

GAMP® 5 2-Day Workshop



Following this 2-Day Workshop, course participants will be able to apply the GAMP® 5 approach to categorise software and hardware for a networked and configured computerised system, to define appropriate engineering and life cycle activities, and to describe the suite of documentation required to maintain the system in an operating and validated state.

This GAMP course is designed for those working within the Pharmaceutical and Medical Device Industry within Production, Quality, Validation, IT, Technical Services and Engineering seeking training in the requirements of GAMP.

This workshop is an element of the Computer System Validation module in the Dublin Institute of Technology (D.I.T.) MSc Degree Program in Process Validation Technologies.

WHAT IS NEW IN GAMP® 5?

- Uses a Risk-Based Approach to Compliant GxP Computerized Systems
- Improving GxP compliance efficiency
- Use of existing documentation and knowledge
- Alignment with ASTM 2500

Still want to know more? Keep your organisation at the cutting edge!

Contact us to book your GAMP® 5 2-Day Workshop for only €650 per participant
Customised inhouse courses also available for delivery upon request



Contact DPS Education on 021 7305000

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More Details: www.dpseng.com



The GAMP® trademark is owned by ISPE: www.ispe.org and/or <http://www.ispe.org/gamp5>

How to make the suite of GAMP® guidance relevant to your role and activities in a modern regulated computerised environment

Learning Outcome

Following this 2-Day Workshop, you will be able to apply the GAMP® 5 approach to categorise software and hardware for a networked and configured computerised system, to define appropriate engineering and life cycle activities, and to describe the suite of documentation required to maintain the system in an operating and validated state.

Course Content

This workshop on GAMP® 5 '*A Risk-Based Approach to Compliant GxP Computerized Systems*' will provide a comprehensive and practical overview of the following:

1. Scalability of all life cycle activities and associated documentation according to risk, complexity and novelty
2. Networked configurable packages that reflect many of today's modern computerised system
3. Efficient integration of engineering and computer system activities
4. Leveraging of supplier activities to the fullest extent while ensuring fitness for intended use

The workshop will extensively parallel the GAMP® 5 principles with a number of the GAMP® Good Practice Guides including:

- Electronic Data Archiving
- Testing of GxP Systems
- Global Information Systems
- IT Infrastructure Control and Compliance
- Validation of Laboratory Computerized Systems
- Risk-Based Approach to Electronic Records & Signatures
- Validation of Process Controls Systems

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A Short Course Certificate from the D.I.T. can be obtained by completing this workshop and the balance of the module. To receive this certificate from the D.I.T., candidates must complete the assignment for the module including a 1500-word essay from this workshop based on a computerised system of their choice as follows:

1. Using the GAMP® 5 approach, categorise the software and hardware for a computerised system and propose suitable life cycle activities and associated documentation.
2. List and describe a suite of lifecycle documentation that will be required to maintain the validated state of the system.

For more information, please contact DPS Education and Training :
021-7305000 or e-mail to education@dpseng.com