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## Thomas A. Little Ph.D.

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### CURRENT POSITION

President and Founder of BioAssay Sciences (BAS)  
President, Thomas A. Little Consulting (TLC)

### EDUCATION

Doctor of Philosophy, Purdue University, August 1986  
Statistical/Analytical Methods  
Industrial Technology/Engineering

Master of Arts Industrial Arts, San Jose State University, 1984  
Major Industrial Technology

Bachelor of Science, Industrial Technology, Brigham Young University, 1983  
Industrial Technology/Engineering  
Minor Business Management  
Biology and Chemistry Emphasis

### EXPERIENCE

#### INDUSTRY

President of Thomas A. Little Consulting (TLC) and BioAssay Sciences. BioAssay Sciences is a world leader in BioAssay Development, validation and control. TLC is a Quality by Design, statistical, analytical methods, FDA/GMP and operational excellence consulting and training company. Responsible for all aspects of consulting, curriculum development

and implementation of Quality by Design, Design of Experiments, Bioassay design and validation, Formulation Development, Analytical Methods and Process Validation, Statistical Process Control, Engineering Statistics, Product Stability, Potency Assay Development and Validation, Measurement Systems Analysis, Mixture DOE, Data Analysis, Product Reliability and general analytics and performance modeling. Clients are a variety of Vaccine, Pharmaceutical, Biotechnology, Medical Device, Food, Semiconductor, Consumer Products and FDA regulated industries which design and manufacture their own products. Consulting activities are worldwide. TLC consultants are experts in statistical methods, bioassay design and development, SAS/JMP, and product/process characterization and control. 1999-Present. TLC has trained over 1500,000 engineers and scientists on the use of statistical and analytical methods for product/product characterization, improvement and control with operations in the US, Canada, Asia Pacific and Europe.

TLC is a strategic business partner of SAS since 1999.

Sr. Director Engineering Systems, Read Rite Corporation.

Responsible for product design and development and magnetic performance optimization, data analysis methodologies, including design of experiments, statistical process controls, factory measurement systems selection, analysis and control, producibility, regression and associated training. Maintained responsibility for all factory data systems and supporting engineering database systems and supporting software applications, managed over 40 engineers in direct support of engineering and factory functions. Worked with President and CEO on yield improvement methods and supported factories in California, Thailand, Malaysia, Japan, and Philippines. 1992 – 1999.

Quality Manager IRIDIUM Space Program, Lockheed Space Systems Division. Responsible for quality systems definition, planning, procurement, statistical analysis of producibility, documentation, and engineering. Program consists of a commercial contract to produce 125 identical spacecraft for cellular telecommunications worldwide. Developed and defined an operational approach for six-sigma quality within product design, development and production. 1991 - 1992

Continuous Improvement Manager, Lockheed Missile Systems Division. Responsible for Total Quality Management activities for 6,000 employees. 1990 - 1991. Reported directly to the company president.

Senior Manufacturing Research Engineer and Consultant, Lockheed Missiles & Space Co., Inc., Sunnyvale, California. Developed strategic plan for implementation of statistical process control throughout Missile Systems Division. Consultant in bar code systems integration and quality systems planning. 1987-1990

## **CONSULTING**

The following is a partial list of clients:

Abbott Labs

Agensys

Allergan

Alnylam

Amgen  
Aptevo  
Apple Computer  
ASM  
Audentes  
Bayer Health  
Boston Scientific  
Bristol Myers Squibb  
Boehringer Ingelheim  
Catalent  
Cardinal Health  
Ceva  
Covance  
Cisco Systems  
Duke Medical Center  
Eli Lilly  
Emergent Biosolutions  
Empire Health  
Eurofins Discover X  
Ferring Pharmaceuticals  
Finisar  
Form Factor  
Genentech  
Gilead Sciences  
GSK  
Glenmark Pharmaceutical  
Halozyme  
Hitachi GST  
JDS Uniphase  
Jounce  
Kimberly Clark Corporation  
KLA Tencor  
Korean FDA  
Lattice Semiconductor  
Lam Research  
Lentigen Technology Inc.  
Lundbeck  
Lumileds/Philips  
Lexmark  
McCain Foods  
Microsoft  
Motorola, Corporation  
National Cancer Institute  
Partner Technologies  
PepsiCo  
Philips  
Portola Pharmaceuticals  
Proctor and Gamble

Pfizer  
 Regeneron  
 Roche  
 SanDisk  
 SAS Institute  
 Seagate Technologies  
 Siemens  
 Stanford University  
 STATS ChipPac  
 Theravase  
 Takeda Pharmaceutical  
 US Army  
 Xilinx

## **EDUCATION**

### **ADMINISTRATION**

Curriculum design of the Master of Science Quality Assurance, San Jose State University.  
1990- 2000

Program Coordinator and Principle Curriculum Developer, Master of Science Quality Assurance SJSU - Fall 1987 to 1990.

### **TEACHING**

Strategic Partner and Instructor, SAS Institute 1999-Present.

#### Current Thomas A. Little Consulting Curriculum

Introduction to QbD and CQAs  
 Statistical Methods and Data Analysis  
 Assay Development and Method Validation  
 Engineering Statistics and Data Analysis  
 Design of Experiments  
 Introduction to Quality by Design  
 Mixture DOE  
 Measurement Systems Analysis  
 Nonlinear Modeling  
 Process Control Design using SPC/PAT  
 Quality Risk Management  
 Reliability Analysis  
 Stability Analysis  
 Bioassay Development and Validation  
 Statistical Methods for Process Validation

#### Operational Excellence

Six Sigma Executive Overview  
 Six Sigma for Champions  
 Manufacturing Process Excellence (Green Belt and Black Belt)

Transactional Process Excellence (Green Belt and Black Belt)  
Basic DMAIC Problem Solving Skills (Yellow Belt)

Developed and taught the Engineering curriculum for Solectron University,

Professor, DeAnza College, 1991 - 1993

Assistant Professor, Industrial Technology,  
San Jose State University - 1986 - 1990.

#### Courses Developed & Taught

##### **San Jose State University TQM 1992 - 1998**

TQM	409	Design of Experiments
TQM	405	SPC for Engineers & Managers
TQM	420	Measurement Systems Analysis
TQM	403	Applying Total Quality Management
TQM	419	Design for Manufacturability

##### **San Jose State University MSQA 1987 - 1990**

INDS	262	Statistical Process Control and Sampling
INDS	270	Special Topics by Directed Study
INDS	273	Directed Project in Quality Assurance

##### **De Anza College 1991**

QA	61	Statistical Quality Control
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##### **San Jose State University, Industrial Technology, 1986 - 1990**

INDS	30	Introduction to Quality Assurance
INDS	31	Statistical Quality Control I
INDS	103	Technical Documentation and Information Systems
INDS	136	Quality Technical Systems Planning
INDS	137	Quality Administrative Systems Planning
INDS	139	Systems Effectiveness Measurements
INDS	206	Facilities Planning and Effectiveness
INDS	216	Seminar in Industrial Statistical Computer Applications

##### **Purdue University, Industrial Technology, 1984 - 1986**

IT	112	Industrial Communication
IT	212	Communication Design
IT	312	Communication Reproduction

## **PROFESSIONAL MEMBERSHIPS**

American Society of Quality – ASQ Statistics Division  
Epsilon Pi Tau - Rho Chapter  
National Association of Industrial Technology

**PUBLICATIONS and PAPERS**

International BioPharm, Acceptance Criteria for Analytical Methods, 2016

International BioPharm, "Scale Up/Scale Down Process Modeling", September 2015

AAPS PharmSciTech, Thomas A. Little, Mark Alasandro, Process and Method Variability Modeling to Achieve QbD Targets, August 2015

International BioPharm, "Equivalence Testing for Comparability", February 2015

BioProcess International, "Essentials in Quality by Design", March 2014.

International BioPharm, "Design of Experiments for Method Development and Validation", March 2014

International BioPharm, "Method Validation by Design to Support Formulation Development", May 2013.

International BioPharm, "Essentials in Quality Risk Management", May 2013.

International BioPharm, "Assay Development and Method Validation Essentials", November 2012.

International BioPharm, "A Systematic Approach for Selecting Critical Process Parameters for Process Control", July 2012.

Little, T (2001)

"10 Requirements for Effective Process Control", Quality Progress, February, 2001. Received "Readers Choice Award for 2001"

Little, T. & Park, H. (1992)

"Assessing Machine Tool Performance". American Machinist, Volume 136, Number 6, pages 39-42. June 1992. A discussion of advanced methods for machine tool performance assessment and statistical process control.

Little, et al (1990)

"Guidelines and Tools for Continuous Improvement"  
Lockheed Corporation, Calabasas CA.

Huxsoll, J. and Little, T. (1990)

"The Status of Quality Assurance In the Biotechnology Industry"  
Regulatory Affairs - Volume 2, Fall 1990, pages 299 - 318

Little, T. and Fales, J. (1988)

Automatic Identification - The Big Picture" Journal of Industrial Technology, 10 pages.

## TECHNICAL PRESENTATIONS

Strategic Bioassay Design, Beginning with the End in Mind. CHI, Immunogenicity and Bioassay Conference, Alexandria Virginia, October 2018.

Essentials in Bioassay Development and Validation, Little T. 2016

Quality by Design Essentials, Chinese FDA, Little T. 2015, 2018

Quality by Design, Korean FDA, Little T. 2015-2016

Well Characterized Biologics Session Leader, Essentials in Quality by Design, Little T. 2014,

ASQ Keynote; Practical Applications of Innovation and Quality, Little T. 2010.

SAS Innovators Conference, Financial Analysis, Little T. 2008.

SAS JMP User Conference, Keynote Address – Little T. 2005  
 “Design for Six Sigma”

ASQ National Six Sigma Conference – Little T. 2003  
 “Advanced Methods in Design of Experiments”

ASQ National Six Sigma Conference – Little T. 2002  
 “Six Sigma in Manufacturing Operations”, Tampa FL.

ISSSP Six Sigma Leadership Conference – Little, T. (2001)  
 “Six Sigma Control: 10 Requirements for Effective Process Control”

ASQC Annual Quality Congress – Little, T. (1996)  
 “10 Keys to Achieving Robust Product and Process Designs”

ASQC Annual Quality Congress - Little, T. & Brekke K. (1995)  
 “Partition of Variation: Improved Method for Variation  
 Assessment and Reduction”

ASQC Annual Quality Congress - Little, T. & Harrelson, C. (1993)  
 “Short Run Capability Assessment Using the t Distribution”  
 A technical discussion of original research for process capability  
 assessment for short or limited production runs. Boston, MA, May

Fourth Annual Ohlone College Business Roundtable - Little, T. (1992)  
 “Design of Experiments: Required Knowledge for the  
 Technical Community”  
 Presentation concerning essentials of designed experiments for

product and process development. Newark, CA, May 7

- ASQC Annual Quality Congress - Little, T. & Park, H. (1991)  
 "Machine Tool Variability Management System"  
 Presentation given to the American Society for Quality Control  
 on SPC and variation assessment tools for machining centers.
- Ohio University - Little, T. (1991)  
 "Design for Manufacturability"  
 Presentation given to the engineering and technology school as a part of  
 the Stock Endowment series.
- ASQC - Little T. (1990)  
 "Design of Experiments for Fun and Profit"  
 Presentation given to Santa Clara Chapter, Santa Clara, CA.
- Presentation to Department of the Navy, Strategic Weapon Systems -  
 Little, T. (1988)  
 "Process Management: Continuous Improvement Within Manufacturing  
 at Lockheed Missiles Systems Division"  
 Presentation given at Eighth Strategic Systems Programs Sponsored  
 Manufacturing Technology Meeting, (October 25)
- ASEE presentation, Little, T. (1988)  
 "Bar Code Application for Quality Assurance Systems"  
 Presentation given at the annual convention for the American Society  
 of Engineering Educators. Presentation covered the application of bar  
 code technology in quality assurance data collection systems  
 development. June 22, 1988, Portland University, Portland, Oregon.
- SCAN-TECH '88 - Little, T. (1988)  
 "Application of Bar Code Technology in Quality Assurance Systems  
 Development". Presentation give at SCAN-TECH '88, an international  
 trade show, covered the automated data entry industry. Presentation  
 covered bar code applications for integration into quality data systems for  
 recursive failure detection, documentation systems, and traceability. AIM  
 sponsored, Chicago, Illinois, November 1988.
- SWE presentation, Little, T. (1988)  
 "Quality - The American Challenge"  
 Presentation given to members of the Society of Woman Engineers.  
 Presentation covered the fundamentals of quality assurance systems  
 with respect to technology, management, and processes. Statistical  
 methods, design control, and competition were discussed with respect  
 to America's need to achieve a higher state of product quality.  
 January conference, Stanford University.

AIM presentation, Little, T. (1988)

"Networking and Data communication Protocols for Automated Data Entry Systems." Presentation given to industry representatives and university professors at the Automatic Identification Manufacturers Association (AIM) Summer Institute at Ohio University, Athens, Ohio, July, 1988.

NAIT presentation, Little, T. (1988)

"Process Management: Continuous Improvement and Productivity". Presentation given at the National Association of Industrial Technology conference, San Jose, California, October 1988.

## **DIRECTED RESEARCH**

The following is a list of Master of Science Quality Assurance directed research that has been chaired by Dr. Little:

PARTITION OF VARIATION FOR ISOLATION OF WITHIN PART VARIATION WHEN CONDUCTING MEASUREMENT SYSTEMS ANALYSIS

Carl Ashcroft, Read-Rite Corporation, Spring 2000

A STUDY OF THE EFFECTIVENESS OF THE t DISTRIBUTION FOR SHORT RUN CAPABILITY ASSESSMENT

Scott Harrelson, Lockheed Missiles & Space Co., Inc., Spring 1992

DATA MANAGEMENT FOR PC BOARD TESTING

David A. Christiansen, Trillium Corporation, Fall 1988

EFFECTS OF CENTRIFUGAL FORCES ON SEMICONDUCTOR DEVICES

David Singh Girn, Siliconix Corporation, Summer 1988

QA PROGRAM FOR THE ENVIRONMENTAL LABORATORY

Trudy M. Nichols, Lockheed Corporation, Summer 1988

MEASUREMENT QUALITY CONTROL FOR MANUFACTURING

Homayoun Kiamanesh, IBM Corporation, Summer 1988

AN EFFECTIVE QUALITY EVALUATION PLAN

James Santos, Syva Corporation, Spring 1988

AN ANALYSIS OF THIN FILM HEAD FLYING HEIGHT

Eileen F. Kelly, Read Rite Inc. Spring 1988

PROCESSING VARIABLES FOR WAVE SOLDERING PROCESS

Michael J. Gallagher, Lockheed, Corporation, Spring 1988

**CONTROLLING SHAPE DISTORTION WITH SPC**

Hermann F. Kunold, Lockheed Corporation, Spring 1988

**QUALITY ASSURANCE IN BIOTECHNOLOGY**

Jean F. Huxsoll, Hanna Corporation, Spring 1988

**INSPECTION ACCURACY**

Kathryn S. Plum, Litton corporation, Summer 1988

**HONORS, & ACTIVITIES**

FDA Committee on Fast track and CMC for Gene and Cell Therapies

Quality Progress "Readers choice" award for February 2001 article titled "10 Requirements for Effective Process control"

In Pursuit of Excellence Award granted by Lockheed to key individuals who stretched the boundaries of technology or science. Granted for work on statistical applications for machine tool characterization and process control. December 1991

Certified Quality Engineer Award from American Society of Quality Control. August 1988

Meritorious Performance and Profession Promise Award  
San Jose State University. June 1987

Awarded the David Ross research grant. Grant for outstanding Ph.D. candidates conducting research. Summer 1986

Eagle Scout, 1968