TAYLOR ENTERPRISES VARIATION.COM

Dr. Wayne Taylor - CV

Dr. Taylor is a leading expert in applying statistics to the Medical Device and other FDA-regulated industries. His book, Statistical Procedures for the Medical Device Industry, sets the standard for using statistics in compliance with the Code of Federal Regulations, 21 CFR §820.250, Statistical techniques.

Dr. Taylor is the leading expert on acceptance sampling in the medical device, diagnostics and pharmaceutical industries. His articles and books on selecting statistically valid sampling plans have become industry standards. He has taught his acceptance sampling courses to over 10,000 students and 100 companies, including the CDRH (Center for Devices and Radiological Health) of the FDA. Dr. Taylor is also a leading expert in Process Validation. He is the author of Annex A of the GHTF Quality Management Systems – Process Validation Guidance – Edition 2.

Dr. Taylor is the founder and chairman of Taylor Enterprises, Inc., where he is responsible for developing the software packages VarTran®, Change-Point Analyzer, Sampling Plan Analyzer, and Distribution Analyzer.

His other books include:

- Optimization and Variation Reduction in Quality: Covers the tools and strategies for reducing variation taught in Baxter's Six Sigma program.
- Guide to Acceptance Sampling: Explains how to select and justify manufacturing sampling plans to reduce inspection costs. This system has saved Baxter over 30 million dollars annually.

Dr. Taylor offers consulting and training on statistical and Six Sigma tools. His most popular courses include:

- Validation Sampling Plans: Explains how to select and justify sampling plans for Design Verification and Process Validation to safeguard consumers while reducing sample sizes and false rejections.
- Successful Acceptance Sampling (manufacturing focus): Explains how to select and justify sampling plans for product release during manufacturing. This course is designed to help improve the effectiveness of your manufacturing sampling program and to reduce costs. The differences between sampling plans for manufacturing and validation are clearly explained.
- Normality Testing and Transformations: One of the best ways to reduce sample sizes is to use a variables sampling plan. However, variables sampling plans

assume that the data follow the normal distribution. This course teaches how to test for normality and handle non-normal data, including fitting other distributions and transforming the data.

- Robust Tolerance Analysis: Explains how to engineer product/process variation during design. The VarTran® software and this course have become a key component of many companies' DFSS (Design for Six Sigma) programs.
- Process Validation Principles: Explains GHTF Quality Management Systems – Process Validation Guidance – Edition 2.

In 2000, Dr. Taylor retired from his position as Director of Quality Technologies at Baxter, where he implemented Baxter's Six Sigma program. He and his staff trained over 800 of Baxter's engineers to serve as Six Sigma black belts. He had been with Baxter for 22 years.

Dr. Taylor's clients include over 200 medical device companies. He has served as part of the third party to close to a dozen companies under consent decrees and has served as an expert witness in multiple court cases, including the blockbuster drug Gabapentin. He is an Accredited Professional Statistician™ with dozens of articles and hundreds of presentations to his credit.

He has made many key contributions to the field of Quality:

- Change-Point Analysis: More powerful and simpler than Shewhart control charts for detecting sustained shifts.
- Normalized Individuals Control Chart: It allows an I-Chart to be normalized by the number of opportunities. This single chart can replace most types of charts, including the I, P, U, Laney P, Laney U and Within/Between Average charts.
- Process Tolerancing: A unified approach to tolerance analysis where worst-case and statistical tolerances are special cases. They can be combined into the same analysis.
- Robust Design: Use of Tolerance Analysis for Robust Design as an alternative to Taguchi Methods.
- Quick Switching Systems: "Quick Switching Systems," Journal of Quality Technology, Volume 28, No 4, October 1996

EDUCATION

Ph.D. Statistics, Purdue University 1983

M.S. Statistics, Purdue University 1978

B.S. Mathematics, Purdue University 1976

HONORS

1996 - Elected a Fellow of the American Society for Quality

2001 – Change-Point Analyzer received ZDNet Editor's Pick 

2008 – Recognized as 100 Notable People in the Medical Device Industry by MD&DI Magazine

2012 – Purdue University - Distinguished Science Alumni Award

BOOKS

Optimization and Variation Reduction in Quality, McGraw-Hill and ASQC Quality Press, 1991.

Guide to Acceptance Sampling, Taylor Enterprises, 1992.

Design of Experiments in Validation, Francis Taylor, 2007. Chapter 7 – The Role of Designed Experiments in Developing and Validating Control Plans.

Statistical Procedures for the Medical Device Industry, Taylor Enterprises, 2017.

SOFTWARE PACKAGES

Acceptance Sampling Programs, Taylor Enterprises, 1992. Accompanies the book *Guide to Acceptance Sampling*.

Simulator, Taylor Enterprises, 1995, (Variation.com/sim)

VarTran®, Taylor Enterprises, 1996. (Variation.com/vta)

Screen, Taylor Enterprises, 1996

Change-Point Analyzer, Taylor Enterprises, 1999. (Variation.com/cpa).

Sampling Plan Analyzer, Taylor Enterprises, 2001. (Variation.com/spa)

Distribution Analyzer, Taylor Enterprises, 2006. (Variation.com/da)

JOURNAL ARTICLES

"Quick Switching Systems," Journal of Quality Technology, Volume 28, No 4, October 1996.

"A Program for Selecting Quick Switching Systems," Journal of Quality Technology," Volume 28, No. 4, October 1996.

"Reducing Sample Size of AAMI Gamma Radiation Sterilization Verification Experiments and Dose Audits," with George W. Phillips, Harold E. Sargent and Joyce M. Hansen, Quality Engineering, 8(3), 489-496, 1996.

"Acceptance Sampling Update," Medical Devices & Diagnostic Industry, October 1995, p. 92-108.

"A Program for Selecting Efficient Double Sampling Plans," Journal of Quality Technology," Volume 18, Number 1, January 1986, p 67-73.

"Using Hypothesis Testing in Medical Packaging Validation," Medical Devices & Diagnostic Industry, October 2008, p. 60-63.

"Selecting Manufacturing Sampling Plans for New and Existing Processes," Journal of Validation Technology, January 2013.

"Examining Changes in Ulnar Collateral Ligament Reconstruction Surgery Patterns Among Professional Baseball Players," Clinical Journal of Sport Medicine, Vol. 35, No. 4, July 2025.

MAGAZINE ARTICLES

"Classifying Defects and Selecting AQLs," FDC Control, Food, Drug and Cosmetic Division ASQ, February 1993.

"Statistically Valid Sampling Plans," FDC Control, Food, Drug and Cosmetic Division ASQ, February 1994.

"The Effect of Lot Size," FDC Control, Food Drug and Cosmetic Division ASQ, February 1994.

"The Importance of Trending Attribute Data," FDC Control, Food Drug and Cosmetic Division ASQ, February 1994.

"Selecting Representative Samples," FDC Control, Food Drug and Cosmetic Division ASQ, February 1995.

"Acceptance Sampling Update," Medical Device & Diagnostic Industry, October 1995, p. 92-108, Canon Communications

"Reducing Variation During Design," News of Society of Concurrent Engineering, May 1996.

EXPERT WITNESS

2008 - In re Gabapentin Patent Litigation, MDL No. 1384 (FSH) (PS)

2013 - Stryker v. Errico et. al., Michigan 2011-0097-CK, Illinois 13 MR 1459

2013 - The Medicines Company v. Teva Parenteral Medicines, lnc, et aI., Civil Action No. 09-cv-750 (RGA) (D. Del.) (Consolidated). The above is also referred to as The Medicines Company versus Hospira, Inc., Civil Action No. 09-750-RGA