



JOIN US FOR OUR NEXT SECTION MEETING!

We cordially invite you to join us on Thursday, November 18th, 2011 at the Arboretum Club, 401 W. Half Day Rd (Rt. 22 East of Buffalo Grove Road, across from Dominick's), in Buffalo Grove. Members and non-members are always welcomed.
E-mail registration: E-mail: asq1212reservations@yahoo.com
Pre-meeting Clinic 5:30 pm Networking/Dinner: 6:30 pm Main Meeting: 7:30 pm.

November 18th Section Meeting Statistical Techniques and Validation

By Regina Fullin and Dr. Wayne Taylor

The November 18 ASQ Section Meeting extends a warm welcome to Dr. Wayne Taylor, Chairman of Taylor Enterprises Inc. Dr. Taylor will share his expertise with the use of statistics in FDA-regulated industries with a discussion of the FDA definition of "Statistically-Valid." He will also discuss process validation in detail with a reprise of groundbreaking FDA training on the topic.

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Wayne Taylor has a Ph.D. in Statistics from Purdue University and is a fellow of the American Society of Quality. He is founder, and chairman of Taylor Enterprises Inc. (www.variation.com), where he provides consulting and training on the Six Sigma approach and other quality statistical techniques. He authored the books *Optimization and Variation Reduction in Quality* and *Guide to Acceptance Sampling*. He has also authored five software packages, including *VarTran*®. The *VarTran*® software has enjoyed particular success as a component of many DFSS (Design for Six Sigma) programs at many companies. *VarTran*® was also adopted at Honeywell and the Six Sigma academy as an essential tool for design of high-quality products.

In 2000, Dr. Taylor retired from Baxter Healthcare Corporation after a 22-year career, where he was Director of Quality Technologies. In this role, he was responsible for the company's Six Sigma program, as he and his staff trained over 800 Baxter engineers as Six Sigma Black Belts. He is a fellow at the Royal Statistical Society and a member of the American Statistical Association.

PRE-MEETING CLINIC: What does "Statistically Valid" Really Mean? This presentation will elucidate the meaning of "Statistically Valid", as viewed from the perspective of an FDA auditor, including the elements that make a procedure statistically valid, and the statistical rigor expected in documents such as process validations, release testing, trending and CAPA documentation.

MAIN PRESENTATION: Process Validation: A Lifecycle Approach This presentation provides training on the latest FDA Guidance document on Process Validation, authored by Grace McNally, Senior Policy Advisor of the U.S. FDA. This document discusses the FDA's current thinking on process validation. Please come prepared to learn how to keep your validated processes in continual compliance!