

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.



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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.

