

Regulatory Compliance and Validation Services

Spreadsheet Compliance Solution

Spreadsheet Validation Services and DaCS™ Software

Client: Pfizer (via ABB Consulting)
Location: Groton, CT, USA plus additional sites
Scope of Work: Spreadsheet Compliance

Following an FDA Audit Pfizer approached our team for assistance on spreadsheet validation

“The DaCS™ software provided us with the technical compliance we needed and it proved simple to install, validate, and use. We undertook the process with the tools and documentation provided.”

“What proved more difficult was defining our spreadsheet business flows to suit a more regulated and controlled process. The defined approach made the task straightforward, and the recommended improvements resulted in considerable savings in time. In some areas we automated data importing and processing and achieved significant efficiencies relative to processing and manipulating our data.”



Frank Pagliusi
Project Manager
Pfizer Safety Sciences



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.

The project began with an assessment of Safety Science spreadsheets used by 4 Pfizer sites (Groton - USA, Amboise – France, Ann Arbor – USA, La Jolla – USA).

Spreadsheets that represented a range of complexity were identified for Validation and conversion into the secure DaCS™ environment.

We provided the technology that is necessary to enable Excel to be used in regulated environments. For this project, DaCS™ was chosen following a thorough investigation of potential solutions as well as the vendors ability to provide compliance and support worldwide. Pfizer wanted a validation process that fitted closely with their current QA practices. The approach had to combine both the DaCS™ system and the individual spreadsheets.



Solution

We provided the DaCS™ software, installed across the existing Pfizer network.

There was no need for additional expenditure on hardware or on infrastructure validation. We provided a full set of validation documentation that included:

- Spreadsheet specifications
- Spreadsheet qualification protocols
- DaCS™ specifications
- DaCS™ environment installation and operational qualifications
- Procedures for spreadsheet development and testing philosophies
- Procedures for system maintenance and operation

Further details can be seen at:

<http://www.spreadsheetvalidation.com/validation.html>

We assisted in project management for the global rollout and also in streamlining the DaCS™ validation activities to work within the Pfizer QA system.

Training was provided for 5 sites on how to undertake spreadsheet validation internally within Pfizer.

This enabled Pfizer to self manage completion of their full spreadsheet inventory.



CSV Compliance Limited,
Clavering House, Clavering Place,
Newcastle upon Tyne. NE1 3NG.
United Kingdom

Email: david.harrison@spreadsheetvalidation.com

Tel: +44 (0)1207 544106

Web: <http://www.spreadsheetvalidation.com>

Project Benefits

- Fully validated spreadsheets removing future compliance concerns
- Full 21 CFR Part 11 compliance for all GxP critical spreadsheets
- An integrated and efficient spreadsheet validation process
- Significant resource reduction in data import, data manipulation and data reporting practices
- The project was completed within budget



“We were very pleased with the efficiency and suitability of the validation philosophies defined by the process,” said Robert Mazarelli, Informatics Director at Pfizer Research Informatics.

“We were able to fit their approach and supplied documentation set straight into our own quality system”.

Robert explained *“We selected a variety of spreadsheets from across the group to ensure coverage of a broad range of functionality, size and complexity”.*

“DaCS has given us a secure method of using Excel complete with independent audit trail, electronic signature capability and portability across our Safe Sciences group within Pfizer”.

CSV Compliance is the global leader in spreadsheet validation services for the Life Sciences and regulated industries. The CSV Compliance team supply spreadsheet validation and compliance services worldwide.