Bio Pharma Chem Skillnet

Gamp 5 & Computer Systems Compliance with Focus on Data Integrity

Delivered by:

velopi

bpcskillnet.ie
training@bpcskillnet.ie

Gamp 5 & CSC with Focus on Data Integrity

This course focuses on GAMP5® guidelines, computer systems regulations, and computer systems validation. A well rounded foundation in all of these areas is essential for effective systems implementation and operation within regulated industries. In today's lean climate of operational excellence, pragmatic methodologies that follow good practice to achieve compliance without incurring non-value adding "cost of quality" overhead is essential.

GAMP5®, a risk-based approach to compliant GxP Computerised Systems, promotes a scalable risk-based approach to projects and ongoing system operation where suppliers are leveraged and business process subject matter expertise is central. This course will provide the necessary GAMP foundation with a view to achieving compliant systems. It will demystify the jargon and give a common language across the different systems contributors and stakeholders. It will also cover the regulators current focus on data integrity.

Who should attend?

Industry trends toward configurable systems are no longer the exclusive domain of IT, validation experts, and supplier consultants. All parties involved in systems projects and ongoing management need to share a collective understanding of industry good practice and compliance, including Operational Managers, process Subject Matter Experts (QA/QC, Production, Engineering), IT professionals, System Administrators, Training specialists, Quality, Validation/Compliance professionals, software suppliers, and systems integrators.

The course is focused on the REGULATED pharmaceutical, biopharmaceutical/biotechnology, and medical device industries.

Learning Objectives

- To understand the bigger picture of current computer systems (GAMP) good practice guidelines, and to pragmatically apply these to achieve compliant systems which are fit for your business processes.
- To understand the key computer systems regulations, how they relate to each other, and to communicate with confidence based on an understanding of the regulatory jargon
- To scale systems projects and operations according to a risk-based approach while minimising the cost of quality
- To engage effectively with suppliers (or customers if you are a supplier) in terms of leveraging supplier quality and validation collateral
- To understand and contribute to the meaning of system definition documents (requirements and design specifications) and to work with verification/validation protocols and testing good practice

The Programme

GAMP Guidelines and CSV / Testing

- The evolution of GAMP good practice guidelines and the key concepts of GAMP5®
- An overview of the different types of systems subject to GAMP5® guidelines and industry regulations (e.g. DCS, SCADA, ERP, PPS, MES/EBRS, WMS, CMS, FMS/BMS, EAMS, LIMS, CDS/NDS, DMS, QMS, LMS, spreadsheets, and niche firmware).
- Scaling the GAMP5® life cycle (concept, project, operation, retirement) for different circumstances using Quality Risk Management principles, a pillar of GAMP5®, and risk classification methodologies.
- System definition documentation including User Requirements, Functional, Specification, Design specifications (Hardware, Software, System, Integration, Module, Configuration specs etc.)
- CSV/Computer Systems "Validation" good testing practice, including the traditional GAMP V model (VMP/IQ/OQ/PQ) and how this relates to the pragmatic "Verification" approach outlined in GAMP5®
- General considerations when testing software (process, types of testing, documentation etc.)
- Supplier management and leveraging supplier materials to reduce project effort and cost
- System operation phase - Procedures (SOP's), policies, and considerations for effective and compliant system operation, including (but not limited to) system support, incident management, change control, configuration management, periodic review, business continuity (including disaster recovery & backup/restore), security, data migration, patch management, & ongoing training.
- Supplier management and leveraging supplier materials to reduce project effort and cost
- Leveraging Good Engineering Practice (e.g. Commissioning, FAT, SAT) and Quality Testing (e.g. installation, functional, and requirements testing or the traditional IQ/OQ/PQ approach)

Regulations

- An overview of key regulations and industry guidelines that inspire the GAMP5® approach and serve as the ultimate systems goal (i.e. we need compliant & fit for purpose systems). This includes the GxP's (including Good Manufacturing Practice, Good Engineering Practice etc.), ICHQ9/10, 21.CFR.Part 11, & EU Annex 11.
- A detailed review of the FDA's 21.CFR.Part 11 components and considerations
- The key provisions in EU Annex 11 (with focus on recently introduced issues)

This training is delivered on behalf of BioPharmaChem Skillnet by Velopi Training. For further information please contact training@bpcskillnet.ie or phone 087 997 0848

BioPharmaChem Skillnet is co-funded by Skillnet Ireland and member companies. Skillnet Ireland is funded from the National Training Fund through the Department of Education and Skills.

An Roinn Oideachais agus Scileanna
Department of Education and Skills

Skillnet IRELAND