BUSINESS EXCELLENCE CONSULTING Inc.

Passion for Quality

TRAINING TITLE:

ASQ Certified Biomedical Auditor Academia (ACAD-008)

OVERVIEW:

The Certified Biomedical Auditor is a professional who understands the principles of standards, regulations, directives and guidance for auditing a biomedical system while using various tools and techniques to examine, question, evaluate and report on that system's adequacy and deficiencies. A biomedical auditor analyzes all elements of the system and reports on how well it adheres to the criteria for management and control of process safety.

TARGET GROUP FOR THE CONFERENCE:

This training is aimed at all persons interested in preparing for the ASQ Certified Biomedical Auditor exam provided twice per year. Attendees will obtain a better understanding of the principles and regulations required to become a biomedical auditor.

LEARNING OBJECTIVES:

- Identify the most widely used biomedical auditor principles
- Apply the appropriate tools for each situation faced on a daily basis by a biomedical auditor
- Prepare for the ASQ Certified Biomedical Auditor exam

MATERIALS:

Each participant will receive:

- *The Certified Biomedical Auditor Primer*, published by Quality Council of Indiana
- Certificate of Attendance

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:

Pepe Rodríguez is founder and President of Business Excellence Consulting Inc., a leading Puerto Rican training and consulting organization. From 2009-11 he served as a Science Advisor for the FDA San Juan District. He has served as instructor of courses on quality and continuous improvement in several countries with thousands of professionals trained in topics such as Quality Engineering, Six-Sigma, Effective CAPA and Root Cause Analysis, HACCP and Quality Management. Pepe holds a bachelor's degree in biology and PhD in immunology, both from the University of Granada, Spain. He served as a senior member of the American Society of Quality and President of the Puerto Rico (ASQ 1500) section during the period 2003-05. He was secretary from 2005-2012. He is also a member of the Regulatory Affairs Professional Society (RAPS), ISPE, AAMI, and the Parenteral Drug Association (PDA). Pepe is also the author of the best-selling books "CAPA for the FDA-Regulated Industry", "Quality Risk Management in the FDA-Regulated Industry", and "The FDA & Worldwide Current Good Manufacturing Practices and Quality System Requirements Guidebook for Finished Pharmaceuticals", published by the American Society for Quality.

Solmarie Vélez Rivera is a training consultant within the FDA-regulated industries with over 20 years of experience. She has a Bachelor Degree in Industrial Engineering from the University of Puerto Rico at Mayaguez Campus. She also has a Master Degree in Business Adminitration from University of Phoenix, Puerto Rico Site. Since year 2013, she is fully devoted to consulting under Business Excellence Consulting Inc, focusing on training on ASQ Certified Quality Auditor Academia, Internal Audits Program, Quality Systems Regulations (21CFR820), CAPA, Root Cause Analysis, Technical Writing, and other topics. She is an ASQ Certified Quality Auditor, Manager of Quality & Organizational Excellence, Biomedical Auditor, and HACCP Auditor.

Manuel E. Peña-Rodríguez is a process improvement and training consultant within the textiles, electronics, and FDA-regulated industries with more than 20 years of experience in those fields. Since January 2006, he is fully devoted to consulting under Business Excellence Consulting Inc, focusing on training and implementation of Lean Six Sigma initiatives and CAPA / Root Cause Analysis workshops. He also serves as professor in the graduate program in biochemistry at the University of Puerto Rico, Medical Sciences Campus, in San Juan. Manuel received his J.D. degree from the Pontifical Catholic University of Puerto Rico and his master's of engineering in Engineering Management from Cornell University in Ithaca NY. He is also a licensed Professional Engineer registered in Puerto Rico. Manuel is an ASQ Certified Six Sigma Black Belt, Manager of Quality & Organizational Excellence, Quality Engineer, Quality Auditor, Biomedical Auditor, and HACCP Auditor. He is also a Senior member of ASQ and former Chair of the Puerto Rico ASQ Section. He is the author of the book "*Statistical Process Control for the FDA-Regulated Industry*", published by ASQ Quality Press in April 2013 and co-author (with José Rodríguez-Pérez) of the article "*Fail-Safe FMEA*" published in the January 2012 edition of the ASQ Quality Progress magazine.

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Title: ASQ Certified Biomedical Auditor Academia (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	**Certification Overview**
9:00 – 10:15	**Auditing Fundamentals** • Audit Types • Audits by Method • Audits by Purpose • Audit Roles and Responsibilities • Ethical, Legal, & Professional Issues
10:15 – 10:30	**Break**
10:30 – 12:00	**Auditing and Inspecion Processes** • Audit Preparation & Planning • Elements of the Planning Process • Auditor Selection • Audit Related Documentation • Auditing Strategies
12:00 – 13:00	**Lunch**
13:00 – 15:00	**Auditing and Inspecion Processes (cont.)** • Audit Performance • Opening Meeting • On-site Audit Management • Exit Meeting • Audit Reporting • Effective Audit Reports
15:00 – 15:15	**Break**
15:15 – 17:00	**Auditing and Inspecion Processes (cont.)** • Record Retention • Audit Follow-up and Closure • Corrective & Preventive Action • Corrective Action Plan Review • Conducting Audit Follow-up • Audit Closure • International Guidelines • FDA CPG 7382.845

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Title: ASQ Certified Biomedical Auditor Academia (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 – 10:15	**Regulatory Requirements** • FDA-Code of Federal Regulations • U.S. Requirements • European Device Directive • Health Canada • Japan • Other International Agencies • FDA Guidance for IVD Products • International Standards for Quality Systems
10:15 – 10:30	**Break**
10:30 – 12:00	**Quality System Regulations** • Management Responsibility • Design Control System • Document & Record Control • Purchasing Controls • Identification & Traceability • Production & Process Controls
12:00 – 13:00	**Lunch**
13:00 – 15:00	**Quality System Regulations (cont.)** • Nonconforming Product • Corrective & Preventive Action • Product Handling, Storage, Distribution, & Installation • Servicing • Statistical Techniques • Post-market Surveillance
15:00 – 15:15	**Break**
15:15 – 17:00	**Biomedical Knowledge – Part I** • Risk Management • ISO 14971 • IEC 63266 • Assessment Tools • Sterilization • Introduction

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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 – 10:15	**Biomedical Knowledge – Part I (cont.)** • Methods and Process Control • Biocompatibility • Control Environments & Utility Systems • Controlled Environments • Utility Systems
10:15 – 10:30	**Break**
10:30 – 12:00	**Biomedical Knowledge – Part II** • Software Product Development • Lab Testing & Failure Analysis • Sources for New & Evolving Standards • Medical Device Directives & Standards • Packaging • Reuse & Cleaning of Medical Devices
12:00 – 13:00	**Lunch**
13:00 – 15:00	**Quality Tools and Techniques** • Quality Control and Prob. Solving • Process Improvement Techniques • Process Capability • Six Sigma • Lean Tools • Measurement System Analysis
15:00 – 15:15	**Break**
15:15 – 16:00	**Quality Tools and Techniques (cont.)** • Cost of Quality • Data Types & Sampling • Qualitative and Quantitative Analysis • Attribute & Variables Data
16:00 – 17:00	**Biomedical Standards**