



EMVO serialization integration



Environmental factors

No barcode, no trade

Failure to comply with the EU regulation until February 9th 2019 means that you cannot legally ship your product anymore.

EMVO and Pharma Manufacturers

Starting from February 9th 2019, the Falsified Medicines Directive (FMD) imposes strict serialisation requirements on pharmaceutical manufacturers, distributors and dispensers in EU countries.

All Marketing Authorisation Holders (MAH) will need to subscribe to the European Medicines Verification Organisation (EMVO) as On-boarding Partner (OBP) or decide which legal entity will act as their OBP. All relevant data of the Marketing Authorisation Holders (MAH) of the corporation/group of companies will be transferred via the OBP to the EMVO (EU Hub).

What is Serialisation

Serialisation consists in DataMatrix barcodes applied to every pack of prescription medicines.

The result, together with product and batch information should be transmitted to the EMVO hub for each batch, before it can go on the market

Our business solution

EMVO Gateway

In order to transfer data to the EU Hub, a registered OBP must use the services provided by one of the registered Gateway Connection Providers.

EMVO Gateway is the only free of charge Connection Provider, offering two possible ways:

- Manual upload – using a hand scanner and inserting series one by one on the interface
- File-based – uploading a package of data in a specific format

What is SerTrace and how does it work

SerTrace is an internal tool that centralise serialisation data from different sources and puts them together in the necessary format in order to be transferred to the EU Hub via EMVO Gateway.

Who is SerTrace referring to

The product came as a custom solution for small and medium size Pharmaceutical Manufacturers that cannot or do not want to spend big amount of money for EMVO integration. For a small company, it can cover the entire cycle level 3 to level 5, with minimum costs.

Limitations

Technically, SerTrace have no limitation regarding data volume, complexity or integration with other applications. The only constraint comes from EMVO Gateway, that, for the time being, accepts only one level of packaging for serialisation.

Our technical solution

Security, Flexibility, Integrability

Web application that can be hosted by the OBP locally or on a Cloud server and can be accessed from anywhere on a secure connection, based on unique credentials.

Can be customised to get integrated with any kind of serialisation machine that has level 1 and 2 software integrated and with any serialisation software

User-friendly graphical interface

Keeping track of all processed data.

Collecting Data

SerTrace is receiving serialization data from serialisation machines or other third-party applications in different specific formats. Standard integration with some of the existing machines and other serialisation applications is already in place, but we can also make custom integration with any other environment

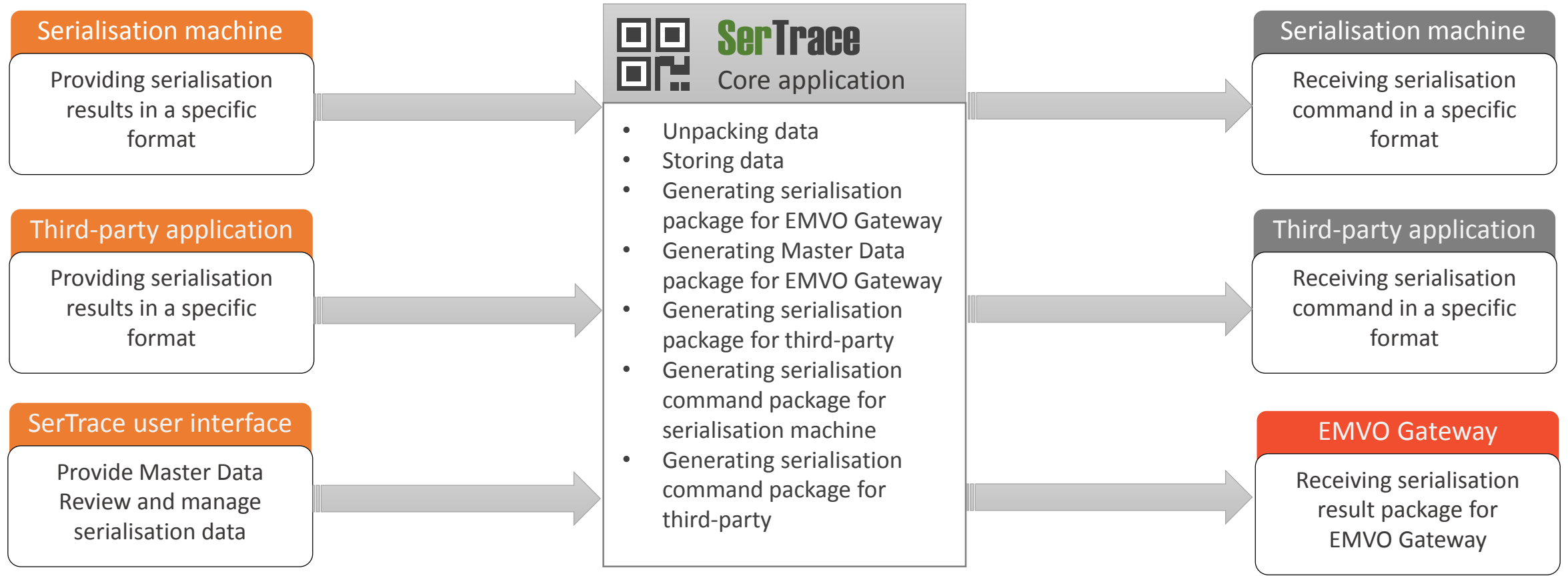
Data management and storage

The received data packages are 'unpacked' and stored in a local database. The information can be accessed and managed from the graphical interface of the application, keeping track of all batches, series and actions.

Packing data for EMVO Gateway or third-party

Packing and exporting serialisation data into the right format, ready to be uploaded on the EMVO Gateway interface, or in the format required by a third-party application

Simplified working process



Advantages and limitations

- ✓ The most affordable solution, by avoiding the big costs of a paid Gateway Provider
- ✓ Covers the needs of a small or medium Pharma Manufacturer as well as a more expensive application does
- ✓ Gets integrated with any machine or third-party software
- ✓ Viable solution for any scenario:
 - You are a MAH producing for yourself
 - You are a MAH, outsourcing production to a third-party
 - You are producing for another MAH
- Due to EMVO Gateway limitation, it does not cover multiple packaging levels (serialised packages inside serialised package)