BUSINESS EXCELLENCE CONSULTING Inc.

Passion for Quality

TRAINING TITLE:

Validation Overview (WORK-018)

OVERVIEW:

GMP regulations worldwide as well as FDA and ICH guidances require that companies should establish and document an overall policy, intentions, and approach to validations. Validation is an essential part of current good manufacturing practices and an element of the Total Quality Management associated to a particular product or process. Validation is a scientific approach of collecting and evaluating data during product lifecycle to evidence that the entire process is capable of consistently delivering quality products. The workshop will deal with an overview of what is validation, their principles and scope to engage effectively in a validation structure to optimize the validation methodology preventing validation errors. This practical workshop will consist of lectures, interactive discussions and practice exam.

TARGET GROUP FOR THE TRAINING:

This practical workshop is designed for those individuals who prepare, coordinate, review, approve and support any validation activity. This practical workshop is designed for all levels of management who need to understand the science of validation. The program will benefit individuals in the pharmaceutical, medical device and related industries like biotechnology as well as suppliers and contract organizations. The course can be of interest to top management responsible for all aspects of validation programs in their companies as well as to professionals in a variety of functions such as: Quality Assurance, Quality Control, R&D, Production, Packaging, Engineering, Facility Engineering, Regulatory Compliance, and so on.

LEARNING OBJECTIVES:

- Identify the most widely used validation principles.
- Define the expected content for validation deliverables through examination of sample documents
- Develop the validation rationale for a variety of circumstances

MATERIALS:

Each participant will receive:

- MS PowerPoint presentations
- Practice Exam of the Workshop Material
- 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:

Arlene Delgado Velazquez is a training consultant within the FDA-regulated industries and educational sectors with 20 years of experience. She has a Bachelor Degree in Industrial Microbiology in the University of Puerto Rico at Humacao campus, P.R. She also has a Master Degree in Industrial Engineering Manufacturing Competitiveness/ Quality Management in the Polytechnic University of Puerto Rico in Hato Rey, P.R. Since year 2013, she is fully devoted to consulting under Business Excellence Consulting Inc, focusing on training on related Quality sectors. She also serves as professor in the Humacao Community College for Biology, Biotechnology, Microbiology and Validation, and GMP courses. She is an ASQ Certified Six Sigma Green Belt, Manager of Quality & Organizational Excellence and Quality Auditor.

Gricel Morales Fontánez is a Quality Auditor and Validation Leader consultant within the FDA-regulated industries with more than 22 years of experience. She also is a training consultant within the educational sectors. She has a Bachelor Degree in Industrial Engineering in the Polytechnic University of Puerto Rico in Hato Rey, P.R. She has a Master Degree in Manufacturing Engineering, Industrial Automation in the Polytechnic University of Puerto Rico in Hato Rey, P.R. She also has a Doctorate in Business Administration, Information Systems in the Argosy University of Sarasota Campus in Florida US.
She was an ASQ Certified Manager of Quality & Organizational Excellence and Quality Auditor.
She also serves as professor in the Interamerican University of P.R. at Health Sciences sector in Ponce Campus for Quality Assurance Systems and Quality Improvements.

BUSINESS EXCELLENCE CONSULTING Inc.

Passion for Quality

Title: Validation Overview (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 – 9:15	**Introduction**
9:15 – 10:30	• Introduction to Validation • Management Responsibility o Resources Allocation • Verification vs. Validation
10:30 – 10:45	**Break**
10:45 – 12:00	• Validation and Qualification • Areas of Validations and Qualifications
12:00 – 13:00	**Lunch**
13:00 – 14:30	• Areas of Validation and Qualifications • ASTM E2500-07 Approach • Documentation Associated to Validation/ Qualification
14:30 – 14:45	**Break**
14:45 – 17:00	• Documentation Associated to Validation / Qualification • Validation Principles and Tools: Risk Based Approach

BUSINESS EXCELLENCE CONSULTING Inc.

Passion for Quality

Title: Validation Overview (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 – 9:15	• Validation Principles and Tools Summary
9:15 – 10:30	• Validation Principles and Tools: o Planning o Sample Size Determination o Protocol Preparation
10:30 – 10:45	**Break**
10:45 – 12:00	• Validation Principles and Tools: o Training o Execution o Data Processing and Analysis ▪ Some Statistical Tools o Handling Deviations ▪ Investigation Tools o Summary and Conclusions o Final Report Preparation
12:00 – 13:00	**Lunch**
13:00 – 14:30	• Validation Principles and Tools: o VMP Format o Requalification/Revalidation after Changes o Continuous Monitoring ▪ Some Statistical Tools Detecting Changes • A Success Validation • Pitfalls of Validations • FDA Findings (Inspectional Observations)
14:30 – 14:45	**Break**
14:45 – 16:00	• Validation Program o Risk Based Approach o VMP and VP o General Requirements o Protocol Format o Summary Reports o Specific Approvals o New or Modified Systems o Assessing Changes o Periodic Monitoring o Continuous Monitoring o Applicable SOP's / References
16:00 - 17:00	Practice Exam