



Connecting People, Science and RegulationSM



U.S. PHARMACOPEIA
The Standard of QualitySM



USP/PDA Joint Conference: Residual Solvents

January 18-19, 2007 | Bethesda, Maryland

Conference Wrap-up

John Towns

Residual Solvents Conference - Wrap-up

■ **A Successful Conference!**

- Well Attended
 - ◆ Those New to the Subject to Experts/Opinion Leaders
- Open Forum with Full Participation
- Brought Forward All the Issues
 - ◆ Sessions were both educational and thought provoking
- Clarified Concerns
- Suggested Alternatives

Residual Solvents Conference Wrap-up (cont.)

▪ **ICH/Ph Eur/USP Residual Solvents Requirements**

- Historical Perspective
- Scientific Rationale
 - ◆ EMEA/European Agencies/Ph. Eur. vs. FDA/USP
- Quality → Safety and Efficacy (impurities—safety only)
- Risk-based Approach vs. Prescriptive Guidance
 - ◆ Quality by Design concepts of safety/efficacy vs capability

Residual Solvents Conference Wrap-up (cont.)

■ Issues Brought Forward

- Reduced Workload
 - ◆ Understanding Implementation
 - Additional Clarification
 - » per General Notices
 - » USP Updates for Methods
 - ◆ Clarification of Test vs. Evaluate
- Alternative Testing Options
 - ◆ Fully Validated Method – Does Not Require Demonstration of Equivalency, although compendial method is for 'non-compliance
 - ◆ Good In-process Controls Predictive of Specification--May Not Require Release Testing
 - ◆ Procedure A →B→C
 - Ability to Move Directly to C?

Residual Solvents Conference Wrap-up (cont.)

■ **Issues Brought Forward (cont.)**

- Uncertainty about FDA Review/Inspection Requirements
 - ◆ Assurance of Taking Right Path
 - FDA's Interpretation
 - » Regulatory Reporting Requirements
 - FDA's Potential Action
- Supplier Acceptance
 - ◆ Certificate of Analysis Qualification
 - Surveys and Questionnaire Options
 - Partner with IPEC on Excipient Information Protocols

Residual Solvents Conference Wrap-up (cont.)

▪ Next Steps

- Roll-out of <467> in July 2007
- Education
 - ♦ Classroom
 - Navigating Chapter <467> Residual Solvents
 - ♦ Other Training Opportunities
 - Laboratory-based (?)
- Interpretation concerns fed back to FDA
 - ♦ Review Guidance vs. Compliance Policy
- USP Project Team Position Paper(s)
 - ♦ General Chapters Expert Committee
- PDA Task Force Lives On



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Thank You

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