TRAINING TITLE:

Quality Risk Management Certification (CERT-004)

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 certification is to offer a systematic and very comprehensive approach to quality risk management. It will assist medical and food product manufacturers with the integration of a risk management system (or risk management principles and activities) into their existing quality management system by providing explanations, examples, methodologies, and tools widely used during risk management processes.

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

The effectiveness of the certification process will be measured using the Kirkpatrick model of training effectiveness, through the use of the following materials for each phase of the model:

- **Reaction:** an evaluation form at the end of the training, covering issues such as training material's organization, trainer's knowledge about the topics, and training environment.
- **Learning:** a pre-test prior to the beginning of the training, plus a post-test at the end of the training. A minimum grade of 70% in the post-test is required to pass the certification.
- **Behavior:** development of Quality Risk Management Plans by participants. Divided into groups, participants will work for one day on the development of real cases of QRM plans for selected site activities.
- **Results:** the company might be able to measure the results of this certification process by analyzing pre- and post-certification risk assessment metrics, such as number of potential failure modes identified by the risk assessment, in comparison to the current failure modes identified through the use of other tools (such as the corrective actions generated through their CAPA system).

MATERIALS:

Each participant will receive:

- *Quality Risk Management in the FDA-Regulated Industry* book, published by ASQ Quality Press
- PowerPoint presentations
- Certificate of Attendance

TRAINING DURATION:

21 contact hours

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:

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: Quality Risk Management 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 – 9:00	**Opening Remarks and Pre-Test**
9:00 – 10:15	**Introduction to Quality Risk Management** • What is Quality Risk Management? • ICH Q9/ISO 14971 Terminology • More than Safety Risks: From Safety Risks to Quality by Design **Principles of Quality Risk Management** • Principles • Science and Risk-based Approaches of Product Quality • Quality Systems Approach
10:15 – 10:30	**Break**
10:30 – 12:00	**General Quality Risk Management Process** • Introduction to Quality Risk Management Process /Responsibilities and Initiation of the Risk Management Process • Risk Assessment ▪ Risk identification ▪ Risk analysis o Controls assessment o Risk Estimation: severity and likelihood analysis ▪ Risk Evaluation • Risk Control ▪ Risk Reduction ▪ Risk Acceptance • Risk Documentation and Communication • Risk Monitoring and Effectiveness Review • Application of risk assessment during life cycle phases
12:00 – 13:00	**Lunch**
13:00 – 15:00	**Integration of Risk Management with Quality Management** • Risk Management Plans ▪ Scope of the Plan ▪ Assignment of responsibilities and authorities ▪ Requirements for review of risk management activities ▪ Criteria for risk acceptability

	▪ Verification activities ▪ Methods of obtaining relevant post-production information ▪ Example of Risk Management Plans applied to manufacturing environment
15:00 – 15:15	**Break**
15:15 – 17:00	**Practical Applications of Quality Risk Management to the Life Science Manufacturing Industry** • Management (audit, training, CAPA system, supplier selection and control, outsourcing, regulatory actions: Recalls Health Hazard Evaluation • Documents and Records / Change Management • Facilities and Equipment • Design and Development • Production and Process Control ▪ Trend Analysis and Statistical Process Control ▪ Aseptic Process ▪ Validations and Revalidations ▪ Laboratory Controls ▪ Packaging and Labelling ▪ Materials

BUSINESS EXCELLENCE CONSULTING Inc.

Passion for Quality

Title: Quality Risk Management 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	**Methodologies and Tools** • Selection of risk assessment techniques ▪ Availability of Resources ▪ The Nature and Degree of Uncertainty / Complexity • Application of risk assessment during life cycle phases • Risk assessment techniques ▪ Basic facilitation tools ▪ Fault Tree Analysis (FTA) ▪ Hazard Analysis and Critical Control Points (HACCP) ▪ Hazard and Operability (HAZOP) ▪ Cause and Effect Analysis / 5 Whys, ▪ Preliminary Hazard Analysis (PHA) ▪ Risk Ranking and Filtering ▪ Statistical Tools
10:15 – 10:30	**Break**
10:30 – 12:00	**Failure Mode and Effect Analysis (FMEA): the Fail-Safe FMEA** • Introduction to the FMEA World
12:00 – 13:00	**Lunch**
13:00 – 15:00	**Failure Mode and Effect Analysis (FMEA): the Fail-Safe FMEA (cont.)** • The FMEA Form
15:00 – 15:15	**Break**
15:15 – 17:00	**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

BUSINESS EXCELLENCE CONSULTING Inc.

Passion for Quality

Title: Quality Risk Management 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	**Practical Case Study**
10:15 – 10:30	**Break**
10:30 – 12:00	**Practical Case Study (cont.)**
12:00 – 13:00	**Lunch**
13:00 – 15:00	**Practical Case Study (cont.)**
15:00 – 15:15	**Break**
15:15 – 17:00	**Post-Test**