Executive Summary

Life Sciences

Driving successful implementation and business value from pharmaceutical serialization

Discover the practical challenges and roadmap for best practice deployment to protect your supply chain, brand reputation, profits and patient safety.
Introduction

Serialization is fast becoming a necessity for the pharmaceutical industry as companies seek to comply with regulatory requirements, combat counterfeit drugs, improve supply chain synergies and efficiencies, protect their reputation and increase consumer confidence in their medications.

Pharmaceutical serialization entails adding a unique identifier to single saleable units of medicines, most commonly prescription drugs, so they can be tracked, traced and authenticated throughout the supply chain.

This process of introducing unique serial numbers will help pharma manufacturers to avoid fines, loss of market share, damage to their brand image, and lawsuits from customers while also delivering a range of benefits for both individual companies and the industry as a whole.

While challenging, serialization is achievable and offers a return on investment and wider business benefits provided the process is well planned and executed. This guide aims to set out a roadmap for successful serialization implementation for pharmaceutical companies of any size and complexity. It is based on the practical experiences and lessons learnt from implementing serialization for some of the world’s largest pharmaceuticals.

Understanding the challenges and complexities

Serialization implementation is a huge project — one that impacts virtually every part of the company. It is not simply an engineering or an IT or a carton layout project — it is all of these and more, impacting every aspect of interaction within the supply chain.

A successful serialization implementation should enable companies to track what happens to the product throughout its lifecycle, document the entire production process and store this data — ensuring relevant information can be extracted easily, quickly and cost-effectively.

To get the whole process right the first time and prevent excessive costs, there are significant operational challenges to consider such as avoiding bottlenecks in the supply chain and ensuring scalability so that it can be implemented across disparate manufacturing facilities and geographies. Network performance is also a major issue since serialization will inevitably create significant amounts of new data.

Taking the First Step

Zenith Technologies, a Cognizant company, is committed to helping pharmaceutical companies of all sizes to implement effective, flexible and affordable solutions to the challenge of serialization. We have done it before, working with some of the biggest companies in the world, so we understand the requirements and have the expertise to help you through the complexities, while reducing risk, cost and downtime.

Our strengths include:
• Experience in implementing serialization projects
• Expertise at implementing large projects
• Knowledge of both the Engineering and IT layers
• Real-world capability and experience in pharmaceutical serialization
• Strong relationships with vendors and partners
• Ability and willingness to offer full life-cycle support
• A comprehensive deployment methodology
• Training expertise and resources
• Ability to provide on-going support
How can you ensure seamless integration?

To generate a successful serialization programme, it is important to ask the right questions to avoid the risks of soaring costs and delays. There will also be many systems involved in the serialization solution and they will all need to ‘talk’ to each other. As such, tight and effective integration will be essential and some key questions to address are:

- Can the system that generates serial numbers communicate with the equipment and software in your product and packaging lines?
- Can you pass the information needed through all your various systems?
- Will your database repository of serial numbers deliver the answers needed rapidly and easily when regulators come calling?
- Is it possible to communicate with the systems used in a pharmacy retail environment (as required by European regulations where patients can scan and authenticate drugs bought at the pharmacy)?

Getting all of this right will require investment but alongside implementation costs, pharma companies need to account for support and maintenance costs as well and build these into their budgets and forecasts. The issue of timings and making sure that all stakeholders have enough time to properly participate is yet another complexity to take into account. Some questions to consider are:

- How long will the end-to-end process take?
- Will you need to take production lines offline, and if so for how long?
- Can you get it finished, tested and ready in time to meet the new regulations?

The only way to get a good understanding and get in control of all the challenges and complexities is to start thinking and acting on serialization as soon as possible. With thorough planning and a systematic approach, you can achieve a successful implementation.

Roadmap to successful serialization

We have worked with some of the world’s largest pharmaceutical manufacturers and have implemented fully integrated Serialized lines that were among the first of their kind in the UK, Ireland and Europe.

Drawing on this experience and our extensive knowledge of the industry, we have developed a serialization approach to help companies implement a cost-effective, flexible and scalable solution with minimum risk or downtime. In addition to this, it also delivers a wide range of business benefits and meets new regulations and requirements.
Standardization deployment

If your serialization solution needs to be deployed in more than two sites, then a standard approach to installation, configuration and testing will bring many benefits. These will include more consistent approaches, reduced testing cycles and a reduction in line and site downtime.

Release management (Rapid Platform Development)

Any solutions you purchase as part of your serialization project are likely to continue to change for at least the next five years. This means that as part of your serialization project, you will need to make the process of receiving, testing and releasing changes to your manufacturing sites and enterprise systems as efficient as possible.

Managing the line impact — OEE

Making changes to your packaging lines, equipment or standard operating procedures will impact the line efficiency rate. Introducing standard ways of working and creating effective, well delivered training packs will help reduce the amount of time your line performance is reduced and may actually increase efficiency.

Post deployment support

Support of your newly installed serialization solutions needs to be planned from the beginning, and certainly as part of Step 3. We have found that using an integrator to deploy your solutions makes them ideal candidates to support the solution long-term. Agreeing a support contract is also critical to ensuring that long-term issues get resolved.

We hope you have found this a useful introduction to the issue of serialization. Well implemented serialization can drive significant business benefits, making your organisation more streamline, efficient, agile and profitable.

About Zenith Technologies

Zenith Technologies — a Cognizant company — is a global enterprise specializing in full lifecycle automation, manufacturing and operational support solutions for the life science industry. Zenith Technologies operates out of 16 global locations and in proximity to all the major life science manufacturing centers. For more information, visit www.zenithtechnologies.com

About Cognizant

Cognizant (Nasdaq-100: CTSH) is one of the world’s leading professional services companies, transforming clients’ business, operating and technology models for the digital era. Our unique industry-based, consultative approach helps clients envision, build and run more innovative and efficient businesses. Headquartered in the U.S., Cognizant is ranked 194 on the Fortune 500 and is consistently listed among the most admired companies in the world. Learn how Cognizant helps clients lead with digital at www.cognizant.com or follow us @Cognizant.