Basic Methods (Day One). This section of the course will detail the basic and intermediate statistical concepts that are essential for professionals in the field. The first day emphasizes the principles of descriptive and inferential statistical applications and focuses on actual study examples, problem solving and interpretation of results. Throughout the course the participants are encouraged to ask questions and discuss examples relevant to their own work. Topic areas to be discussed include, but are not limited to:

• Basic statistical terminology including simple statistics as well as geometric (e.g., means, standard deviations) transformations needed to effectively communicate and understand your data results
• The statistical testing (one sided, two sided, non-parametric, sample size, and power considerations) essentials required to initiate a research investigation (i.e., research questions in statistical terms)
• Concepts of accuracy and precision in measurement analysis to ensure appropriate conclusions in experimental results including between and within laboratory variation results
• Discussion of statistical techniques to compare experimental approaches with respect to specificity, sensitivity and linearity
• The instructor gives a detailed description of topics discussed in his latest publication, “Introduction to Statistical Analysis of Laboratory Data” by Alfred A. Bartolucci, Karan Singh and Sejong Bae (2015).

Advanced Topics (Day Two). This section of the course will go beyond the basics and cover more complex issues in laboratory investigations with examples. Topics will include:

• Association studies including correlation and regression analysis with laboratory applications
• Analysis of robustness and ruggedness
• Method comparison using more accurate alternatives to correlate analysis and other pair-wise comparisons
• Outliers, limit of detection and limit of quantitation
• Statistical quality control for process stability and capability

ABOUT CfPIE
Learn from the Leader
In a life sciences industry that has faced nearly $15 billion in fines and compliance-related settlements over the last several years, The Center for Professional Innovation & Education (CfPIE) is a better alternative for maintaining high standards, protecting industry reputations, and enhancing personal growth. Since 2001, we have embraced a singular goal—to provide the highest quality education to life science professionals. Today, as the global leader in quality life sciences training, we offer the largest range of course options for professional development in pharmaceutical, medical device, biotech, and skin/cosmetics disciplines. We are dedicated to enriching that reputation by conveying content relevant to the needs of individuals and organizations facing intense scrutiny in those highly technical disciplines.

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The Center for Professional Innovation & Education, Inc.
7 Great Valley Parkway
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Malvern, Pennsylvania 19355

PAYMENT
$2150.00 per person (INCLUDES BREAKFAST & LUNCH)

EARLY BIRD DISCOUNT
If you register at least thirty days in advance you will receive a $200 discount on the course.

ADDITIONAL DISCOUNTS
Contact us at 610-648-7550 or info@cfpie.com for information regarding partnership discounts or how your organization can become a partner with CfPIE.

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All cancellations must be in writing and are subject to a $350.00 cancellation fee. If cancellations are made more than 30 days prior to the course, a refund less the cancellation fee will be provided. If cancellations are made less than 30 days prior to the course, a voucher good for attendance at an upcoming course will be provided. The voucher, which can be used by the registrant or anyone else within his/her company, will be valued at the registration fee minus the $350.00 cancellation fee.

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INTRODUCTION TO STATISTICAL ANALYSIS OF LABORATORY DATA
June 24 & 25, 2019 - Boston, MA
October 24 & 25, 2019 - Malvern, PA

CONTACT
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Malvern, Pennsylvania 19355

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INSTRUCTOR CREDENTIALS

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.

Dr. Bartolucci received his PhD in Statistics from the State University of New York at Buffalo and his MA in Mathematics from Catholic University, Washington DC, and his BA in Mathematics from Holy Cross.

Publications:
He is widely published with over 300 publications and some of his recent works include:

• Bartolucci, Al: Bayesian modeling of pharmaceutical data addressing the average effect of bivariate parameters of interest in a bioequivalence framework, page 166, December 2011, Journal of International Modeling and Simulation, Vol
• Bartolucci, Al: An application of EM algorithm in prostate carcinoma data, page 525, Epidemiology, Health and Medical Research
• Bartolucci, Al: Meta-analysis of multiple primary prevention trials of cardiovascular events using aspirin, page, American Journal of Cardiology

LEARNING OBJECTIVES

Those completing the course will have an understanding of the concepts of statistical design, analysis and graphing methods required in laboratory data analysis and reporting. Attendees will be able to interpret and report results related to design and analysis issues as presented in the scientific literature concerning laboratory data analysis, as well as, quality control methods.

WHO SHOULD ATTEND

This course is designed as an introduction to the statistical principles of laboratory data analysis and quality control that form the basis for the design and analysis of laboratory investigations.

The course curriculum will benefit R&D managers, analytical laboratory supervisors and staff, manufacturing and production professionals, scientists, technicians and others who wish to comprehend and interpret methods of data analysis relevant to laboratory experimentation. WHERE applicable, topics are presented with relevant regulatory requirements.

This training will concentrate on the philosophy and understanding of the statistical principles required in conducting sound scientific investigations of laboratory processes and validation, including design and sample size issues. It will not simply present statistical formulae and the lectures are oriented toward professionals having minimal formal training in statistics or mathematics beyond basic algebra. However, for those with more formal training in statistics wishing to actually apply the techniques, appropriate time and references will be given for the procedures involved.

HOTEL INFORMATION

The Hilton LAX, Los Angeles, CA (CfPIE room rate of $167/night if booked 3 weeks in advance of the course date)

The Desmond Hotel & Conference Center, Malvern, PA (CfPIE room rate of $141/night if booked 3 weeks in advance)

Club Quarters Hotels, Boston, MA (CfPIE room rate of $255/night if booked 4 weeks in advance)

DoubleTree by Hilton London - Victoria (CfPIE room rate of £199.00/night if booked 4 weeks in advance)

LEARNING OBJECTIVES

FIRST DAY

Statistical Measures and Descriptive Statistics: Central tendency (average or mean, median, mode), dispersion measures such as range, variance, standard deviation, coefficient of variation, unbiased estimates, measurement summary and precision.

Graphical Techniques: Histograms, bar charts, scatter plots. Graphical representation of lab results.

Distributions and Formal Statistical Laboratory Tests: Normal, t-distribution (one sample, two sample, paired), one way ANOVA to assess effect and necessity of replication, skewed distributions with applications to experimental results with alternative statistical comparison methodologies.

Estimation Statistics: Point and interval estimates, accuracy, precision. Further concepts of method validation such as sensitivity, specificity, selectivity, linearity.

SECOND DAY

Defining Robustness and Ruggedness: Design selection criteria, calculations, interpretation, effects of repeated experimentation, multiple lab results.

Defining Linearity Further: Applications to method comparison and interpretation. Examination of outliers in exploratory analysis of assay results.


Limit Strategies: Limit of detection, limit of quantitation.

Calibration problem: Techniques involving crude and precise methodologies and measurement of bias.

Validation Using Statistical Process Control: Use of quality control charts to determine laboratory process stability and capability.