

## Recipharm takes the lead in serialisation challenge with €40m investment

RECIPHARM, the contract development and manufacturing organisation (CDMO), has taken the decision to lead the market in coding and serialisation to actively help pharmaceutical companies prepare for the implementation of new regulations.

The company has unveiled that it plans to invest €40m over the next three years to ensure state-of-the-art solutions for serialisation processes.

The move by the company comes as the announcement of the EU Falsified Medicines Directive (EUFMD) Safety Features Delegated Regulation is released. This means that the serialisation of licensed drug products will be a legal requirement for companies in the EU from early 2019.

Recipharm already provides serialised products in markets including Turkey, Korea and China. A newly established, dedicated global steering committee will now also work closely with clients in Europe to ensure they plan and implement changes that comply with pending regulatory requirements for drug serialisation.

The CDMO's company-wide serialisation project is being led by Staffan Widengren, Director Corporate Projects at Recipharm. He said: "Having worked with many clients in Asia on track and traceability, we know the complications and challenges of serialising a product from start to finish. The process can be complex and time consuming, particularly if the right tools and expertise are not in place, so we need to move this issue up the agenda for firms in Europe".

He added: "We know that several pharmaceutical companies are behind in their preparations, mainly because the changes seem so far away. In reality, these organisations must look ahead and face this issue head on as changes take a long time to implement in a complex supply chain.

"As a company, we are aiming to be as proactive as possible with the introduction of serialisation in order to support and advise our clients, create a clear strategy and prepare them for inevitable changes. If companies are underprepared, the new requirements have the potential to significantly impact their product supply. As a result, we expect to see increased demand for specialist outsourced services as the deadline looms ever closer."

The industry-wide serialisation, aggregation and verification directive is expected to improve traceability of drugs, help in the fight against counterfeit products entering the supply chain and ultimately improve patient safety.

However, the implementation of required changes to the 2D barcodes on all saleable drug items is set to require significant investment from the pharmaceutical industry.

Recipharm serves 250+ customers and expects 85% of its production to require serialisation. The CDMO will also be ready for US serialisation from November 2017 in-line with the US Drug Supply Chain Security Act (DSCSA).



Kjell Johansson, President Manufacturing Services Europe, commented: "The task force we have established at Recipharm will drive this project across all of our sites to ensure we support clients in terms of education and readiness for the changes ahead. Ultimately, our aim is to use our expertise to guide clients through this process and add as much value as possible. At the same time, we will work with our customers to minimise the cost implications."

"Over the next few months, we will be consulting with our customers about payment models and the most efficient way to incorporate the cost of serialisation into their projects in both the short and long term."

Recipharm is preparing a range of educational papers aimed at training staff internally across its global network and supporting customers with the challenges of serialisation, verification and complying with new regulatory requirements.

### Contact information

Kjell Johansson, President Manufacturing Services Europe, [kjell.johansson@recipharm.com](mailto:kjell.johansson@recipharm.com), + 46 739 622 620

For media enquiries, please contact Raman Sehgal at ramarketing: [raman@ramarketingpr.com](mailto:raman@ramarketingpr.com), 07808796300, [ramarketingpr.com](http://ramarketingpr.com), Twitter: @ramarketingpr, Facebook: /ramarketingpr, LinkedIn: /ramarketing

### About 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. This will help the fight against counterfeit products entering the supply chain and ultimately improve patient safety.

### About Recipharm

Recipharm is a leading CDMO (Contract Development and Manufacturing Organisation) in the pharmaceutical industry employing some 2,500 employees. Recipharm offers manufacturing services of pharmaceuticals in various dosage forms, production of clinical trial material including API and pharmaceutical product development. Recipharm manufactures several hundred different products to customers ranging from Big Pharma to smaller research- and development companies. Recipharm's turnover is approximately SEK 3.4 billion and the Company operates development and manufacturing facilities in Sweden, France, the UK, Germany, Spain, Italy and Portugal and is headquartered in Jordbro, Sweden. The Recipharm B-share (RECI B) is listed on NASDAQ Stockholm.

For more information on Recipharm and our services, please visit [www.recipharm.com](http://www.recipharm.com)