

# 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.

Many companies use similar spreadsheets to perform the same activities, yet they end up developing and validating their own unique solution from scratch each time.

## ABB Spreadsheet Compliance Generic Spreadsheet Solutions

Everyone's spreadsheets are unique, yet the purposes that they were designed for are often similar between different departments and companies. Most people will design these spreadsheets from scratch, even though much of the work has been done before by other people.

ABB offer a number of pre-developed “generic” spreadsheets. Usually these spreadsheets need minor modifications to meet your own unique requirements, but the spreadsheets have already been through multiple cycles of trial, use and improvement, meaning that you receive a complete working version, rather than an unproven first draft.

ABB offer a complete solution with these generic spreadsheets, this includes security and audit trail features, validation documentation, testing qualifications of the core functionality, and the confidence of knowing that these spreadsheets have already been used and validated for regulatory use.

Our inventory includes CAPA, environmental monitoring, analytical regressions, SAP/ERP/LIMS import and exporting, direct instrument capture, inventory management, database connection for import and output, to name but a few.

### Generic Spreadsheet Solution Benefits

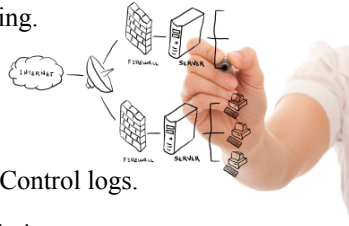
- Significantly cuts development time for your Excel application and provides an immediate working version.
- Flexibility of Excel allows you to quickly adapt and modify the functionality to meet your own unique needs.
- Ready developed documentation sets and test evidence to save development time and cut overall validation needs.
- A proven solution from the world leaders in spreadsheet validation gives immediate confidence for your “custom” application.



## ABB Generic Spreadsheets

The following provides examples of our currently available spreadsheets, all of which can be viewed by yourselves as working prototypes via webcast to check on suitability for your own use.

- CAPA (Corrective Action and Preventive Action) processes.
- LIMS, SAP, ERP, Database importing and exporting processes.
- Environmental monitoring.
- Inventory management.
- Analytical regressions.
- Document and Change Control logs.
- Elisa plate reader calculations.
- Direct instrument capture such as balances and simple instrumentation.



If your current need is not mentioned above, please contact us, as it is likely that we will have dealt with a similar spreadsheet, and the time to make a generic version for you would be significantly less than starting from scratch yourselves.

## Spreadsheet Programming

To complete your unique applications ABB can offer professional VBA programmers to implement robust macros, designed to meet both the users needs and the regulatory needs of demonstratable and secure use.

## ABB Services

ABB provide a full range of consultancy services for spreadsheet validation, including spreadsheet development, training and testing services. For more information visit our website.

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## ABB Documentation

All ABB generic spreadsheets come with complete sets of functional specifications, testing documentation and test evidence.

- Validation plans and application risk assessments focus on the critical aspects of your functionality.
- Specifications to document how the application works.
- Core functionality testing to prove calculations and processes are accurate.
- Easy to modify documentation templates to adapt qualification activities to your own unique usage.



## ABB Spreadsheet Best Practice

All spreadsheets include industry best practice features and additions to improve compliant use. Examples include.

- Spreadsheet version numbering.
- Fully automated audit trails for data input and processing.
- Worksheet and workbook time, location and file stamps.
- Electronic signatures and approval processes built into the data throughput.
- Logical worksheet formatting to ease operator input.
  - Worksheet layouts, comments and conditional formatting.
  - Data validations.
  - Cell colour coding.
- Reporting macros.
- Graphical trending displays.



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.

