



SEA VISION



## CASE STUDY

Serialization experts  
deliver robust global  
solution with added  
value and minimal  
downtime





We've met a significant milestone for 2017 with 23 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.

**VP of Packaging**

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## Quick Facts

Company: Multi-national pharmaceutical organization

Location: 25 sites worldwide

Project mission: To implement serialization processes across 200 production lines while achieving wider business benefits

Product/services: Establishing a fully validated protocol for solution implementation

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## Challenges

- Meeting evolving global serialization standards
- Rolling out new processes across a high number of sites and production lines
- Geographical spread
- Minimizing downtime, risk & costs
- Selecting the right serialization solution and implementation partner
- Finding a long-term solution that can adapt to changing requirements

## Solution Delivered

- Serialization enterprise solution
- Protocol design
- Pilot phase
- Deployment
- Roll-out to multiple sites
- Detailed reports
- Validation and qualification
- Solution covers 25 sites, 15 countries and over 200 lines
- 6-8-week installation
- Scheduled downtime minimized to 3-5 days
- Super users trained
- Software upgrades and 24/7 support

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## Introduction

Driven by the introduction of global serialization requirements, pharmaceutical companies worldwide are introducing track-and-trace solutions to protect patients from the potential risks associated with counterfeit products and improve traceability throughout the supply chain.

Serialization requires a unique product serial number to be added to the lowest saleable unit of a drug product's packaging. This enables product numbers to be checked against a manufacturer's database throughout the supply chain and at the point-of-dispense to confirm a medicine's authenticity.

As a process, serialization requires the generation of serial numbers, the printing of these onto the packaging unit and the transfer of this data into databases. For most manufacturers, adhering to new regulations will mean updating the machinery they use in their packaging processes – and this means selecting the right serialization solution and integration partner to ensure success and minimize downtime.

Zenith Technologies and SEA Vision have formed a global partnership to support pharmaceutical companies with the challenge of installing and integrating serialization across manufacturing sites. Together, the companies deliver a complete turnkey serialization solution to customers, covering initial consultation and software selection through to operations support, implementation, training and post-project support.

## Customer Challenge

One of the world's largest pharmaceutical companies needed to implement a standardized serialization solution across 200 production lines and 25 sites located in 15 countries, all at varying stages of introducing serialization regulations.

A project of this scale had the potential to cause significant business disruption, which needed to be minimized.

The chosen solution/partner needed to bring expertise in managing the risks associated with implementing new serialization processes, while also limiting costs.



## Serialization Solution

SEA Vision offers a complete system for track-and-trace that has a proven track record within the pharmaceutical sector – built and designed on best practice. It includes a server and a line manager for serialization and aggregation, as well as a range of manual work stations for aggregation and reworking operations. As a modular, flexible solution, the system is customizable to specific serialization requirements and features scalable architecture to accommodate future software updates.

In a typical packaging line that comprises a print and check and a case packer, two vision systems are installed. The first is mounted on the print and check machine and performs a commissioning function by using cameras to check the serial numbers printed on cartons. The second is mounted on the case packer and checks serialized carton codes before they are placed into cases. It then controls the serialized case label's code to aggregate the cartons within the case.

The system architecture uses standard cameras to acquire inspection images, while control is performed using specially designed software. This PC-based approach ensures faster processing times, centralization of inspection parameters and character font management. It is adaptable to varying applications, offers easy validation and change control processes, all of which result in significant cost savings for the manufacturer.

The solution's software algorithms have been fully developed internally by SEA Vision's R&D engineers, including on-going maintenance and functionality updates. This ensures a high level of flexibility in satisfying customer requests and rapid release of new processes. It also provides a solution that can grow with a manufacturer's needs and new regulatory requirements with no impact on validation as plugins do not affect core software that is already installed and validated.

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The pharmaceutical company needed a partner that would be flexible and adaptable to its needs. The team shared its long-term deployment plan with us, allowing us to prepare for the future. As a result, we were able to work in true partnership in terms of both consulting and engineering - it was far more than just a transactional customer-supplier relationship.

**Marco Baietti, commercial director at SEA Vision**

## The Implementation Process



The combined Zenith Technologies and SEA Vision team began by working as part of the client's design team to implement an enterprise solution that would deliver serialization functionality to its entire network.

The process of rolling out the serialization solution across the client's worldwide operations began in early 2012, prioritized according to market requirements. Zenith Technologies managed the 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, the Zenith Technologies team designed and managed the installation and performance qualification.

A fully validated approach was established via a double FAT/SAT protocol, so that the software suite could be tested in SEA Vision's facility, focusing on the implementation specifications. It was then pilot tested on-site at the manufacturer's facility to assess the environment specific and functionality specifications. Software packages from Level 2 and 3 were only released to the manufacturer once these procedures had been successfully completed.

This approach guarantees both reliability and consistency as all plants use the same software. The Zenith Technologies team provided skilled engineers to cover the worldwide installation and validation of server environments, working closely with the client's own experts to manage the installation and testing. Over a six-month period, the team used the test and pilot projects to create a deployment process that could 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.

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. The dedicated team was able to perform approximately 85% of the implementation work remotely, and this delivered further significant efficiencies.

The same team that delivered implementation of the system is also continuing to manage software upgrades and providing 24/7 support for all client sites. Zenith Technologies and Sea Vision have established a worldwide network of after sales service and a local sales force to provide local technical assistance and direct customer care.

This helps to ensure a fast and effective response is delivered by the people best placed to overcome any issues - the experts who created the templates and took the new systems through the processes of implementation, testing, validation and qualification.



# Results & Benefits

## Successful project implementation through standardization

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To date, a total of 25 sites and 200 production lines have been equipped to support serialization both on time and to budget. Thanks to the high configurability of the system, Zenith Technologies and Sea Vision were able to meet the complex challenges of installing over 200 systems.

Using a standardized approach, the over 200 systems currently installed run with the same configuration and software. Any additional installations mirror previous ones which minimizes the risk of any unexpected issues occurring. At the same time, long-term planning allowed for the reserving and allocating of skilled resources to perform each installation without causing any impact on planned timelines.

## Business efficiencies, reduced risk & unplanned downtime

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

The template process also minimized the duplication of work and delivered a standardized solution across the company. This leads directly to more streamlined management of the system and more effective support. The pharmaceutical company was able to achieve serialization compliance ahead of most comparable organizations within the industry.

## Fully integrated system that is scalable

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Zenith Technologies and SEA Vision's principle aim is to ensure that a serialization solution is fully integrated in machine PLC logic. Using this approach can limit or cancel any manual reworking activity after batch closure.

The server solution is based on a central core with several plug-ins for additional functionality. This ensures a solution that can grow with the client's unique needs, and with the introduction of new regulatory changes, all with a minimized impact on validation processes.

## Compliant to global requirements and serialization regulations

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At the outset of the project, the main challenge which the pharmaceutical company faced was related to the high number of lines impacted by the project and their geographical spread.

To meet continuously developing market and country requirements, modifications were integrated into the software to proactively meet all future needs.

This means that once a version is validated and ready to be deployed, work begins on the next release, collecting all requirements and improvements from facilities and markets. This approach has been made standard across the project and brings continuous improvements to processes and quality.

## Robust, flexible and reliable software solution

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SEA Vision's proprietary software, including libraries and vision algorithms, ensures the highest level of flexibility in satisfying customers' requests.

The software is based on a single development program, meaning that the company never supplies or develops a 'bespoke' solution, but instead continuously implements and supplies new functionalities as 'add-ons'.

This has created a robust, field proven solution which offers customers compatibility with their systems.

## Dedicated support model with super user at each site

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A super user has been trained at each of the client's sites with the aim of always having a technical interface that could interact efficiently with Zenith Technologies and SEA Vision's support team.

A skilled team of support technicians is dedicated to the pharmaceutical company, providing an around the clock skilled interface. In the case of new or unknown problems, these are immediately escalated to an after sales manager and software developer in case a problem needs to be solved by a bug fix. To date, 98 per cent of issues have been solved remotely without any need for site intervention, which is testament to the effectiveness of the support model.



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