TRAINING TITLE:

Statistical Process Control for the FDA-Regulated Industry (WORK-005)

OVERVIEW:

Over the centuries, the Quality of products and services has been one of the common characteristics of successful organizations. The term "Quality" has been evolving throughout the various generations. Philosophies such as Quality Control, Quality Assurance, and Total Quality Management have been recognized at different points in history. Nevertheless, all these philosophies share something in common: the use of Statistical Process Control (SPC) to achieve higher levels of excellence. The concept of SPC applies to any type of industry: automotive, textiles, pharmaceutical, biologics, medical devices, electronics, aerospace, banking, educational services, and so on. With the advances in technology, more people are immersed into the SPC arena everyday. Computer software such as Minitab, Statgraphics, SigmaXL, and others, make the analysis of the data a simpler task. The focus of this workshop is to understand and apply the different SPC tools in a company regulated by the Food and Drugs Administration: pharmaceutical products, biologics, medical devices, food, cosmetics, and so on. The course is not intended to provide an intensive course in statistics; instead, it is intended to provide a how-to guide about the application of the diverse array of statistical tools available to analyze and improve the process in an organization regulated by the FDA.

TARGET GROUP FOR THE TRAINING:

This training is aimed to scientists, analysts, technicians, managers, supervisors, and all other professionals responsible to measure and improve the quality of their processes. Attendees will obtain a better understanding of some of the statistical tools available to control their processes and be encouraged to study, with a greater level of detail, each of the statistical tools presented throughout the workshop.

LEARNING OBJECTIVES:

- Identify the most widely used statistical tools in an organization regulated by FDA
- Apply the appropriate tools for each situation faced on a daily basis in an organization regulated by FDA
- Develop a methodology to apply the learned tools in a systematic way

MATERIALS:

Each participant will receive:

- MS PowerPoint presentations
- *Statistical Process Control for the FDA-Regulated Industry*, published by ASQ Quality Press.
- Certificate of Attendance
- Final Exam (70% minimum score required to approve the course

TRAINING DURATION:

7 contact hours

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.

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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Passion for Quality

Title: Statistical Process Control for the FDA-Regulated Industry

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	**Regulatory Importance of Statistical Process Control** • Process Control within the Code of Federal Regulation • Process Control within the FDA Guidances • Process Control Within International Guidances and Standards
9:00 – 9:15	**SPC and the Life Sciences Regulated Industry** • Recent observations about misuse of statistical process control • SPC and CAPA
9:15 – 9:45	**Process Variation** • The causes of variation
9:45 – 10:15	**Basic Principles About Statistics** • Types of data • Sampling • Describing the sample • The Normal distribution
10:15 – 10:30	**Break**
10:30 – 11:00	**Graphical Tools** • Histogram • Box plot • Dot plot • Pareto diagram • Scatter plot • Run chart • Normality test • The importance of assessing normality
11:00 – 11:30	**Measurement System Analysis** • Overview • Metrics • Performing a gage R&R

11:30 – 12:00	**Process Capability** • Process capability and process performance indices • How to interpret the process capability and process performance indices • Process capability analysis for nonnormal data • Performing a process capability analysis
12:00 – 13:00	**Lunch**
13:00 – 14:30	**Hypothesis Testing** • Comparing means • Comparing medians • Comparing variances
14:30 – 15:00	**Regression Analysis** • Least squares method • Regression metrics • Residual analysis • Simple linear regression • Multiple linear regression
15:00 – 15:15	**Break**
15:15 – 15:45	**Design of Experiments** • Design of Experiments terminology • Full factorial experiments • Fractional factorial experiments • Blocking • Repetition and replication • Experimental strategy
15:45 – 16:30	**Control Charts** • The rational subgroup • Non-random patterns • Variables control charts and attributes control charts • Variables control charts • Attributes control charts
16:30 – 17:00	**Final Thoughts** • Order of tools • Continuous process monitoring versus once-a-year analysis and reporting • Proactive or reactive? • Next steps