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Recipharm delivers first serialised batch to Saudi Arabia

Recipharm, the contract development and manufacturing organisation (CDMO), has delivered its first batch of serialised drug products to Saudi Arabia, following the introduction of new regulatory requirements in March 2017.

The €300,000 project, which is in addition to a wider €40 million investment into new serialisation technology and processes to comply with the European Falsified Medicines Directive (FMD), enables Recipharm to supply serialised products to Saudi Arabia.

Since the Saudi Food and Drug Authority (SFDA) enforced the latest version of the Saudi Drug Code (SDC), which aims to protect against counterfeit pharmaceuticals, Recipharm has serialised, packed, QP released and shipped more than 240,000 units to this market from its facility in Lisbon, Portugal. This includes three different stock keeping units (SKUs) and drug formulations including tablets to treat nausea and discomfort caused by gastroparesis and powder and tincture for skin infections.

The CDMO's company-wide serialisation project is being led by Staffan Widengren, director corporate projects at Recipharm. He said: "Recipharm has been supplying serialised products to markets including Turkey, Korea and China for many years and our investment in the Saudi Arabian market is the latest step in our goal to assist pharmaceutical companies with the complex web of requirements in the US, Europe and Asia."

"We are already supplying serialised products in several markets including Turkey, Korea and China, which was a major advantage when preparing for the new Saudi requirements. That said, the project required a significant outlay, a high degree of technical complexity and the need to involve multiple stakeholders, including quality assurance, IT, packaging, engineering and dedicated serialisation teams, as well as our serialisation hardware and software partners."

In June 2016, Recipharm announced Marchesini and SEA Vision as its hardware and software providers for pharmaceutical serialisation. The new solution is completely integrated with the customer's operations at enterprise resource planning (ERP) level and connected directly to its own Level 4 platform to manage serialisation and regulatory data.

Recipharm has facilities in more than 20 locations across the globe and plans for a further six in the UK, Germany, Sweden, Spain and France to supply serialised products to Saudi Arabia according to customer requirements.

Staffan Widengren continued: "Global regulatory requirements are advancing to overcome the growing challenge of counterfeit medicines. As a CDMO with customers in most territories, we must be ready and able to meet the varying regulations across the globe and have invested heavily in new serialisation technologies and processes in recent years."

"Those companies that delay their preparations risk disruption to product supply, with potentially significant consequences for patients. In the case of Saudi Arabia, we were ready to meet the compliance deadline and having already launched our pilot line for European requirements, we will also be prepared for this challenge."

Recipharm serves 250+ customers and expects 80% of its production to require serialisation in line with the European FMD. The CDMO will also be ready to meet US serialisation requirements from November 2017 set out by the US Drug Supply Chain Security Act (DSCSA).

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About serialisation

Serialisation is a means to trace and track pharmaceuticals from manufacture through to prescription, using barcodes 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 Contract Development and Manufacturing Organisation (CDMO) in the pharmaceutical industry employing around 5 000 employees. Recipharm offers manufacturing services of pharmaceuticals in various dosage forms, production of clinical trial material and APIs, 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 5.3 billion and the company operates development and manufacturing facilities in France, Germany, India, Israel, Italy, Portugal, Spain, Sweden, the UK and the US and is headquartered in Stockholm, 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