

# INCOSE Chicagoland April Meeting



Locations:

**Topic: *Sampling Plans for Validations/Verifications***

**Presenter: *Dr. Wayne A. Taylor - Accredited Professional Statistician***

**Date: Thursday, April 16<sup>th</sup>, 2015**  
**Agenda: 6:00-6:30 p.m. CT – Dinner (\$5 Member / \$8 Nonmember) & Networking**  
6:30-6:45 p.m. CT – Introductions & Announcements  
6:45-8:00 p.m. CT – Presentation and Q&A

1. **Schaumburg, IL** – IBM, 10 N. Martingale Rd, Schaumburg, IL 60173 (3rd Floor Conference Room)
2. **Lake Forest, IL** – Hospira, 375 N. Field Drive, Building H3, Lake Forest, IL 60045 (1st Floor R&D Innovation Conf Rm)
3. **Milwaukee, WI** – Astronautics, 4115 N. Teutonia Ave., Milwaukee, WI 53209 (Board Room)
4. **Madison, WI** – Bjorksten | bit 7, 5407 Fen Oak Ct., Madison, WI 53718 (Mendota Conference Room)

## **Abstract**

As a Statistician the question I get asked most often is: "How many samples do I need." When I respond, the next question is, "Do I really need that many?" Methods are provided for selecting sample sizes for validations/verification studies basing the sample size on both the risk and the expected performance. Methods are also provided for reducing the number of samples including variables plans and stress testing. Finally, methods are covered that increase the chances of a good product/process passing while maintaining the protection against a bad product/process.

## **About Our Speaker**

Dr. Taylor is the founder and chairman of Taylor Enterprises, Inc. where he is responsible for the development of the VarTran<sup>®</sup>, Change-Point Analyzer, Sampling Plan Analyzer and Distribution Analyzer software packages as well as providing consulting and training on the Six Sigma approach and tools including Robust Design, Tolerance Analysis, Design of Experiments, SPC, Acceptance Sampling, and Statistics. 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 author of the books *Optimization and Variation Reduction in Quality* and *Guide to Acceptance Sampling*. The first book 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 is used throughout the medical device 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 author of Annex A of the Global Harmonization Task Force guideline titled Process Validation Guidance for Process Validation Engineers. 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 and Change-Point Analysis. 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<sup>™</sup>..

**Questions?: For more information, go to <http://www.incose.org/Chicagoland/>.**