
# SERIALISATION

Safeguarding the manufacture and delivery of our customers' products is always a priority at Recipharm. To ensure that security is maintained from the production and packaging of medicines, to purchase by end consumers, we take responsibility for our link in the pharmaceutical supply chain with a serialisation process that helps keep us at the forefront of the CDMO industry.

## BACKGROUND

Counterfeited medicines, reimbursement fraud and theft throughout the supply-chain are increasing problems for the pharmaceutical industry. Even though falsified medicines in Europe are a relatively small problem – around 1% of the supply according to the World Health Organisation (WHO)[1] – in the developing world the supply is between 30–40%, leaving people with sparse resources in the hands of scrupulous counterfeiters. 30% of drugs sold in Kenya during 2012 is believed to be counterfeit.[2] Drugs bought through other channels, over the internet, gyms etc, could of course be anything from "sugarpills" to harmful copies. Boric acid, leaded highway paint, arsenic, heavy metals and floor polish are different types of toxic or harmful ingredients found in falsified medicines. The faker adds whatever is needed to make the copy look like the real drug.

Counterfeit medicines are a profitable business with low risks, compared with supplying narcotics. The profit margin for a counterfeit Viagra could be as high as 25,000%.[3]

Global pharma companies selling products with a high risk of being counterfeited have for a number of years implemented a technique for a traceable, unique ID on each product pack – they have serialised. This helps in tracking the product from production, through the supply-chain and finally to the end consumer. Throughout the world governments are now seeing this as a way to combat medicine fraud.

## THE LEGISLATIVE COMPLEXITY

Several countries including Turkey, Brazil, China and South Korea already have different types of regulations with demands on different types of serialisation solutions for pharmaceuticals. Several others have pending requirements, including the EU, Saudi Arabia and Taiwan. California have an e-pedigree law in place, with requirements for 2015 – but US has voted for a bill on federal regulations not going as far, rather requiring information on batch-level like the French system (CIP13) for 2015, with serialisation following two years later and full track & trace within ten years. This bill will prohibit states to enforce tougher requirements than the federal ones.[4]

In all countries, the unique information required for a pack should be printed both in human readable form – but also in some sort of data matrix or barcode. Even though most countries go for a GS1 standard, these differ, e g the linear barcode (required in China) and the 2D Matrix (Turkey). Some countries require randomised serial numbers (eg EU), whereas some jurisdictions require the government or a local agency to issue strings of numbers for a batch to the product owner (eg China), and yet some countries have no requirements on randomisation or pre-decided numbers.

Additionally, there are also requirements for printing techniques (laser print or ink) and for tamper evidence e g security seals or labels, foil, or glued cartons. The serialised carton around a blister card would be of no use if you can tamper with the carton and replace the original drug with a counterfeit one.

## RECIPHARM'S EXPERIENCE

Recipharm already has experience in serialised production. From our UK facility in Manchester over 40 batches have been delivered from a fully validated line to the Turkish market since 2010. This has been without issues. Management of the serial number database runs seamlessly, as does the printing and checking equipment. From our site in Fontaine les Dijon, France, a project to be able to deliver serialised products to China is just finalising. Even though there was limited time to implement the project, product will be delivered according to requirements within a year from start. This knowledge and experience is now being shared across the whole group via a centrally coordinated team.

Discussions are ongoing with customers on how to implement serialisation on their products in the best way and how to communicate the serial numbers. These discussions give additional insights and knowledge regarding software solutions and the different type of line equipment, since some customers, particularly the larger ones have often already implemented serialisation in their own manufacturing.

## RECIPHARM'S APPROACH

Recipharm, being a CDMO works with all types of customers and by definition must have a very flexible, yet clear approach on the serialisation services that can be performed. In addition to the complexity, we are prepared to manage requirements from customers who have a very prescriptive approach through to these who want us to devise a solution on their behalf.

A centrally coordinated project team is tasked with ensuring that the organisation is "serialisation ready", managing activities such as supplier evaluation and user requirement specifications (URS), IS/IT issues, together with continuous monitoring of legislative and technical developments in the area. The local projects at each facility links to the central team and have responsibility for areas such as gap analysis and understanding the impact on the organisation regarding artwork, in-process controls, planning and dispatch.

Understanding customer needs and wants is integral to this and plans are in place to train all customer-facing staff in serialisation so the best possible solution can be reached.

Supplier evaluation together with the IS/IT solutions must be future-proof and flexible enough to accommodate changes. For example the coming Delegated Acts to the EU Falsified Medicines Directive planned for the second half of 2014 is not defined at the time of writing.

Since the serialised data is an asset in itself – and the physical product effectively worthless without it – extra care must be put into IS/IT security. Data flow, data management and storage are fundamental activities as are the design of the interfaces both internally (between systems at line-level, site and ERP level) and externally (how customers, governments or third parties will receive serial numbers) which must work seamlessly. Recipharm's serialisation project will design the IS architecture to support this.

## CONCLUSION

Serialisation is a complex area and the requirements are likely to develop and change over time. It is not an area that can be ignored regardless of whether the drug being sold is a brand new high value molecule or a commodity generic.

## REFERENCES


1. *WHO "Medicines: Counterfeit Medicines" Fact sheet no 275 (Jan 2010)*
2. *AFP "Counterfeit medicine trade targets Africa's poor" Google News August 22nd 2013*
3. *Fat profits behind steady rise in fake drugs worldwide" Deutsche Welle, September 30th 2013*
4. *US Senate H.R. 3204, the Drug Quality and Security Act*


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