BUSINESS EXCELLENCE CONSULTING Inc.

Passion for Quality

TRAINING TITLE:

Computer System Validation for FDA-Regulated Industry (WORK-017)

OVERVIEW:

This course focuses on developing and implementing regulated computer systems with an appropriate level of documented evidence to satisfy FDA expectations. The course targets deliverable document content and how to avoid rework and unnecessary expense through a proactive approach. The core elements of a satisfactory computer validation program will be emphasized. Attendees will gain insight into the basics of computer validation, regulations applicable to computer system validation, how to plan computer system validation for the system's lifecycle, and how to develop an organization's own system.

TARGET GROUP FOR THE TRAINING:

This course is designed for Validation, Quality, IT, and Business personnel responsible for implementing and using regulated computer systems in the pharmaceutical, biotech and medical device industries. The course is of special value to personnel seeking experience with computer validation and issues associated with FDA regulated computer systems. The course is especially designed for attendees seeking a thorough introductory level of understanding, yet is also designed to be valuable to those with prior experience seeking to remain current with industry trends and approaches.

LEARNING OBJECTIVES:

- Define the elements of computer system validation
- Evaluate sample documents
- Develop the validation rationale for a variety of circumstances

MATERIALS:

Each participant will receive:

- MS PowerPoint presentations
- Certificate of Attendance
- Final Exam (70% minimum score required to approve the course)

TRAINING DURATION:

14 contact hours

ACCREDITED IACET PROVIDER

BEC is authorized by IACET to offer 1.4 CEUs for this program. FULL attendance to the learning event is mandatory to receive CEUs.

COURSE INSTRUCTOR:

Donaline Egipciaco is a process improvement consultant with a proven track record working in many industries, including Pharmaceuticals, Biotechnology, Aerospace, and Medical Devices. During her more than 20 years of experience, she has worked as Pharmaceutical Process Transfer Operations leader, Remediation Project Manager, Computer Validation Projects, Investigations developer, auditor and CSV trainer. Donaline has a Bachelors Degree in Business Administration and a Masters Degree in Strategic Management from Universidad del Este, in Cabo Rojo, Puerto Rico.

BUSINESS EXCELLENCE CONSULTING Inc.

Passion for Quality

Title: Computer System Validation for FDA Regulated Industry (Day 1)

Lunch from 12:00 – 13:00.

Coffee break: 15 min. each during morning and afternoon session. Time schedule are rough estimates and may vary consequently.

Agenda	
8:30 – 9:00	**Opening Remarks**
9:00 – 9:45	**General Overview** • FDA thinking • Computer system validation: Definition, scope, purpose • Electronic records / Electronic signature overview
9:45 – 10:15	**Computerized Systems** • Qualification and validation • After validation process • GAP analysis • Legacy system • Commercial off-the-shelve system
10:15 – 10:30	**Break**
10:30 – 11:15	**Regulated Requirements** • 21 CFR Part 11 and 21 CFR Part 820
11:15 – 12:00	**SDLC** • Definition • Process step-by-step; Requirements
12:00 – 13:00	**Lunch**
13:00 – 14:00	**GAMP** • Definition • GxP, GAMP5 • Initial Impact Assessment • Protocol discrepancies and deviations
14:00 – 15:00	**CSV Process – New Systems** • Plan phase • Validation steps • Life cycle • FAT / SAT • System release notice
15:00 – 15:15	**Break**
15:15 – 17:00	**Retire Phase** • Data retirement methods • Risk assessment

BUSINESS EXCELLENCE CONSULTING Inc.

Passion for Quality

Title: Computer System Validation for FDA Regulated Industry (Day 2)

Lunch from 12:00 – 13:00.

Coffee break: 15 min. each during morning and afternoon session. Time schedule are rough estimates and may vary consequently.

Agenda	
8:30 – 9:45	**21 CFR Part 11** • Overview • History and background • Part 11 requirements • Electronic Records / Electronic Signature
9:45 – 10:15	**GAMP5 International Guideline** • Purpose • Alignment / Application • Key concepts • Principles
10:15 – 10:30	**Break**
10:30 – 11:15	**Checklists for Assessments Examples** • Templates discussion
11:15 – 12:00	**Protocols Templates** • What to do and what to justify • Examples discussion • Requirements
12:00 – 13:00	**Lunch**
13:00 – 14:00	**Validation Assesment Checklist** • Definition • Initial impact assessment • Protocol discrepancies and deviations • Examples
14:00 – 15:00	**GAP Analysis** • Requirements • Results
15:00 – 15:15	**Break**
15:15 – 17:00	**Validation Closing** • Requirements • Release • Questions and answers