



Dr. Wayne A. Taylor - CV

Dr. Taylor is a leading expert on the application of Statistics to the Medical Device and other FDA regulated industries. His book *Statistical Procedure for the Medical Device Industry* sets the standard for applying statistics in compliance with Section §820.250, Statistical Techniques of the Code of Federal Regulations.

Dr. Taylor is the founder and chairman of Taylor Enterprises, Inc. where he is responsible for the development of the *VarTran®*, *Change-Point Analyzer*, *Sampling Plan Analyzer* and *Distribution Analyzer* software packages as well as providing consulting and training on statistics and the Six Sigma approach including Robust Design, Tolerance Analysis, Design of Experiments, SPC, and Acceptance Sampling.

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

He is also author of the books *Optimization and Variation Reduction in Quality* and *Guide to Acceptance Sampling*. The first outlines the approach implemented at Baxter for achieving Six Sigma quality. The second book outlines a simple-to-use approach for selecting and justifying sampling plans as well as reducing inspection costs that are used throughout the medical industries. This system has saved Baxter over 30 million dollars annually.

Dr. Taylor is the leading expert on acceptance sampling in the pharmaceutical, medical device and diagnostics industries. His articles on selecting statistically valid sampling plans have become standards in the industry and are used by the FDA in their new inspector training. He has taught his 2-day course, Successful Acceptance Sampling, to over 5,000 students and 50 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 Global Harmonization Task Force guideline *Quality Management Systems – Process Validation Guidance – Edition 2*.

His 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. He has served as an expert witness in several court cases, including the blockbuster drug Gabapentin.

The VarTran software and Dr. Taylor's course **Robust Tolerance Analysis** have rapidly become a key component of many companies DFSS (Design for Six Sigma) programs. Honeywell, the Six Sigma Academy and numerous other companies have adopted VarTran as an essential tool for designing high-quality products.

He has made many key contributions to the field of Quality including Variation Transmission Analysis, Process Tolerances, Quick Switching Systems, Change-Point Analysis, and Normalized Individuals Control Charts. He has dozens of articles and hundreds of presentations to his credit.

Dr. Taylor received his Ph.D. in Statistics from Purdue University. He is a fellow of the American Society for Quality, as well as a member of the American Statistical Association where he is an Accredited Professional Statistician™.

EDUCATION

Ph.D. Statistics, Purdue University 1983

M.S. Statistics, Purdue University 1978

B.S. Mathematics, Purdue University 1976

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 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.

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.

HONORS

1996 - Elected a Fellow of the American Society for Quality

2008 – Recognized as 100 Notable People by MD&DI Magazine

2012 – Purdue University - Distinguished Science Alumni Award

COURT CASES

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

2013 - *The Medicines Company v. Teva Parenteral Medicines, Inc., et al.*, Civil Action No. 09-cv-750 (RGA) (D. Del.) (Consolidated)

The above was also referred to as The Medicines Company versus Hospira, Inc., Civil Action No. 09-750-RGA

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