BUSINESS EXCELLENCE CONSULTING Inc.

Passion for Quality

TRAINING TITLE:

21 CFR 820 (WORK-014)

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). 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). Under section 520(f) of the act, FDA issued a final rule in the Federal Register of July 21, 1978 (43 FR 31 508), prescribing CGMP requirements for medical devices. This regulation became effective on December 18, 1978, and was codified under part 820. After an extensive effort to align the CGMP regulation with the requirements for quality systems contained in applicable international standards, the part 820 revision was published on October 7, 1996 (61 FR 52602) and went into effect June 1, 1997.

TARGET GROUP FOR THE TRAINING:

This workshop 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:

Upon completing this workshop, participants will be able to:

- Identify the most up-to-date information and interpretation on the Quality System Regulation, and how compliance with the regulation is determined
- Improve confidence in preparing for, and hosting of an FDA inspection

MATERIALS:

Each participant will receive:

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

TRAINING DURATION:

7 contact hours

ACCREDITED IACET PROVIDER

BEC is authorized by IACET to offer
0.7 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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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	**U.S. FDA Overview** • Adulteration and Misbranding • FDA Inspections and Recall
9:45 – 10:15	**Part 820 QUALITY SYSTEM REGULATION** **Subpart A--General Provisions** o § 820.1 - Scope. o § 820.3 - Definitions. o § 820.5 - Quality system.
10:15 – 10:30	**Break**
10:30 – 11:15	**Subpart B--Quality System Requirements** o § 820.20 - Management responsibility. o § 820.22 - Quality audit. o § 820.25 - Personnel.
11:15 – 12:00	**Subpart C--Design Controls** o § 820.30 - Design controls. **Subpart D--Document Controls** o § 820.40 - Document controls. **Subpart E--Purchasing Controls** o § 820.50 - Purchasing controls. **Subpart F--Identification and Traceability** o § 820.60 - Identification. o § 820.65 - Traceability. **Subpart G--Production and Process Controls** o § 820.70 - Production and process controls. o § 820.72 - Inspection, measuring, and test equipment. o § 820.75 - Process validation.

12:00 – 13:00	**Lunch**
13:00 – 14:00	**Subpart H--Acceptance Activities** o § 820.80 - Receiving, in-process, and finished device acceptance. o § 820.86 - Acceptance status. **Subpart I--Nonconforming Product** o § 820.90 - Nonconforming product. **Subpart J--Corrective and Preventive Action** o § 820.100 - Corrective and preventive action.
14:00 – 15:00	**Subpart K--Labeling and Packaging Control** o § 820.120 - Device labeling. o § 820.130 - Device packaging. **Subpart L--Handling, Storage, Distribution, and Installation** o § 820.140 - Handling. o § 820.150 - Storage. o § 820.160 - Distribution. o § 820.170 - Installation.
15:00 – 15:15	**Break**
15:15 – 17:00	**Subpart M--Records** o § 820.180 - General requirements. o § 820.181 - Device master record. o § 820.184 - Device history record. o § 820.186 - Quality system record. o § 820.198 - Complaint files. **Subpart N--Servicing** o § 820.200 - Servicing. **Subpart O--Statistical Techniques** o § 820.250 - Statistical techniques.