

GAMP® – Advanced Course

Computer Systems Validation, CSV, with GAMP® is a large subject. To enable this to be covered in some details and taking in the differing background knowledge of the audience, Eutech Validation offers two relevant courses on this topic as follows:-

- A *Basic Course* that assumes no previous knowledge apart from a basic understanding of the life science industry and quality requirements. This course aims to tell the audience as simply as possible the necessary steps to take to validate computer systems.
- An *Advanced Course* that assumes the knowledge encapsulated in the *Basic Course*. This course elaborates on many of the topics mentioned in the *Basic Course*, and aims at giving the participants an understanding of the principles and driving forces behind CSV and GAMP®.

The *Advanced Course* covers those items not included in the *Basic Course* as follows:-

CSV Regulations

- Brief history of regulations
- How regulation are enforced
- CSV requirements within GxP regulations
- EU Annex 11 and its changes
- 21 CFR Part 11: background and current status including guidance
- PIC/S and other regulations and guidance

The GAMP®5 Guide

- A history of GAMP
- Understanding the changes from GAMP®4 to GAMP®5
- Understanding the limitations of GAMP
- The family of GAMP guides
- Applying GAMP

Validation Planning

- More on validation
- More on risk assessments
- Identifying electronic signatures
- Supplier audits
- Different development lifecycles
- Comparing Good Engineering Practice and CSV

The Validation Phases

- More on specifications
- The different types of testing
- Source code reviews
- Configuration management
- Managing testing
- Infrastructure qualification
- Spreadsheet validation

ERES Requirements

- EU electronic record (ER) requirements
- US electronic record (ER) requirements
- EU electronic signature (ES) requirements
- US electronic signature (ES) requirements

Operational Requirements

- Managing SOPs
- Baseline software and documentation
- Archiving
- Decommissioning