AESICA
A Consort Medical Company

AESICA WHITE PAPER

MEETING CURRENT AND FUTURE SERIALISATION CHALLENGES

Serialisation has emerged as a complex challenge for the pharmaceuticals sector which is facing a multiplicity of differing regulations that vary from one country to another. Several countries including China, South Korea, Turkey, Argentina and Brazil already have regulations in place that must be complied with, whilst many others, including countries in the EU, face pending requirements.

In all countries, the unique information required for packaging needs to be printed both in human readable form and with either a 2D matrix bar code or a linear bar code (as is the case with China). Some countries, such as EU, require randomized serial numbers. Countries, like China, require their government or local agencies to issue strings of numbers for each batch to the product owner. Some other countries have no requirements on randomization or pre-assigned numbers. Requirements for laser print or ink printing techniques and for tamper evidence including security labels, anti-counterfeiting "self-destructive" carton boxes or glued carton boxes and the situation becomes complex.

The main goal of all these new requirements is to maintain customer safety while fighting drug counterfeiting, streamlining the recall process and minimizing financial loss.

Aesica, which has long established expertise in the commercial production & packaging of pharmaceutical products at its Pianezza, Italy, Monheim, Germany and Queenborough, UK sites, has developed the answer. The company has taken the initiative to devise a modular solution that has the benefit of being the same for all countries, whilst enabling customers to meet specific serialisation regulations that vary markedly in different countries across the globe. The highly flexible system achieves this through its capability to maintain data in multiple formats bespoke to each country's individual regulatory requirements. Consequently, customers benefit from the assurance that Aesica can manage all their serialisation data locally. The company is currently applying its solution to enable customers to meet the specific serialisation demands of China and South Korea. The implementation of serialisation services for the Chinese market, which is one of the most complex, took under six months for Aesica to complete The company's serialisation module is also already on hand for customers that need to satisfy the demands of Brazil, the especially complex serialisation regulations of Turkey and Argentina and the less stringent requirements faced by EU countries.

A key benefit of Aesica's solution is the flexibility and the speed with which it can respond to changing customer needs. After discussing and analyzing the precise customer requirement, Aesica can respond by carrying out and initiating its serialisation services in very rapid time.

Furthermore, in the output phase, Aesica can create whatever files are required by the customer including satisfying demand for a format that suits a specific country, for example China. Both the input and output of the data generated for serialization and aggregation is completely customized.

Aesica's packaging lines are flexible enough to support multiple serialisation and coding requirements. No matter what system the customers are using, Aesica is able to receive the information, including purchase orders and pre assigned serial codes, and to upload the data into their ERP application. Aesica can identify each individual packaging unit down to the smallest saleable unit.

Another strong advantage of Aesica's solution is the provision of full logistical flow and aggregation support – providing customers with the capability to seamlessly track and trace every single package of medication. The module supports all levels of aggregation including units, shippers and pallets. Aesica can aggregate individual unit serial numbers as packages are bundled, boxed and placed on shipping pallets.

How does the Aesica module meet the international challenges?

For China

In order to be compliant with the guidelines of the Ministry of Health of China (regulation SFDA No. 64[2012]), from January 2014, Aesica had to identify the following:

- Adequate solutions and /or processes and/or hardware and software necessary to:
  - Render saleable units tamper evident
  - Serialise saleable units
  - Establish the relationship between shipper cartons and saleable units contained within it, putting in place a full traceability process, from production through to the final user

Aesica is familiar with the critical interfaces between the various scientific and functional aspects and knows how to balance them to reach the optimal solution, which accommodates relevant regulatory requirements and market technology demands. Ultimately, this results in increased control, high efficiency and minimized risk.