BUSINESS EXCELLENCE CONSULTING Inc.

Passion for Quality

TRAINING TITLE:

Practical FMEA for the FDA-Regulated Industry (WORK-020)

OVERVIEW:

The importance of quality systems has been recognized in the life sciences industry and it is becoming evident that quality risk management is a valuable component of an effective quality system. The present FDA focus on risk-based determination is requiring that the regulated industries improve dramatically their understanding and capability of hazard control concepts. The purpose of this workshop is to offer a systematic and very comprehensive approach to quality risk management, using the Failure Mode and Effects Analysis (FMEA) tool.

TARGET GROUP FOR THE CONFERENCE:

This certification will benefit manufacturers of FDA-regulated products to improve their risk management process, 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 Pharmaceutical, Biotechnology and Medical Device companies.

LEARNING OBJECTIVES:

- Identify the most widely used risk management principles
- Apply the appropriate tools to integrate the risk management system into an existing quality management system

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:

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 – 10:15	**Failure Mode and Effect Analysis (FMEA): the Fail-Safe FMEA** • Introduction to the FMEA World
10:15 – 10:30	**Break**
10:30 – 12:00	**Failure Mode and Effect Analysis (FMEA): the Fail-Safe FMEA (cont.)** • The FMEA Form
12:00 – 13:00	**Lunch**
13:00 – 15:00	**Failure Mode and Effect Analysis (FMEA): the Fail-Safe FMEA (cont.)** • Best Practices: How to Perform an Effective FMEA • Final Words: FMEA Do's & Don'ts
15:00 – 15:15	**Break**
15:15 – 17:00	**Failure Mode and Effect Analysis (FMEA): the Fail-Safe FMEA (cont.)** • Case Study