



Transitioning from paper-based records to digital manufacturing to improve data integrity

At a Glance

Company: World leading research based global pharmaceutical company

Location: United States

Project Mission: A drive towards digitalization – Transition from paper batch records to digital manufacturing in order to improve data integrity

Challenges:

- Organisational change
- Remote Delivery

Solution Delivered:

- PEL (Production Equipment Logs) implementation
- Supervisory staff trained

The Challenge

The client needed to replace its paper-based manufacturing records with a digital system at its facility in North Carolina. The company manufactures a range of products at the site including aerosols, tablets and dermatology products for treating respiratory and central nervous system diseases, HIV and anti-infective research.

The project was part of the client's global push towards digital manufacturing. In the US, there has been growing focus from the FDA on digital manufacturing and regulatory concerns around data integrity when it comes to outdated paper-based production logs. Implementing the solution was straightforward as Zenith and the client have a long-standing partnership which has seen the deployment of the desired production equipment logs (PEL) software on sites across the world.

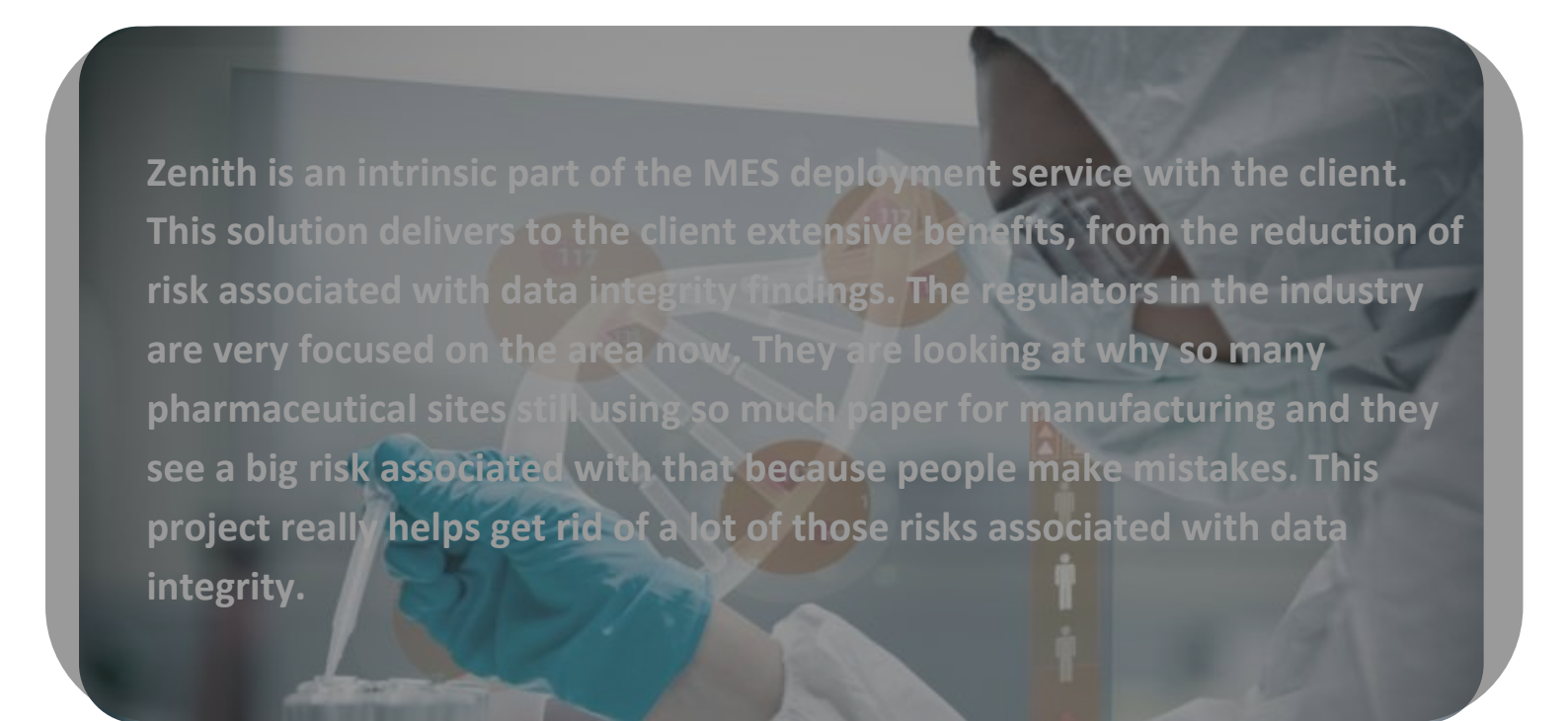
The biggest challenge would come in the form of change management as the move from paper to digital records involves considerable business change that needs to be managed. For example, training must be delivered and changes to operating procedures and work instructions documentation must be completed.

Our Solution

PEL provides data integrity and removes errors associated with paper batch records. The solution is a quick, affordable and easy to implement solution that gives manufacturers a first taste of digital manufacturing before implementing full MES (Manufacturing Execution Systems).

As a transitional step, it allows for a more gradual change management process and gives operators more time to familiarise themselves with digital manufacturing before implementing more sophisticated systems.

A core project team of four worked from Zenith's Warrington facility to deploy the system with the support of the wider business' resources and the client's internal team.



Zenith is an intrinsic part of the MES deployment service with the client. This solution delivers to the client extensive benefits, from the reduction of risk associated with data integrity findings. The regulators in the industry are very focused on the area now. They are looking at why so many pharmaceutical sites still using so much paper for manufacturing and they see a big risk associated with that because people make mistakes. This project really helps get rid of a lot of those risks associated with data integrity.

The Team

Analysed current system set-up and worked with technical departments to identify new system requirements (security, firewall)

1. Prepared the software
2. Trained staff and supported site preparations including work station readiness
3. Delivered the software install remotely

Most of the work was performed remotely with the Zenith team visiting the site twice at the outset, to meet the client's project team and deliver training as well as supervising dry run usage at kick-off, and again at the end to support go-live.

Results

The new system was installed and deployed in a seamless launch with wholly positive feedback from the client's site operators and manufacturing director.

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We had excellent feedback from the site director following the tour of the packaging lines after the system went live, it was very complementary about the project team, the deployment process, the training and the way that the operators picked it up."

Nick Barnett, MES Program and Project Manager at Zenith Technologies

Benefits

- Seamless launch of new processes
- Completed on scope, on time and to budget
- Wholly positive feedback from site operations and directors

