

End to End Pharmaceutical Serialization Project Case Study

Serialization expertise delivers robust solution
with added value and minimal downtime...

At a Glance

Company: Multi-National
Pharmaceutical Organisation

Location: 20 Sites Worldwide

Project Mission: To be an integral
part of the implementation of
serialization across 200 product
lines

Product / Services: System Design
& Implementation

Challenges:

- Meeting new serialization regulations
- Protecting against counterfeit drugs
- Improving traceability in the supply chain
- Rolling out across 20 sites
- Minimising downtime, risk & costs

Solution Delivered:

Serialization Enterprise solution

- Design phase
- Pilot phase
- Deployment
- Roll out to multiple sites
- Detailed reports
- Validation and Qualification

Introduction

Pharmaceutical companies worldwide are introducing product serialization, partly to meet new regulations but primarily to protect consumers and patients against counterfeit products while improving traceability with supply chains. Serialization involves adding a unique serial number to the lowest saleable unit prescription medicine and some non-prescription medicines, depending on the market requirements. This serial number can be checked against the manufacturer's database to ensure the product is genuine. The scheme is being rolled out globally but implementation is being staggered.

Serialization consists of the generation of the unique serial numbers, their distribution to packaging sites, the printing of the serial number on the packaging unit and the recording and storage of the data linking the serial number to the packaging unit it has been printed on. This often involves updating the machinery used in the packaging process – and this means an efficient and effective Serialization deployment process is required in order to minimise downtime.


Customer Challenge

One of the world's largest pharmaceutical companies approached Zenith to consult with the design, implementation and support of their serialization strategy. The company had already chosen two vendors to supply the serialization solution. Our client has recognised that Zenith's expertise could help them to reduce downtime, risk and costs.

Our Solution

The Zenith Serialization team began by working as part of the client's design team to develop an enterprise solution that would deliver serialization functionality to its entire network. Once the design stage was completed, the team concentrated on the specifics by creating a test lab within one of the client's facilities to validate the chosen serialization solutions.

The next step in the process was to move to a pilot site within a live production environment. Our team worked closely alongside our client's own experts to manage the installation and testing on the pilot site. Over a six-month period at the end of 2013 the team used the test and pilot projects to create a deployment process that can be used repeatedly at each different site. The deployment Process included the creation of a milestone sequence and a project plan for the deployment. This determined the time required to achieve each significant milestone in the deployment plan.



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Our Solution Continued...

The procedure of rolling out the serialization solution across the client’s worldwide operations began in early 2014, prioritised according to market requirements. Zenith managed the serialization solution deployment, progress reporting and Project governance. Site specific information was gathered and used to populate the templates needed in the deployment process. This was followed by, deployment, validation and qualification. Finally our team designed and managed the Installation and Performance Qualification.

Implementation at each of the new sites required a six to eight week initial installation for the first product line. Subsequent product lines within a facility could be equipped and put back into production within three to five days thanks to the efficiency of the template system created by the Zenith team.

Equipped with laptops provided by our client and able to login to the company’s internal systems, our dedicated team was able to perform approximately 85% of the implementation work remotely, and this delivered further significant efficiencies.

The same Zenith team that delivered implementation of the system is also managing software upgrades and providing 24/7 support for all client sites. This helps to ensure a fast and effective response delivered by the people best placed to deliver the right solutions to any issues – the experts who created the templates and took the new systems through the processes of implementation, testing, validation and qualification.

Results & Benefits

Developing and validating an initial pilot solution which could be used to create the deployment template delivered significant efficiencies for our client, while also reducing risk and minimising downtime of production lines.

The template process also minimised the duplication of work and delivered a standardised solution across the company. This leads directly to more streamlined management of the system and more effective support. Our client was able to achieve serialization significantly ahead of most comparable organisations within the industry.

During 2014 a total of 10 sites and 47 production lines were equipped to support serialization. At that stage our client provided the following feedback:

“We’ve met a significant milestone for 2014 with 10 sites now capable of connecting lines to the serialization systems. This is a magnificent achievement especially when you couple that with the fact that we are within budget”

Solution Continued

- Solution covered 10 sites / 47 production lines
- Implementation, 6-8 weeks installation
- Scheduled downtime minimised to 3-5 days
- Software upgrades and 24/7 support

The Results

- System implementation success – to budget & time
- Reduced risk and minimal production downtime
- Standardised solutions across sites
- Streamlined management of the system
- Compliant to serialization regulations