Global CompliancePanel

Netzealous
Knowledge, a Way Forward...

2-day In-person Seminar:

Laboratory, Medical and Device Performance and Validation following Regulatory and ICH Statistical Guidelines

Boston, MA

May 4th & 5th, 2017

8:30 AM to 4:30 PM

Price

Price: **$1,495.00**

(Seminar for One Delegate)

Register for 5 attendees

Price: **$4,485.00** You Save: $2,990.0 (40%)*

~~$7,475.00~~

ENROLL

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

Al Bartolucci, Ph.D.

Dr. Al Bartolucci is Emeritus Professor of Biostatistics at the University of Alabama where he also serves as a Senior Scientist at the Center for Metabolic Bone Diseases, AIDS Research Center and Cancer Center.

He previously served as Chairman of the Department from 1984 through 1997. He has also taught Statistical Software courses involving Data Exploration, ANOVA/Regression and Design of Experiments. His teaching experience includes areas such as, Clinical Trials, Survival Analysis, Multivariate Analysis, Regression Techniques and Environmental/Industrial Hygiene Sampling and Analysis, Bayesian Statistics, and Longitudinal Data Analysis.

Overview :

This course is designed to introduce to individuals the understanding and interpretation of the statistical concepts one uses when investigating quantitative ICH Guidelines such as analytical methods validation, procedures and acceptance criteria in calibration limits, and process and quality control. One also considers ICH Q8 and Q9. These techniques covers both clinical and laboratory applications. This applies to many areas such as stability testing, outlier analysis and risk management. It is not a course in statistics but introduces the participant to an applied approach to the statistical techniques one uses, how they are reasonably interpreted.

Agenda:

Day One

Lecture 1: Overview of ICH Methodology

Lecture 2: Introduction to the simple regression model

- Interpreting the slope and intercept in validation procedures
- Residual analysis and error detection
- Stability and Potency issues

Lecture 3: Outlier strategies using the linear model in calibration methods

- Imputation techniques for missing data
- Outlier strategies for non normal or ranked data
- Consequences of outlier elimination/substitution
- Sample size and analysis issues

Lecture 4: Confidence and tolerance bounds on risk models

- Parametric and non parametric (non normal data) procedures
- Exact computational techniques

Day Two

Lecture 1: Discussion of risk management in general

- Traditional risk management strategies in clinical settings
- Predictive models in risk assessment
- Discussion of the Design Space
- Risk Management in pre-analytical phase of laboratory testing

Lecture 2: Introduction to validation of models in hazard assessment and risk management

- Demonstration of laboratory Validation procedures
- Bivariate models and confusion matrices and derived statistics
- ROC plot

Lecture 3: Statistical process laboratory control and capability

- Normal and non normal data procedures
- Evolutionary Operations Process

Lecture 4: Confidence and tolerance bounds on limits of risk

Learning Objectives:

- Evaluate linear quantitative measurement procedures and sources of error.
- Distinguish the difference between confidence and tolerance intervals
- Evaluate the appropriateness of the effect of sample size in given procedures.
- Evaluate laboratory/clinical quality control based on risk management
- Interpret statistical process control
- Distinguish between FDA requirements and ICH guidelines

Who Will Benefit:

- Quality Managers
- Quality Professionals
- Assay Development Scientists
- Research Scientists
- Data Analysts
- Laboratory Data Managers

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
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What You will get

1. Learning Objectives
2. Participation certificates
3. Interactive sessions with the US expert
4. Post event email assistance to your queries.
5. Special price on future purchase of web based trainings.
6. Special price on future consulting or expertise services.
7. Special price on future seminars by GlobalCompliancePanel.
8. Seminar Kit – includes presentation handout, ID card, brochure, trainings catalog, notepad and pen.
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Contact Information: Event Coordinator

NetZealous LLC, DBA GlobalCompliancePanel
161 Mission Falls Lane, Suite 216,
Fremont, CA 94539, USA
Toll free: +1-800-447-9407
Fax: 302 288 6884
Email: support@globalcompliancepanel.com

www.globalcompliancepanel.com

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

Look forward to meeting you at the seminar

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