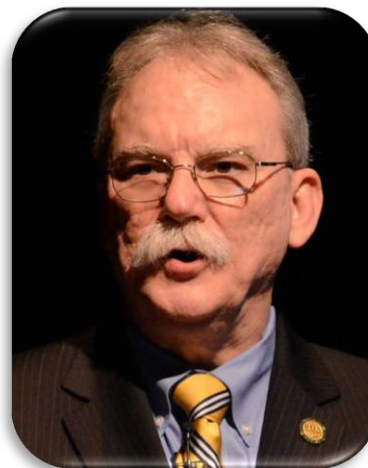


Future Challenges and Objectives for PDA in AsiaPac

Connecting People, Science and Regulation®

SELAMAT DATANG
歡迎光臨 환영합니다
WELCOME
ようこそ ยินดีต้อนรับ
स्वागत MABUHAY



Richard M. Johnson
President & CEO
Parenteral Drug Association

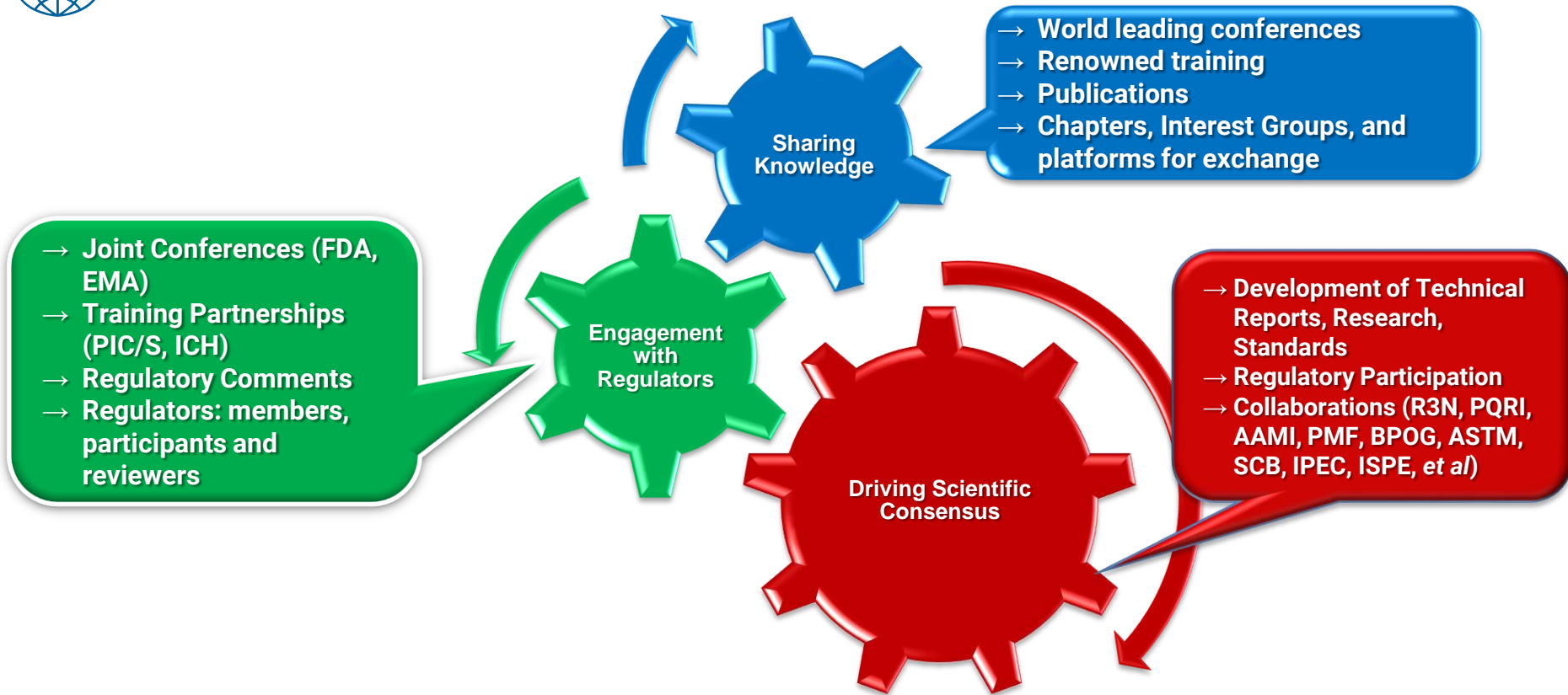
- The Parenteral Drug Association (PDA) is the leading global provider of science, technology, and regulatory information.
- The PDA creates awareness and understanding of important issues facing the pharmaceutical and biopharmaceutical community and delivers high-quality, relevant education to the industry.
- 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*

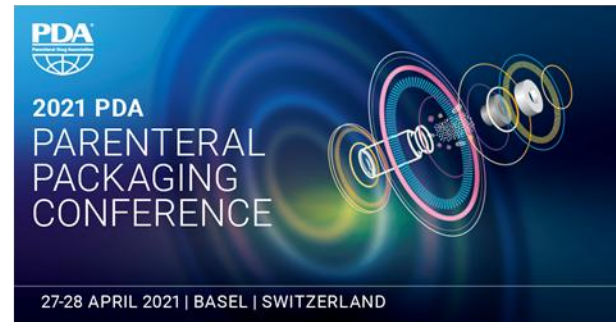


Key Actions by PDA

- **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

- 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

- 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)



PDA Contact Info:

Global HQ

PDA Member Relations

4350 East West Hwy. Suite 600, Bethesda, MD 20814 USA

info@pda.org or +1-301-656-5900

PDA Asia Pacific

20 Bendemeer Rd, #04-02 BS Bendemeer Centre Singapore 339914

Tel: +65 64965504

PDA Europe

Am Borsigturm 60

13507 - Berlin, Germany

Tel: +49 30 436 55 08-0 or -10