BUSINESS EXCELLENCE CONSULTING Inc.

Passion for Quality

TRAINING TITLE:

Cleaning Validation Lifecycle (WORK-022)

OVERVIEW:

As cleaning process technology and analytical methodology advance, so do the challenges associated with establishing, managing, and maintaining a scientifically sound cleaning validation program. Regulatory agencies expectations, such as FDA and ICH, are focused on risk-based regulatory initiatives that emphasize the manufacturers' attention to the risks of cross-contamination. The solution is to understand lifecycle management techniques for an effective cleaning validation program. This workshop will cover elements of a cleaning validation program from start to finish, exploring such concepts as the cycle development, operational parameters, determination and adequacy of residues to be targeted, selection of analytical and sampling methods, cleaning validation requirements and maintenance of validated state. 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 cleaning validation activity. This practical workshop is designed for all levels of management who need to understand the science of cleaning 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 cleaning 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 principles of the cleaning validation lifecycle approach
- Describe the use of the guidelines (such as PDA) and regulations requirements (such as FDA, PIC/IS and WHO)

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:

21 contact hours

ACCREDITED IACET PROVIDER

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

COURSE INSTRUCTOR:

Myrelis Aguilar Cepeda is a Validation Lead and a Quality Assurance Systems consultant within the FDA-regulated industries with more than 12 years of experience. She has a Bachelor Degree in Biology from the University of Puerto Rico at Rio Piedras campus, PR. and a Medical Technology Certification from the Interamerican University Cupey Campus, PR. She also has a Master Degree in Industrial Engineering Manufacturing Competitiveness and Quality Management from the Polytechnic University of Puerto Rico in Hato Rey, PR. Since year 2012, she is fully devoted to consulting under Business Excellence Consulting Inc., focusing on training on related Quality and Technical sectors. She is an ASQ Certified Quality Auditor.

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Title: Cleaning Validation Lifecycle (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 -8:45am	**Introduction**
8:45 – 10:30am	• Scope • Objectives
10:30 – 10:45	**Break**
10:45 – 12:00	• Regulations and Standards • Cleaning Process Overview
12:00 – 13:00	**Lunch**
13:00 – 14:30	• Cleaning Process Design and Development o Physical and Chemical Aspects • Types of Cleaning Process
14:30 – 14:45	**Break**
14:45 – 17:00	• Types of Cleaning Process (cont.) o Soil Evaluation

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Title: Cleaning Validation Lifecycle (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 – 9:00	• Day 1 Recap
9:00 – 10:30	• Equipment Considerations o Case Study: Total Surface Area Determination
10:30 – 10:45	**Break**
10:45 – 12:00	• Operational Considerations o Cleaning Agent Selection o Types and Quality of Water
12:00 – 13:00	**Lunch**
13:00 – 14:30	• Product Considerations o Cleaning Development at the Lab o Cleaning Process Scale Up
14:30 – 14:45	**Break**
14:45 – 17:00	• Operator Training • Other Factors to Consider • Cleaning Validation Master Plan & SOPs o Case Study: Cleaning SOP Development

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Title: Cleaning Validation Lifecycle (Day 3)

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	• Day 2 Recap
9:00 – 10:30	• Residue Limits
10:30 – 10:45	**Break**
10:45 – 12:00	• Case Study: Residue Limit Determination • Bioburden and Endotoxin Limits and Visually Clean Criterion • Sampling
12:00 – 13:00	**Lunch**
13:00 – 14:30	• Analytical Methods • Equipment and/or Product Grouping/Matrixing/Family Approach • Cleaning Process Validation
14:30 – 14:45	**Break**
14:45 – 16:00	• Maintenance of Validated State
16:00 – 17:00	• Exam & Evaluation