# EU FMD Express CMO Serialization TraceLink User Requirements Specification (URS)

Document ID: EU FMD Express CMO Einstein 2 V2018.2.0 User Requirements Specification
Document Revision: 1.0
Issue Date: 11-Jun-2018
TraceLink Version: Einstein 2 V2018.2.0

tracelink
Life Sciences Cloud

# Revision History

| Document Version | Date | Primary Author | Description |
|---|---|---|---|
| 1.0 | 11 Jun 2018 | Caitlin Czulada | Release |

# TABLE OF CONTENTS

# 1 INTRODUCTION

## 1.1 Purpose

The purpose of an EU Falsified Medicines Directive (FMD) Serialization system, commonly referred to as "Level 4 and 5", is to manage all serialization data exchange with partners and line management systems. This document is the User Requirements Specification (URS) document which will identify and specify the requirements for the Level 4 and 5 Serialization system, including:

1.1.1 Functional Capabilities

Master Data Management

Partner Management and Connectivity

Serial Number Generation and/or Management

Serial Number Exchange

Internal Packaging Lines

Centralized Global Repository and maintaining Serial Number Status

1.1.2 Platform Infrastructure

This URS is the basis for functional specifications, validation, and acceptance of the provided services.

## 1.2 Intended Use

The requirements in this document are representative of the capabilities required to validate the TraceLink Life Sciences Cloud. The covered applications are Master Data Exchange, Serial Number Manager, Serial Number Exchange, and Serialized Operations Manager. This document is intended to cover the requirements of the EU FMD Express CMO Serialization offering, **not** the full scope of capabilities provided by the TraceLink Life Sciences Cloud, nor all the use cases that a life sciences company might have.

## 1.3 Definitions and Abbreviations

| | |
|---|---|
| Aggregation | Aggregation is the process of recording the serial number of a container with the serial numbers of its contents, often referred to as parent/child relationship, or a serialized container to content relationship. |
| Alphanumeric | The character set made up of numeral digits and alphabetic letters. |
| Batch | A group of products, usually associated by a manufacturing or packaging operation. |
| Bundle | A group of items held together, usually by shrink-wrap. |
| Case | A container of product cartons which **may** or **may not** be bundled. |
| CMO | A Contract Manufacturing Organization is a company providing manufacturing, and sometimes packaging, services for one or more companies based on contracts or service agreements. Also referred to as a Contract Packaging Organization (CPO) or Third-Party Manufacturer (TPM). |
| Commissioned | The process of associating an EPC (Unique identifier) with a particular object (product, shipment, asset, or container). |
| Decommissioned | The process of removing (decommissioning) the EPC (Unique identifier) from the item so that it is no longer tracked. Unlike the "Destroying" business process, the item **may** still physically exist after decommissioning even though it no longer carries serialized identification. |
| Electronic Product Code Information Services (EPCIS) | The EPC Information Services (EPCIS) is a GS1 EPCglobal standard designed to enable EPC-related data sharing within and across enterprises. This data sharing is aimed at enabling participants in the EPCglobal Network to obtain a common view of the disposition of EPC-bearing objects within a business context. |
| Expiry | The date of expiration or the last day the item **should** be used. |
| Functional Specification (FS) | A functional specification (also, functional spec, FS, specs, functional specifications document - FSD) in systems engineering and software development is the documentation that describes the requested behavior of an engineering system. The documentation typically describes what is needed by the system user as well as requested properties of inputs and outputs (e.g. of the software system). |

| | |
|---|---|
| GLN | The Global Location Number is a 13-digit number created by a GS1 Company Prefix, a Location Reference, and a Check Digit. A Global Location Number (GLN) is used to identify any location (physical or legal) that needs to be uniquely identified for use in the supply chain. The GLN makes it possible to determine the unique and unambiguous identification of physical locations and legal entities used in the supply chain. |
| GTIN (Global Trade Item Number) | An identifier used for trade items developed by GS1. Such identifiers are used to look up product information in a database (often by inputting the number through a barcode scanner pointed at an actual product). The uniqueness and universality of the identifier is useful in establishing which product in one database corresponds to which product in another database, especially across organizational boundaries. Usage is granted to organization members of GS1. |
| Installation Qualification (IQ) | An activity that demonstrates that the process or equipment meets all specifications, is installed correctly, and that all required components and documentation needed for continued operation are installed and in place. |
| Item | The product secondary package; typically a carton.<br>**Note**: Also referred to as "smallest saleable unit". |
| Manufacturer | The entity or organization responsible for packaging the product. |
| Operational qualification (OQ) | An activity that demonstrates that all facets of the process or equipment are operating correctly. |
| Performance qualification (PQ) | The documented evidence that the system, equipment, or process is capable of consistently producing a quality, safe product. The Performance Qualification protocol describes the procedures that verify the specific capabilities of a process equipment/system through the use of simulation material and/or actual product. |
| Serial Number | A unique number that represents the portion or component of a Unique Identifier (UID). |
| Serialized Global Trading Item Number (sGTIN) | The combination of a global trade identification number and serial number which uniquely identify an item. |
| User | The entity, individual, or organization responsible for making use of the product, process, or systems. |
| Validation | The documented process/procedures used for obtaining, recording, and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications. |

# 2 OVERVIEW

## 2.1 Background

With the adoption of global track and trace regulations intended to protect patient safety and ensure product integrity, serialization is common across most current and emerging regulations. This means that by 2019, the majority of the global drug supply will fall under some type of serialization requirement. Global requirements in scope:

- European Union: Manufacturers serving the EU are preparing to meet serialization requirements at the package level starting in February 2019, requirements that include supporting both global and national identifiers and following strict uniqueness regulations.

## 2.2 General Requirements

A global serialization platform with flexibility is required to manage the following high-level business processes:

- Serialization impacts both internal and external packaging. The system **should** be able to support both internal and external packaging and provide that information back to the appropriate Marketing Authorization Holder (MAH).

- The ability to manage serialization packaging requirements in order to generate serial numbers rules, request serial numbers from a MAH, provide serial numbers to the packaging sites, commission serial numbers, and release the reports to the MAH.

## 2.3 Requirements Matrix

| Number | Requirement Description |
|---|---|
| **Serial Number Generation and Management**<br><br>Serial Number Generation and Management capabilities are required to create/obtain and manage the allocation of serial numbers that will be assigned to different products and different internal packaging locations. The Service **shall** be able to support both scenarios of generating and managing serial numbers within the Service.<br><br>This capability is required to generate serial numbers and service requests to provision serial numbers to requesting locations. To enable this, a template approach **should** be used to define the parameters for serial number generation for each product packaging code.<br><br>This section describes the core functionality requirements for Serial Number Generation and Management, which includes:<br>• Serial number template viewing<br>• Serial number generation for random numbers | |
| SNM - 1 | The Service **shall** allow for the creation of serial number templates via UI. |
| SNM - 2 | The Service **shall** provide the ability for designated business or admin users to create and edit templates for serial number generation for the following product packaging codes:<br>● GTIN-14 (SGTINs)<br>● NTIN |
| SNM - 3 | The Service **shall** provide the ability to configure GTIN-14 or NTIN random number generation with the following option (configured for each packaging code that will use randomization):<br>● Maximum request quantity for serial number requests (requests exceeding this value will be denied)<br>● Minimum threshold for serial number balance that will trigger the generation of more numbers<br>● Maximum threshold to instruct of the high-water mark to use when generating additional serial numbers (e.g., maximum balance)<br>● Set length of GTIN-14/NTIN random numbers between 10 and 20<br>● Ability to specify random numbers to be numeric only (includes numbers 0 to 9) or alphanumeric (includes numbers 0 to 9, upper case letters A to Z, and lowercase letters a to z of the western alphabet)<br>● Ability to limit letters to only upper case letters, only lower case letters, or both(the default selection will be to include only upper case letters)<br>● Ability to exclude any upper and/or lower case letters that can be difficult to interpret(the default selection will be to exclude the upper case letters I, J, L, O, Q, U and the lower case letters i, j, l, o, q, u) |

| Number | Requirement Description |
|---|---|
| SNM - 4 | The Service **shall** provide the ability for designated business or admin users to create and edit templates to request serial numbers from an external system for the following product packaging codes:<br>● GTIN-14 (SGTINs)<br>● NTIN |
| **Serial Number Exchange with Internal and External Lines**<br><br>The serial number exchange process enables internal and external partner packaging locations to request, exchange, and track the commissioning of serial numbers with an enterprise serialization management system.<br><br>Transactions **may** also include country-specific event triggers from packaging sites to meet certain regulatory requirements.<br><br>This section describes the core functionality requirements for Serial Number Exchange which includes:<br>• Configuring packaging codes<br>• Serial number events | |
| SNX - 1 | The Service **shall** support the definition of packaging locations and packaging codes for each subscribing entity. |
| SNX - 2 | The Service **shall** support the packaging locations requesting serial numbers and receiving a list of random numbers. |
| SNX - 3 | The Service **shall** support the packaging locations commissioning the serial numbers to a specific product code, lot number, and expiration date. |
| SNX - 4 | The Service **shall** support the packaging locations updating the serial number status (destroyed, or decommissioned). |
| SNX - 5 | The Service **shall** support the packaging locations updating the serial number status from reserved to deactivated. |
| SNX - 6 | The Service **shall** support that packaging locations are able to report that the batch has been completed. |

| Number | Requirement Description |
|---|---|
| **Serial Number Reporting to a Marketing Authorization Holder (MAH)**<br><br>The following requirements pertain to the capabilities required to report data back to a Marketing Authorization Holder (MAH). It is recognized that each partner **may** have a different set of requirements. Custom requirements are not outlined in this document.<br><br>This section describes the core functionality requirements for reporting data back to a MAH which includes:<br>• Sending data to the MAH | |
| SOM - 1 | The Service **shall** have the ability to send commissioning data to the MAH at the point of shipment. |
| SOM - 2 | The Service **shall** have the ability to send commissioning data to the MAH using the End of Batch trigger. |

## APPENDIX A – SIGNATURE TABLE

**Note**: The signature table is purposefully left blank to allow for customers to determine whether or **not** to enter their own applicable data.

| Printed Name | Initials | Signature |
|---|---|---|
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |