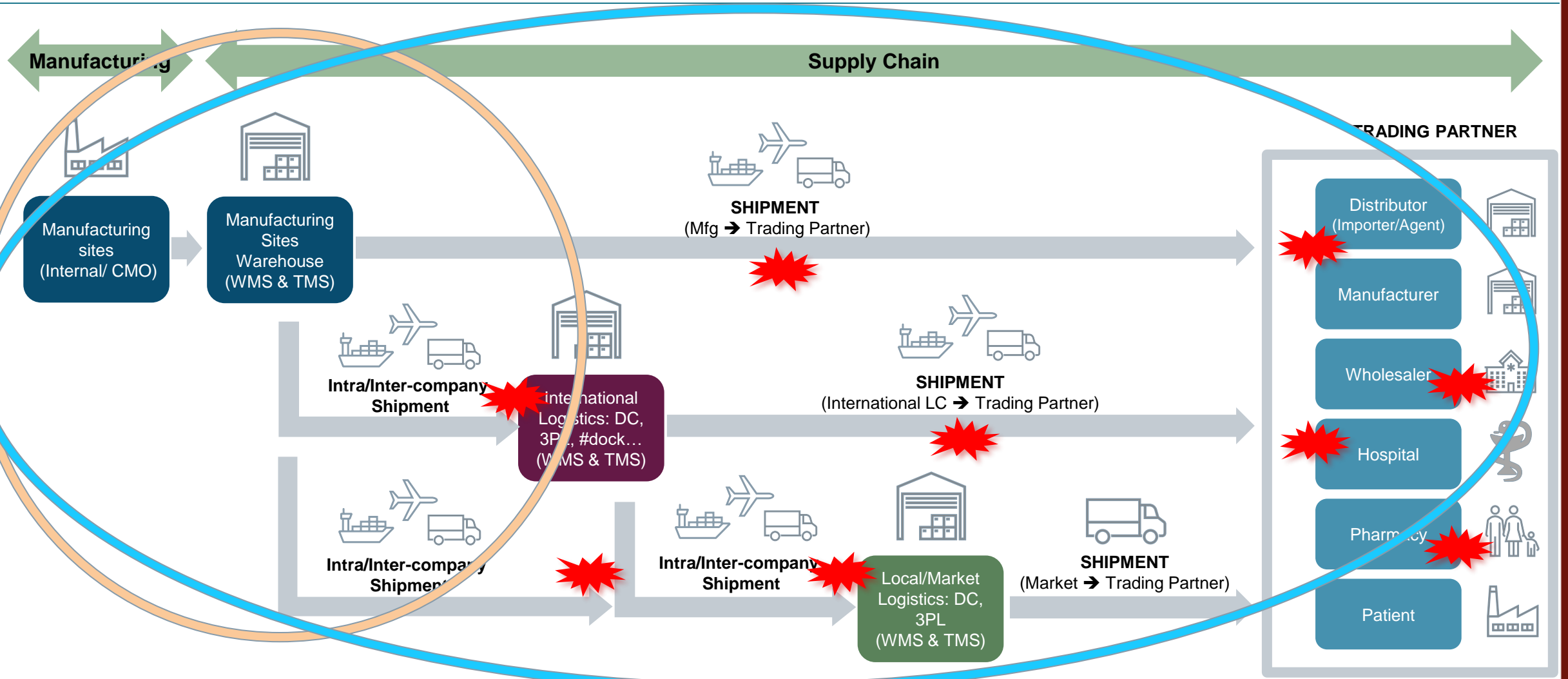
Code	End User -- Root Causes	OBP -- Root Causes	
A2 BATCH NOT FOUND	<ul style="list-style-type: none"> - Scanner/input error - Human error (i.e. typo) 	<ul style="list-style-type: none"> - 2D matrix encoding issue - Batch not uploaded - Master data versioning - Batch data versioning 	***
A24 / A7 STATUS CHANGE FAILURE	<ul style="list-style-type: none"> - Double dispense - Process error - Scanner/input error 	<ul style="list-style-type: none"> - Master data versioning - Batch data versioning - Failed decommissioning 	*****
A3 SERIAL NUMBER NOT OFUND	<ul style="list-style-type: none"> - Scanner/input error - Human error (i.e. typo) 	<ul style="list-style-type: none"> - Master data versioning - Batch data versioning - Serial number not uploaded * 	**
A52 EXPIRY MISMATCH	<ul style="list-style-type: none"> - Scanner/input error - Human error (i.e. typo) 	<ul style="list-style-type: none"> - 2D matrix encoding issue 	*
A68 BATCH MISMATCH	<ul style="list-style-type: none"> - Scanner/input error - Human error (i.e. typo) 	<ul style="list-style-type: none"> - Serial number not uploaded 	***

Alerts have many causes > many are not caused by OBP but are still their responsibility



Serialized Supply Chain Mapping - Overview

The supply chain mapping aims at providing an overview of how Products are supplied from Manufacturer to Trading Partners.



Note: Mfg site Whs and International Logistics Whs can be either Foreign or In-Country this will determine how they are subject to a mandate.