Serialisation
- the facts
The serialisation challenge

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The pharmaceutical industry is increasingly falling victim to counterfeit medicines, reimbursement fraud and theft throughout the supply chain.

Falsified medicines present a major threat to public health, as well as damaging the reputation of pharmaceutical brands. As falsifications become more sophisticated, the industry is taking action.

The European Union has established the Falsified Medicines Directive (FMD) Safety Features Delegated Regulation, meaning from early 2019, the serialisation of licensed drug products will be a legal requirement for companies in the EU. Serialisation will also become compulsory in the US from November 2017 in line with the US Drug Supply Chain Security Act (DSCSA).

The impact of the FMD and DSCSA will reach all corners of the industry, ranging from pharmaceutical manufacture to marketing, package design and dispensary.

The scale and complexity of the task ahead is daunting to many. Recipharm is facing the serialisation challenge head on and our team is here to help you on your journey.

We are your partner for serialisation.

*World Health Organisation

7–15% of all medicines circulated in developed countries are falsified*

30–40% of all medicines circulated in developing countries are counterfeit*

Serialisation will become compulsory in the US from November 2017

All licensed drug products in the EU require serialisation from February 2019
Understanding the challenges

Key considerations

The challenge of meeting global serialisation requirements can be time consuming and complex.

In many cases, serialisation solutions and processes need to be implemented across multiple production lines in different locations. Many manufacturers have a number of markets to address across the globe. This brings with it a degree of legislative complexity that needs to be effectively managed.

For example, some countries, including those in the EU, require randomised serial numbers, while others, such as China, need the government or local agency to issue numbers to the product owner. There are also specific requirements relating to printing techniques.

Get to know the specific requirements of your markets and understand how these will affect the serialisation pathway you take. Also, don’t forget to consider your long term track and trace goals to ensure your operations can adapt to the evolving regulatory landscape.

Potential hurdles

Timing
Many pharmaceutical manufacturers are falling behind in their preparations for serialisation. While the EU 2019 deadline looms closer, the European Stakeholder Model (ESM) suggests that four to five years is a realistic time frame for implementation.

Disruption
Even those companies that do meet the deadline risk disruption to their product supply due to potential technical issues and downtime. Evidence from early adopters of serialisation processes suggests that productivity or overall equipment effectiveness (OEE) can decrease by as much as 10 per cent.

Cost
While larger drug developers may have the resources to deal with the financial demands of serialisation, small and mid-sized companies are faced with a greater challenge. Many pharmaceutical companies are concerned about the cost implications of introducing new technologies and processes.
Overcome the hurdles with Recipharm

As a forward-thinking contract development and manufacturing organisation (CDMO), serialisation is firmly on our agenda. It is our job to help our customers on their journey to compliance.

In 2014, we launched a full scale serialisation project, establishing a dedicated task force and a commitment to invest more than €40 million to ensure state-of-the-art processes for serialisation. The latest technology is being implemented across 15 of our European locations and over 70 production lines.

Almost all of our customers will require serialisation so we’ve taken the time to listen to their challenges and understand their unique requirements. It is our goal to reduce the time and cost burden of complying with the new regulations. That’s why we’ve developed a standard solution for serialisation, with a novel pricing model requiring no upfront investment and the flexibility to meet individual customer needs.
Our serialisation offering

**Track record.** Recipharm has provided serialised products in markets including Turkey, Korea and China for a number of years. Our serialisation offering is being extended to meet the demands of the evolving track and trace landscape, including the pending US and European serialisation regulations.

**Scale.** Recipharm will have serialisation capabilities across more than 70 production lines and in 15 European locations.

**Customisable.** We know that your products may need to meet the requirements of several different markets. Our standard solution is designed to meet all regulatory requirements for serialisation and can be adapted to meet individual needs.

**Novel pricing model.** We understand that you may be concerned about the potential financial impact. Our novel pricing model is designed to spread the cost of serialisation across ongoing supply agreements. This means no major upfront investment.

**Expertise.** Understanding the various market and regulatory requirements can be confusing. Our experienced team is here to listen to your own unique requirements and can guide you through your serialisation journey.

**Showcase line.** A pilot showcase line has been operational since 2016. Our customers had the opportunity to view and trial our standard solution for serialisation and aggregation.
Recipharm has a track record in delivering serialised products in the Asian market and recently completed a complex project in China.

Serialisation and aggregation was first introduced in China in 2013 and implementation has been phased based on therapeutic drug class.

Using a meticulous and methodical approach, we developed an adaptable solution to meet the requirements of a top ten pharmaceutical company. Since February 2014, nearly 200 serialised batches have been supplied to this market.

- Full compliance with China’s regulations was achieved in record time (just 12 months) and a number of strategies to anticipate delays were adopted.
- New technology was introduced across a production line to ensure each individual box had its own 1D barcode and unique serial number.
- Integration was key, with Recipharm working closely with the pharmaceutical customer, forming project teams and a joint steering committee.
- Costs were minimised by an innovative approach and the implementation of reliable and pragmatic technical solutions.

"Traditionally, full compliance with China’s regulations has proven a major challenge for the pharma sector. This project proves that Recipharm has the skills and knowledge to deliver serialisation to all markets."

Stéphane Guisado, General Manager at Recipharm in Fontaine.
Contact us

Recipharm was established in Sweden in 1995 and has since grown to become a leading contract development and manufacturing organisation (CDMO). We employ around 5000 people and the Recipharm B-share (RECI B) is listed on NASDAQ Stockholm.

For over 20 years we have focused on supporting pharmaceutical companies in taking their products from early development through to commercial manufacturing. Throughout the entire product lifecycle, we are there for our clients. Time and time again, we have delivered innovative solutions.

Visit recipharm.com to learn how our serialisation process can meet your compliance needs.