BUSINESS EXCELLENCE CONSULTING Inc.

Passion for Quality

TRAINING TITLE:

Sampling Best Practices for the FDA-Regulated Industry (WORK-009)

OVERVIEW:

Acceptance sampling is a widely used technique for the inspection of incoming and outgoing product. Sampling standards, such as ANSI/ASQ Z 1.4 for inspection by attributes, are used to select sample sizes. The sampling standards are based around the concept of the AQL (Acceptance Quality Limit). It is important that the AQL is suitably established, and that the appropriate sample sizes are chosen so that correct decisions are made on the acceptance or rejection of lots. This course will provide detailed information on the correct procedures to be followed in choosing samples sizes.

TARGET GROUP FOR THE TRAINING:

This practical workshop is designed for those individuals who are involved or expect to be involved in the development of acceptance sampling plans. The course will benefit individuals who have responsibility for selecting sample sizes for inspection of incoming or outgoing lots of product, Quality Engineers and Quality Auditors, Quality Assurance staff responsible for setting acceptance quality limits (AQL's), and all other personnel impacted by sampling plans.

LEARNING OBJECTIVES:

On successful completion of this training course, participants should be able to:

- Select sampling sizes for inspection using the international sampling plans, such as ANSI/ASQZ1.4
- Implement sampling procedures based on AQL's
- Apply the switching rules and use of the normal, tightened and reduced sampling tables

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: Practical Sampling Applied to the Life Science Industries

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 – 9:30	**Introduction to Acceptance Sampling** • Sampling and FDA • Objective of sampling inspection • Sampling practices • Attributes or variables inspection • Lot inspection • Sequence or isolated lots
9:30 – 10:15	**Sampling Plans Basics** • Acceptance Quality Limits (AQL) • Setting the AQL • Limiting Quality (LQ) • Types of Inspections • Switching rules
10:15 – 10:30	**Break**
10:30 – 10:45	**Operating characteristics curves**
10:45 – 11:00	**Types of Sampling Plans** • Single sampling plans • Double sampling Plans • Multiple sampling plans • Drawing of samples (random method) • Regulatory requirements
11:00 – 12:00	**The Z1.4 System "Sampling Procedure and tables for inspection by attributes" (ANSI/ASQ Z1.4-2008)** • The inspection level • Preparing a specification for use in conjunction with ANSI/ASQ Z1.4 • Classification of nonconformities and nonconforming items • FDA use of sampling plan s

12:00 – 13:00	**Lunch**
13:00 – 14:00	**The Concept of Lot and Other Definitions** • Expression of Nonconformance • Meaning of inspection level
14:00 – 15:00	**Setting the AQLs** • Preferred and Nonpreferred AQLs • Setting the AQL • Drawing a sampling plan from the tables
15:00 – 15:15	**Break**
15:15 – 16:00	**Types of Inspection** • Normal Inspection • Switching rules • Tightened Inspection • Reduced Inspection • Double and multiple sampling
16:00: – 16:45	**Zero Acceptance Number Sampling Plans (Squeglia)**
16:45 – 17:00	**Final remarks** **Relevant bibliography**