Epitome
Training Catalogue

Anthem GxP Solutions Pvt. Ltd.
Computer System Compliance Training Programs

Overview:
Computer System Compliance has evolved in last decade to become an integral part of GxP requirements. While the methodology has developed and matured with latest version of GAMP guidelines, the complexity of software technology still leaves a gap between the Regulatory Expectations and the awareness and knowledge at working level executives. Epitome Technologies, with its rich experience of Compliance, has designed this Program to bridge this gap. Presented by industry experts with vast experience of Technology and Compliance, the program covers a Practical Approach to Computer System Validation and Electronic Records Management (e.g. US FDA 21 CFR Part 11 Compliance.)

Program 1: Computer System Validation Overview and Approach
This fundamental training program introduces participants to regulatory requirements for computer systems in the pharmaceutical industry and tried, tested, and internationally recognized methods of meeting those requirements. GAMP 5 evolution and practices are explained in detail in this program.

Program 2: GAMP5 Approach and Documentation
This program describes how the GAMP Good Practice Guides may be applied to achieve compliance for the systems to meet current regulatory requirements. The course covers recommended good practice based on a life cycle approach for the development and management of computer systems and shows how the principles and concepts of GAMP 5 may be practically applied to leverage supplier documentation to avoid unnecessary duplication and cost.

Program 3: Achieving and Maintaining 21 CFR Part 11 Compliance
This program reviews the requirements, FDA guidance and industry positions on the Electronic Records & Electronic Signatures rule. The seminar addresses enabling technologies and mechanisms to ensure that the system remains compliant throughout its lifetime.

Program 4: Part 11 Compliance for MS Excel Spreadsheets
The program provides a full in-depth review of the technical and procedural requirements of 21 CFR Part 11, along with interpretations of how the requirements are applied. All attendees will receive training on best practices in validating MS Excel spreadsheets, including best practices and risk assessment strategies to help determine the scope of the validation.

Program 5: Two Day - On Site Training-cum-workshop
Programme on ERP System (SAP) Validation
The increased use of information technology and ERP systems in all aspects of manufacturing is leading to the automation of more and more processes. Key decisions and action are routinely being taken using ERP system with regulated records being generated electronically. Increasingly, confirmation and approval of these actions and decisions is also being provided electronically. SAP as emerged as dominant player for pharmaceutical industry for such solutions globally and in India. This program covers essentials of ERP validation and workshop using SAP system as reference.

Program 6: Two Day-On Site Training-cum-workshop
Programme on Process Control System Validation
Process Control System Validation is becoming Very Essential for the Pharmaceutical
companies as US FDA/EU auditors are becoming more vigilant when it comes to Automation System Validation and Documentation part during Audits. It is a big challenge for Pharmaceutical Companies to seamlessly integrate Validation practices for installed automated equipments and systems being purchased. With the help of this training program, executives will be able to use GAMP 5 approach for managing such documentation & reduce repeat documentation, costs.

**Program 7: Two Day-On Site Training-cum-workshop**

**Programme on Laboratory Computer System & Software System Validation**
This course covers the life cycle for Computer laboratory equipment validation, from requirements specification to testing following best practices suggested by GAMP5 guidelines. It addresses the requirements for the control of electronic records and signatures within a laboratory environment. The course is aimed at fulfilling the requirements of the latest industry requirements such as; 21 CFR Part 11 and Annex. 11.

**Benefits of Using Epitome for Compliance Training**
- Experience with FDA and GxP requirements. Epitome professionals are experts at compliance issues with years of real-world experience. Let our experience provide your employees with a firm foundation when dealing with 21 CFR Part 11.
- Improved Value to Your Quality Systems – Expect short-term gains of 10-25% simply by educating your workforce about Part 11 requirements.

**What you will learn:**

**After completing this training, participants will:**
- Completely understand the key concepts of GAMP 5.
- Have a thorough understanding of the V model and its application to GxP computer systems.
- Understand the major life cycle phases of computerized systems, from Concept to retirement. Be able to identify key validation deliverables.
- Understand software categorization and the Validation efforts required for Various computer systems.
- Understand computer system validation from a regulator’s Perspective.
- Understand Electronic Records Electronic Signatures (ERES) and CFR Part 11 Compliance.
- Know how to leverage supplier involvement to reduce duplication.

**Course materials:**
Participants will receive a copy of the presentation(s), relevant notes and workshop materials. A certificate of completion will be issued to participants who successfully complete the assessment.

**Assessment:**
A written assessment is conducted at the end of the all two days programs.

**Course Format:**
The two days programs are a combination of lecture-style learning and active workshops with participants working in small groups on assigned tasks.

**Who should attend:**
- Quality Assurance personnel
- Operations or Manufacturing personnel
- IT personnel