SERIALISATION FOR THE CHINESE MARKET – STEPPING UP TO THE MARK:

How forward looking CDMOs adapt, respond rapidly and develop highly methodical strategies to meet the challenging requirements of China’s stringent and fast changing regulations.

In today’s highly competitive international serialisation markets, a complex web of regulatory regimes have grown up - none more so than in leading Asia-Pac countries such as China. Full compliance with China’s regulations, especially in the field of serialisation, is often highly challenging. There is no room for compromise when it comes to meeting deadlines. The timelines set by laws have to be met in full and on time. Furthermore, they are often imposed with relatively short notice regarding implementation lead-time. Consequently, as a forward looking Contract Development and Manufacturing (CDMO) partner, Recipharm has developed the skills, knowledge, specialist expertise, technologies and responsive outlook to meet such challenges head-on. The organisation has found ways of satisfying all customer demands that have emerged as a direct result of stringent and unbending regulations. At the heart of the solution is a highly adaptable, meticulous and methodical approach to developing strategies.

Recipharm can aptly demonstrate how it falls squarely into this category – developing a highly successful strategy to implement a challenging Chinese serialisation project in full and to the time specified. The company commenced a project with one of the top ten pharmaceutical companies in early 2013 to deliver serialisation boxes of tablet and capsule drugs to the Chinese market in January 2014. This allowed a timescale of less than a year to develop and implement projects that successfully met the deadline of December 2013 – by implementing serialisation on time and to the required high standard.

COMPLYING WITH NEWLY ESTABLISHED SERIALISATION PROTOCOLS

In order to fight against counterfeiting, China requested pharmaceutical manufacturers to implement serialisation for all products distributed within China. The Chinese regulatory authority that governs serialisation introduced a new regulation. This set strict importation deadlines in place, with zero flexibility or room to manoeuvre on the precise delivery date.

From the outset of the project, multiple challenges that would need to be overcome were identified. These ranged from the ordering of goods, quality control, production, batch release, warehouse management, shipping and IT.
The pharmaceutical company needed a CDMO that would ensure that each individual box consignment was given its own 1D barcode and unique serial number and that aggregation – the reading and checking of all serial numbers for each shipping carton and linking it to the number of the corresponding cases with an SSCC number and barcode – was comprehensively carried out. To achieve this, and to overcome the problem of limited space in the packaging line, Recipharm took an integrated approach to the case packers. Cameras were installed inside the packers in order to collect the serial numbers of each box in an efficient row-by-row system, and to collect the serial numbers of the corresponding cases concerned. Pre-printing of case labels on the case before filling of the case packers, combined with full-case-to-pallet-aggregation to facilitate project logistics, served to maximise efficiency.

In response to this challenge, Recipharm worked closely with the pharmaceutical company to develop the following strategy to ensure a positive outcome. Two project teams (one per company) and a joint steering committee were formed. This served as an integrated unit to ensure that an effective channel for regular communication between the companies was firmly established from the outset. Their extensive remit covered everything from technology, IT, quality assurance, packaging, supplier identification, the supply chain, plus full project and contract management. The constant interchange and sharing of expertise served to minimise the costs of the project, as well as contributing massively to its success.

**WORKING TOGETHER TO SAFEGUARD MANUFACTURING AND DELIVERY**

To ensure simplification and cohesion, a decision was taken to have the same suppliers for serialised folding boxes and the same IT solution to manage serialisation, handle aggregation and to generate communication files. After conducting trials to make a proper determination, an informed decision was taken by Recipharm and the pharmaceutical company’s manufacturing sites to buy printed cartons. This was chosen as an alternative to inefficient online printing at required packaging lines speed.

As a consequence of these two strategic decisions, all implemented projects proved relatively simple and unproblematic to reach agreement on. Furthermore, both teams shared all transparency issues with each other to ensure fast and effective resolution. Additionally, common audits were carried out to ensure that the supplier responsible for the folding boxes provided reliable packaging materials. Audits of the IT solution supplier were also performed and the outcomes of that audit were shared.

**PLANNING THAT PROTECTS EVERY LINK IN PHARMACEUTICAL SUPPLY CHAINS**

Anticipating problems before they have a chance to emerge has long been a challenge in pharmaceutical manufacturing, not least in the area of serialisation. The solution lies in advanced planning. Consequently, potential serialisation delays in Q1 2014 were avoided, primarily because potential manufacturing challenges were identified during the advanced planning carried out by the pharmaceutical company and Recipharm joint teams as early as June 2013. This ensured that the usual trouble-shooting during the project that started at the beginning of January 2014 had no impact on market supply.

Advanced planning ensured that all suppliers were thoroughly vetted and selected during the period between February and June 2013 with orders placed in early July of that year. The qualification of one supplier, the new carton supplier for the project, commenced in June 2013. The data flow description was carried out and completed by the pharmaceutical company, folding boxes supplier, and Recipharm between June 2013 and February 2014. All system development was implemented between September 2013 and January 2014 with the same provider initiating and completing all system installation work, including qualification and training between December 2013 and February 2014.

According to World Health Organisation (WHO) estimates, 10% of drugs sold are falsified.
Efficiently managed timelines and the meticulous selection of best fit suppliers enabled Recipharm to successfully package and supply 34 serialised batches between February and June 2014 alone.

As a result of the strategy and approach devised and put in place by Recipharm and the pharmaceutical company, successful production of serialised batches started in February 2014 and, as early as July 2014, two main packaging campaigns were completed. The result was no shortage in the regular market supply. The second half of 2014 was dedicated to improve the serialisation system to ensure robust supply to Chinese market. A new version has been implemented fixing the known issues and helping to improve packaging line efficiency.

A CONTINUOUS PROCESS FOR CREATING BEST PRACTICES
During the successful realisation of the project, Recipharm had to absorb, understand and implement the use of new technology in order to support customer development. This demonstrates that Recipharm is committed to working closely with customers, and having the confidence to face new challenges with them. Even if these challenges require that Recipharm embraces new activities and acquires a new core competency, the company is adept at meeting that challenge in full to achieve the target results.

From a strategic point of view, more than having a set of technologies and capabilities set in place, Recipharm has demonstrated that it has the intent and foresight to learn and evolve according to customer needs.

The strategic move to support Recipharm customers is a continual process. A partnering commitment runs much deeper than that. Indeed, during the actual implementation of new projects, the organisation is developing and adapting new features to ensure that best results are achieved. Since this project, new market needs emerged and Recipharm Fontaine is fully preparing to meet them. Stay tuned.

ABOUT RECIPHARM
Recipharm is a leading CDMO (Contract Development and Manufacturing Organisation) in the pharmaceutical industry based in Sweden employing some 2,200 employees. Recipharm offers manufacturing services of pharmaceuticals in various dosage forms, production of clinical trial material including API and pharmaceutical product development. Recipharm manufactures more than 400 different products to customers ranging from Big Pharma through to smaller research and development companies. Recipharm’s turnover is approximately SEK 3.3 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.

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When we started this project, our primary objective was to add a new, traceable number on folding boxes. During the process, we realised the need to revise our thinking and that transversal collaboration was needed on several levels. As a result, two outputs were produced: physical goods and valuable information. It’s very exciting.

– Max Molimard, Head of Serialisation Project and Production Manager at Recipharm, Fontaine.

3,000 hours were invested to implement the serialisation solution. 2.9 million serialised units were delivered in 2014.