



B U S I N E S S
EXCELLENCE
C O N S U L T I N G **Inc.**

Passion for Quality

TRAINING TITLE:

Basic Applied Statistics (WORK-006)

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. However, most of the questions being asked to me everyday are not about how to perform the analysis once the person determines which tool to use, but about which is the appropriate tool to use for each specific situation.

The focus of this course is to understand and apply various SPC tools. Through computer exercises, the participant will be able to learn about the application of the diverse array of statistical tools available to analyze and improve their processes.

Although the examples and case studies presented throughout the workshop are based on situations found in an organization regulated by FDA, they can also be used to understand the application of those tools in any type of industry.

Attendees must bring a laptop computer to this workshop in order to use a 30-days trial version of SigmaXL or Minitab statistical software.

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 conference. The content of this presentation is the result of the author’s almost 20 years of experience in the application of statistics in various industries, and his combined educational background of engineering and law that he has used to provide consulting services to dozens of organizations.

LEARNING OBJECTIVES:

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

MATERIALS:

Each participant will receive:

- 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:

14 contact hours



BEC is authorized by IACET to offer 1.4 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.



Title: Basic Applied Statistics (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
9:00 – 9:45	Regulatory Importance of Statistical Process Control <ul style="list-style-type: none"> • Process Control within the Code of Federal Regulation • Process Control within the FDA Guidances • Process Control Within International Guidances and Standards
9:45 – 10:15	SPC and the Life Sciences Regulated Industry <ul style="list-style-type: none"> • Recent observations about misuse of statistical process control • SPC and CAPA
10:15 – 10:30	Break
10:30 – 11:00	Process Variation <ul style="list-style-type: none"> • The causes of variation
11:00– 12:00	Basic Principles About Statistics <ul style="list-style-type: none"> • Types of data • Sampling • Describing the sample • The Normal distribution
12:00 – 13:00	Lunch
13:00 – 14:30	Graphical Tools <ul style="list-style-type: none"> • Histogram • Box plot • Dot plot • Pareto diagram
15:00 – 15:15	Break
15:15: – 17:00	Graphical Tools (cont.) <ul style="list-style-type: none"> • Scatter plot • Run chart • Normality test • The importance of assessing normality



Title: Basic Applied Statistics (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 – 9:00	Review from Previous Day's Topics
9:00 – 10:15	Measurement System Analysis <ul style="list-style-type: none"> • Overview • Metrics • Performing a gage R&R
10:15 – 10:30	Break
10:30 – 12:00	Process Capability <ul style="list-style-type: none"> • 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 – 15:00	Regression Analysis <ul style="list-style-type: none"> • Least squares method • Regression metrics • Residual analysis • Simple linear regression • Multiple linear regression
15:00 – 15:15	Break
15:15 – 16:30	Control Charts <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> • Order of tools • Continuous process monitoring versus once-a-year analysis and reporting • Proactive or reactive? • Next steps