



Ensuring patients get a continuous supply of medication during COVID – 19

At a Glance

Company: British multinational pharmaceutical company

Location: Global sites across Europe, and the US all serving the Russian market. Project supported from global locations including: UK, India and Ireland

Project Mission

To upgrade the PIMMS serialisation systems across 13 priority sites to ensure compliance of products for the Russian market

Product / Services

- Project management, engineering & documentation, testing
- PIMMS Sea Vision Serialisation

Challenges

- 13 sites across the globe needed to be equipped to serve the Russian market and meet serialisation regulation timescales
- Tight implementation date of the 1st July 2020 in order to continue supply
- Creating an agile approach that improved site compliance and system use
- Juggling the challenges of COVID-19 whilst meeting the aggressive schedule

Introduction

Like many other countries, Russia is introducing mandatory market regulations for all pharmaceutical products and medicines to be marked with unique identification (serialised barcodes) to guarantee the authenticity of product to patients and to prevent counterfeit medicines from entering the supply chain.

Serialisation approaches generally fall into two approaches:

- Point of Dispense Authentication (PODA) which requires one level of serialisation and allows goods to be scanned at the point of dispensing e.g. at the pharmacy, and authenticated by a central system for that market
- Track & Trace (T&T), which requires two levels of serialisation and allows goods to be scanned as they pass through all the interim points in the supply chain before reaching the point of dispense e.g. when shipped from the factory, when stored in the warehouses of logistics companies, when crossing customs at country borders etc.

In addition to a T&T approach, the Russia Market regulations required a crypto code to be printed on each individual unit to avoid the “hacking” of serial numbers. SEA Vision developed new functionality to address this, which was released in a new version of the software (version 1.17.12).

All the sites who supply to the Russian market – 13 priority sites – needed to be upgraded to this new version before the initial regulation implementation date of the 1st July 2020 in order to continue supplying.

The whole project i.e. SAP and PIMMS followed a more agile approach in order to improve site compliance, system use and to meet the regulatory deadline. Consequently, PIMMS needed to be deployed by mid-April to allow the updates of SAP and functionality to be activated and ready by the 1st July. There are many, wider aspects to the Russia deployment that are outside the scope of PIMMS. This has been a first for the Serialisation programme to roll-out compliance in a series of upgrades.

This project had ambitious timescales that needed to be stuck to without delay and within the safety guidance of the developing COVID-19 environment.

Our Solution

The project scope was to upgrade the PIMMS Serialisation systems on 13 priority sites that supply products to Russia spanning across UK, Switzerland, France, US, Spain, Italy and Ireland within an aggressive timescale.

Zenith were responsible for the deployment of the PIMMS environment at the secondary sites, connecting the packing lines on each site to the global repository of serialisation data, spanning from level 2 to level 4 of the Purdue model (from control system through MES to business system).

This included preparing all deployment documentation, collaborating with the sites on preparations for the upgrade, performing the upgrades, including executing TIPs (Technical Installation Plans) and signing off the upgrades with site Quality via IQRs (Installation Qualification Reports). For each site a transition - to the Support organization was performed.

The key elements of a PIMMS system, all of which were upgraded are:

- Client workstation - one per packing line
- OCVs – between one and multiple OCVs per packing line – these are the PCs on the packing line that connect to the optical vision systems that read and verify the serialized barcodes that are printed onto the cartons (packs), cases and pallets
- Offline workstations – e.g. in warehouses, for shipment or in Quality areas for QA review and approval of batches

Results and Benefits

Thanks to our experienced engineers, all 13 sites were upgraded on time and to budget. This included 123 packing lines, 58 offline client PC's, 225 OCV's and 36 IQR's releasing lines back to production in a timely manner.

Zenith used extensive knowledge of the serialisation processes and technology with our ability to work as a global team to reliably deploy the serialisation upgrade to the customer sites.

Aggressive Timescale: There was a challenge to complete the upgrade in a short time to allow sites to meet the deadline set by the market. The resulting schedule was very aggressive, delivering one site upgrade each week across quarter 1 of 2020. Delivering this volume of work associated with the accelerated schedule required the team to expand beyond the core serialisation deployment team.

Latest Software Version: New features, functionality of the software and the potential of bugs, issues and faults which were all overcome through extensive testing in test labs.

Minimal Downtime & Disruption: The deployment strategy and process needed to be created in a way that would ensure this business-critical application could be upgraded on sites with the minimum impact to the sites production schedule. This included the coordination of multiple core and local customer groups and functions including – business process, quality, IT networks:- firewall, security, infrastructure and database.

COVID – 19 Environment: Many of the team were situated on-site during the Pilot Site to gain familiarity with the new software and to be able to rapidly respond to any new issues that might be encountered. Beyond this, the plan was to send only 1 or 2 team members to the remaining sites, with most of the upgrade work being done remotely by the other team members. As the COVID-19 situation developed to a global pandemic, Zenith kept the project on-track and continued progressing the preparations with sites. Italy was impacted greatly just ahead of the upgrade. This included the ability of the team to travel to site and the site restricted their own workforce to limit only business-critical production staff to going on site. We collaborated with the site staff to plan and ensure that we could perform the upgrade with the entire deployment team remote from site, and this worked superbly well. As the pandemic continued, five sites were upgraded entirely remotely.

At a Glance

- 13 priority sites supplying products to Russia upgraded before deadline
- Responsible for the deployment of the PIMMS environment
- Global repository of serialisation data from control system through MES to the business system
- Preparing all supportive and deployment documentation
- Upgrades were required on Client workstations, OCV's and Offline workstations

Results

- All 13 sites were upgraded on time and to budget
- Team performed upgrades on very short timescales
- Regulation deadlines were met so the company could continue to supply Russian market
- Minimal downtime and disruption to operations
- No project delays due to the global impact of COVID-19

