

Fighting Counterfeit Medical Devices in Africa: The Role of Track and Trace Systems

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Agenda

Understanding Medical Device and Counterfeits

01

The Facts and Classification

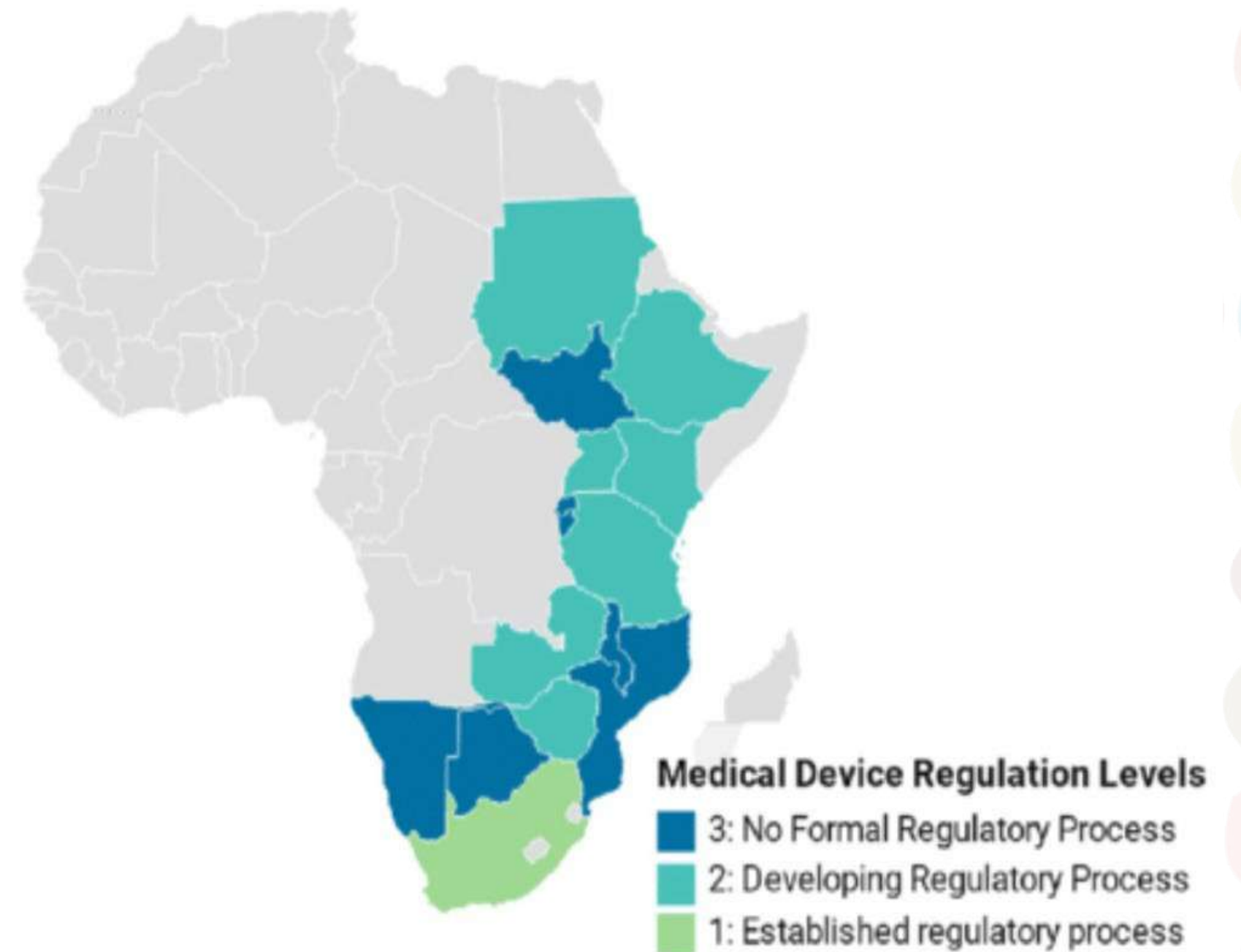
02

VISIOTT | TPS as a Solution Provider

03

Understanding Counterfeit Medical Devices in Africa

- **Definition:** Counterfeit devices mimic authentic products but lack certification, safety, and effectiveness.
- **WHO:** ~10% of medical products in low- and middle-income countries are substandard or falsified.
- **Impact:** High risk of ineffective or harmful products leading to serious health issues or death.





Emir Giray – 4 Years Old
Type 1 Diabetes



submed Easy Alkollü Mendil %70 İpa, 8x11cm Cilt Temizleme Mendili Swap, Paket 6x6cm, 100 Adet
 + Trendyol Plus'a Özel
 Sepette 258.40 TL
 272 TL



Extent of Counterfeiting in Africa

- Many African countries heavily affected by counterfeit medical products.
- Threat to public health with high prevalence of substandard and falsified products.
- Immediate need for effective solutions to protect patients.

Market Segmentation by Device Class:

Class I (Low-Risk Devices): Examples: Bandages, stethoscopes, surgical gloves.

Market Share: Represents around 15-20% of the market.

Growth Driver: Expanding healthcare access and need for basic healthcare tools.

Class II (Moderate-Risk Devices): Examples: Blood pressure monitors, syringes, diagnostic kits.

Market Share: Accounts for approximately 30-35%.

Demand: Increasing need for diagnostic devices and chronic disease management tools.

Class III (High-Risk Devices): Examples: Infusion pumps, ventilators, diagnostic imaging equipment.

Market Share: About 40-45% of the market.

Growth Driver: Rising demand for advanced healthcare infrastructure and better diagnostics.

Class IV (Very High-Risk Devices): Examples: Implantable devices like pacemakers, heart valves.

Market Share: Roughly 5-10% but growing due to specialized hospitals and medical tourism.

Track and Trace as a Solution

Traceability Systems: Use unique device identification (UDI) codes to verify the authenticity of devices at every stage, from manufacturing to patient use.

Benefits:

- **Enhanced Safety:** Ensures only verified devices reach patients.
- **Increased Accountability:** Identifies counterfeit sources and mitigates risks through rapid recalls.
- **Market Transparency:** Builds trust within healthcare systems by safeguarding supply chains.

Advantages of Traceability Systems

- Enables rapid counterfeit detection and removal from the market.
- Allows patients to verify their devices, enhancing trust.
- Assists in compliance with international safety regulations.

What is UDI?

UDI systems are intended to benefit healthcare providers, manufacturers, authorized health authorities, hospitals and institutions, and individual consumers by providing:

- Faster discovery of possible flawed medical device information by health authorities.
- Quicker access to recall information, and visibility into current inventory.
- A reduction in medical errors through consistently documented product expiration dates.
- Identification of any counterfeit products being used in healthcare facilities.
- Assurances that information regarding an implanted device is safely retained and traceable.

General UDI labeling requirements

There are two components to a medical device UDI: the UDI device identifier (UDI-DI) and the UDI production identifier (UDI-PI). The UDI is presented as a barcode label (human and machine readable) on device packaging or on the device itself and acts as the access key to all device UDI attributes.

UDI-DI: This is the static portion of the UDI which identifies the manufacturer along with the specific device version. The UDI-DI (device identifier), also known as the Global Trade Item Number (GTIN) is assigned by an approved organization, such as GS1, and contains:

- Company prefix
- Manufacturers internal product code
- Check character

The UDI-DI is the primary identifier to be used in looking up device attributes in country-specific databases and is assigned prior to placing a product on the market. Note that the device identifier is different for different packaging levels of the same device.

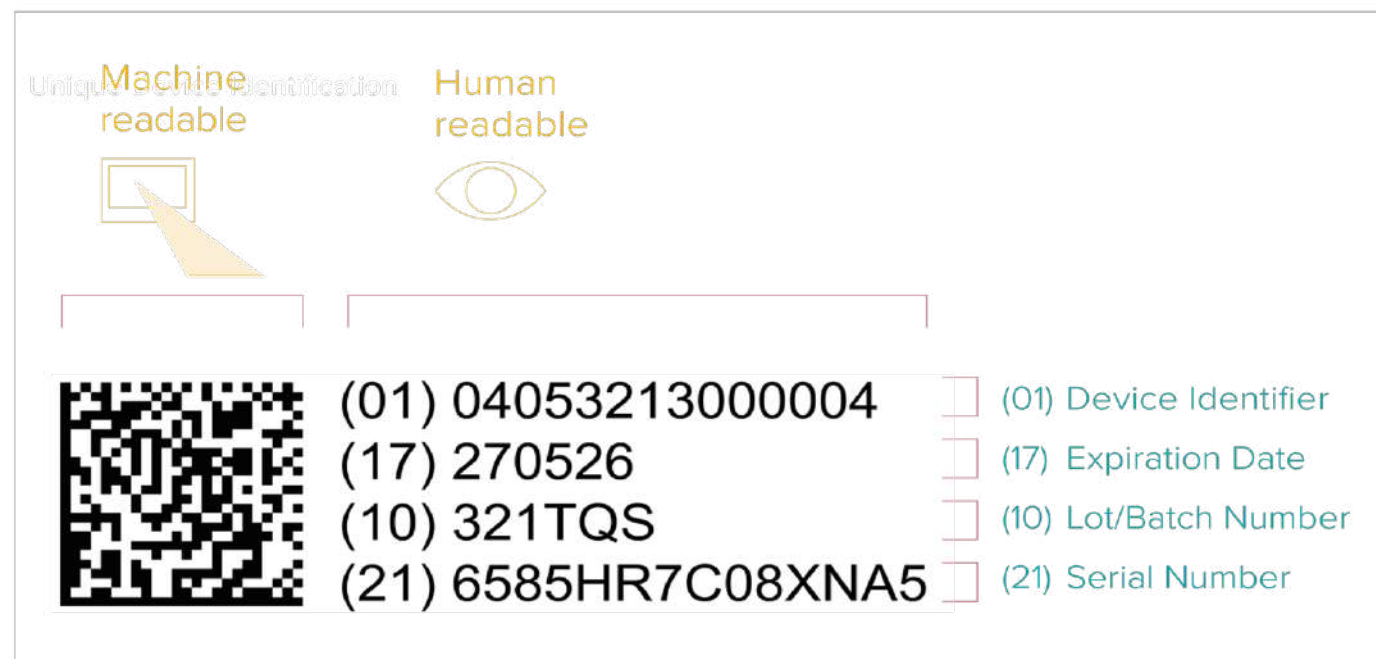
UDI-PI: This is the dynamic portion of the UDI which is assigned by the manufacturer and identifies one or more of the following:

- Manufacturer's lot or batch number
- Serial number
- Manufacturing date
- Expiration date
- Other attributes as defined by country-specific regulations

The UDI-PI actual values do not appear in country-specific databases (with the exception of the EU vigilance database).

Unique Device Identification (UDI) System

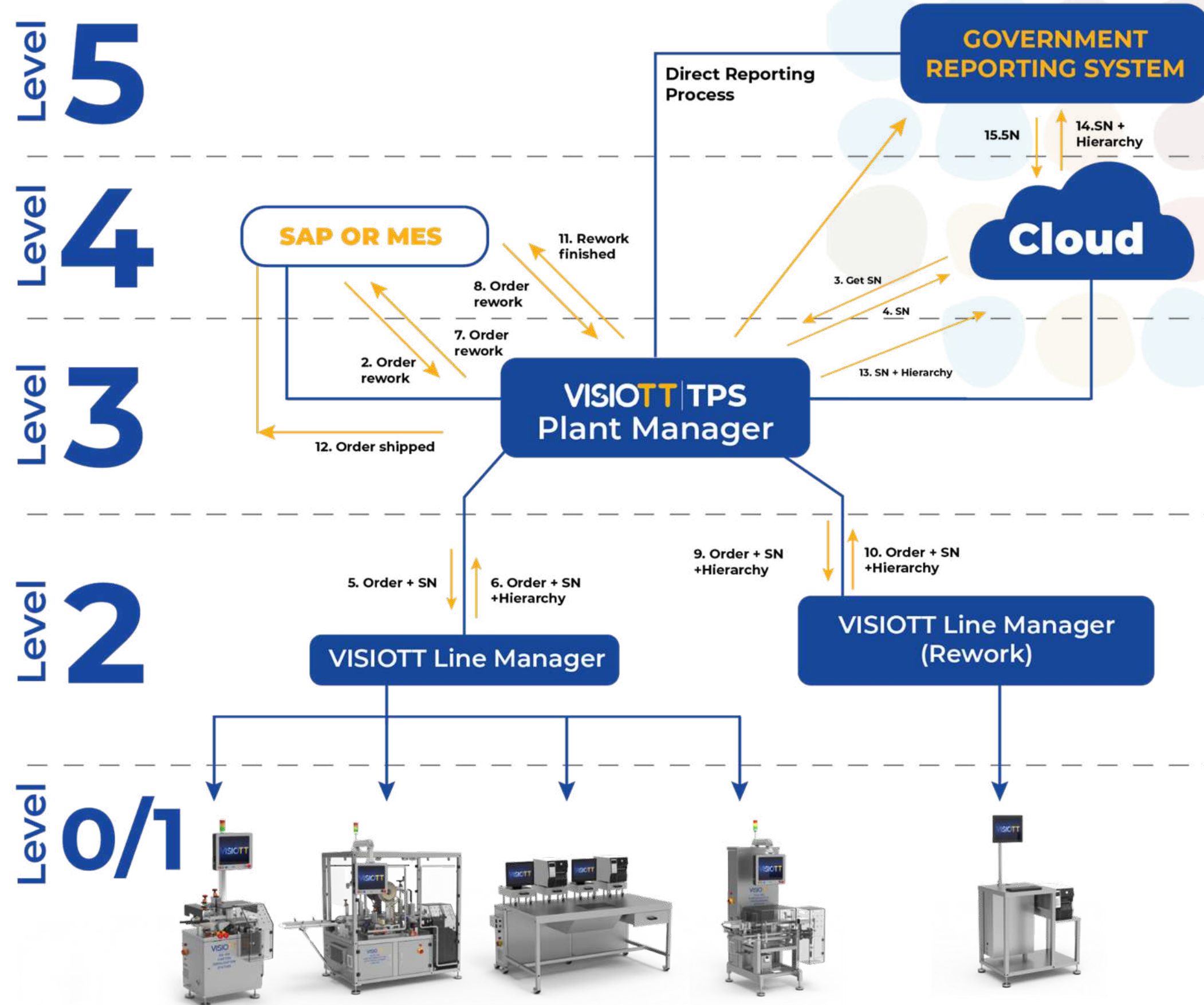
- Global standardization for traceability.
- Essential for quick detection of counterfeit products.
- Facilitates efficient recall management and product verification.



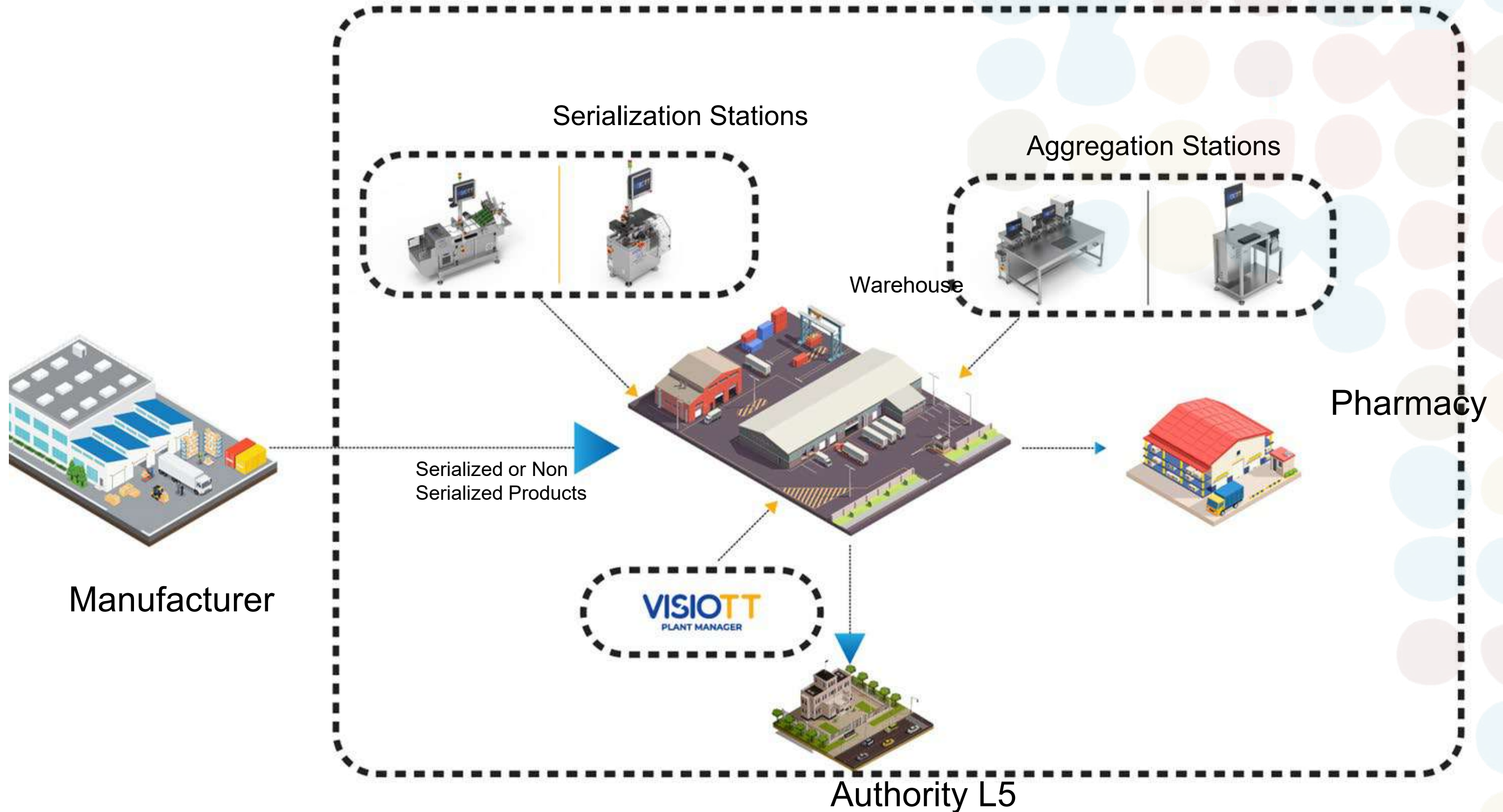
GS1 DataMatrix code for capturing UDI code



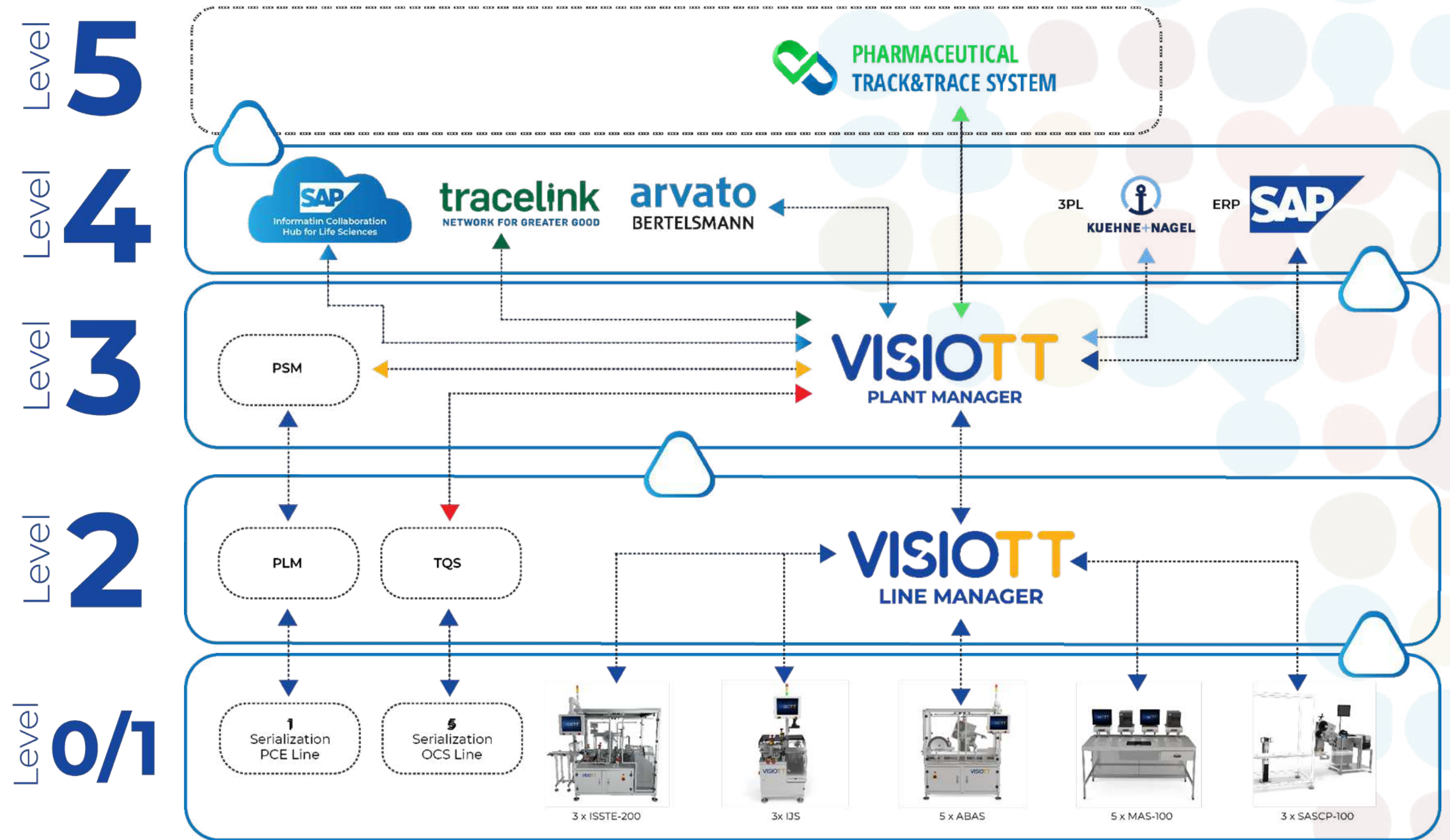
GS1-123 barcode lineare comunemente utilizzato per l'UDI



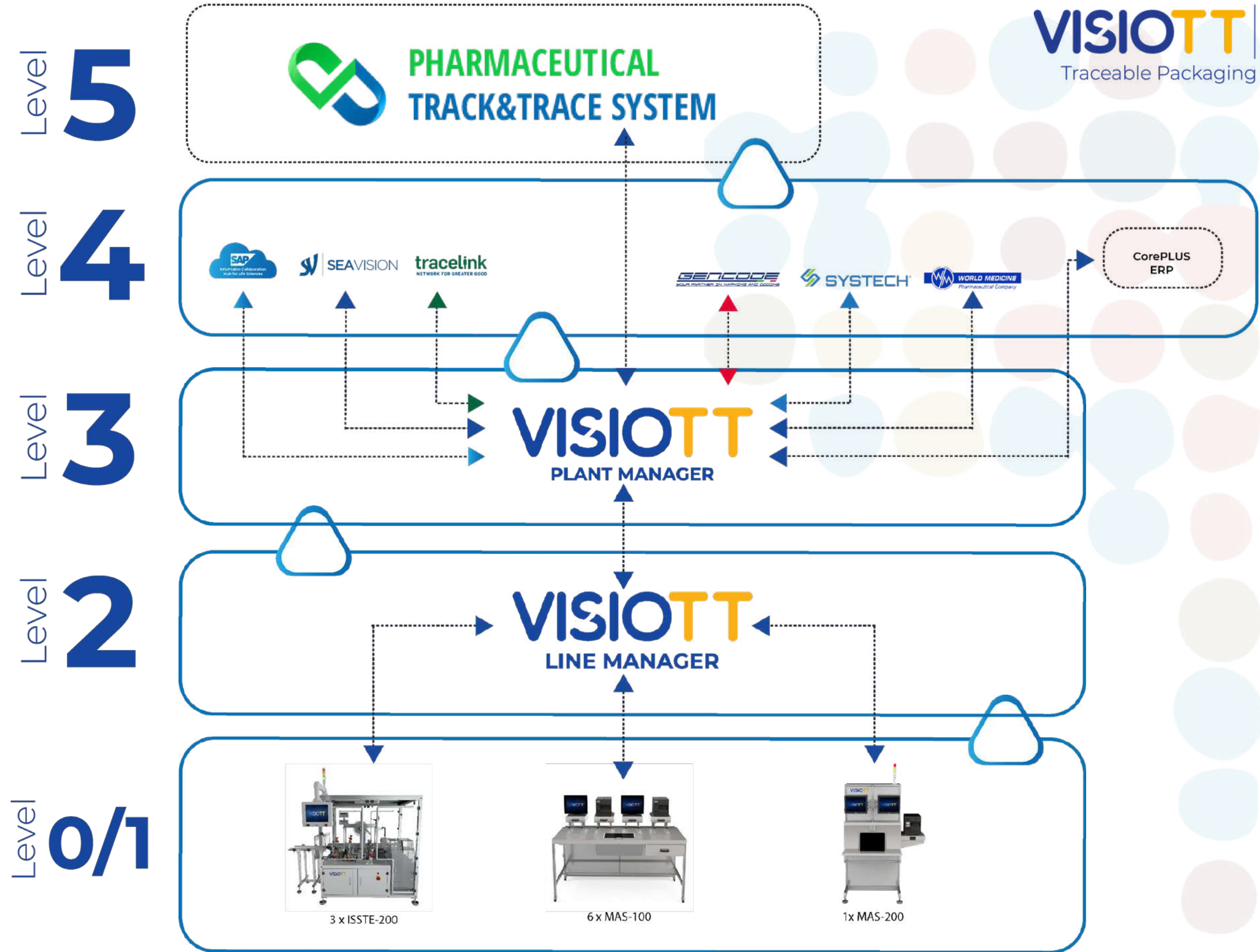
Export Model & Import Model



COMPANY A

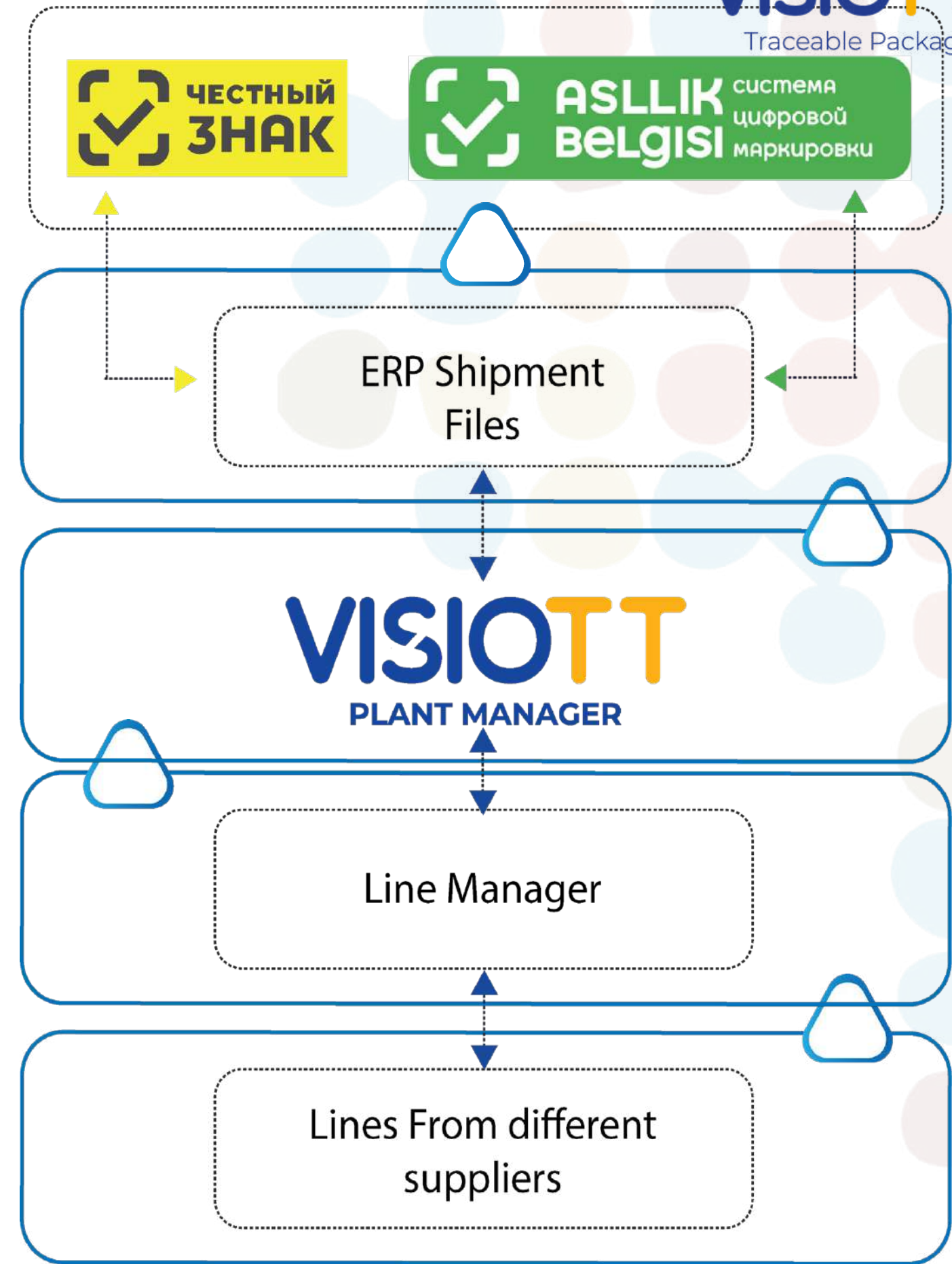


COMPANY B



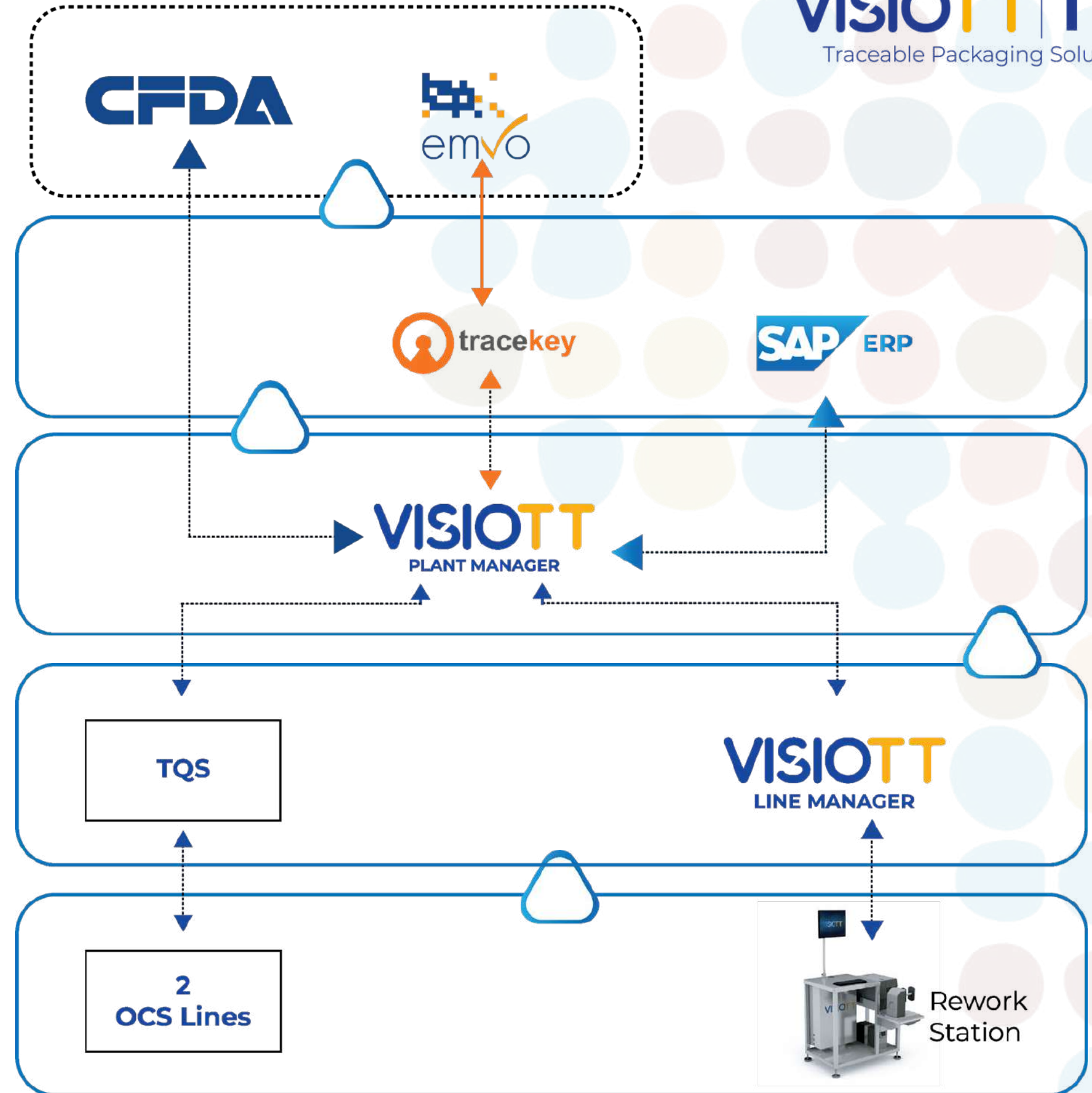
COMPANY C

- Level 5
- Level 4
- Level 3
- Level 2
- Level 0/1



COMPANY D

Level 5
Level 4
Level 3
Level 2
Level 0/1

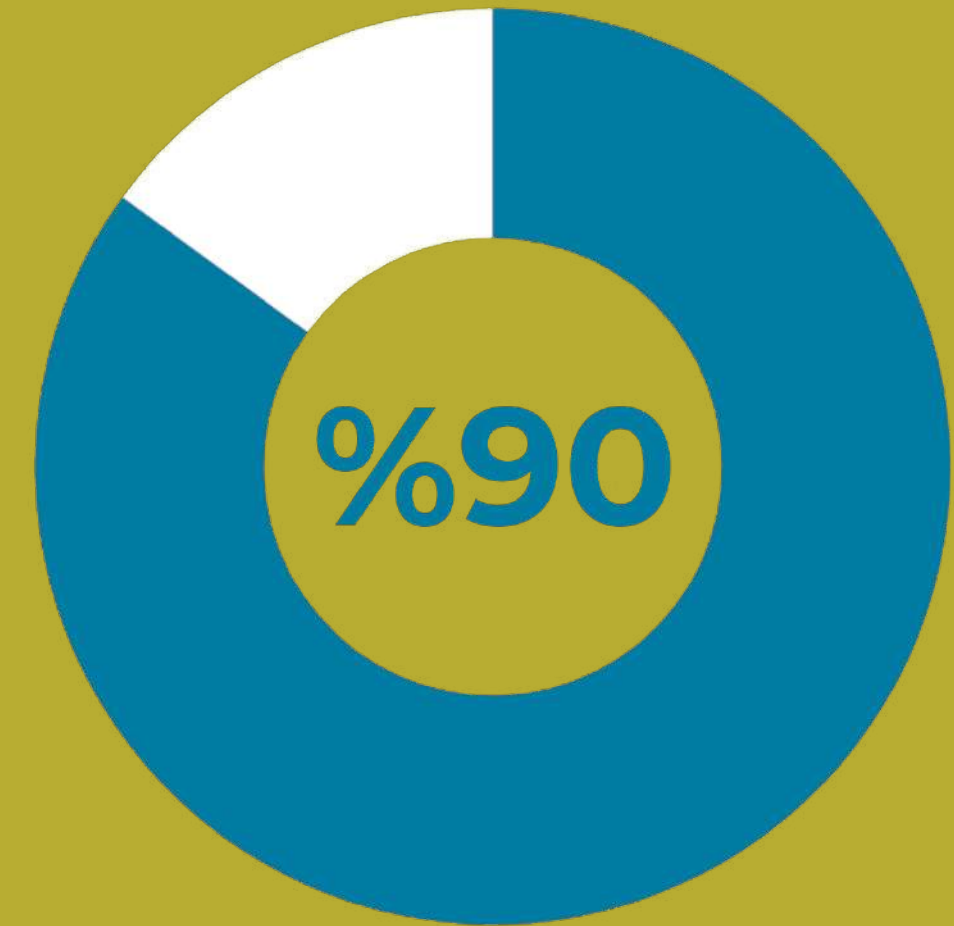






PIONEER IN TRACK AND TRACE SOLUTIONS IN THE WORLD

Turkey: First and best practice in the world
End to end Pharmaceutical track and trace implementation
in 2008.



Market Share
Pharmaceutical in Turkey

+5000

**Installed
Lines All Around
the World**

All in One Solutions



HARDWARE

Serialization
Aggregation
Labeling
Checkweigher
Case Packer



SOFTWARE

Level 2 Line Manager
Level 3 Plant Manager
Level 4 Enterprise Manager



SERVICE

Consultation
Validation
Installation
Training
24/7 After-sales support
Spare part supply



INTEGRATION

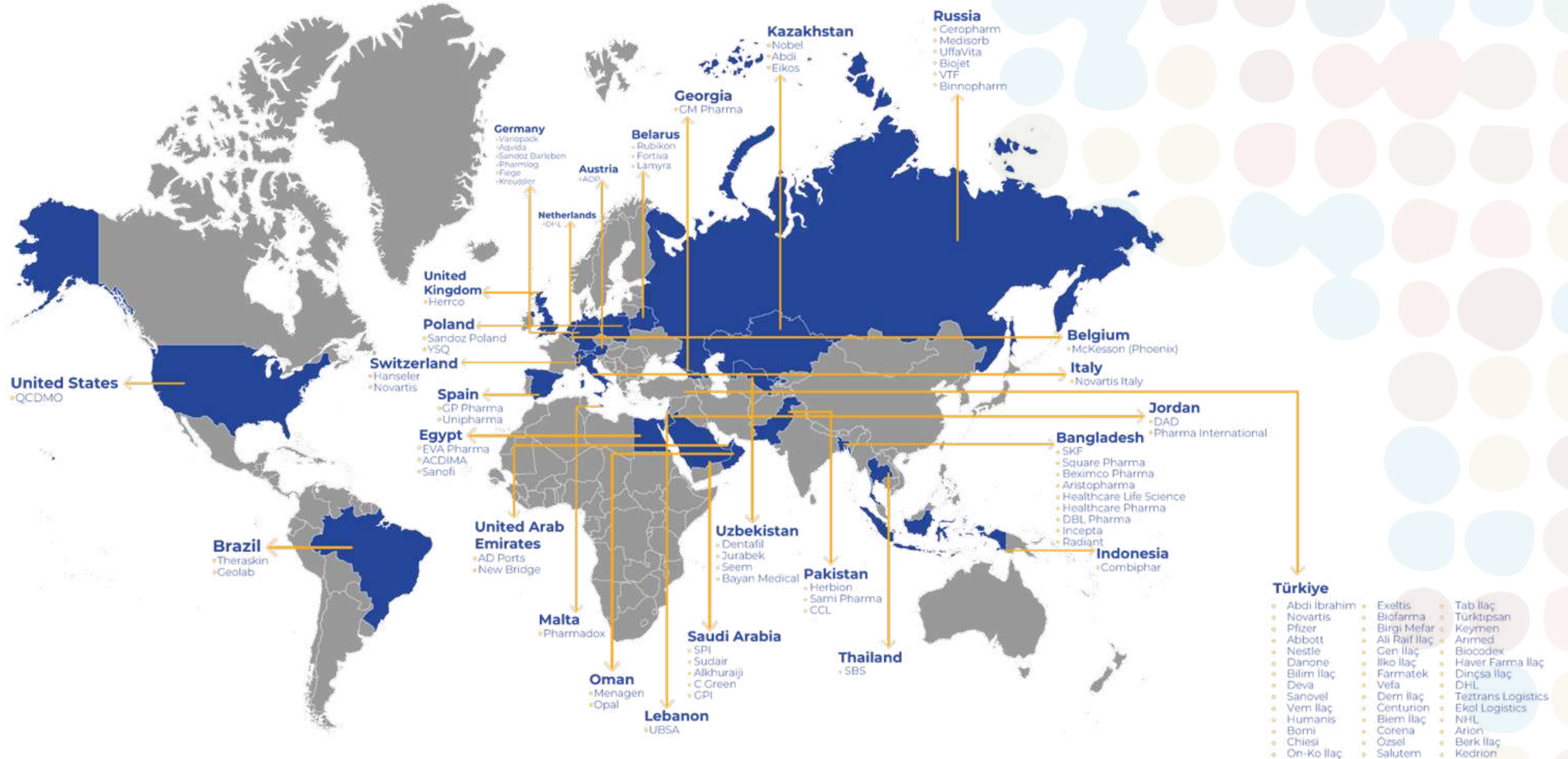
ERP
WMS
L4 Software

Full Track and Trace Software Levels Covered

- Created ISA 95, OPC, SCADA standards
- Meet the requirements of all track and trace regulations around the world
- Send notifications to authorities such as EU, Turkey, KSA, Russia, Uzbekistan, Kazakhstan, UAE, etc (exchange data)
- Communication with CMO, MAH, Distributor, Warehouse, etc
- High-capacity integration of SAP, 1C, ARVATO, ORACLE ERP systems









THANK YOU