Using Excel Spreadsheets in FDA Regulated Environment

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Easy-to-create, surprisingly powerful and flexible, spreadsheets are so common they almost seem invisible. You can use spreadsheets in Good Manufacturing Practices (GMP), Good Clinical Practice (GCP), and Good Laboratory Practices (GLP) environments, but as with any computer system, the FDA expects measures to be in place to ensure system data are controlled and protected. There are two general strategies for spreadsheet compliance with 21 CFR 11 and Annex 11. Below mentioned are certain points that must be kept in mind when using Excel spreadsheets in FDA regulated environment.

1. Regulatory Requirements
Spreadsheet structure is similar to a computer program. Formulas in a spreadsheet are basically a form or computer program and hence must be appropriately validated before using.

2. Common FDA Audit Findings
The common FDA audit findings are: No validation or control procedures, rounding-off errors, incorrect use of formulas and equations, incorrect formula automation, lack of predetermined specs, poor documentation, incorrect unit description, security and data integrity issues, lack of change control and lack of data validation.

3. Reasons to not Validate Excel
The common reasons to not to validate excel are: It is used for ‘informal’ calculations, used for data “storage” or cataloguing, not used for ‘final’ reports, used for exploratory or early stage work and validation is hard and expensive.

4. Change History
When using Excel spreadsheet, each spreadsheet should have a change history worksheet. Every time the spreadsheet is updated, an entry should be made in this Change History with the version number, date of change approval, change control number, name of person(s) who made the change, spreadsheet validation protocol document number, location of spreadsheet file in the network and itemized description of all changes made.
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