



Connecting People, Science and RegulationSM



U.S. PHARMACOPEIA
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USP/PDA Joint Conference: Residual Solvents

January 18-19, 2007 | Bethesda, Maryland

Opening Remarks

Roger L. Williams, M.D.

Learning Objectives

- Explain the ICH/PhEur/USP Residual Solvents Guidance and Requirements
- Describe manufacturer and supplier perspectives, assessment strategies, methodologies, and real-world applications
- Assess supplier, drug substance and drug product pharmaceutical manufacturers' implementation strategies
- Implement pharmacopeial and alternative methodologies

USP's Goals

- Ensure smooth implementation of the General Chapter <467>
- Educate those who use the General Chapter through innovative training opportunities

USP's Path to this Conference

- **Deliberations at the Prescription/Nonprescription Stakeholder Forum**
- **Formation of a Project Team**
- **Discussion on the topic within PDA**
- **Formation of a Joint Planning Team with PDA Task Force**
- **Collaboration with PDA**
- **Future USP educational programs**

Other Educational Activities

- **USP Educational Course: Navigating General Chapter <467> *Residual Solvents***
 - One-half day seminar; first offering at Pittcon; Eight U.S. six and European locations at www.usp.org
 - Reviews USP history and intention behind the General Chapter
 - Case studies to chart paths through the identification and limit testing decision matrix
 - Reviews where General Chapter <467> does and does not apply
 - Recommends next steps



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Thank You...

USP Residual Solvents Project Team—Planning Committee Members

- Thomas E. Chapman, Ph.D. (USP Residual Solvents Project Team Chair), Director Pharmaceutical Services, BioScreen Testing Inc.
- Barbara Ferguson, Associate Director and Compendial Liaison, Schering-Plough Corporation
- Larry A. Ouderkirk, Director, Compendial Operations Staff/Standards and Technology Team, FDA
- David R. Schoneker, M.S., Director of Global Regulatory Affairs, Colorcon/IPEC
- Neil A. Schwarzwald, Global Compendial Consultant, Eli Lilly and Company



Thank You...

USP General Chapters Expert Committee – Residual Solvents Subcommittee

- Fred Xi, Ph.D., Subcommittee Chair
- Gregory P. Martin, M.S., Subcommittee Member, Vice Chair, General Chapters EC
- Oscar Quattrocchi, M.S., Subcommittee Member



Thank You...

USP Staff

- Jennifer Belsky, Ph.D., Group Leader, Research Development Laboratories
- Todd L. Cecil, Ph.D., Vice President, Standards Development
- Kelly T. Coates, CMP, Manager, Meeting Services
- Angela G. Long, Vice President, Volunteer and Organizational Affairs
- Horacio Pappa, Ph.D., Senior Scientist, Latin American Specialist