



RESOURCES

Home
Resources
Resource Center

Case Study: Ferrer | Building a Master Data Strategy for EU FMD



As a large and diverse international pharmaceutical manufacturer, Ferrer recognized that it would need a multidisciplinary approach to prepare its master data for EU FMD compliance. Learn how TraceLink played a role in ensuring their master data was correctly updated to the EU hub, a key component of their successful serialization implementation. Ferrer’s poster, “Master Product Data Strategy for EU FMD Implementation,” was one of 11 featured during FutureLink Barcelona’s interactive Poster Sessions.

Master Product Data Strategy for EU-FMD implementation: the key of success in serialization

Author(s): Cristina Bonache (Corporate QA), Laia Gállego, PhD (Corporate QA), and Blanca Sánchez (Global RA)

Business Challenge & Solution

Ferrer was founded in 1959. Ferrer is a privately-held international pharmaceutical company headquartered in Barcelona. It is active throughout the full value chain, from R&D to international distribution. Present in more than 110 countries, with 19 international affiliates, Ferrer is active in the pharmaceutical, health, fine chemical and food sectors, key areas for contributing to people's health and wellbeing.

In such a big and diversified company, the management of master data is already a challenge, but even more if the master data must be used to meet a regulation like the Directive 2011/62/EU to fight falsified medicines and the EMVS Master Data Guide (involving about 25 variables to complete for each product).

The upload to the EMVO of the company master data can be successfully achieved through multidisciplinary team work, alignment across the company systems, simple but powerful tools like Excel, and "lots of reviews and patience".

Team



Objectives

- Our final goal, to upload our master data product to the EMVO, required several steps:
- Obtain a deep knowledge of the EMVS Master Data Guide and Tracelink Master Product Data management.
- Gather all the required information to compile a unique database.
- Upload the right master data product to Tracelink.
- Meet the 9th February 2019 deadline to upload the Master Product Data to the EMVO and its distribution in the NMVSs.

And do not forget...
Sign the QBP contract with EMVO and contracts with NMVSs (mandatory), otherwise your data will neither be uploaded nor distributed. *Without the master data product uploaded it's not possible to serialize in Europe.*



Key Activities and Resources

Our basis?

- Regulatory Affairs provided a complete list of prescription drugs dossiers authorized in Europe, under the scope of EU-FMD. This was the most trustful information which was an excellent basis to start building a new data base.
- Each dossier had several SKUs, where only the commercialized were taken into consideration to build up the database.
- Massive SAP csv extracts were requested to the IT team.
- Massive extract of Eudragrance Database was requested to PV.

This allowed us to create a mother spreadsheet with all the info crossed to start reviewing, modifying and updating our systems.

What do you need to create a product in Tracelink for EU?

Where did we obtain the information from?

Source	Information
Regulatory Affairs	Product Name, Strength, Dosage, Form, etc.
SAP	Product Code, Description, etc.
Eudragrance Database	Excipients, etc.
Internal Systems	Manufacturing Site, etc.

Critical Success Factors

- An expert in Excel lookup and data cleansing.
- An expert in SAP and master data product codification.
- Reliable information of products (RA).



Outcomes

Organizing data

- Product Group code has a big impact in the organization of the data in Tracelink.
- In this case, scenario coding scheme was used so that the connection used for the product could be identified easily by anyone.

Example:

PRODUCT GROUP CODE	SCENARIO
FERRER-SANTCUGAT	MAH-Manufacturing Site of MAH
FERRER-LESVI	MAH-CMO
TEVA-FERRER	MAH-CMO
TEVA-FERRER-NORMON	MAH-PCMO-CMO

Codifying and updating systems MD

- Work with the "Coding requirements guide" of the EMVS is a MUST. Otherwise there will be issues with NMVS.
- Attention to multimarket clusters. Not all countries coding schemes are compatible.
- Tracelink information must be the same as in other systems: SAP (ERP) or systems gathering information to print serialized data in lines.



Results & Feedback

- 603 Master Product Data were uploaded correctly to the EU-HUB.
- 282 Master Product Data from Customers were created in Tracelink to serialize.
- 197 SKUs involve a VCMO scenario (extra effort on aligning MD).

Connections / Roles	SKUs
28 Customers	282
3 Ferrer's manufacturing sites	262
48 CMOs	341
Test of MD created	885



Recommendations

Advice

- Use the most trustful source in your company which gathers the maximum of fields required.
- Have a clear scenario for each product (manufactured in-house, CMOs, is a customers' product...)
- Create Master Data Partner for CMOs, Customers, and Annex 5 (distributors or local representatives) before uploading the Master Product Data.
- Align your systems at the same time as Tracelink, do not leave it! Otherwise information won't match.

Lessons Learned

- The list of products under the scope of EU-FMD is the first thing to do in the serialization project.
- Master Product Data compilation is an undervalued and underestimated work despite its complexity and critical role in the serialization. For instance, a single mistake can lead a batch into destruction. Companies need to assign appropriated resources to cover this side of serialization.
- Assessment of artworks is needed for multimarket clusters.
- Do not leave the signing of NMVS contracts as a "secondary" task. In Germany, if the contract is not signed, it is not possible to commercialize serialized products (master product data can't be uploaded).

Next Steps/Improvements

- A new RA database is being built using the information gathered for serialization.
- Master Product Data is a never ending story. It needs changes, new products, deactivation of SKUs...



View Poster Session Gallery

Case Study European Union Falsified Medicines Directive Global Track & Trace Regulatory/Compliance European Union

Subscribe to Agile Supply Chain Insights

Subscribe to stay informed with the latest patient-centric agile supply chain thought leadership content.

Related Content

Serialized Supply Chain

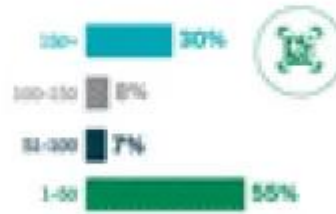
TraceLink's serialization program assessment continues to reveal that pharmaceutical manufacturers of every size want greater visibility into their serialized operations. They want the ability to answer critical business questions using serialization data. They want to replace manual processes with proactive monitoring tools to help them control costs and reduce risk. And they want self-service analytics that let them scale operations as their businesses grow. How do your goals align with these industry benchmarks?

QUICK LOOK: A SNAPSHOT OF SERIALIZED OPERATIONS

Number of Full-Time Employees



Number of SKUs



Number of Markets



SKUs that Require Special Handling



Serialized Operations: Challenges and Opportunities

How do your serialized operations compare with more 100+ pharmaceutical companies? Get the results of TraceLink's serialization program assessment.

[View More](#)



Solving the COVID-19 Pharma Supply Chain Struggle

See exclusive research on COVID-19's impact on pharmaceutical supply chain agility, visibility, and resilience. Get actionable insights.

[View More](#)



How Does Serialized Product Intelligence Enable Root Cause Analysis of Compliance Errors?

Watch this product demo to see how Serialized Product Intelligence empowers serialized operations teams with self-service troubleshooting capabilities.

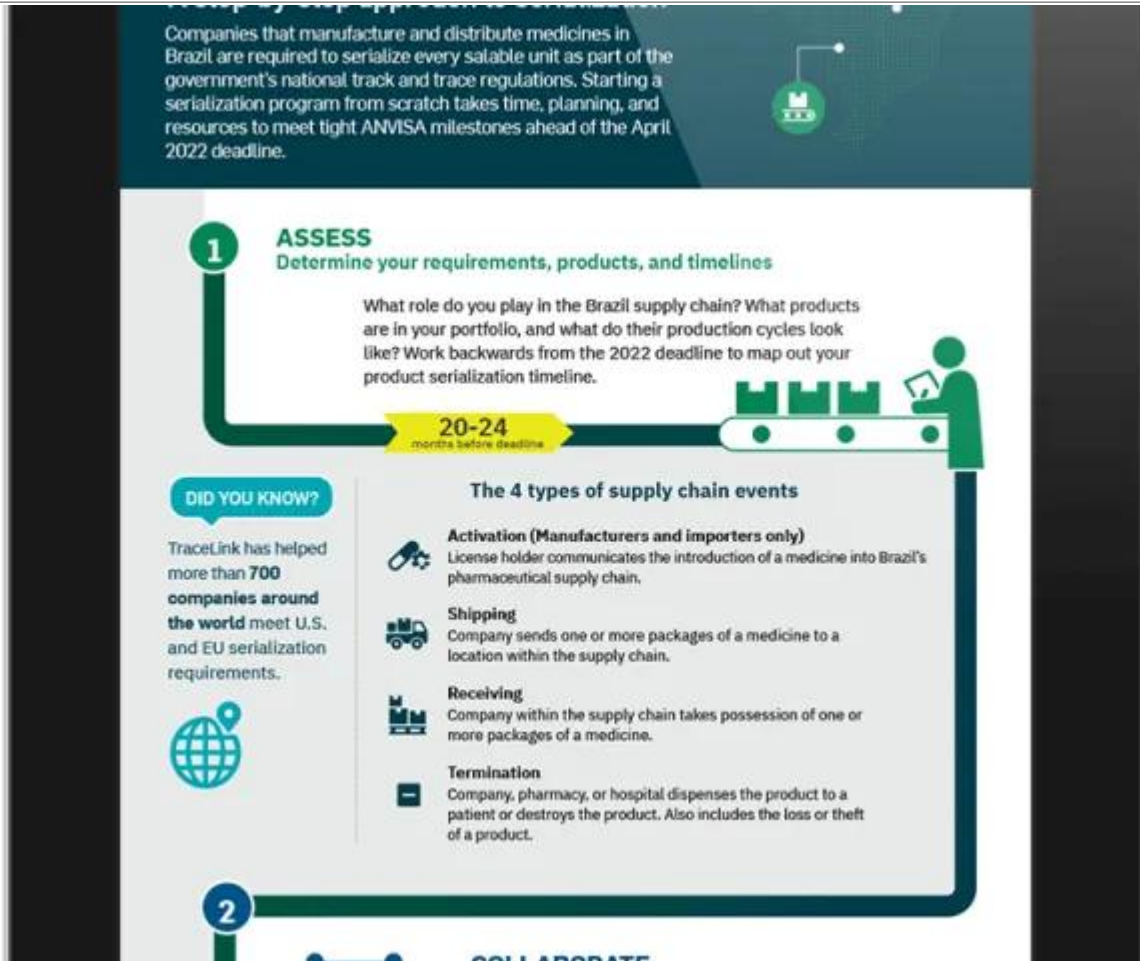
[View More](#)



Poll: Russia Crypto Codes Create Unique Operational Challenges Manufacturers Must Address Now

Companies are moving forward with Russia compliance and crypto code strategies. Are you behind?

[View More](#)



Brazil Compliance: A Step-by-Step Approach to Serialization

Begin your Brazil serialization journey and see why you need to start today to meet the April 2022 ANVISA deadline. Download the infographic.

[View More](#)



Why An Open, Standards-Based Approach is Essential for the Pharmaceutical Supply Chain

Learn five critical criteria to determine whether you want a trusted partner or just a vendor.

[View More](#)