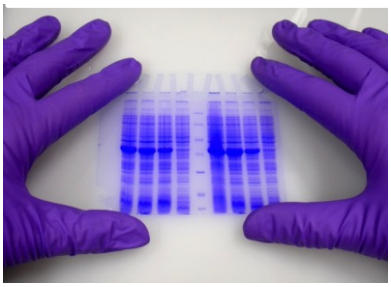
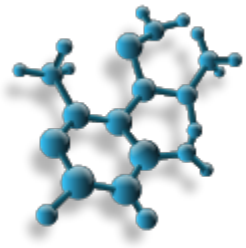
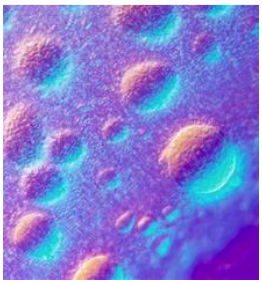
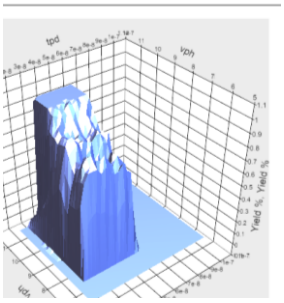
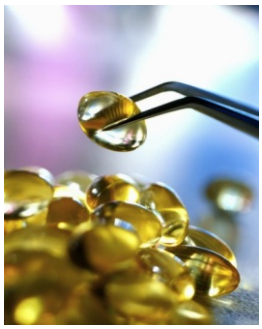
THOMAS A. LITTLE CONSULTING TLC

2014 Statistical and Analytical Curriculum

Biotechnology, Pharmaceutical and Medical Device

Content

About Thomas A. Little Consulting

Thomas A. Little Consulting (TLC) is an internationally recognized scientific and engineering consulting firm with a proven record for achieving results. TLC has an extensive ICH and QbD curriculum SAS/JMP based for method, product and process development, data analysis, characterization, optimization and control. TLC is a strategic partner of SAS/JMP.

TLC offers specific courses in analytics, data analysis, design of experiments, performance modeling, statistical process control, assay development and method validation, measurement systems analysis, mixture design of experiments, quality risk management and failure modes and effects analysis. These courses are used by a variety of fortune 500 companies to train their analysts, scientists and engineers. TLC has extensive experience in the biotechnology, pharmaceutical and medical device industries and has trained over 60,000 scientists, engineers and business professionals globally.

In addition to training TLC works actively with the drug development team to assure product development and submission study design, data analysis, risk assessments, design of experiments, assay development and validations all meet the high standards of regulatory review and use best in class approaches to product development and report generation.

Thomas A. Little has consultants located in the United States and globally and offers training in English and Mandarin. www.QualitybyDesignConsulting.com

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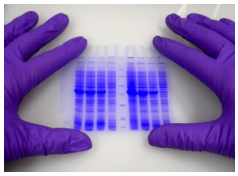
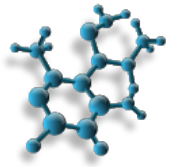
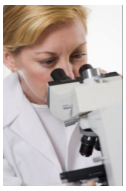
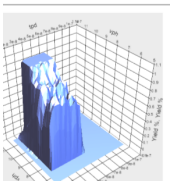
Recommended Software Tools

JMP versions 10.2 and 11.0 are world-class analytical engines for general data visualization and analysis, problem solving and design of experiments. ***JMP*** a business unit of SAS is a strategic business partner of TLC and a preferred solution for statistical and analytical methods.
www.jmp.com

Quality by Design Curriculum

The following are recommendations for some of the most commonly used courses in industry and directly support FDA regulations and key initiatives such as PAT and Quality by Design.

Days	QbD/DFLSS Practitioner
1	Intro to Quality by Design
3	Statistical Methods and Data Analysis
2	Quality Risk Management and FMEA
2	Root Cause Analysis and CAPA
2	Process Mapping
2	Design of Experiments
1	Mixture DOE
2	Robust Optimization Design Space and Tolerance Design
1	Statistical Methods for Process Validation
2	Assay Development and Method Validation
1	Stability Analysis
2	Process Control Design using SPC/PAT
1	Nonlinear Modeling (Relative Potency)
1	Introduction to JMP Scripting

Introduction to QbD and Critical Quality Attributes

IQbD

Course Description

This course is specifically designed to meet the analytical and business needs of those individuals working within FDA regulated industries. Foundations of QbD are discussed; methods for generation of CQA's are presented. The course requires 8 hours of instruction.

Attendees

This course is required for all managers, directors, scientists, business professionals and engineers who actively work on all aspects of drug product and drug substance development and manufacturing.

Prerequisites

There are no prerequisites for this course.

Course Objectives

1. Understand what is QbD
2. Define FDA/EU expectations
3. Discuss ICH development guidelines for QbD
4. Understand the QbD development framework
5. Apply line of site from clinical to release
6. Impact of QbD on drug development and submission

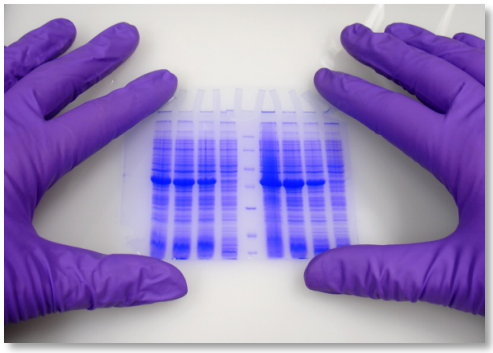
Detailed Course Outline

Section I Introduction to Quality by Design

FDA and EU guidance on QbD
Purpose and opportunity
QbD benefits and impact on FDA submissions
Systematic product development
10 principles of QbD
QbD examples

Section II Critical Quality Attribute Generation

CQA's definition in product development
CQA's flow down and validation



Statistical Methods and Data Analysis

SMDA

Course Description

This course is specifically designed to meet the analytical needs of those individuals working within FDA regulated industries. Areas of focus are; JMP basics, analysis of data for basic engineering and scientific applications including statistics, distribution analysis, capability assessment, variation analysis, comparison tests, sample size selection, hypothesis testing, confidence intervals and multiple factor modeling. The course requires 24 hours of instruction.

Attendees

This course is required for all scientists, engineers and quality professionals who actively work on all aspects of discovery, product and process development where the goal is to characterize, optimize and improve product and process performance.

Prerequisites

There are no prerequisites for this course.

Course Objectives

7. Use data to solve engineering and scientific problems.
8. Understand the ideas associated with sampling and data collection.
9. Demonstrate the ability to evaluate distributions.
10. Select appropriate sample sizes for performance evaluation.
11. Conduct comparative tests using data.
12. Use regression techniques in order to analyze data and make process/product improvements.
13. Select appropriate analysis technique based on type of data.
14. Apply JMP to data analysis problems.

Detailed Course Outline

Section I Introduction to JMP

Table commands
Column commands
Row commands
Subset commands
Saving Scripts, Journals and Projects

Section II Statistics Foundations & Distribution Analysis

Measures of center and spread
Standard error and central limit theorem
Normal distribution

t distribution and confidence intervals
Test for normality
Individuals and tolerance intervals (normal)
Process capability (normal)
Nonnormal distribution fitting and process capability

Section III Nominal X, Continuous Y

Contour plots, Components of Variance, REML and POV
Sample size for the mean and standard deviation
t test – one sample
t test – two sample
Test for differences in variances
t test – paired
One-way ANOVA and F test
N-way ANOVA
Nonparametric data analysis (optional)

Section IV Continuous X, Continuous Y

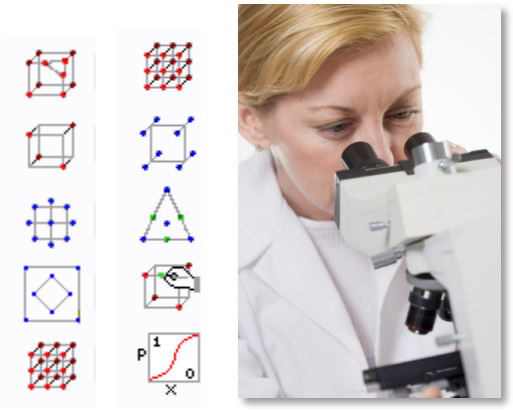
Simple linear regression, correlation
Multiple regression
ANCOVA

Section V Nominal X, Nominal Y

Mean and sigma for proportion defective
Sample size and statistical tests for proportion defective
Mean and sigma for defect per unit
Chi-square test for defects and proportion defective
Pareto graphs and cross tabs analysis

Section VI Continuous X, Nominal Y and Partition

Logistic regression
Nominal logistic regression (optional)
Recursive partitioning



Design of Experiments

DOE

Course Description

This course is specifically designed to meet the analytical needs of those individuals working within FDA regulated industries. The course covers both basic and advanced concepts for the design and analysis of experiments. The course requires 16 hours of instruction.

Attendees

This course is required for all scientists, engineers and quality professionals who actively work on all aspects of discovery, product and process development where the goal is to characterize, optimize and improve product and process performance.

Prerequisites

Engineering statistics and data analysis is recommended.

Course Objectives

1. Select factors and responses for experiments.
2. Design experiments appropriate for the information of interest.
3. Use and apply the structures of orthogonal arrays for product and process development and problem solving.
4. Ensure the experimental design is efficient.
5. Use regression techniques in order to analyze the results and make process/product improvements.
6. Use JMP software to design and analyze experiments.

Detailed Course Outline

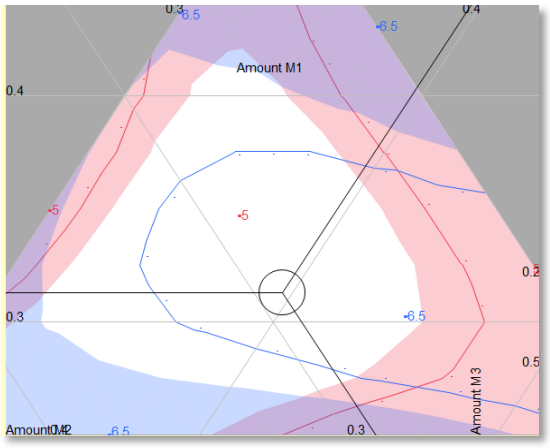
Section I Introduction to DOE
Section II Experimental Preparation
Section III Full Factorial Designs
Section IV Screening Designs
Augment design
Section V Custom Designs
Generating custom designs
Evaluating custom designs
Analysis of custom designs
Simulation for full distribution modeling
Strategies to minimize experimental size
Adding covariate and uncontrolled factors
Life or repeated measures experiments

Disallowed combinations (nested DOEs)
Split Plot designs
Adding dummy variables
Blocking designs
Mixtures in custom designs
Setting constraints in a DOE

Section VI Response Surface Designs

Section VII Special Topics In DOE (optional)

Supersaturated designs
Strip plot designs



Mixture Design of Experiments

MixDOE

Course Description

This course is specifically designed to meet the analytical needs of those individuals working within FDA regulated industries. Course covers all aspects of mixture design including pre-DOE, simplex lattice, centroid, screening and custom mixture designs. The course requires 8 hours of instruction.

Attendees

This course is required for all scientists, engineers and quality professionals who actively work on all aspects of discovery, product and process development where the goal is to characterize, optimize and improve product and process performance.

Prerequisites

ESDA and DOE are suggested courses prior to MixDOE.

Course Objectives

1. Apply the principles of robust design to Mixture Experiments.
2. Design mixture experiments appropriate for the information of interest.
3. Use and apply the structures of simplex and optimal designs for product and process development and problem solving.
4. Ensure the mixture design is efficient.
5. Use regression techniques in order to analyze the results and make process/product improvements.
6. Use *JMP* software to design and analyze experiments.

Detailed Course Outline

Section I **Introduction and Two Factor Mixture Designs**
- Experimental preparation and pre-DOE
- Two Factor Mixture Designs

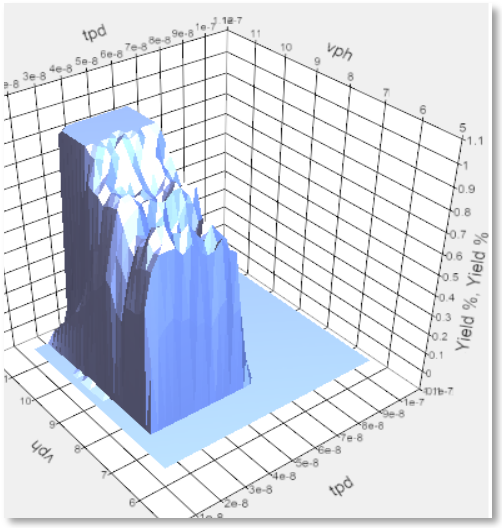
Section II **Simplex Lattice Designs**

Section III **Simplex Centroid and ABCD Screening Designs**
- Simplex Centroid
- ABCD Screening Designs

Section IV **Extreme Vertices Designs**

Section V **Optimal Designs**

Section VI **Custom Design**



Robust Optimization, Design Space and Tolerance Design

ROTD

Course Description

This course is specifically designed to meet the analytical needs of those individuals working within FDA regulated industries. Robust optimization and tolerance design presents the methods and practices associated with designing and optimizing products and processes and to discusses tolerance design methods to protect product quality and clinical benefits. The course requires 16 hours of instruction.

Attendees

This course is required for all scientists, engineers and quality professionals who actively work on all aspects of discovery, product and process development where the goal is to characterize, optimize and improve product and process performance.

Prerequisites

ESDA and DOE are recommended course prior to taking ROTD.

Course Objectives

1. Learn and apply the principles of robust product design.
2. Design experiments appropriate for the information of interest.
3. Use and apply the structures of orthogonal arrays for product and process development and problem solving.
4. Ensure the experimental design is efficient.
5. Use regression techniques in order to analyze the results and make process/product improvements.
6. Optimize the response at its most robust condition.
7. Tolerance the factors and responses.
8. Use JMP software to design and analyze experiments.

Detailed Course Outline

Section I Distribution and tolerance design foundations

System, parameter and tolerance design
Tolerance design methods

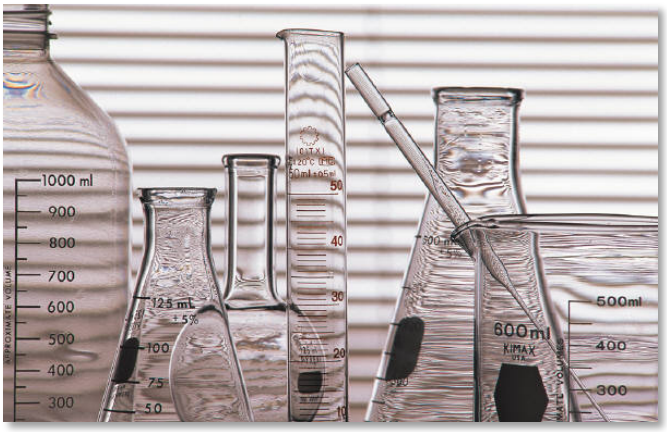
Section II DOE review and robust design principles

Eight robust design principles

Section III DOE using custom designs
- Custom designs
- Strategies to minimize experimental size
- Adding covariate and uncontrolled factors
- Special topics for custom designs (optional)
  - Blocking designs
  - Setting constraints in the design

Section IV Robust optimization methods
- Tighten the tolerance of X
- Design to the flats
- Use interactions to tune out sensitivities
- Use parameter combinations

Section V Tolerance design and margin analysis
- Tolerance design procedure
- Tolerance stack up analysis



Assay Development and Method Validation

Assay Development and Method Validation
Course Description

This course is specifically designed to meet the analytical needs of those individuals working within FDA regulated industries. This course is designed for those individuals directly working on assay development, test validation, variation assessment and measurement systems analysis (MSA). It is assumed they come from a variety of backgrounds and disciplines and will be working on a variety of projects. Presentation of the course material is designed for sixteen hours of instruction.

Attendees

This course is required for all employees who actively work on any aspect of assay, measurement, product and process development where the goal is to improve product and process measurement performance.

Prerequisites

DOE is a recommended course prior to taking AD-MSA.

Course Objectives

1. Design experiments for assay characterization.
2. Design experiments for nonlinear modeling
3. Design experiments for variation reduction
4. Evaluate measurement errors and isolate sources of variation
5. Determine methods to correct systematic errors in instruments and assay methods
6. Determine inspection and test related errors

Detailed Course Outline

Section I Statistical Foundations and Variation Assessment
- Introduction to assay and test development, validation and MSA
- Review of basic statistics
- Variation analysis methods

Section II DOEs for Assay Development and Evaluation
- Assay characterization experiments
- DOE for variation reduction
- DOE for robustness
- DOE for nonlinear characterization

Section III Chemical and Biological Assay Evaluation and Validation
- Accuracy

Precision (Repeatability, Intermediate Precision, Reproducibility)
Detection limit
Quantitation limit
Suitability
Linearity
Range
Specificity
Robustness

Section IV MSA for Variables Data (Physical and Destructive)

MSA terms and definitions
GR&R procedure and analysis
Secondary breakdown of repeatability
Discrimination ratio
Bias
Linearity
MSA for destructive testing
MSA studies using fluids
Calibration, correlation and compensation

Section V MSA for Attributes Data (Visual and Mechanical)

Operational definitions
Effectiveness
Probability of a false alarm
Probability of a miss
Bias
Escape rate
Statistical tests for attributes

Section VI Multifactor MSA Studies

Using POV for multiple factor gage studies

Statistical Methods for Process Validation

Statistical Methods for Process Validation
Course Description

This course is specifically designed to meet the analytical needs of those individuals working within FDA regulated industries. A key component of pharmaceutical, medical device and biotechnology product development is to perform process validation and qualification studies. The basic concepts, requirements and statistical methods for process validation are presented.

Attendees

This course is required for all employees who actively work on process sciences, process development and process validation.

Prerequisites

ESDA and DOE are recommended prior to this course.

Course Objectives

1. Design, analyze and report validation studies
2. Select appropriate analytical tools for process validation
3. Define process controls and reviews for continued process verification
4. Determine sample size for validation studies
5. Determine sources of process and material variation
6. Establish process capability and design margin
7. Report on process validation and qualification performance
8. Apply JMP to validation data analysis and reporting

Detailed Course Outline

Section I Process Qualification and Validation Introduction

Process Validation and Drug Quality
General Approach to Process Validation
Statutory and Regulatory Requirements for Process Validation
Process Validation Recommendations

Section II Stage 1: Process Design

Building and Capturing Process Knowledge and Understanding
Establishing a Strategy for Process Control

Section III Stage 2: Process Qualification

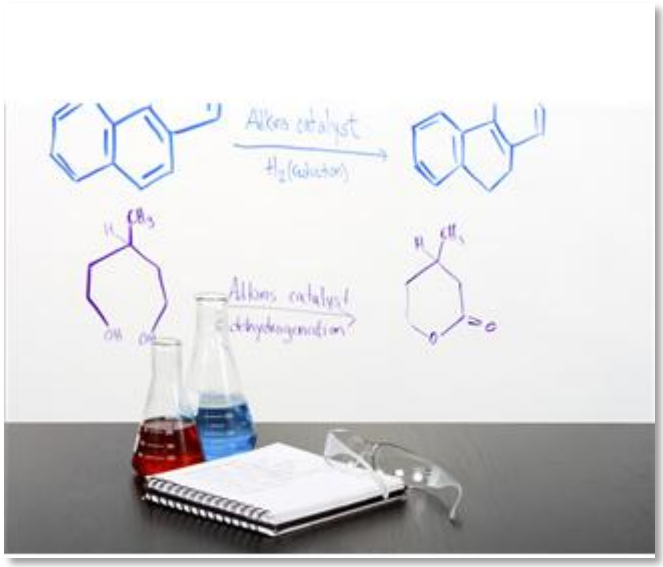
Design of a Facility and Qualification of Utilities and Equipment
Process Performance Qualification
PAT during Qualification
PPQ Protocol
PPQ Protocol Execution and Report

Section IV Stage 3: Continued Process Verification

Establishing a Monitoring Program
Data Analysis Trending and ongoing Capability Monitoring
Deviations/Investigations and CAPA
Change Control
Complaints
CPV Data Review and Reporting

Section V Analytical Tools for Process Validation

DOE design space
DOE, CPP and PAR analysis
POV and Sample Size during PV
Process Capability and Design Margin
Control Charts during Validation
ANOVA and ANOM
Equivalence Testing



Measurement Systems Analysis

MSA
Course Description and Audience:
Course is designed for Engineers, Scientists and Managers who have direct responsibility for measurement evaluation, selection, and control. Course covers the basic concepts associated with measurement systems analysis, repeatability, reproducibility, accuracy, linearity, stability, standards selection and use, calibration and compensation and measurement control.

Course Objectives:
As a result of the course the participant will be able to:
1. Determine gage capability.
2. Assess accuracy, linearity, stability, repeatability and reproducibility in test equipment.
3. Design and deploy SPC for measurement control.
4. Select and establish standards.
5. Describe proper methods for instrument calibration and compensation.
6. Conduct gage capability for inspection activities.
7. Discuss how MSA impacts customer satisfaction.

Detailed Course Outline:

Section I Introduction to MSA
- MSA is a key to systematic product development
- Background statistical principles
- Sources of error
- Focus on the measurement process

Section II Terms and Definitions
- Repeatability
- Reproducibility
- Accuracy
- Linearity
- Stability

Section III R&R, Linearity, & Accuracy
- 2 factor crossed design for Variables MSA
- Repeatability & Reproducibility

R&R and Capability Example
Accuracy example
Linearity example

Section IV Correlation, Calibration and Compensation

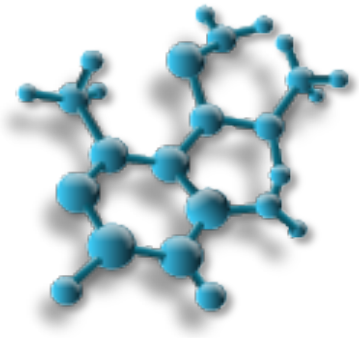
Correlation and compensation
Soft compensation versus standard calibration
Scatterplot Method
Problems with r^2

Section V SPC for Measurement Control

Selection and utilization of Standards
SPC for Measurement Control
SPC using stable standards
SPC using unstable standards

Section VI MSA for Attributes

Operational Definitions
Effectiveness, P(miss), P(false alarm)
Kappa, escape rate and bias



Reliability Analysis

RA

Course Description

This course is specifically designed to met the analytical needs of those individuals working within FDA regulated industries. Areas of focus are distribution analysis, area under the curve estimation, hypothesis testing, life and survival estimation, thermal sensitivity, confidence intervals and multiple factor modeling. The course requires 8 hours of instruction.

Attendees

This course is required for all scientists, engineers and quality professionals who actively work on all aspects of discovery, product and process development where the goal is to characterize, optimize and improve product and process performance.

Prerequisites

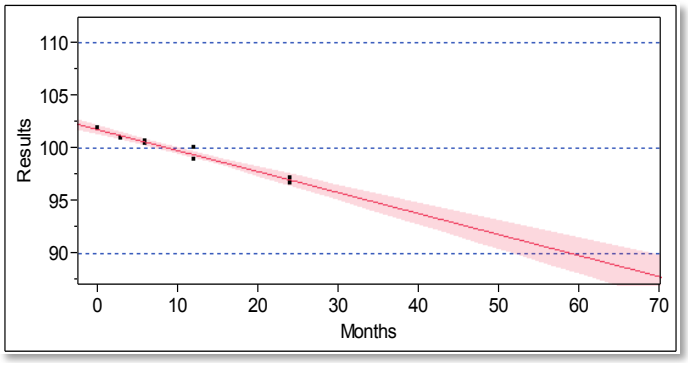
ESDA is a recommended course prior to taking LTRA.

Course Objectives

1. Determine product reliability performance.
2. Understand and apply non-parametric reliability analysis.
3. Understand and apply parametric reliability analysis.
4. Perform multivariate reliability assessment.
5. Understand and apply recurrence analysis.
6. Use Arrhenius transformations in reliability modeling.
7. Select appropriate sample sizes for MTBF studies.
8. Model reliability improvement using reliability growth models.

Detailed Course Outline

Introduction to reliability analysis and basic statistics
Nonparametric reliability analysis (Kaplan-Meier)
Parametric reliability analysis (LogNormal, Exponential, Weibull)
Competing Causes
Lifetime distribution analysis
Fit Life by X
Multivariate reliability analysis (Parametric Survival)
Recurrence analysis
MTBF analysis
Reliability growth analysis



Stability Analysis

SA

Course Description

A key component of pharmaceutical, medical device and biotechnology product development is to determine product stability and shelf life. The basic statistical assumptions, tests and life predictions methods will be presented with examples. Determination of whether to pool data, use a common slope or fit the data individually will be presented. Sample size selection and stability estimation in compliance with FDA guidance is discussed.

Attendees

This course is required for all scientists, engineers and quality professionals who actively work on all aspects of discovery, product and process development where the goal is to characterize, optimize and improve product and process performance.

Prerequisites

ESDA is a recommended course prior to taking this course.

Course Objectives

1. Design and analyze stability studies.
2. Determine the appropriate fitting method for any stability data set.
3. Determine shelf life.
4. Select appropriate analysis technique based on type of data.
5. Use and interpret the stability script and associated report.

Detailed Course Outline

Section I Stability Definition and Introduction
- FDA guidelines

Section II Stability Study Design
- Sample size
- Test conditions

Section III Stability Data Analysis and Life Prediction
- Extendibility and Confidence Intervals
- Shelf Life Determination
- All batches pooled
- All batches with individual fits
- Common slope
- Common Intercept

Section IV Stress Testing

Process Control Design Using SPC/PAT

PCDUSPC

Course Description

This course is specifically designed to meet the analytical needs of those individuals working within FDA regulated industries. Course covers the basic concepts and methodologies associated with designing closed loop process controls using statistical process control for variables and attributes data. Variation assessment, subgroup formation, sample size selection, SPC control chart selection, out of control action plan generation are presented along with measures of process capability. The course requires 16 hours of instruction.

Attendees

This course is required for all scientists, engineers and quality professionals who actively work on all aspects of discovery, product and process development where the goal is to characterize, optimize and improve product and process performance.

Prerequisites

ESDA and DOE are recommended courses prior to taking PCD-SPC.

Course Objectives

1. Understand the language and compute the basic statistics associated with SPC.
2. Apply the ten process control requirements to achieve process control.
3. Determine rational subgroup formation, sample size and frequency.
4. Select appropriate control chart for process control requirements.
5. Compute appropriate control limits.
6. Develop appropriate SPC Charts and associated OCAPs.
7. Determine process capability.
8. Describe the roles and responsibilities for using SPC.
9. Use JMP to analyze process variation patterns, generate SPC charts and determine process capability.

Detailed Course Outline

Section I Introduction and Basic Statistics

SPC a basis for control
Basic statistics
Normal distribution
Standard error of the mean
Central limit theorem

Section II Ten Requirements for Designing Effective Process Control

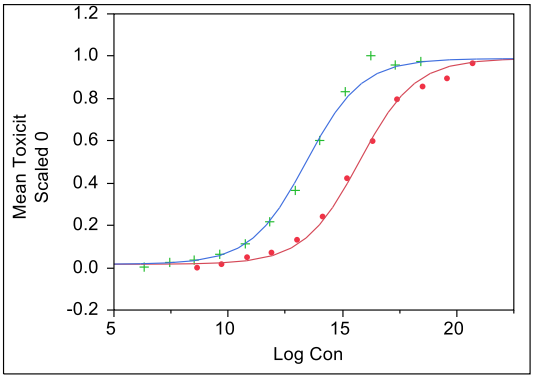
1. Clear product specifications
2. Effective metrology
3. Process characterization
4. Sampling plan
5. Control chart selection (variables and attributes)
6. Alarms, closing the loop and out-of-control action plans (OCAP)
7. Process documentation
8. Operator and engineering training
9. Database
10. Routine line audits

Section III Process Capability

Determining process stability prior to computation of capability
Cp and Cpk
Sigma and z as measures of process capability
Tests for normality
Distribution fitting for nonnormal parameters

Section IV Process Control Implementation Roles and Responsibilities

Management
Process engineer
Process control specialist
Supervisor
Operator



Nonlinear Modeling and Dose Response

Nonlinear Modeling and Dose Response
Course Description

This course is specifically designed to meet the analytical needs of those individuals working within FDA regulated industries. Areas of focus are regression and linear and nonlinear modeling. The course requires 8 hours of instruction.

Attendees

This course is required for those individuals that directly work with assay development and method validation. Further it may be helpful for those individuals that work with process characterization and generation of predictive models.

Prerequisites

Engineering Statistics and Data Analysis is recommended.

Course Objectives

1. Determine the best fit for linear models
2. Identify when nonlinear models may be appropriate
3. Select and fit nonlinear models
4. Evaluate and predict performance from nonlinear models
5. Evaluate the lack of fit from nonlinear models
6. Determine EC50 and relative potency using JMP

Detailed Course Outline
Basics of Linear Modeling

- Linear Regression
- Sniper Plots
- Fit Special

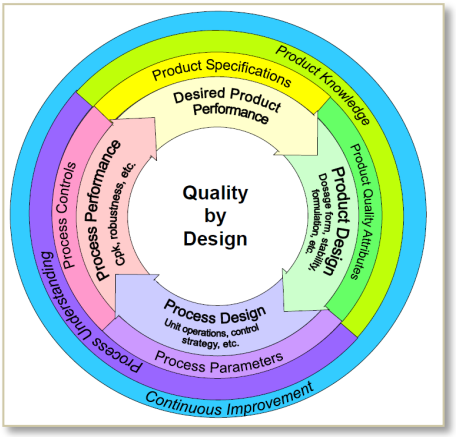
Nonlinear Models

- Nonlinear platform
- Model selection
- Model evaluation
- Adding X factors

Bio Assay and Relative Potency

- EC50
- Potency and Relative Potency
- JMP Bioassay Addin

Nonlinear DOE



Quality Risk Management and FMEA

QRM-FMEA

Course Description

This course is specifically designed to meet the analytical needs of those individuals working within FDA regulated industries. Areas of instruction covers the topics associated with risk management including risk management definitions, risk management process and risk assessment tools including Failure Modes and Effects Analysis. The course requires 16 hours of instruction.

Attendees

This course is required for all scientists, engineers and quality professionals who actively work on all aspects of discovery, product and process development where the goal is to characterize, optimize and improve product and process performance.

Prerequisites

There are no prerequisites for this course.

Course Objectives

1. Understand the definitions, process and tools associated with Quality Risk Management
2. Identify potential design, process or test issues associated with product and performance risk
3. Understand the tools and methods for risk assessment and prioritization
4. Understand the various types of FMEAs
5. Apply the basic steps for FMEA generation
6. Know when and how to apply FMEA to product and process development
7. Prioritize and manage risk reduction opportunities from FMEA results

Detailed Course Outline

Section I Quality Risk Management Principles and Process

Risk management principles
Risk management process
Responsibilities
Risk assessment
Risk control
Risk communication
Risk review

Section II Risk Analysis Tools

Basic quality tools and risk weighted analysis
Cause and effect diagrams
Process flow and risk assessment
Pareto and Risk Weighted Pareto analysis
Histograms, capability, simulation and Margin
Control charts
Regression
DOE (product and process) and MSA

Section III Technical Risk Assessment and Failure Modes and Effects Analysis

Application areas for FMEA
FMEA preparation
FMEA generation workshop

Section IV Methods for Reducing Risk

FMEA action plans and risk reduction

Root Cause Analysis and CAPA

RCA-CAPA

Course Description

This course is specifically designed to meet the analytical needs of those individuals working within FDA regulated industries. This course is designed for those individuals working directly on product and process development and corrective/preventative action. It is assumed they come from a variety of backgrounds and disciplines and will be working on a variety of process improvement areas across the company. The course is designed for 16 hours of presentation.

Attendees

This course is required for all scientists, engineers and quality professionals who actively work on all aspects of discovery, product and process development where the goal is to understand the root cause of performance problems and implement appropriate CAPA procedures to assure the problem never occurs again.

Prerequisites

There are no prerequisites for this course.

Course Objectives

1. Identify a problem that requires action
2. Define a problem in measurable terms
3. Contain the problem while developing a durable solution
4. Measure core performance and establish metrics
5. Collect and analyze data relevant to the problem of interest
6. Analyze the system of causes and determine root cause
7. Plan and implement corrective and preventative relevant to the root cause of the problem
8. Evaluate the effectiveness of the solutions
9. Establish controls to sustain solutions
10. Use Excel or JMP for basic statistics and data analysis

Detailed Course Outline

Section I Introduction to root cause analysis

Need for improvement
Savings associated with root cause analysis
Eight+ basic quality tools

Section II Define and contain the problem

Define the problem
Contain the problem
Determine scope, objectives and goals
Project leadership and planning

Section III Measure the problem

Map the process
Determine data collection plan
Establish metrics and capability

Section IV Analyze data and determine root cause

Analyze and summarize the data
Analyze and summarize the process map
Determine root causes and summarize all findings

Section V Improve performance

Brainstorming solutions and CAPA
Benefit, cost, risk and complexity determination
Measuring solution effectiveness

Section VI Control and standardize improvements

Process owner
Select controls

Harmonized QbD/Product Development and Lean Six Sigma Curriculum

The following is a summary table of the QbD curriculum harmonized with the LSS Curriculum. Additional courses may be added from the LSS curriculum if individuals are working on black belt projects.

QbD and Lean Six Sigma Curriculum

Days	Product Development and QbD Curriculum	Process Sciences	Analytical Sciences	Quality Assurance	Modular Green Belt	Modular Black Belt
1.5	Introduction to QbD, VOC and Critical Quality Attributes	•	•	•		
3	Engineering Statistics and Data Analysis	•	•	•	•	•
2	Design of Experiments	•	•	•	•	•
1	Mixture DOE	•	•			
2	Assay Development and Method Validation		•			•
2	Quality Risk Management and FMEA	•	•	•		•
2	Root Cause Analysis and CAPA	•	•	•	•	•
1	Robust Optimization and Tolerance Design	•	•			•
2	Analytical Methods for Process Validation	•		•		
1	Stability and Degradation Analysis	•	•			
2	Process Control Design using SPC	•	•	•	•	•
1	Nonlinear Modeling (Dose Response, Relative Potency)	•	•			
20.5	Total	18.5	18.5	14.5		
	Modular Green Belt/Black Belt Courses				Green Belt	Black Belt
2	Process Mapping and Process Improvement	•	•		•	•
1	Lean Methodologies				•	•
1	Measurement Systems Analysis				•	•
1	Reliability Analysis					
					13	18
	Certified QbD Practitioner, examination and demonstrated development application				One Project	Two Projects

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