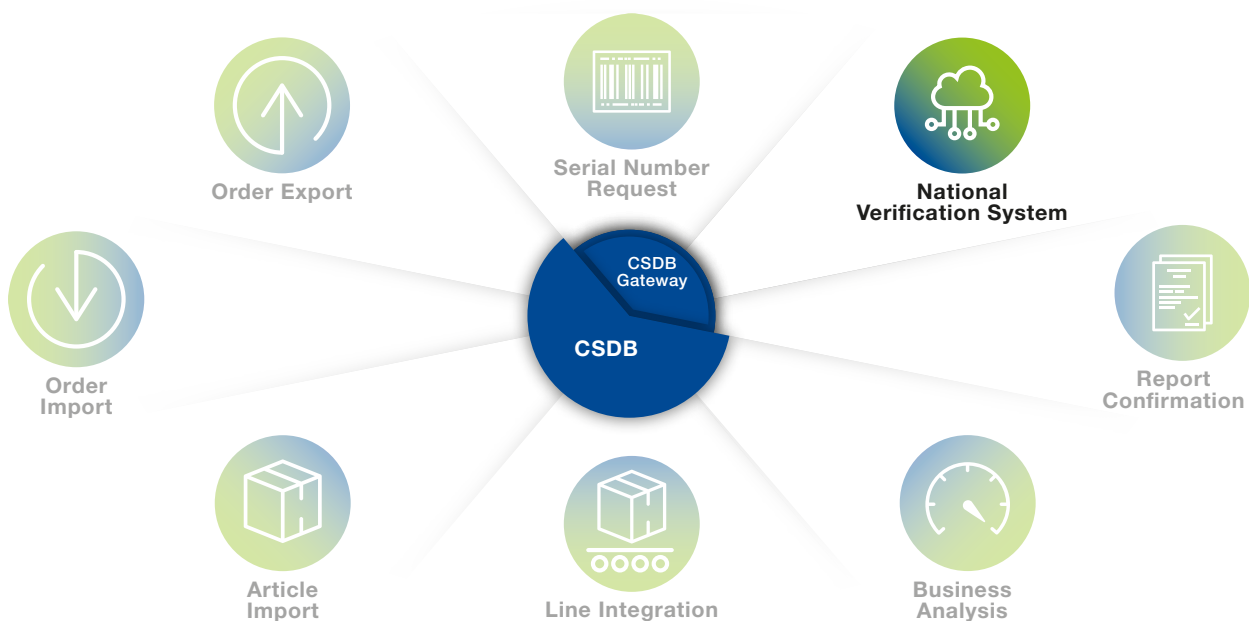


CONVERTER

AUTOMATED FOR THE EMVO WEB PORTAL



USE CASES

- As a CSDB Contract Manufacturing Organization (CMO) you have a Marketing Authorization Holder (MAH), which does not have its own serialization solution.
- As a subsidiary operating as MAH, which, however, has a separate EMVO account and its own product licenses with production data that it must transmit independently;
- If the interface between Arvato and EMVO becomes unstable you need an alternative.

SOLUTION

For MAHs, there is the option to manually insert production data as XML via an EMVO web portal account. The converter tool builds this XML file from a VP-056 from the CMO, then it just needs to be uploaded via the EMVO Portal.

ADVANTAGES

In the EMVO web portal, you have to manually enter each serial number per batch; with the automatic generation of an XML from a VP-056 this can be done easily and error-free for a complete batch.

Arvato CSDB Use Case

- VP-056

Requirements

- MAH with CSDB < v1.10 and target markets in the EU (compulsory, since the EU Hub is properly connected from 1.10).

Or

- MAH without its own serialization solution, few batches per year, CMO with CSDB
- Access to production report via sFTP

DOCUMENTS AND TEMPLATES

Traxeed delivers the following documents with the Converter Tool:

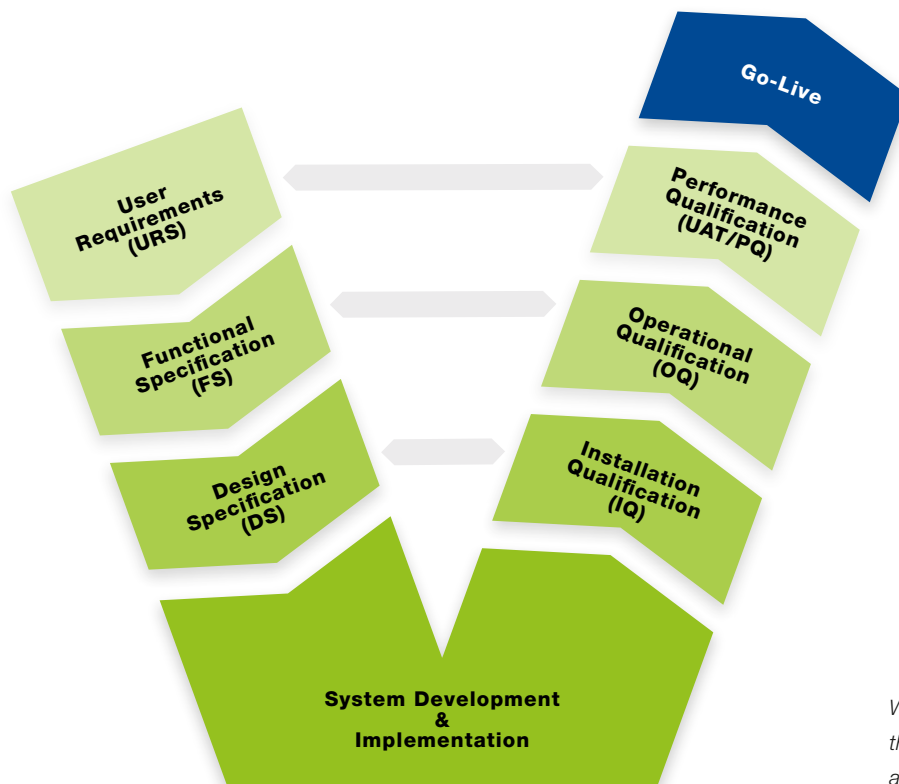
- User Requirement Specification (URS)
- Functional Specification (FS)
- Risk Analysis (RA)
- Test Cases (TC) for Function (OQ) and Acceptance Tests (PQ)
- Tracability Matrix (TM)
- User Manual (UM)

With the supplied documentation, an efficient validation of the tool can be carried out. The validation documents are adapted to the specific CSDB core and CSDB gateway parameters.

FURTHER DOCUMENTATION AND SERVICES

The following advanced services are optionally offered for a complete documentation of the implementation:

- Creation of the Design Specification (DS)
- Execution of a function test (OQ)
- Hyper care



With the V-model approach, the highest quality standards are maintained