BUSINESS EXCELLENCE CONSULTING Inc.

Passion for Quality

TRAINING TITLE:

Medical Device Quality System Expert Certification (CERT-008)

OVERVIEW:

Manufacturers must establish and follow quality systems to help ensure that their products consistently meet applicable requirements and specifications. The quality systems for FDA-regulated products (food, drugs, biologics, and medical devices) are known as current good manufacturing practices (cGMP's). The cGMP requirements for medical devices in part 820 (21 CFR part 820) were first authorized by section 520(f) of the Federal Food, Drug, and Cosmetic Act (the act). This certification provides useful and up-to-date information about this critical topic to thousands of engineers, scientists, and manufacturing and quality personnel across the life sciences industries. Evaluating and improving the medical device quality system is the focal point of this certification.

TARGET GROUP FOR THE CONFERENCE:

This certification will benefit manufacturers of FDA-regulated medical devices in documenting their quality systems in order to avoid FDA or other regulatory bodies' inspection findings. It will be a great resource to Quality Assurance, Manufacturing, Regulatory Affairs, Supplier Quality and Quality Control personnel and management within the medical device companies.

LEARNING OBJECTIVES:

- Identify the most important elements of a medical device manufacturer's quality system
- Apply the appropriate tools for each situation faced on a daily basis by a medical device manufacturer's 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
- MS PowerPoint Presentation
- 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:

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 Administration 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 (21 CFR 820), CAPA, Root Cause Analysis, Technical Writing, and other topics. She is an ASQ Certified Quality Auditor and Manager of Quality & Organizational Excellence.

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.

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.

BUSINESS EXCELLENCE CONSULTING Inc.

Passion for Quality

Title: Medical Device Quality System Expert Certification (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 and Knowledge Assessment Exam**
9:15 – 10:15	**Medical Device Laws (U.S. & EU, cGMP History)** • FDA overview • Medical device definitions • History of medical device regulations
10:15 – 10:30	**Break**
10:30 – 11:00	**Medical Device Laws (U.S. & EU, cGMP History)** • Medical devices classification • Global medical devices market regulations • FDA laws • EU Medical Device Directive
11:00 – 12:00	**Principles of U.S. QSR 21 CFR 820** • FD&C Act overview • General principles • Scope • 21 CFR 820 (Subparts A, B, D, M, C, E, F)
12:00 – 13:00	**Lunch**
13:00 – 15:00	**Principles of U.S. QSR 21 CFR 820** • 21 CFR 820 (Subparts H, O, G)
15:00 – 15:15	**Break**
15:15 – 16:30	• 21 CFR 820 (Subparts K, L, I)
16:30 – 17:00	• 21 CFR 820 (Subparts J, M, N)

BUSINESS EXCELLENCE CONSULTING Inc.

Passion for Quality

Title: Medical Device Quality System Expert Certification (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	**Combination Products (21 CFR Part 4 and EU Guidelines)** • Introduction • 21 CFR Part 4 • Combo products in Europe Drug cGMP elements complementing 21 CFR 820
10:15 – 10:30	**Break**
10:30 – 11:30	**Case Study #1: Warning Letter Analysis**
11:30 – 12:00	**ISO 13485: Analysis and Comparisons to US FDA QSR** • ISO 13485 Overview • ISO 13485:2012 vs. ISO 13485:2003 • Comparison of elements of ISO 13485 with FDA QSR • Auditing under ISO 13485 The process approach
12:00 – 13:00	**Lunch**
13:00 – 13:30	**FDA Inspections – Enforcement Statistics** • Inspection objectives • FDA inspection reasons / types • FDA inspection authority • FDA Inspection process • Classification of inspection reports Statistics
13:30 – 15:00	**FDA Inspection System – QSIT** • What is QSIT • FDA inspection seven subsystems Inspection approach and strategies
15:00 – 15:15	**Break**
15:15 – 16:15	**FDA Inspection System – QSIT** • How will each subsystem be inspected What is FDA looking for
16:15 – 17:00	**FDA: The Price of Noncompliance** • Regulatory actions (483, Warning Letter, Consent Decree, etc.) • Debarment / disqualification lists • Example on progressive enforcement

BUSINESS EXCELLENCE CONSULTING Inc.

Passion for Quality

Title: Medical Device Quality System Expert Certification (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 – 10:15	**Auditing Principles** • Auditing fundamentals • Auditor competencies • Audit stages (planning, performance, reporting, follow-up)
10:15 – 10:30	**Break**
10:30 – 11:30	• **Case Study #2: Preparing and Audit Checklist**
11:30 – 12:00	**Human Factors and Medical Devices** • Human factors at FDA • Standards and guidelines • Key safety design concepts
12:00 – 13:00	**Lunch**
13:00 – 14:00	**ISO 14971:2012** • Definitions • ISO 14971:2012 vs 2007 • Risk Assessment Process • Risk Management Process • Risk Management Process Methods and Tools • Risk Ranking and Filtering.
14:00 – 15:00	**Sterilization and Biocompatibility** • Applicable standards • Sterilization methods • Packaging considerations • Validations concepts • Biocompatibility
15:00 – 15:15	**Break**
15:15 – 17:00	**Case Study #3 and Final Exam**