




2-day In-person Seminar:

Statistics for the Non-Statistician

-  Washington, DC
-  September 22nd & 23rd, 2016
-  9:00 AM to 6:00 PM



Steven Walfish

President, Statistical Outsourcing Services

Steven Walfish brings 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.

Overview :

Statistical tools and techniques are very commonly used to help measure and improve the quality of a firm's process and product. If statistical analysis is not properly performed and/or understood, a firm can run the risk of distributing the kind of product to the market that ultimately fails, resulting in lost time and money. And of course, with statistics, practice makes perfect. During this two-day HIGHLY interactive training program, participants will be given the opportunity to apply statistics learned to real-world example data sets! The program begins by providing a basic overview of the most common statistical tools and terms. The course covers the use of statistical software packages.

Price

Price: **\$1,295.00**

(Seminar for One Delegate)

Register now and save \$200. (Early Bird)

Register for 5 attendees (With stay)

Price: **\$3,885.00** You Save: \$2,590.0 (40%)*

~~\$6,475.00~~

ENROLL

**Please note the registration will be closed 2 days (48 Hours) prior to the date of the seminar.



Agenda:

Day One

Lecture 1: Introduction and Basic Overview of Common Statistical Tools

Exercise: Identify Participants' Statistical Experience and Course Goals

- Types of Data
 - Continuous versus discrete
 - Descriptive versus inferential
- Data Presentation and Graphics
- Normal Distribution
- Introduction to Hypothesis Testing
 - P-value
 - z-test
 - t-test
 - Chi-square
 - F-test
- Discuss applicable software packages for use:
 - Microsoft Excel - SAS
 - Mini-tab - JMP

Lecture 2: Apply Statistics to Specification Setting

- Setting appropriate product specifications
- Determine FDA requirements for OOS results
- Determine how to best investigate OOS results
- Introduction to Interval Estimation
 - Confidence Interval
 - Tolerance Interval
- Outlier Analysis
- Exercise: Setting Statistical Based Specifications

Lecture 3: Regression analysis and variance components

- Correlation
- Linear models
- New Patient Rights
- Residual analysis
- Lack of fit
- Hazards of regression
- Multiple regression
- Non-linear regression (4-parameter models)
- Analysis of stability data including shelf life estimation

Lecture 4: Implement Design of Experiments (DOE)

- Design experiments appropriately and effectively
- Ensure that experiments are reproducible
- Improve process capability by reducing variability
- Analysis of variance
- Exercise: Mock Experimental Design

Day Two

Lecture 1: Validate your Testing Methods using Statistics

- Analyze ICH guidelines (Q2A & Q2B)
- Ensure robustness and ruggedness of your method
- Develop protocols based on sound statistical methods
- Quantify validation characteristics:
 - Linearity - range
 - accuracy - limit of detection (LOD)
 - precision - limit of quantitation (LOQ)
- Regression analysis and variance components
- Analysis of Stability data.
- Exercise: Analysis of a Method Validation Study Including Protocol Development

Lecture 2: Trending Analysis

- Define Statistical Process Control (SPC)
- Determine how SPC can be applied to and help your process
- Identify the benefits of using SPC
- Trend Analysis
- Comply with FDA Requirements for Process Analytical Technology (PAT)
- Define Process analytical technologies and identify related tools
- Identify the role statistics play in the PAT framework
- Comply with the FDA's 2004 PAT draft guidance requirements
- Process Analytical Technology
- Exercise: Review and Critique a Sample SPC Control Chart

Lecture 3: Design a Statistically Sound Sampling Plan

- Define different types of sampling
 - Random
 - stratified
 - composite
- Create and justify your sampling plan
- Account for sampling and measurement error
- Determine the relationship between sample size, statistical precision, and statistical power
- Exercise: Create a Mock Sampling Plan

Lecture 4: Statistically Analyze Annual Product Review (APR) Data

- Examine statistical techniques relevant to APRs
- Use descriptive statistics to present the data
- Use graphs and plots effectively
- Interpret statistical data to identify trends and deviations

Exercise: Apply Learned Statistical Techniques to Real-World Data

Discussion: Wrap-up Question and Answer Session

Group Participation

10%	2 Attendees to get offer
20%	3 to 6 Attendees to get offer
25%	7 to 10 Attendees to get offer
30%	10+ Attendees to get offer

Payment Option

- 1 Credit Card: Use the Link to make Payment by Visa/Master/American Express card click on the register now link
- 2 Check: Kindly make the check payable to NetZealous DBA GlobalCompliancePanel and mailed to 161 Mission Falls Lane, Suite 216, Fremont, CA 94539, USA
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What You will get

- 1 Learning Objectives
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Contact Information: Event Coordinator

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Kindly get in touch with us for any help or information.

Look forward to meeting you at the seminar

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