



American Society for Quality (www.asq.org) – Washington D.C. and Maryland Metro, Section 509 (www.asq509.org)

Biomed/Biotech Special Interest Group (SIG) Meeting

USP Verification Program

- A Unique 3rd party Certification Program

To be presented by

Stephen W. Andruski, PhD, CQA (swa@usp.org)
Manager, Verification Programs, US Pharmacopoeia

USP Reference Standards Evaluation – From Material to Reference Standard

To be presented by

Mark R. Pitluck, PhD (mrp@usp.org)
Manager, Reference Standards Programs, US Pharmacopoeia

Wednesday, December 7, 2011

6:00 – 6:20 PM – Networking; Pizza/drink

6:20 – 8:30 PM – Program

8:30 – 8:50 PM – Door-prizes drawing; Networking

Online Registration site: <http://www.asq509.org/ht/d/DoSurvey/i/35817>

Open to Public - \$5 for non-ASQ members to cover pizza/drink cost;

Free to ASQ Members, students, local interns, postdocs, FDA Commissioner's Fellows, and current job seekers

Location: Kelly's Deli Conference Center, 7519 Standish Place, Rockville, MD 20855

Registration Deadline: Please register by Wednesday noon, December 7, 2011.

Question: Please contact Dr. C.J. George Chang, Chair of Biomed/Biotech SIG, ASQ509; gchang2008@yahoo.com or 240-793-8425 (cell).

Driving directions: **By Car:** From I-270 (N or S bound): Take Exit 9A and exit from the FIRST right exit; turn left (east) onto Shady Grove Dr.; turn right (south) onto Rockville Pike (**Route 355**); turn left (east) onto East Gude Dr.; turn left (north) immediately onto Crabb's Branch Dr.; turn left (west) immediately onto Standish Place. The first building on your right side is 7519 Standish Place; open parking). The venue is on the first floor with its entrance opposite to the left side of building main entrance. **By Metro train:** Off from Red Line **Shady Grove Station**, and take RideOn **Route 59 TOWARD ROCKVILLE** and get off from "**Calhoun Place**" stop. Standish Place is next to the Bus stop. Our venue is within 2 min of walking distance from the stop.

Presentation Summary:

"USP Verification Programs – A Unique 3rd Party Certification Program"

The **USP Verification Program** began in 2002 with the Dietary Supplement Verification Program (DSVP) to ensure quality dietary supplements in the marketplace and to raise consumer awareness regarding supplement quality. The Verification Program is built on a program model which includes not only cGMP auditing and sample testing, but also includes a product document review component and continuing surveillance activities after initial product verification. The USP Verification Program is a unique, thorough and rigorous program for **third-party certification**. Since 2002, the Verification Program has expanded to include programs for **dietary ingredients, excipients and drug substances**. USP's Verification Program verifies the identity, strength, purity, and quality of supplements and ingredients. Supplements and ingredients that pass all USP verification requirements are awarded use of a distinctive "**USP Verified**" mark. Participation in the program is voluntary and available to manufacturers worldwide. USP's verification services draw upon its experience of more than 185 years in setting federally recognized public standards for

medicines and dietary supplements. This talk will provide an overview of the components of the USP Verification Programs and discuss the potential benefits to participants, users of the products and regulatory bodies.

“USP Reference Standards Evaluation – from Material to Reference Standard “

USP Reference Standards (RS) are highly characterized specimens reflective of specified drugs and foods (drug substances, biologics, excipients, dietary supplements, food ingredients, impurities, degradation products, reagents, and performance verification standards). When approved as suitable for use as comparison standards for documentary tests or assays (i.e., as a monograph component) in the *United States Pharmacopeia (USP)* or *National Formulary (NF)*, USP RS also assume official status and legal recognition in the United States. Official applications of USP RS include quantitative uses (assays for drug substances and formulations, limit tests, or blanks and controls), qualitative uses, (identification tests, system suitability tests, or chromatographic peak markers), and method-specific uses (performance verification standards, AVR, melting point standards, and the particle count set). Reference Standards Evaluation is responsible for evaluating and establishing materials as reference standards suitable for the intended monograph use. This talk will provide an overview of Reference Standards Evaluation and the critical work of this group in evaluating materials for establishing reference standards.

Presenters' Bios:

Stephen Andruski, PhD, CQA – Manager, Verification program, USP

Dr. Steve Andruski received his BS in Chemistry from the University of Wisconsin – Milwaukee. After graduating, he worked at Aldrich Chemical Company in Milwaukee for 2½ years doing small-scale production and **process development** for new catalog compounds. Steve returned to school and obtained his PhD from the University of Arizona working under Richard S. Glass. Steve's graduate work involved a mixture of synthetic and physical organic chemistry in the field of organosulfur chemistry. Following two years of post-doctoral work at the University of Kansas, Steve joined the Process Research group at FMC Corporation in Princeton, NJ where he performed **process research and development** on novel pesticides. While there he was part of the team that developed and supported start-up of the commercial process for the herbicide, carfentrazone ethyl. Steve also wrote the chemistry section of the EPA registration package (his first exposure to QA and Regulatory work), prepared the European Tier summaries and led the synthetic work on the preparation of impurities required for the analytical portion of the EPA registration package. After nearly ten years at FMC, Steve left to join the rapidly-growing contract research organization Albany Molecular Research, Inc. (now AMRI) in Albany, NY. Initially he joined the **Chemical Development** group working on a variety of customer projects from small-scale custom synthesis work to route-scouting and scale-up work in preparation for the GMP synthesis of clinical trial material. Steve moved into the **Analytical** Department performing method development, method validation and support of GMP production, eventually leading a group of six analysts at AMRI's large-scale GMP manufacturing facility in Rensselaer, NY. After almost twelve years with AMRI, Steve left to join the **Verification Program** staff at the US Pharmacopeia in Rockville, MD where he currently has the position of **Manager**.

Mark R. Pitluck, PhD - Reference Standards Manager, Reference Standards Evaluation, USP

Mark received his BS in Chemistry from Loyola University of Chicago and his PhD in Analytical Chemistry from Marquette University. His graduate work evaluated the use of size-exclusion and ion-exchange chromatography with atomic absorbance spectroscopy detection for metal-fulvic acid stability constant determinations. Mark began his professional career as a **Development Scientist** at Pfizer's manufacturing site in Groton, CT. He developed test procedures for routine product control, tested non-routine samples, and investigated complex problems. Mark left Pfizer to join Nalco Chemical Company which is the world's largest marketer and manufacturer of specialty chemicals and services in water and industrial process treatment. He held a variety of **scientist** positions initially at Nalco's research center in Naperville, IL and then at the Chicago manufacturing site. He transferred into management and held positions of **Quality Assurance Manager** and **Quality Assurance Superintendent**. He also served as the **ISO coordinator**. His work at Nalco focused on continuous improvement and efficiency for which he received numerous quality awards. Major projects included QUEST to establish world-wide raw material and product uniformity, 30/30 to reduce cost of manufacture by 30% over 30 months, and CustAmine to provide customer specific corrosion inhibitor products for cooling towers. Mark returned to Pfizer where he held positions of **Manager/Team Leader** Control Lab Operations, **Senior Manager/Team Leader** Control Lab, and **Director** of Quality Operations. Again his work focused on continuous improvement and efficiency with emphasis on real time SPC for maintaining critical test method parameters. Mark left Pfizer to join US Pharmacopeia where he currently holds the position of **Reference Standards Manager** in Reference Standards Evaluation. His team evaluates materials for establishing small molecule reference standards.