

The FDA regulations and EG-GMP-guideline commits pharmaceutical companies with an additional guideline to validate their computational systems if these are integrated in GMP-areas as the production, warehousing, sales department and quality control.

FDA regulations and the EG-GMP-guideline provide an additional guideline to pharmaceutical companies obliging them to validate their computational systems when the latter are integrated in GMP-areas, such as production, warehousing, sales department and quality control.

Included into computer based systems are Microsoft Excel Applications as these are regularly used in QC and QA for calculations and evaluation of data.

Microsoft Excel Applications are also included into computer based systems because they are regularly used in QC and QA for calculations and data evaluation.

PSE will ensure that:

- \* Excel spreadsheets are based on cGMP.
- \* Development, organization and documentation of Excel applications are controlled.
- \* Standard requirements concerning GMP are well known and followed.
- \* Required tasks () are () elaborated and responsibilities are assigned during the validation process.
- \* Excel sheets support and assure achieving top quality products; additionally the operation of the used systems is adequate concerning GMP guidelines.

Excel sheets do not only support the fabrication of top quality products, but they also assure it; additionally, they guarantee that the operation of systems is adequate concerning GMP guidelines.

The development and validation of Excel spreadsheets in a GMP-compliant way, performed by PSE, are on the current and sophisticated level of available technique. We ensure that your excel spreadsheets comply with all legal requirements and guidelines, such as:

- \* **Annex 11 – EU-GMP** – “Computerized Systems”
- \* **Annex 15 – EU-GMP** – “Qualification and validation”
- \* **21 CFR Part 11** – “Electronic Records; Electronic Signatures”

- \* **PI 011/03** – “Good Practices for Computerized Systems in Regulated ‘GXP’ Environments”
- \* **GAMP 5** – “A Risk-Based Approach to Compliant GxP Computerized Systems”

Main features of an Excel Spreadsheet development and validation:

- Labeling of entry cells;
- Use instructions;
- Color differentiation for input and output cells;
- Data Validation on input cells;
- Description of formulas printout; ? Printout with the description of formulas
- Acceptance criteria for final result;
- Print date, excel file path and spreadsheet name on footer.
- Specification of the function, including detailed specification for the creation of formulas used for calculations if necessary;
- Regulations concerning an explicit classification of the Excel Spreadsheet version;
- Regulations concerning a control and authorization of each particular Excel Spreadsheet version;
- Documentation of formats, conditional formats and validity tests of cells;
- Documentation of the cell protection;
- Explicit storage folder of these files;
- Operators training;
- Change control;
- Version control;
- Secure formulas;
- Secure spreadsheets;
- Mechanisms against unauthorized access;
- Secure workbook.