AESICA
A Consort Medical Company

TECHNICAL INFORMATION SHEET

SERIALISATION

Serialisation is a means to trace and track pharmaceuticals from manufacture through to prescription, using bar codes to record information about product origin, shelf life and batch.

Aesica is one of the first CDMOs to have serialisation implemented and fully operational across our business. We have developed a module that is both flexible and scalable, enabling it to meet the serialisation requirements of a wide range of countries.

At present, this module is designed to handle the products that it routinely packs, mainly composed of three levels of aggregation: sales packs, shippers and pallets. However, it is fully able to manage additional levels in the future.

At the heart of the module is a proven world-class platform for printing variable data (human readable, 2-dimensional and linear barcodes). This coding is of the highest quality with clear and easy to read alphanumeric characters.

For more complex coding options, the platform has the ability to print:

- 1-dimensional bar codes (linear: GS1 128, UPC).
- Alternate fonts.
- 2-dimensional codes (GS1 Data Matrix, Quick Response QR).

The serialisation module has been integrated into the production line and is capable of high resolution printing at fast line speeds, with advanced communication protocol for remote operation and high speed serialisation.

Flexibility and adaptability are essential as several countries – including China, South Korea, Turkey, Argentina and Brazil– already have different types of regulations that demand different types of serialisation solutions for their pharmaceuticals, whilst several others like the EU and US have pending requirements.

Aesica Capabilities

- Identify each individual packaging unit down to the smallest sellable unit.
- Aggregate individual unit serial numbers as packages are boxed and placed on shipping pallets.
- Provision of data for track and trace.
- Report serial numbers to the required government agencies once products have been produced and imported.

Steps in Project Management for Serialisation

- Investment analyses and guidance.
- Change management.
- Training.
- Overall Equipment Efficiency (OEE).
- Performance optimization.
- Business benefits and non-regulatory requirements.
- Packaging process knowledge.
- SOP processes.
- Vendor coordination and selection.
- Equipment specifications.

Packaging Development

- Anti-counterfeit and product security.

IT

- System interfaces.
- ERP and logistics systems.
- Configuration.
- Communications with vendor.
- Controller interfaces.
- Vision/inspection knowledge.

GMP Compliance

- Validation documentation.
- Standard Operating Procedures (SOP).
- Risk assessment.
- Test plans.
- Good manufacturing/distribution/ supply practice (GMP, GDP & GSP).

Logistics and Warehouse

- Product flow.

To discover how we can support your needs contact:

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