Modern Track&Trace systems to counteract fraud and safeguard the quality and safety of pharmaceutical products.

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Agenda

- ✓ Serialization and Aggregation in Manufacturing Industry

- ✓ Regulatory requirements of Health Authorities

- ✓ Case study: In Line Implementation or Vendor Serialization

- ✓ The Future of the Track&Trace

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Agenda

Serialization and Aggregation in Manufacturing Industry

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Serialization and Aggregation in Manufacturing Industry

Continuous and accurate monitoring of each produced item.

3 essential levels of tracking

01

Serialization

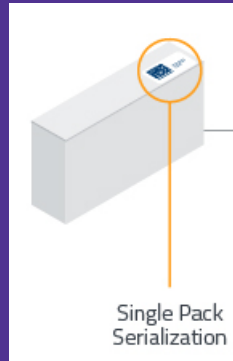The unique identification of an item is the first step in a production monitoring process.

Our focus

- Knowing the moment each piece was handled on the production line.

- Immediately recognizing the authenticity of the products.

Single Pack Serialization

02

Shipping Case Aggregation

Aggregation to shipping case allows to know any handled of the products and every technical issue during shipping process.

Our focus

- Case hierarchy to keep track of technical issues.

- Greater safety for patients thanks to the serialization of the case.

Case Aggregation

03

Pallet Aggregation

Aggregation level that gives us all products information with a quick and simple scan by one barcode available on pallet.

Our focus

- Complete information hierarchy for a higher level of quality.

- One quick scan to have all information.

Pallet Serialization

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Serialization and Aggregation in Manufacturing Industry

3 essential levels of tracking

01

Serialization

Human Variable Data
Product code GTIN
Serial Number
Expiry date
Batch number

Data encoded in the Data Matrix Code (DMC)
AI (01) - Product code (GTIN or NTIN)
AI (21) - Serial number
AI (17) - Expiry date
AI (10) - Batch number

02

Shipping Case Aggregation

Data encoded in the Data Matrix Code (DMC) and Barcode
AI (01) - Product code (GTIN or NTIN)
AI (21) - Serial number
AI (17) - Expiry date
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Human Variable Data
Product code GTIN
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03

Pallet Aggregation

Human Variable Data
Product code GTIN
Serial number
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Data encoded in the Data Matrix Code (DMC) and Barcode
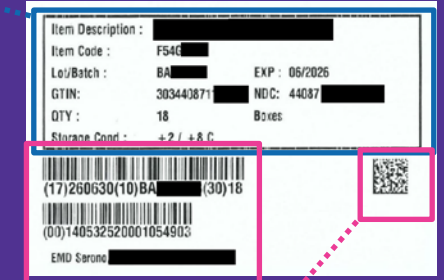AI (01) - Product code (GTIN or NTIN)
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Agenda

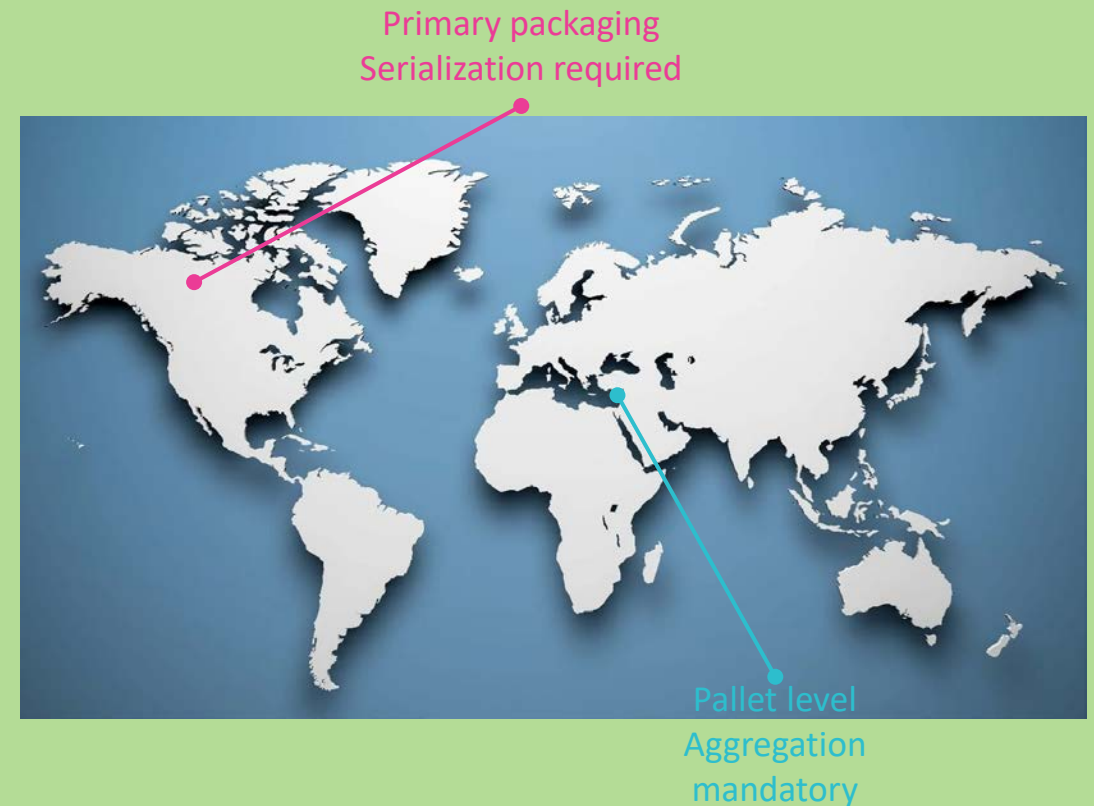**Regulatory requirements of Health Authorities**

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Regulatory requirements of Health Authorities

Although global logistics has, over time, adopted a shared international standard, indeed most countries and markets are aligned with the GS1 standard, each country has its own health authority and, therefore, each country has its own needs. A modern company must follow the market and therefore adapt to all the different standards required, but this cannot make it lose the fixed points of traceability.

01

Requirements analysis

Each health authority issues requirements for the marketing of pharmaceutical products in its country of competence. These rules also contain information regarding the traceability of products. So, each country specifies whether tracking must be done at the box, shipping case or even pallet level. It specifies which data must be encoded and which in human readability.

Primary packaging
Serialization required

Pallet level
Aggregation mandatory

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Regulatory requirements of Health Authorities

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02

Determining the necessary serialization levels

In some countries aggregation levels, in addition to serialization, are not always required, because distribution could be very extended, so it would require a disaggregation process that could increase costs. Therefore, when carrying out production lines development plans, it is good practice to comply with regulatory requirements so as not to increase costs without providing real added value.

No GS1 standard

Partial containers serialized

Regulatory requirements of Health Authorities

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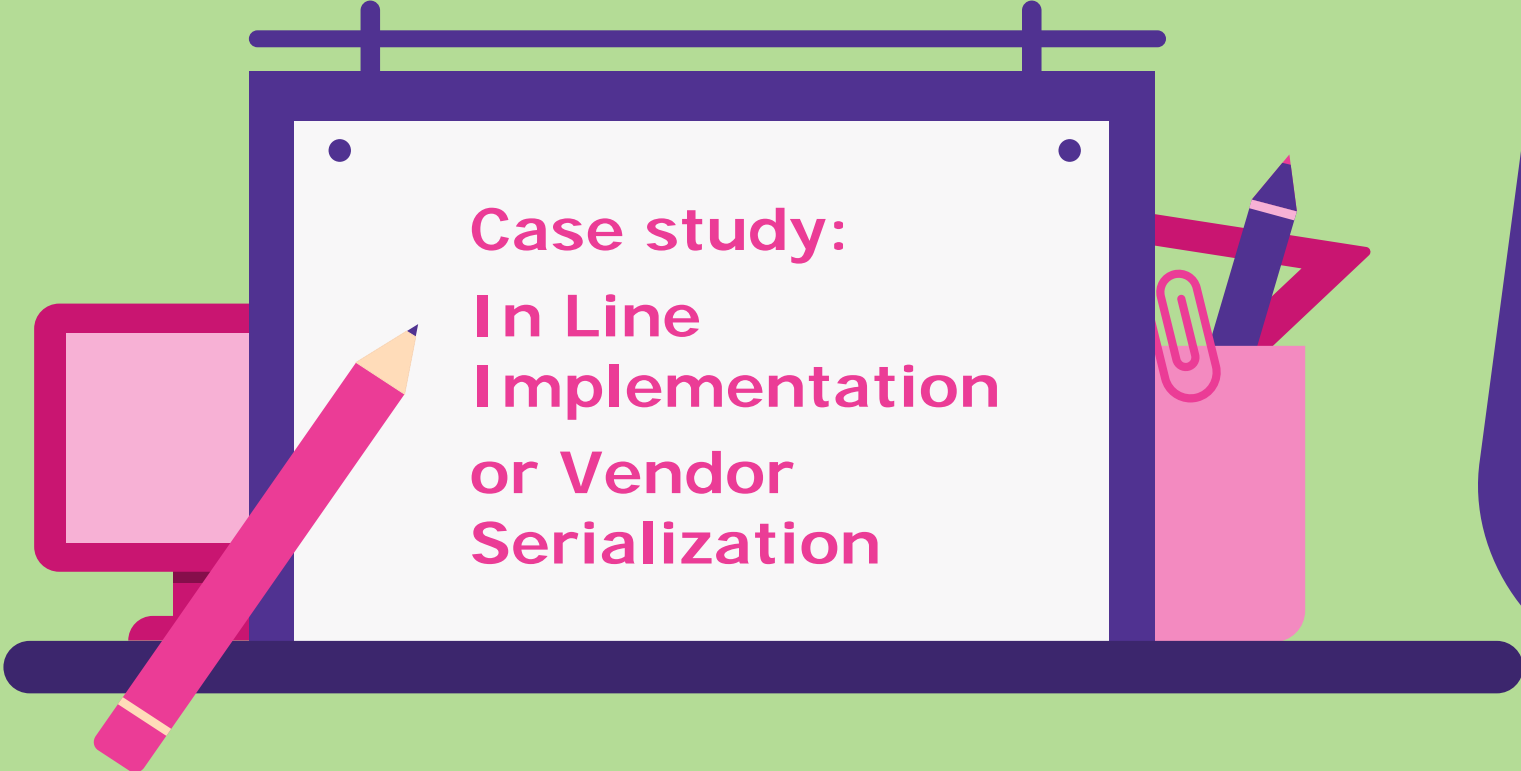
03

Establishing information for distribution

Among fundamental information to be completed there is:

- Language: patients must be able to understand all information;
- Date format: It is essential to respect the format understood in the country of the destination;
- Data Coding: there are many codes that can be used but health authorities establish the rules.

Spanish language

Data bar GS1 Coding mandatory

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Case study: In Line Implementation or Vendor Serialization

The choice

The first step in choosing an internal serialization or using an external supplier is related to the analysis of the SKUs and the target markets.

Considering:
1. the high number of countries of destination of our SKUs;
2. the constant increase of countries that require the traceability of the products;
3. the presence of different production sites in different countries of the world;

our company's choice was to internalize the serialization process by implementing it directly on the production lines.

Case study: In Line Implementation or Vendor Serialization

Hardware Implementation

The serialization process requires some essential elements for its in line implementation per production line:

Serialization
- n.1 printer and n.1 vision control system for printing and checking serialization data;

Shipping Case Aggregation
- n.1 system acquisition of serialized data of items to be aggregated to the shipping case;
- n.1 printer and n.1 vision control system for printing and checking serialization data printed on shipping case;

Pallet Aggregation
- n.1 system acquisition of serialized data of shipping cases
- n.1 printer and n.1 vision control system of pallet serialization data

Hardware implementation is composed of no less than:
- n.3 printers: pre-existing printers could be adapted;
- n.3 vision and control systems;
- n.1 off-line reworking station for technical issues during normal in line process.

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Case study: In Line Implementation or Vendor Serialization

Software Implementation

The second part of the implementation involved the choice of software that would allow the management of Track&Trace information at the production site level but also at the company level.
There are, at least, two software for managing such a complex process:

- Software to manage Track&Trace process in line level and manufacturing site level: this software must allow the management of a multi products database, recipes validated, but above all to manage all information that must automatically come from advanced batch management systems (MES).

- Software to manage "supply chain of the SNs":
  one of the most important elements is the level 5 software of the pyramid of the automation, which manages the whole SN history: generation, exchange with partners, exchange with CMOs, with customers, health authorities, warehouses; always in compliance with the requirements of the HA.

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Case study: Advanced Serialization

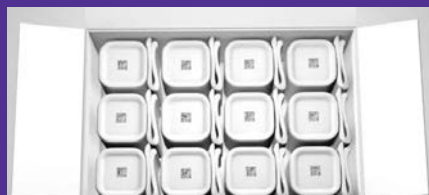Merck

The Future of the Track&Trace

A modern manufacturer must have a modern Track&Trace system, which allows them to have control and traceability throughout the product life cycle. As we have seen, there are different levels of control available, but the future is just around the corner, and new features will have to be implemented to keep up.

Among the possible future target for the Track&Trace could mentions following:
- the use of the GTIN, already used for serialization process, to link at the electronic leaflet;
- increase the identification of the primary packaging for a high-quality level for anti-counterfeiting;
-   identification of blister by data matrix code.

Serialization

Shipping Case
Aggregation

Pallet Level
Aggregation

Next Steps
of the Track&Trace

THANK YOU