

GAMP® – Basic 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 content of the *Basic Course* is as follows:-

Introduction to CSV and GAMP®5 Guide

- The need for regulations.
- EU Annex 11.
- MHRA guidance.
- Recognise the difference between computers and equipment.
- Different types of computers.
- Elements of computers.
- Introducing the GAMP guide.

The GAMP®5 Guide

- The five GAMP principles.
- The GAMP classification of hardware and software.
- The GAMP lifecycles for each classification of software.

Validation Planning

- Validation terminology and principles.
- Initial risk assessment.
- Determining the validation deliverables.

The Validation Phases

- Managing specifications.
- Test documentation and testing procedure.
- Test reports and the validation report.

Operational Requirements

- Change control.
- SOPs.
- Training.
- Periodic review.