

Serialization Solution

A Mobile Printer Station for Serialization and Aggregation



Eltronic

PHARMA ENGINEERING



Schur[®] Marking

An EU and US compliant solution

The Serialization Solution is a mobile printer station for serialization in compliance with the EU and US regulations.

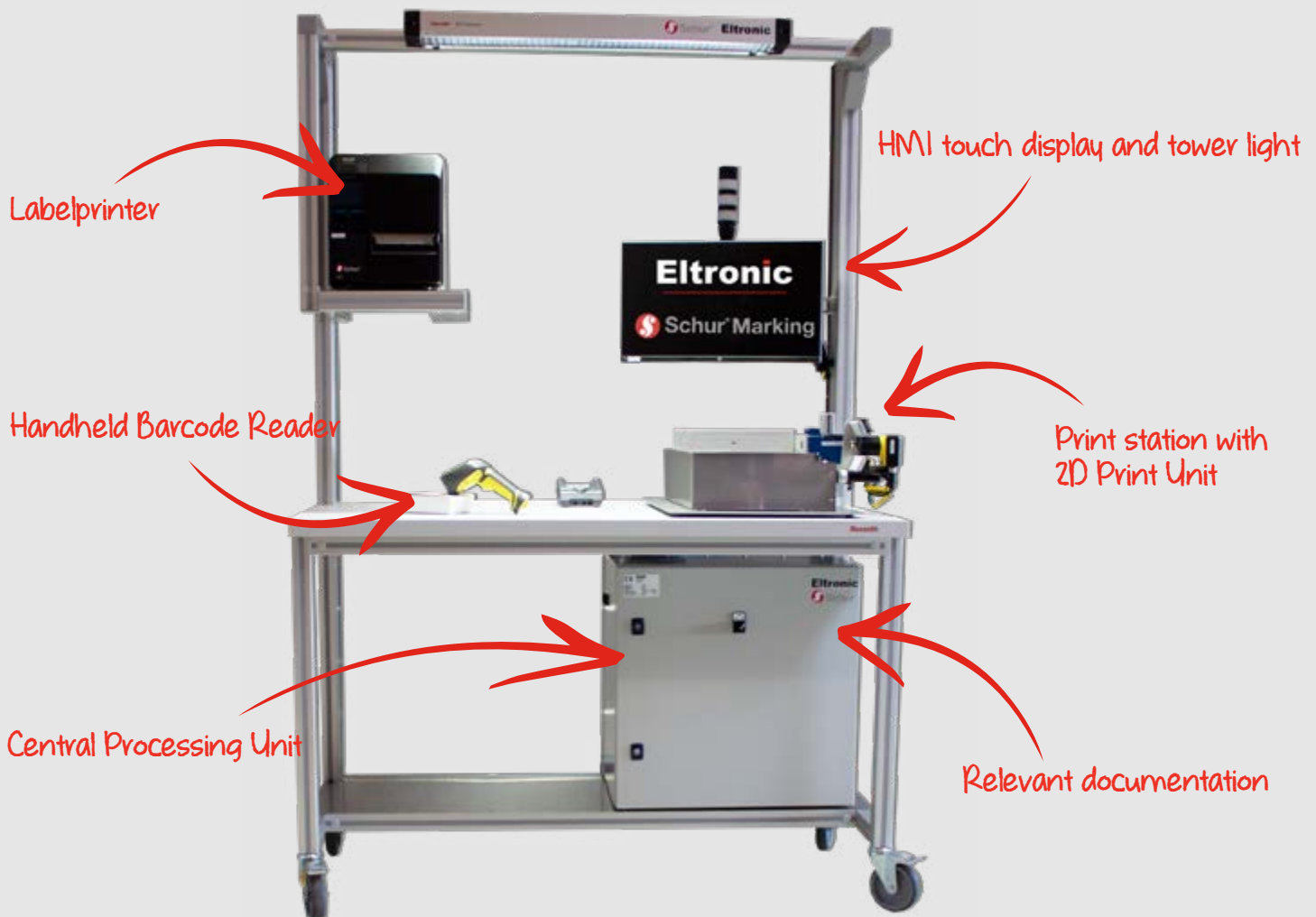
We provide you with a complete solution for serialization and verification of UI and ATD as well as aggregation up to level 2 (item and bundle).

We are also able to advice you on ATD adaption and integration of the system into existing packaging lines.

The Serialization System is available in a manual and a semi-automatic version.

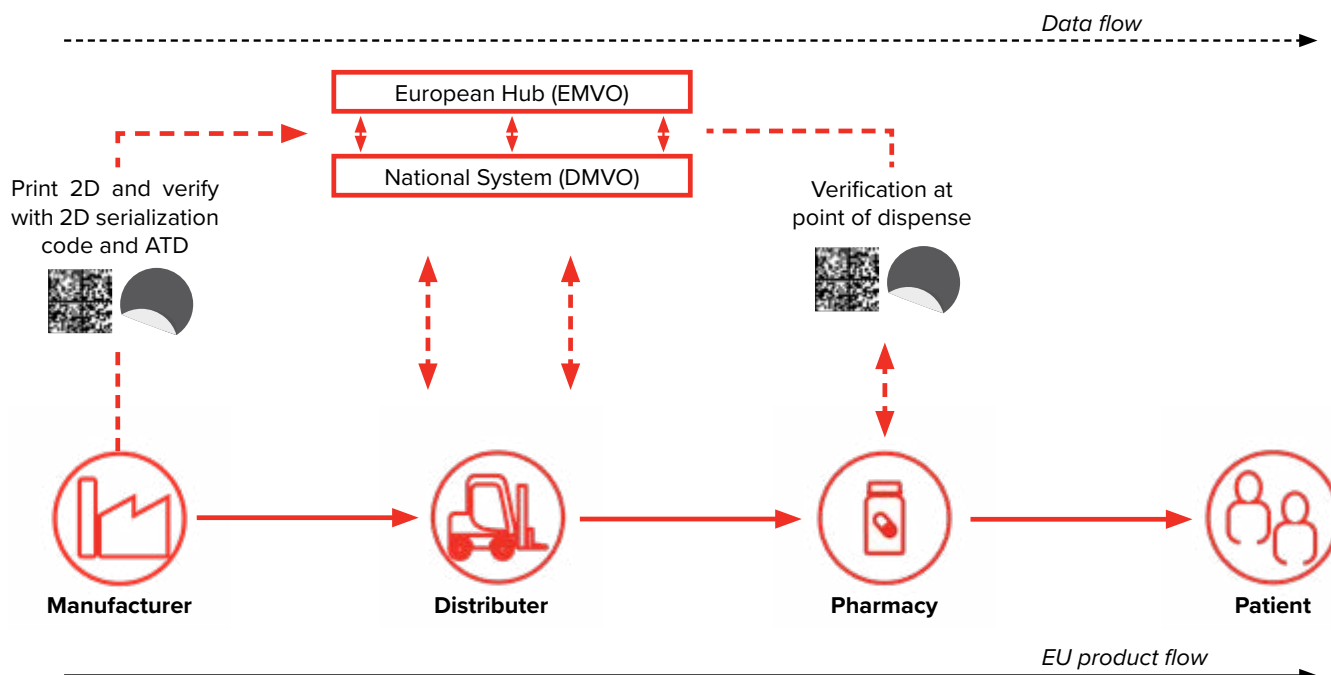
- ✓ An all-in-on solution
- ✓ Minimal burden on employees
- ✓ Authentication of products
- ✓ Supply chain transparency
- ✓ Improved product quality
- ✓ Reduction in non-conformities

Solution Elements



Serialization Solution

Supply Chain Data and Product Flow (EU)



Standard Solution

FMDSFDR (EU) and 21CFR11 compliant.

- Mobile printer station
- Unit and bundle aggregation
- Manuals and user requirement specifications
- IQ and OQ of HW and SW
- PQ protocol and report template
- Relevant SOP
- Process risk assessment
- Two months support

Add-on: Aggregation

Aggregation of units up to level 4/5 (case and pallet).

Add-on: US extension

US DSCSA compliant and full traceability using track and trace.

The Falsified Medicine Directive

“To reduce the occasions on which falsified medicines enter the legitimate supply chain” is the aim of the EU Falsified Medicines Directive (2011/62/EU).

The safety measures require wholesale distributors and pharmacists to verify the authenticity and tamper integrity of the medical product and identify individual packs.

By 9th February 2019 all prescription products must be labelled with an UI and an ATD.

Unique Product Identifier (UI)



A two-dimensional barcode and human readable information providing identification and authentication of the individual unit.

Anti-tampering Device (ATD)



Product sealings that make it possible to visually verify whether the outer packaging has been tampered with.

Project Execution Plan

The solution is based on a URS developed by Eltronic in close cooperation with you. The URS is signed when both parties approve.

We carry out the IQ and OQ qualifications, set up HW and SW and ensure that the prerequisites are met prior to the training of your dedicated personnel.

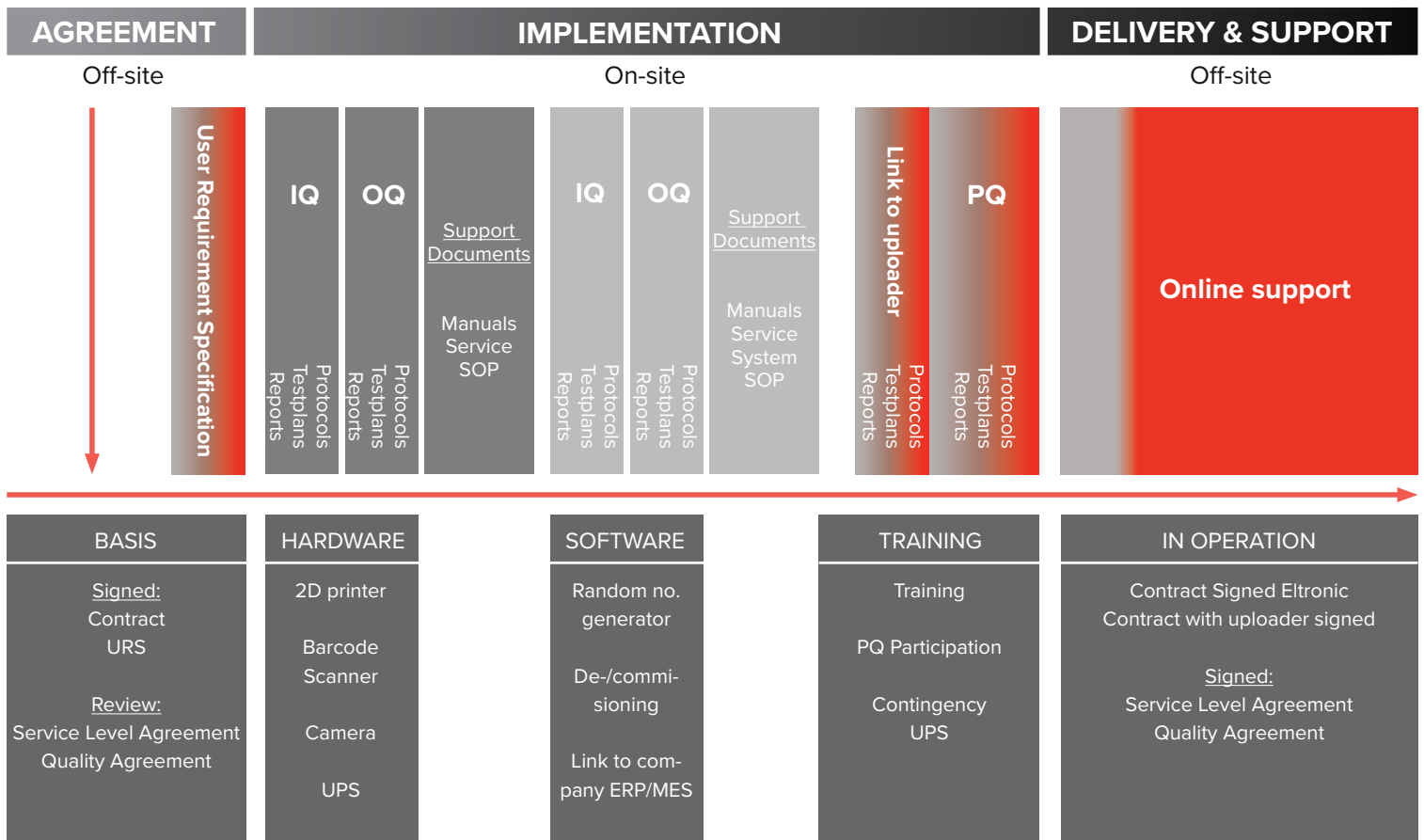
We enable the contact to a provider that upload your unique product data to the European Hub.

The post implementation support becomes effective when the process validation has been QA-approved.

Limited work for you

The plan is designed so the amount of work required from you is limited to the absolute necessary. You need to:

- Approve relevant standard operating procedures
- Provide input to system interface between the serialization unit and the company MES/ERP
- Participate in training and perform process validation



About Eltronic Pharma Engineering

Eltronic Pharma Engineering is a team of highly specialized and experienced GMP consultants and IT and automation specialists. We help our customers with all aspects of quality management and GMP compliance and processes.

Eltronic Pharma Engineering is a part of Eltronic A/S - an engineering company with approx. 300 employees focused on increasing the productivity, flexibility and efficiency of its customer's business.

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About Schur® Marking

Schur Marking delivers innovative and professional marking solutions for among others the pharmaceutical industry. We advise on the most suitable solution through competent sparring – both before, during and after having implemented a solution, ensuring that it complies with all legal

requirements and that it optimizes your efficiency and competitiveness.

Schur Marking is part of the Schur group, which is a thoroughly consolidated group of companies with approx. 850 employees.

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