BUSINESS EXCELLENCE CONSULTING Inc.

Passion for Quality

TRAINING TITLE:

FDA Readiness Inspection Best Practices (WORK-028)

OVERVIEW:

FDA investigators are knocking at your door. Are you ready? Your first thoughts may be of logistics (meeting space, document availability, the condition of your facility) but what about personnel? Are your employees prepared to face FDA investigators who are trained to thoroughly investigate a manufacturer's entire operation? The employees that know the most about your front-line operations are usually the ones who have the least experience with inspections and therefore are more likely to slip up. That's why training of subject matter experts (SME) deserves at least as much attention in your inspection readiness plan as more tangible aspects like documentation and equipment function.

This workshop will assist those individuals involved in FDA inspections to understand the regulatory requirements and current practices of cGMP inspections.

TARGET GROUP FOR THE TRAINING:

This workshop will benefit people involved in the manufacturing, processing, packing, or holding of FDA-regulated products in understanding the regulation 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 FDA-Regulated industry.

LEARNING OBJECTIVES:

Upon completing this workshop, participants will be able to:

- Identify the regulatory requirements and current practices of cGMP inspections
- Describe current regulatory issues and strategies
- Discuss the prime target for FDA inspections
- Evaluate the best practices before, during, and after the 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.

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: FDA Readiness Inspection Best Practices

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 – 10:15	• US FDA: Structure and Authority • Regulatory Requirements
10:15 – 10:30	**Break**
10:30 – 11:15	• Types of Inspection • Inspection results: Form 483 and the Establishment Inspection Report (EIR)
11:15 – 12:00	• The cost of Non-Compliance: Untitled/Warning Letters, Injunctions and Seizures • FDA Online Tools: Recalls/Warning Letters/ FOI Pages
12:00 – 13:00	**Lunch**
13:00 – 14:00	• FDA Enforcement Story: Current Trends o The FDA Office of Criminal Investigation (OCI) • FDA Inspector Preparation: Data Integrity Finders
14:00 – 15:00	• How to be Ready for FDA Inspections o The FDA Inspection Process o FDA Domestic vs. Foreign Inspections o Pre-Inspection Activities: the Value of a Mock Audit • Inspection: Do & Don'ts
15:00 – 15:15	**Break**
15:15 – 17:00	• Interaction with FDA Inspectors: o Interviews with Employees o Body Language and Other Signs o Knowing your Inspector(s) • Post-Inspection Activities - How to Respond to an FDA 483: Do & Don'ts • Practical Examples