Future Challenges and Objectives for PDA in AsiaPac

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President & CEO
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About PDA

• The Parenteral Drug Association (PDA) is the leading global provider of science, technology, and regulatory information.

• The PDA creates awareness and understanding of important issues facing the pharmaceutical and biopharmaceutical community and delivers high-quality, relevant education to the industry.

• Since its founding in 1946 as a nonprofit organization, PDA has been committed to developing scientifically sound, practical technical information and expertise to advance pharmaceutical/biopharmaceutical manufacturing science and regulation, so members can better serve patients.
2020 – A Year of Challenges

• In this period of global disruption, let’s remember all those who have been impacted by the pandemic and the economic effects.

• Let’s also thank all those who have stepped up:
  – First Responders, healthcare workers, and our community which is continuing to provide critical medicines, continuity of safe, effective supplies, and our hope for a future without COVID.
PDA’s Model: Advocacy & Outreach

→ Joint Conferences (FDA, EMA)
→ Training Partnerships (PIC/S, ICH)
→ Regulatory Comments
→ Regulators: members, participants and reviewers

→ World leading conferences
→ Renowned training
→ Publications
→ Chapters, Interest Groups, and platforms for exchange

→ Development of Technical Reports, Research, Standards
→ Regulatory Participation
→ Collaborations (R3N, PQRI, AAMI, PMF, BPOG, ASTM, SCB, IPEC, ISPE, et al)
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Key Actions by PDA

• COVID Task Force
  – Developing guidance on manufacturing, supply chain, control related to pandemic

• Manufacturing Science and Operations Program
  – Focusing efforts on improving manufacturing

• Combination Products Steering Committee
  – Developing focus on combination products

• Remote Audits and Inspections Task Force
  – Developing best practices
Asia Pacific Focus

• Currently 18% of PDA global membership

• Significant region for pharmaceutical manufacturing, with growing importance in biologics manufacturing

• Need expanded participation from members in Asia Pacific
Global Conferences

- Bringing key global conferences to you
  - Virtual participation possibilities
  - Key sessions timed to be compatible with AP Time Zone
  - Conference presentations available on demand
Selection of Recent Technical Publications

- TR 84 Integrating Data Integrity Requirements into Manufacturing & Packaging Operations
- TR 83 Virus Contamination in Biomanufacturing: Risk Mitigation, Preparedness, and Response
- TR 82 Low Endotoxin Recovery
- TR 81 Cell-Based Therapy Control Strategy
- TR 80 Data Integrity Management System for Pharmaceutical Laboratories
- PDA Reporte Tecnico No. 13 (Revisado) Fundamentos de un Programa de Monitoreo Ambiental en Español (versión digital de un solo usuario)

PDA Points to Consider

- Points to Consider for the Aseptic Processing of Sterile Pharmaceutical Products in Isolators
- Points to Consider for Sensitivity to Oxidation by Peroxide
- Points to Consider for Risks Associated with Sterilizing Grade Filters and Sterilizing Filtration
- Points to Consider for Implementation of Pre-Use Post-Sterilization Integrity Testing (PUPSIT)

PDA Survey

- PDA Research: 2021 Post-Approval Change Issues and Impacts Survey
- PDA Research: 2019 Technology Transfer Industry Survey
- PDA Research: 2019 Sterile Lyophilized Drug Product Loading Survey
- PDA Research: 2019 PDA Traceability of Primary Packaging Survey
Selected Active Areas

Sterile Manufacturing
- QRM for Aseptic (Std.)
- PUPSIT Research
- Zero Defects for Visible Particles (TR)
- PFS Design Control Annex (TR)
- Isolator Technology (TR)

Quality & Supply Chain Management
- Purchasing Controls (Std)
- Data Integrity (multiple TRs)
- QRM for Excipients (TR)
- Post Approval Change Management Plans (TR)
- Phase-Appropriate GMPs -- Technology Controls for Pilot Plants (TR)

Biotechnology
- Cryopreservation (Std)
- Cell & Gene Therapy
- Phage Retention Nomenclature Rating for Small and Large Virus Retentive Filters Std)
- Virus Contamination in Biomanufacturing: Risk Mitigation, Preparedness and Response (TR)
- Process Validation for Protein Manufacturing (TR)

Manufacturing Science
- Big Data in Mfg. (TR)
- Operational Metrics (TR)
- Cleaning Validation (TR)
- Tech Transfer (TR)
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