

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 maximised the functionality they can receive from Excel, and many have not validated their use of Excel to the standards required to meet current regulations.

ABB Spreadsheet Compliance Spreadsheet Development Service

Excel is the universal standard for data handling and data processing and the vast majority of companies use Excel for handling regulatory data. However, in many companies Excel spreadsheets are developed with little consideration of improving production efficiency and even fewer are developed with validation in mind.

Spreadsheets have the capability to do much more than simply allow data input and perform a few calculations. A well designed spreadsheet can significantly improve your business throughput, saving operator time and identifying areas where improvements can occur. The key to maximising the spreadsheets performance is to integrate its use into your business processes rather than use it as a calculation or a reporting tool at the end.

ABB can help you develop spreadsheets and macros that maximise your business processes.

ABB offer a complete service to develop and validate your spreadsheets and provide documented evidence of their correct functionality. The process is designed to maximise your efficiency whilst also meeting your regulatory requirements.

Development Service Benefits

- Maximise the use of Excel, improve your current spreadsheets
- Complete confidence in your spreadsheet outputs both for regulatory compliance and operational accuracy.
- All development supported by our proven documentation set, which is already in use within the top pharmaceutical companies worldwide.
- Receive a turn key solution from the world leaders in spreadsheet validation.

"It used to take us 5—10 hours to analyse the data from the source system. Now with the improved process we are able to obtain the results from the raw data within minutes. We estimate the saving to be in excess of \$3million over 5 years."



Quality Control Supervisor,
Leading Molecular Diagnostics Company, USA.





Business Process Improvement

Do any of these situations or practices sound familiar? If so we may well be able to help improve your business processes with minor adjustments to your existing spreadsheets.

“Why have operators input data into the spreadsheet when it can be automatically imported into the spreadsheet from LIMS, ERP, databases or instrumentation”

“Once data exists in a system, why not use Excel to generate regular reports”

“When manually putting data into spreadsheets why not use data validation and conditional formatting to prevent operator transcription errors and minimise the need for review checks”

“For operations that involve repeated operator actions, why not use validated macros to automate the activities”



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Business Benefits

- Maximise operator and user time by minimising their data processing times.
- Minimise or completely remove the need for data transcription. Transcription is a major source of error which results in wasted time and possibly wasted products.
- Generate more useful information from your existing data. You don't need additional reporting software if your data exists or can be exported into Excel format.
- Analyse data within a software program that all your users are familiar with and all have access to. Allow your users to analyse data and generate reporting formats rather than paying your complex database vendors to generate report templates for you.



Spreadsheet Development Process

ABB has developed and validated 1000's of spreadsheets from most of the worlds top pharmaceutical companies.

- Detailed user requirements review to ensure your spreadsheets do what you need and maximise every possibility to improve business functionality.
- Spreadsheet development good practice features such as version control and security features.
- Documented specifications to define how your spreadsheet functions for both regulatory and business purposes.



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.

