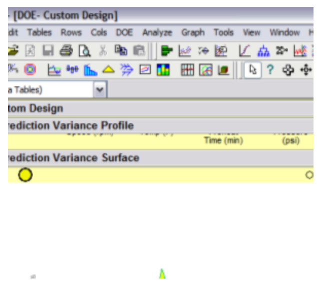

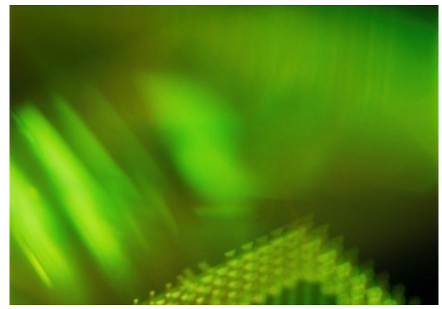

Statistical and Analytical Methods Curriculum Guide 2014

Courses	Days
Engineering Statistics and Data Analysis	3
Design of Experiments	2
Mixture DOE	1
Robust Optimization and Tolerance Design	2
Measurement Systems Analysis	1
Reliability Analysis	1
Process Control Design using SPC	2
Quality Risk Management and FMEA	1
Root Cause Analysis and Problem Solving	2
Business Statistics and Data Analysis	2
Advanced Business Statistics and Data Analysis	2

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 SAS/JMP based curriculum for 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 scientists and engineers. TLC has extensive experience in the biotechnology, pharmaceutical and medical device industries and have trained over 80,000 scientists, engineers and business professionals globally.

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

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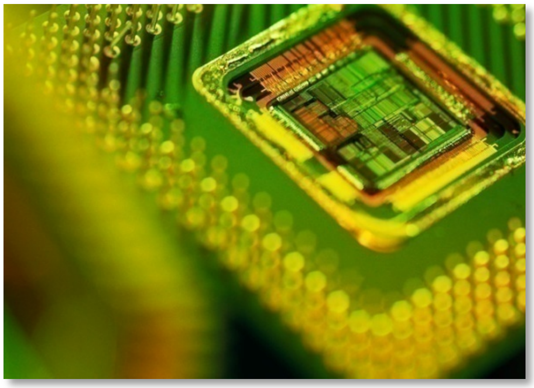
Recommended Software Tools

JMP version 11 is a world-class analytical engine 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

Although TLC prefers the use of SAS/JMP for engineering and business performance application work, TLC will support the training and deployment of Minitab as an analytical engine alternative on a limited basis and for select clients. www.minitab.com



Engineering Statistics and Data Analysis

ESDA

Course Description

ESDA is specifically designed to meet the analytical needs of those individuals working within a variety of industries. Areas of focus include: 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. Presentation of the course material is designed for 24 hours of instruction.

Attendees

ESDA 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. Use data to solve engineering and scientific problems.
2. Understand the ideas associated with sampling and data collection.
3. Demonstrate the ability to evaluate distributions.
4. Select appropriate sample sizes for performance evaluation.
5. Conduct comparative tests using data.
6. Use regression techniques in order to analyze data and make process/product improvements.
7. Select appropriate analysis technique based on type of data.
8. 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

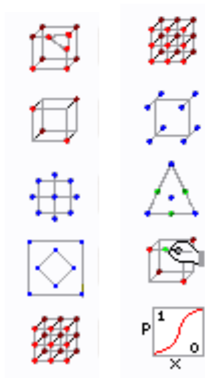
Mean and sigma for proportion defective
Sample size and statistical tests for proportion defective
Mean and sigma for defect per unit
Chi-square test for defects and proportion defective
Pareto graphs and cross tabs analysis

Section VI Continuous X, Nominal Y and Partition

Logistic regression
Nominal logistic regression (optional)
Recursive partitioning

Section VII Nonlinear Modeling

Nonlinear modeling



Design of Experiments

DOE

Course Description

Design of Experiments is specifically designed to meet the analytical needs of those individuals working within a variety of industries. Instruction covers both basic and advanced concepts for the design and analysis of experiments. Presentation of the course material is designed for 16 hours of instruction.

Attendees

Design of Experiments 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 a recommended prerequisite for this course.

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

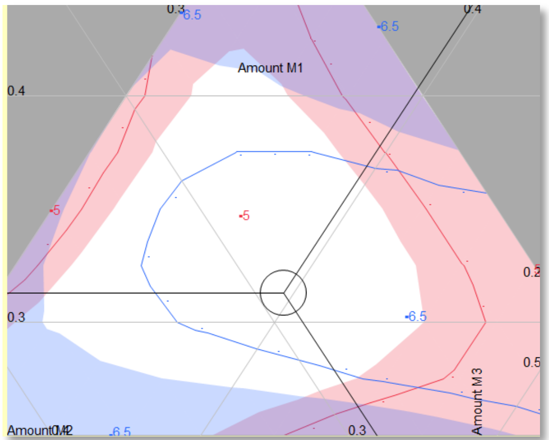
Augment design

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

MDOE

Course Description

Mixture Design of Experiments is specifically designed to meet the analytical needs of those individuals working within a variety of industries. Instruction covers all aspects of mixture design including pre-DOE, simplex lattice, centroid, screening and custom mixture designs. Presentation of the course material is designed for 8 hours of instruction.

Attendees

Mixture Design of Experiments 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 and Design of Experiments are recommended prerequisites for this course.

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

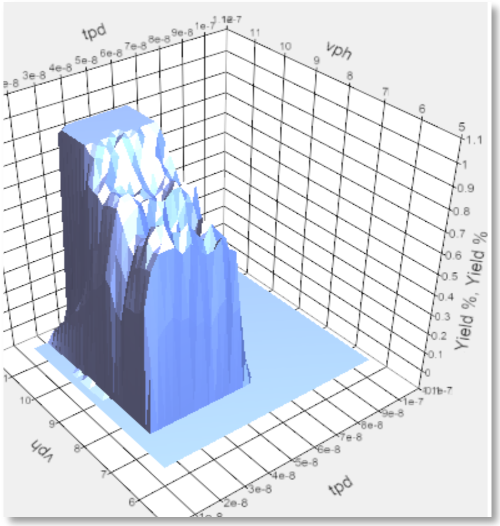
Section II **Simplex Lattice Designs**

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 and Tolerance Design

ROTD

Course Description

ROTD is specifically designed to meet the analytical needs of those individuals working within a variety of industries. Robust Optimization and Tolerance Design presents the methods and practices associated with designing and optimizing products and processes and to discuss tolerance design methods to protect product quality and clinical benefits. Presentation of the course material is designed for 16 hours of instruction.

Attendees

Robust Optimization and Tolerance Design 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 and Design of Experiments are recommended prerequisites for this course.

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

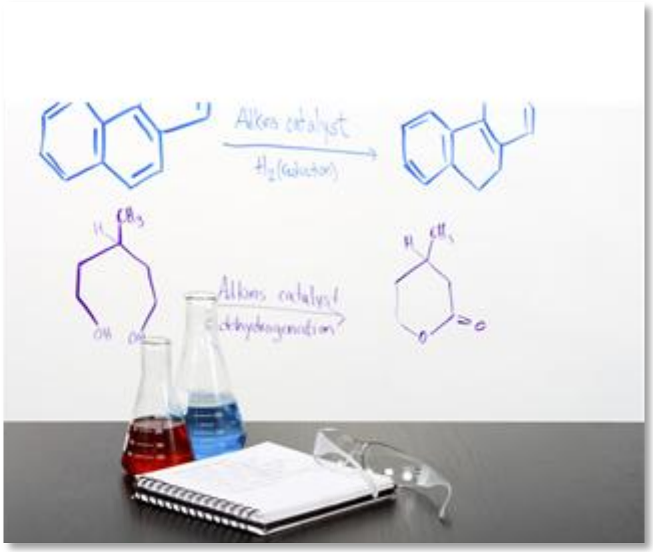
System, parameter and tolerance design
Tolerance design methods

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



Measurement Systems Analysis

MSA
Course Description and Audience:
Measurement Systems Analysis is designed for Engineers, Scientists and Managers who have direct responsibility for measurement evaluation, selection and control. This 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

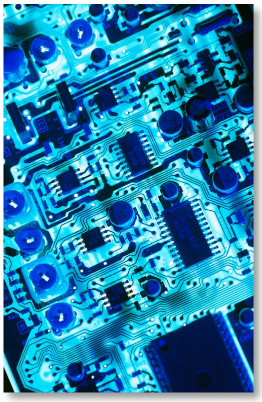
- Correlation and compensation
- Soft compensation versus standard calibration
- Scatterplot Method
- Problems with r^2

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

Reliability Analysis is specifically designed to meet the analytical needs of those individuals working within a variety of industries. Areas of focus include: distribution analysis, area under the curve estimation, hypothesis testing, life and survival estimation, thermal sensitivity, confidence intervals and multiple factor modeling. Presentation of the course material is designed for 8 hours of instruction.

Attendees

Reliability Analysis 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 a recommended prerequisite for this course.

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

Process Control Design using SPC

PCD-SPC
Course Description

This course is specifically designed to meet the analytical needs of those individuals working within a variety of 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

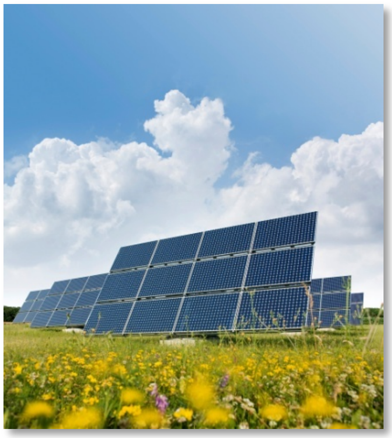
1. Clear product specifications
2. Effective metrology
3. Process characterization
4. Sampling plan
5. Control chart selection (variables and attributes)
6. Alarms, closing the loop and out-of-control action plans (OCAP)
7. Process documentation
8. Operator and engineering training
9. Database
10. Routine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



Quality Risk Management and FMEA

QRM-FMEA
Course Description

This course is specifically designed to meet the analytical needs of those individuals working within a variety of industries. Areas of instruction cover 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 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

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 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 Problem Solving

BDPS

Course Description

This course is specifically designed to meet the analytical needs of people working within a variety of 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

Business Statistics and Data Analysis

BSDA

Course Description

This course is for all Marketing, Sales, HR, Business Analysts and Managers who routinely analyze data for business application. Areas of focus are foundation statistics, distribution analysis, capability assessment, graphing, comparison tests and sample size selection. This course is designed for 16 hours of presentation.

Attendees

This course is required for all Marketing, Sales, HR, Business Analysts and Managers who routinely analyze data for business application.

Prerequisites

There are no prerequisites for this course.

Course Objectives

1. Understand the ideas associated with sampling and data collection.
2. Demonstrate the ability to evaluate distributions.
3. Select appropriate sample sizes for performance evaluation.
4. Conduct comparative tests using data.
5. Use regression techniques in order to analyze the results and make performance improvements.
6. Select an appropriate analysis technique based on the type of data.

Detailed Course Outline

Section I Introduction to JMP

Table commands
Column commands
Row commands
Subset, Stack and Join commands
Saving data and graphs

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

Process capability normal and non-normal distribution fitting
Trend Analysis

Section III Nominal X, Continuous Y

Sample size for the mean
t test – one sample, two sample and paired
Test for differences in variances
One-way ANOVA
Customer Satisfaction and Nonparametric data analysis

Section IV Continuous X, Continuous Y

Simple linear regression, correlation

Section V Nominal X, Nominal Y

Test for proportion data
Chi-square test for defects and proportion defective
Pareto graphs and analysis

Section VI Continuous X, Nominal Y

Logistic regression

Advanced Business Statistics and Data Analysis

ABSDA

Course Description

This course is for all Marketing, Sales, HR, Business Analysts and Managers who routinely analyze data for business application. Areas of focus are analysis of data for business planning, forecasting, data mining, variation analysis and multiple factor modeling. This course is designed for 16 hours of presentation.

Attendees

This course is required for all Marketing, Sales, HR, Business Analysts and Managers who routinely analyze data for business application.

Prerequisites

Business Statistics and Data Analysis

Course Objectives

1. Use data to solve business and transactional problems.
2. Select appropriate analysis technique based on type of data.
3. Analyze complex multifactor data sets.
4. Estimate the effect size from the data relative to the business case of interest
5. Generate prediction equations to predict business behavior based on critical inputs.
6. Use multiple regression techniques in order to analyze data and make business process improvements.

Detailed Course Outline

Section I Advanced Graphs
- Advanced Pareto Plots
- Confidence Intervals and Tests
- Stacked Bar Graphs
- Graph Builder

Section II Variation Analysis
- EMS and REML
- POV Analysis
- MSA for Attributes

Section III Data Mining
- Recursive Partitioning

Section IV Time Series and Forecasting

UWMA and EWMA
Seasonal ARIMA
Learning Curves
Nonlinear Regression

Section V Multiple Factor Analysis

N-way ANOVA
Multiple Regression
ANCOVA

Please contact Thomas A. Little Consulting for quotation of training and consulting services.

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