GMP Training Systems, Inc.
Creators of the GMP Ready-to-Use Training System™

Introduction to Design of Experiments for Process Characterization

Workshop Abstract

This course is designed to help scientists and engineers understand the statistical methods used in characterization of a process. Variability is part of every process, design of experiments helps to separate systematic variability from special cause variability.

You will get a chance to examine the different sources of variability how it relates to analytical method development, process improvement and sample size selection. The concept of experimental budget will be introduced to help you plan the total number of experiments needed. You will also learn to improve process output characteristics including quality, cost, and robustness through generating empirical models of your processes in the fewest experiments possible.

This highly interactive course will allow participants the opportunity to develop strategies for analysis of experimental data. The objective is to provide participants with key technical information along with perspectives to enable them to apply the technologies to their own projects and evolve their own statistical methods to support the various stages of product development.

Learning Objectives

Upon completion of this workshop, participants will be able to:

- Learn the technical details and rationale for selecting and analyzing well designed statistically based experiments.
- Develop the confidence to design and execute experiments that maximizes information in your day-to-day activities.
- Participate in discussions with other course attendees to increase your confidence and proficiency in statistical hypothesis testing
- Determine the most robust settings in your process to minimize the different sources of variability.

Who should attend

This course is developed to provide valuable assistance to all regulated companies that need to understand their processes including companies in the Medical Device, Diagnostic, Pharmaceutical, and Biologics fields. Those who will benefit include:

- Development scientists
- Analytical method development personnel
- QA/ QC personnel

Workshop instructor

The instructor for this workshop is Steven Walfish. Mr. Walfish is the founder and President of Statistical Outsourcing Services. He brings nearly 20 years of industrial experience providing statistical solutions to complex business problems. Mr. Walfish was Senior Manager Biostatistics, Nonclinical at Human Genome Sciences in Rockville MD. Mr. Walfish has held positions with PricewaterhouseCoopers, Chiron Diagnostics and Johnson & Johnson. Mr. Walfish holds a Bachelors of Arts in Statistics from the University of Buffalo, Masters of Science in Statistics from Rutgers University and an Executive MBA from Boston University.

Workshop Outline

- Introduction to Statistical Hypothesis Testing
  - Null hypothesis versus the alternative
  - Different errors that can be made in doing statistical tests
  - When do we use the Z-test and when do we use the t-test
  - Testing variances
- Overview of Analysis of Variance and Variance Components
  - Fixed versus Random Effects
  - What does a p-value mean and how do I interpret them?
  - Understanding an ANOVA table
  - How do I use ANOVA to calculate variance?
  -
- Fractional Factorial Designs including Plackett Burman
  - Screening experiments
  - Resolution of a design
  - What is an interaction?
  - Building an appropriate model

Workshop Outline (continued)

- Three level designs including Box-Behnken
  - How do I test if there is curvature in my response?
  - How are three factor models different than center points?
  -
- Response Surface Designs
  - Building a predictive model
  - Using contour plots to find the optimums
  -
- Response Desirability for Multiple Responses
  - Balancing multiple responses for the same experiment
  - Find the best sub-optimal region