



Spreadsheet Validation

The SSL International group is located across 35 countries around the world and is a manufacturer of healthcare products sold into consumer markets worldwide. The product portfolio includes Durex and Scholl, both market leading global brands, as well as a diverse range of locally owned consumer healthcare products.

Client: SSL International plc
Location: UK, Spain, Thailand
Scope of Work: Spreadsheet Validation

“Spreadsheets were identified as a compliance concern in all of our manufacturing sites worldwide. In total we estimated that there were 100 spreadsheets that we needed to deal with. ABB provided us with a complete solution to spreadsheet compliance. The product proved straightforward to install worldwide, despite having a variety of regional variations in Excel, language, and regional settings.”

Nick White
Technical Assurance Director
SSL International plc



During a recent Quality Assurance inspection of computer systems, spreadsheets were identified as the most common compliance concern, being used for a variety of GxP critical uses within Quality Control, Quality Assurance, Production and Product Distribution. The Director of Quality Assurance saw an opportunity to quickly minimize the compliance concern by initiating a worldwide project to deal with spreadsheet non-compliance within the SSL group.

Background

Healthcare companies regularly use Excel spreadsheets for data manipulation, data storage, and data reporting. The flexibility and familiarity of Excel is unsurpassed in the healthcare marketplace as an analytical tool. However despite its popularity and ease of use, the software presents a large number of security, traceability and validation concerns for companies using Excel in regulated environments.

Following an internal QA systems inspection, SSL undertook a worldwide initiative to remediate Excel spreadsheets. ABB was selected to help due to their previous working relationship with SSL in the field of computer systems validation.

The ABB solution to allow spreadsheets to meet regulatory compliance, is to perform efficient validation of each spreadsheet and to house the validated spreadsheets within the DaCS™ software from Wimmer Systems. This DaCS software technology is necessary to provide logical security and audit trail capability within Excel. ABB partners with Wimmer Systems to provide the overall spreadsheet solution, providing software, support, and validation services worldwide.

The project began with identification of spreadsheets needing validation worldwide. This was followed by a pilot of the DaCS software and the validation process

at the Peterlee manufacturing site in the UK. The DaCS™ system was then immediately rolled out to two additional sites in England (Oldham and Cambridge). A further expansion occurred to sites in Barcelona, Spain and Bangkok, Thailand).

SSL International plc wanted a spreadsheet validation process for both the DaCS™ system and the individual spreadsheets that fitted closely with the current SSL International QA and validation practices.

Solution

To set a secure environment for validating spreadsheets, ABB provided the Wimmer Systems DaCS™ software, installed across the existing SSL controlled network. There was no need for additional expenditure for hardware, software or infrastructure validation.

Each site adopted their own independent configuration and file locations. This mirrored the differences in local usage and configuration needs.

ABB provided installation of DaCS, DaCS Validation, and DaCS Training at each site.

Each install, validation and training session was completed in 2-3 days, allowing each site to be up and running with a secure and validated environment in less than one week.

“The DaCS software was installed, configured and validated within 2 days. With the addition of DaCS training and spreadsheet validation training we had a complete system and spreadsheet compliance process available to us in under 5 days” said Dolores Succarats, IT Manager in Spain.

In addition to providing the DaCS environment, ABB also provided the spreadsheet validation knowledge and process in the form of an all-encompassing spreadsheet validation package. ABB trained SSL on how to validate their own spreadsheets using the ABB process. The process provides a quick and efficient validation path for each GxP critical spreadsheet. More information on the process can be seen at:

<http://www.spreadsheetvalidation.com/solutions/ssvalidation.htm>



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Project Benefits

- A secure and audit trailed Excel environment allowing 21 CFR Part 11 compliance for all GxP critical spreadsheets.
- A pragmatic and proven spreadsheet validation process providing validated spreadsheets and removing future compliance concerns.
- Quick and efficient worldwide rollout, with regional variations in usage and configuration simply integrated into the system.
- The project was completed on time and within budget.

The ABB Spreadsheet Validation Process provides the following components.

- Understanding the issues of spreadsheet compliance and spreadsheet validation
- Generating a spreadsheet inventory and risk based assessment of each spreadsheet
- Integrating the approach into your current QA processes and validation practices
- Project planning and resourcing
- Spreadsheet and macro development
- Spreadsheet specifications
- Spreadsheet qualification
- Maintaining compliance and ongoing procedural controls

The final result is a set of fully validated spreadsheets, maintained and used from a secure 21 CFR Part 11 compliant environment. Many of the spreadsheets were designed to allow the use of electronic signatures within the DaCS software.

SSL now has the internal capability to validate future spreadsheets using the ABB process.

“The project not only provided us with a clear insight into spreadsheet validation, but also identified a number of areas where we could use electronic signatures within DaCS to help reduce our dependence on paper printouts from Excel” said Chairat Warungkanakul, MIS Manager in Thailand.