BUSINESS EXCELLENCE CONSULTING Inc.

Passion for Quality

TRAINING TITLE:

FDA's 21 CFR 117 Proposed Rule
(WORK-027)

OVERVIEW:

On January 4, 2013, FDA released the long-awaited proposed rule implementing section 103 of the Food Safety Modernization Act ("FSMA") and revising FDA's food current good manufacturing practice ("CGMP") regulations, coded as 21 CFR 117. In this one-day workshop we will cover in detail the main aspects of the new regulation, including a thorough review of each subpart.

The proposed rule revises FDA's current regulations in part 110 regarding the manufacturing, processing, packing, or holding of human food in two fundamental ways. First, it would add new provisions to implement section 103 of FSMA. Second, it would update, revise, or otherwise clarify certain requirements of our current regulations in part 110. The new provisions and revisions to the current CGMP requirements would be established in part 117.

TARGET GROUP FOR THE TRAINING:

This workshop will benefit people involved in the manufacturing, processing, packing, or holding of human food in understanding the new 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 food industry.

LEARNING OBJECTIVES:

Upon completing this workshop, participants will be able to:

- Identify the most up-to-date information and interpretation on the 21 CFR 117 Proposed Rule, and how compliance with it is determined

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.

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Title: Overview of FDA cGMP Regulations

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	**Subpart A--General Provisions**
10:15 – 10:30	**Break**
10:30 – 11:15	**Subpart B--Current Good Manufacturing Practices**
11:15 – 12:00	**Subpart C--Hazard Analysis and Risk-Based Preventive Controls**
12:00 – 13:00	**Lunch**
13:00 – 14:00	**Subpart D--Modified Requirements**
14:00 – 15:00	**Subpart E-- Withdrawal of an Exemption Applicable to a Qualified Facility**
15:00 – 15:15	**Break**
15:15 – 17:00	**Subpart F--Requirements Applying to Records That Must Be Established and Maintained**