

Regulatory Compliance and Validation Services

Regulated companies use Excel spreadsheets for data manipulation, data storage, and data reporting. The flexibility and familiarity of Excel is unsurpassed as an analytical tool.

However, many companies have not validated their use of Excel to the standards required to meet current regulations. You need to demonstrate to your auditors that your spreadsheets are accurate.

ABB Spreadsheet Compliance Spreadsheet Validation Service

Excel is the universal standard for data handling and data processing and the vast majority of companies use Excel for handling regulatory data.

Demonstrating that your spreadsheets are functioning correctly and produce accurate data is critical not only for your own business processes, but also for satisfying your regulatory auditors. If you cannot show with documented test evidence that spreadsheets are generating the correct data, then your auditors can stop the use of your Excel spreadsheets or worse still stop your operations until the situation is resolved.

ABB offer a complete service to validate your spreadsheets and provide documented evidence of their correct functionality. The process is designed to maximise efficiency and focuses on repeatability for your whole inventory.

- Detailed user requirements and specifications ensure that your spreadsheets are designed to meet their needs.
- Comprehensive qualification testing to demonstrate correct functionality coupled with evidence that the operation is secure and maintained within a recorded environment.

Validation Service Benefits

- Continue the use of Excel, with your current spreadsheets and trained users and satisfy your regulatory auditors.
- Complete confidence in your spreadsheet outputs both for regulatory compliance and operational accuracy.
- An “off the shelf” documentation set, configurable for your own quality system and already proven in the top pharmaceutical companies worldwide.
- Receive a turn key solution from the world leaders in spreadsheet validation and developed with assistance from the FDA.



Spreadsheet Validation Process

The ABB Spreadsheet Validation Solution has been provided by a dedicated spreadsheet team since 2003. The process has dealt with 1000's of spreadsheets from most of the worlds top pharmaceutical companies.

- Risk based inventory analysis and criticality assessments to prioritise your project scope and validate only what you currently need and can afford.
- Detailed user requirements review and consultancy to ensure your spreadsheets do what you need.
- Spreadsheet development and reformat to add ABB good practice features such as version control and security features.
- Documented user and functional specifications to define how your spreadsheet functions.
- Comprehensive yet risk based installation, operational and performance qualification testing to ensure accurate functionality in a controlled environment.
- Validation planning, reporting and experienced project management.



Spreadsheet Validation Tools

- Inventory analysis and criticality provided by a combination of software technology and pragmatic consultancy experience.
- Fully developed and proven document set covering the whole of the project lifecycle, from planning to reporting.
- Best in field 3rd party software tools such as Finsbury Solutions DaCS™ and Exchecker to provide secure environments and spreadsheet analysis.
- “One stop” supplier to analyse, supply and train your company on the whole spreadsheet validation process.

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ABB Spreadsheet Validation Experience

ABB are the world leaders in spreadsheet validation. Use their experience to ensure a successful, efficient and scalable validation project.

- Use ABB's pre-developed process, or adapt their proven process into your own quality systems and validation practices.
- Why risk such a critical and resource intensive project to validation teams with little or no experience of validating spreadsheets?
- ABB are the industries key speakers on spreadsheet validation at conferences and providing white papers for journals. ABB present joint sessions with the FDA, Pfizer and Allergan as case studies.



- A scalable process, suitable for individual spreadsheets through to whole company or departmental inventories.
- A scalable consultancy service that can provide a complete turn-key solution with minimal end user input or ABB can provide training on the whole process and leave you to undertake your own project.



ABB Engineering Services is the global leader in spreadsheet validation services for the Life Sciences and regulated industries. ABB operate in over 100 countries worldwide and employs 103,000 people serving customers in the chemicals, consumer, life sciences, manufacturing, metals, paper, petroleum and utility industries.

