



## Spreadsheet Validation

**Client:** Pfizer  
**Location:** Groton, New England, USA and additional sites  
**Scope of Work:** Spreadsheet Validation

*Bob Mazarelli (Pfizer), with Derek Wimmer (Wimmer Systems) and David Harrison (ABB) presenting the case study at the IVT Laboratory Controls and Compliance conference in Philadelphia, USA.*

*“The Wimmer Systems 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 by ABB.*

*What proved more difficult was defining our spreadsheet business flows to suit a more regulated and controlled process. ABB’s 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



**The Pfizer Safety Sciences group are located across 7 sites around the world and undertake preclinical activities vital to the development and introduction of new drug products within the Pfizer group.**

**During a recent FDA inspection, spreadsheets were sited as a significant compliance concern, and improvements were required against spreadsheet validation and their compliance with 21 CFR Part 11.**

### 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 the FDA inspection Pfizer undertook the project with the aid of ABB Process Solutions. 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 conversion.

ABB’s partner Wimmer Systems provided the technology that is necessary to enable Excel to be used in regulated environments. For this project, Wimmer Systems’ DaCS™ system 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 for both the DaCS system and the individual spreadsheets that fitted closely with the current Pfizer QA and validation practices.

### Solution

ABB provided the Wimmer Systems DaCS software, installed across the existing Pfizer controlled network. There was no need for additional expenditure on hardware, software or infrastructure validation. ABB 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/solutions/solutionsindex.htm>.

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

A variety of spreadsheets were selected within the group from different sites, selection ensured coverage of a broad range of functionality, size and complexity. Each spreadsheet was moved into the controlled DaCS environment which provided:

- Logical security for the application and spreadsheets
- Independent audit trail of operator and system actions
- Use of electronic signatures on individual spreadsheets to fit the data flow processes
- Secure yet portable data, protected by the unique DaCS digital integrity features

Training was provided for 5 sites on how to undertake spreadsheet validation internally within the Pfizer groups. This enabled Pfizer to self manage completion of their full spreadsheet inventory.

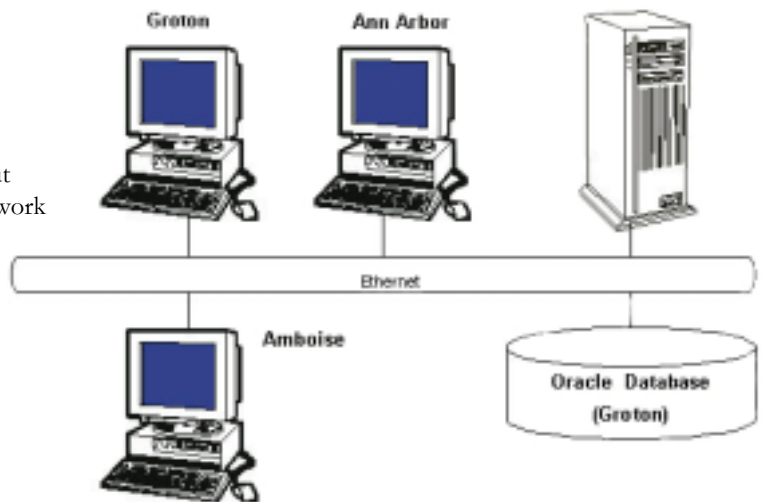


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## Project Benefits

- 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 ABB process,” said Robert Mazarelli, Informatics Line Manager (Safety Sciences) at Pfizer Research Informatics. “We were able to fit their approach and supplied documentation set straight into our own quality system.”

For more information on how ABB's Industrial IT technology can be employed to solve your spreadsheet validation issues, visit us at

[www.spreadsheetvalidation.com](http://www.spreadsheetvalidation.com)  
[www.abb.com/lifesciences](http://www.abb.com/lifesciences)