



U.S. Pharmacopeia
The Standard of QualitySM

USP Annual Scientific Meeting 2006 Reference Standards Track Where We Are, Where We Should Go

Track Managers:

Ronald G. Manning, Ph.D., Vice President, Monograph and Reference Standards Development, USP
Shawn F. Dressman, Ph.D., Director, Reference Standards Evaluation, USP

Track Description:

Current topics in the science of reference standards (RS) will be addressed. These include (1) Qualification, (2) Packaging, Storage and Distribution, (3) Performance Verification RS, (4) RS for Potency Determination, and (5) RS from an ISO perspective.

Planning Committee:

- Philip J. Palermo, Ph.D., Chair, Reference Standards Expert Committee and Private Consultant
- Raymond A. Cox, M.A., Vice-Chair, Member, Reference Standards Expert Committee and Consultant
- David A. Fay, Ph.D., Member, Reference Standards Expert Committee and Senior Research Associate, Tyco Healthcare/Mallinckrodt
- Samir A. Hanna, Ph.D., Member, Reference Standards Expert Committee and Vice President, World Wide Quality Control & Bulk Chemical Quality Assurance (Formerly Bristol Myers Squibb)
- Gregory T. Kaster, M.S., M.B.A., Member, Reference Standards Expert Committee and Manager, Compendial Services & Reference Standards, Abbott Laboratories
- Pauline M. Lacroix, M.Sc., Member, Reference Standards Expert Committee and Coordinator, Health Products and Food Branch, Health Canada
- Wesley E. Workman, Ph.D., Member, Biologics and Biotechnology: Proteins and Polysaccharides and Reference Standards Expert Committees and Laboratory Services–Biopharma Quality Operations Center, Pfizer Global Manufacturing

Speakers:

- Lise H. Alaimo, Ph.D., Senior Manager/Team Leader, Reference Standards, Pfizer
- Matthew W. Borer, Ph.D., Member, Reference Standards Expert Committee and Research Advisor, Eli Lilly and Company
- Adrian F. Bristow, Ph.D., National Institute for Biological Standards and Control (NIBSC)
- Raymond A. Cox, M.A., Vice-Chair, Reference Standards Expert Committee and Consultant Quality Assurance and Reference Standards
- Shawn F. Dressman, Ph.D., Director, Reference Standards Evaluation, USP
- John L. Esker, Ph.D., Director, Reference Standards Laboratory, USP
- L. Valentin Feyns, Ph.D., Scientific Fellow, Monograph and Reference Standards Development, USP
- Vivian A. Gray, Member, Reference Standards and Biopharmaceutics Expert Committees, Chair, Dissolution Calibrators Ad hoc Advisory Panel, Co-Chair, Performance Tests-Inhalation Ad hoc Advisory Panel and President, V.A. Gray Consulting, Inc.
- Walter W. Hauck, Ph.D., Senior Scientific Fellow, Monograph and Reference Standards Development Division, USP
- Gregory T. Kaster, M.S., M.B.A., Member, Reference Standards Expert Committee and Manager, Compendial Services and Reference Standards, Abbott Laboratories
- Susan Kirshner, Ph.D., Food and Drug Administration
- Venkat Mukku, Ph.D., Member, Biologics and Biotechnology: Proteins and Polysaccharides Expert Committee and Laboratory Head, Global Cellular and Analytical Resources, Amgen, Inc.
- Alan W. Nichols, MA, Director, Reference Standards Production, USP
- Philip J. Palermo, Ph.D., Chair, Reference Standards Expert Committee and Private Consultant
- Vinod P. Shah, Ph.D., Consultant, Distinguished Pharmaceutical Scientist, USP
- John E. Simmons, Ph.D., Member, Pharmaceutical Drug Substances and Excipients Advisory Group and Chief Science Officer, Simmons FDA CMC Consulting
- Henry F. Steger, Ph.D., Independent Consultant
- Erika Stippler, Ph.D., Visiting Scientist, USP and Photonic Applications Systems Technologies (PHAST)

SESSION I Overview of the Reference Standards Expert Committee Hot Topics and Qualification of Reference Standards Wednesday, September 27, 2006 (1:00–3:00 p.m.)

Session leader: L. Valentin Feyns, Ph.D.

Session speaker(s): Philip J. Palermo, Ph.D.
John E. Simmons, Ph.D.
Lise H. Alaimo, Ph.D.
Shawn F. Dressman, Ph.D.

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Session format: Lecture and panel discussion

Session description: The session will begin with an overview of hot topics by Dr. Philip Palermo followed by a discussion on qualification. The qualification of Reference Standards (RS) will be presented from different perspectives. How does USP qualify a material to be a RS? Does industry follow a comparable scheme? What are the regulatory perspectives on qualification of a compendial/industry RS? A panel discussion will highlight differences in practice regarding what kind of data and how much data are needed to establish an RS.

SESSION II **Continued Suitability of Reference Standards**
Wednesday, September 27, 2006 (3:30–5:30 p.m.)

Session leader: Shawn F. Dressman, Ph.D.

Session speaker(s): John L. Esker, Ph.D.
Gregory T. Kaster, MBA
Matthew W. Borer, Ph.D.

Session format: Lecture and panel discussion

Session description: Current practices regarding maintenance of RS inventories will be presented, including USP, EP, and industry perspectives on packaging, storage, distribution, and recertification. How often should standards be requalified? What tests should be performed during requalification? How much does an assigned value have to change before it is no longer appropriate to use, and what actions should be taken to correct it? Are RSs to be held to the same level of control as drugs? Should compendial RS be labeled with expiration dates? How should RS customers receive/store standards? Must refrigerated items be kept cold throughout transit? Should packaging contain monitoring devices? The panel discussion will focus on what constitutes necessary rules for the RS industry

SESSION III **Standards for Performance Verification**
Thursday, September 28, 2006 (8:30 a.m.–12:00 noon)

Session leader: Ronald G. Manning, Ph.D.

Session speaker(s): Vinod P. Shah, Ph.D.
Walter W. Hauck, Ph.D.
Vivian A. Gray
Erika Stippler, Ph.D.

Session format: Lecture, point-counterpoint, and roundtable

Session description: The need for RS in system suitability and dosage form performance verification tests will be presented, contrasted, and discussed. Emphasis will be on USP calibrator tablets for qualification of dissolution testers prior to determining drug release from solid oral dosage forms. The rationale for performance verification will be presented and generalized to other dosage form types (inhalation, topical/dermal). The adequacy of mechanical calibration as an alternative to determine overall system suitability via chemical calibration will be considered. What are the regulatory requirements? What new performance verification standards are needed and what attributes must these standards have?

SESSION IV **Replacing Bioassays: Challenges, Opportunities, and Implications**
for Reference Standards
Thursday, September 28, 2006 (1:30–5:00 p.m.)

Session leaders: Venkat Mukku, Ph.D.
Wesley E. Workman, Ph.D.

Session speaker(s): Venkat Mukku, Ph.D.
Susan Kirshner, Ph.D.
Adrian F. Bristow, Ph.D.
L. Valentin Feyns, Ph.D.

Session format: Workshop

Session description: This interactive workshop will discuss opportunities and challenges in replacing traditional, especially animal-based, bioassays, for example with cell-based assays or binding assays. The discussion will cover both regulatory and scientific aspects. The reference standard angle of the discussion will also focus on the issue of appropriate units in potency assays and how to reconcile (or not) discrepancies between activity-based versus mass balance based units.

Note:

This will be a combined session of the **Biologics and Biotechnology and Reference Standards Tracks**

SESSION V **Reference Standards – ISO Perspective**
Friday, September 29, 2006 **(8:30–11:00 a.m.)**

Session leader: Ronald G. Manning, Ph.D.

Session speaker(s): Henry F. Steger, Ph.D.
Raymond A. Cox, M.A.
Alan W. Nichols, M.A.

Session format: Lecture and panel discussion

Session description: What are the ISO requirements for RS? How do USP RS fit into the ISO formalism? What is a Certified Reference Material (CRM) and how does it compare to USP RS and industry house standards? Should USP develop CRMs? What are the implications if USP publishes uncertainty values with its RSs? What are the requirements for industry quality control standards?