

PDA Aseptic Processing of Biopharmaceuticals Conference 2024



PDA Aseptic Processing of Biopharmaceuticals Conference 2024

CONNECTING
PEOPLE
SCIENCE^{AND}
REGULATION[®]

Scientific Program Committee



Hue Kwon
Chair



Emily Cheah
Member



Ivy Louis
Member



Javier Camposano
Member



Seung Hwan Oh
Member



Gabriele Peron
Member



Paolo Golfetto
Member

PDA APAC Team



Tony Chan



Cizlie Sunto



Sharon Mascarinas

Member-Led...Mission-Driven

PDA is a Global Community

We connect the international pharmaceutical industry to catalyze collaboration, deep discussions, impactful solutions, and dynamic leadership.



**International
Membership**



**25 Global
Chapters**



**Volunteer
Opportunities**



**Interest
Groups**



**Technical
Advisory Boards**

Introducing the New Interest Group in 2024: Drug Compounding



Volunteer Progression – From the Ground Up

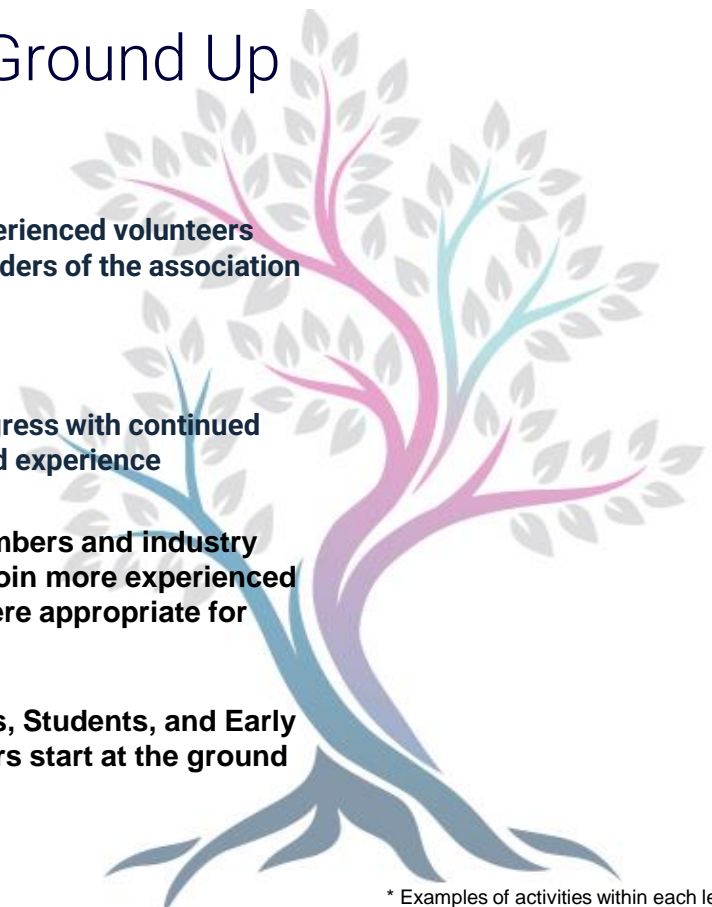


Long-term, experienced volunteers develop into leaders of the association

Volunteers progress with continued involvement and experience

Long-term members and industry veterans may join more experienced volunteers where appropriate for their skill level

New volunteers, Students, and Early Career members start at the ground level



* Examples of activities within each level

PDA Connect

CONNECT WITH EXPERTS,
SHARE IDEAS, EXPAND YOUR
KNOWLEDGE

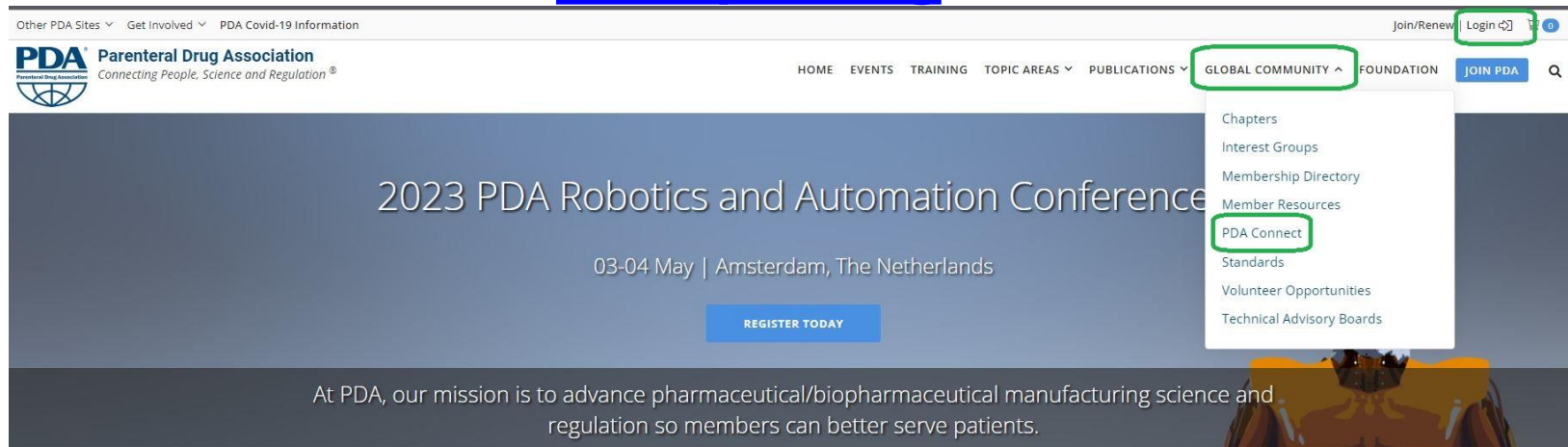
TAKE PART IN THE
CONVERSATIONS VIA
PDA CONNECT®



PDA Connect: A Forum for PDA Members

Continue the discussion. Join PDA Connect!

www.pda.org



<https://www.pda.org/pda-connect/portal/quick-start-video>

How to Post a discussion



Select Announce
“In the category” this
action will add it to
the IG discussion
thread.

The screenshot shows the 'New Discussion' form with several red annotations:

- A red circle highlights the 'Recent Discussions' button at the top left.
- A red circle highlights the 'My Discussions' button at the top center.
- A red circle highlights the 'New Discussions' dropdown menu at the top right.
- A red circle highlights the 'Select an IG' dropdown menu under 'Category (Interest Group)'. A red arrow points from this circle to the 'In the category' radio button below.
- A red circle highlights the 'Add Title or Discussion Topic' text box under 'Discussion Title'.
- A red circle highlights the 'Add your question or topic of discussion.' text area.
- A red circle highlights the 'Post Discussion' button at the bottom right.

Recent Discussions My Discussions New Discussions ▾

HOME · NEW DISCUSSION

New Discussion

Category (Interest Group)
Select a category... **Select an IG**

Discussion Title
Add Title or Discussion Topic

Type your message
Add your question or topic of discussion.

Select Announce “In the category” this action will add the topic/question to the discussion thread.

Announce Don't announce In the category In the category and recent discussions.

Topic Area(s): Select one or more Topic Areas to continue

Aseptic Processing and Sterilization Biopharmaceuticals and Biotechnology Device/Combination Products
Manufacturing Science Outsourcing Quality and Regulatory Supply Chain

Cancel Save Draft **Post Discussion**

Influence...Foresight

PDA is committed to scientifically sound, practical applications of technical insights and information.

P U B L I C A T I O N S



- ⌘ Technical Reports
- ⌘ Points to Consider
- ⌘ ANSI/PDA Standards
- ⌘ PDA Journal of Pharmaceutical Science and Technology
- ⌘ PDA Letter
- ⌘ PDA Books
- ⌘ Surveys

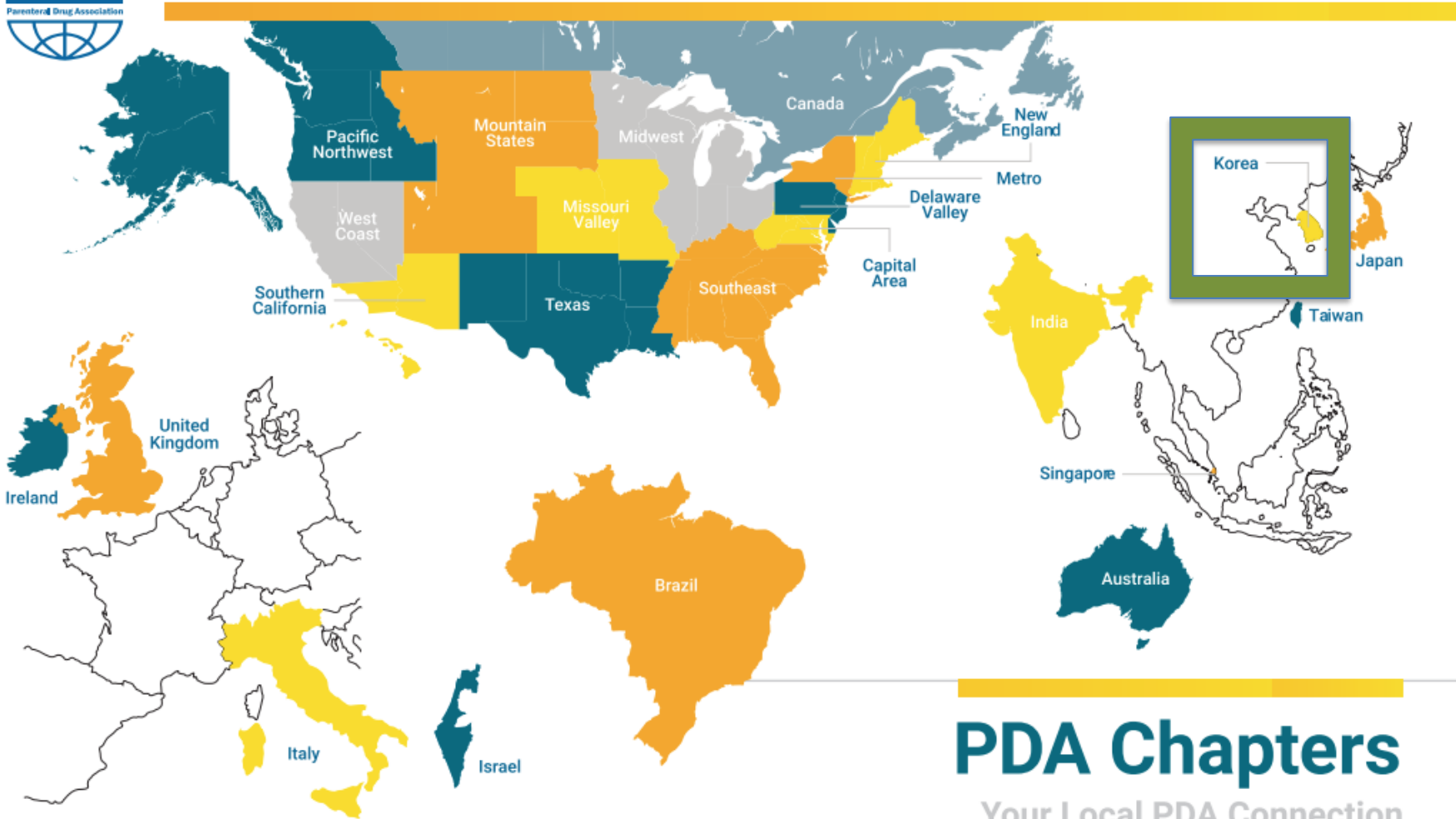
PDA Technical Reports (TRs)

- [Technical Report No. 68 \(Revised 2024\): Risk-Based Approach for Prevention and Management of Drug Shortages](#)
- [Technical Report No. 73-2: Application of Medical Device Regulation Annex 1 Requirements for Staked Needle Syringes](#)
- [Technical Report No. 91 Post-Approval Change Management](#)
- [Technical Report No. 43 \(Revised 2023\): Identification and Classification of Nonconformities in Moulded and Tubular Glass Containers for Pharmaceutical Manufacturing](#)
- [Technical Report No. 90: Contamination Control Strategy Development](#)
- [Technical Report No. 89: Strategies for Vaccine Development](#)
- [Technical Report No. 41 Revised 2022 \(TR 41\): Virus Filtration](#)
- [PDA Technical Report No.65 Revised 2022 \(TR 65\) Technology Transfer](#)
- [PDA Technical Report No. 13 Revised 2022 \(TR 13\) Fundamentals of an Environmental Monitoring Program](#)
- [PDA Technical Report No. 88 \(TR 88\) Microbial Data Deviation Investigations in the Pharmaceutical Industry](#)



TR Periodic Review Volunteer Opportunity

- **TR 12** Siliconization of Parenteral Drug Packaging Components
- **TR 28** Process Simulation Testing for Sterile Bulk Pharmaceutical Chemicals
- **TR 34** Design and Validation of Isolator Systems for the Manufacturing and Testing of Health Care Products
- **TR 45** Filtration of Liquids Using Cellulose-Based Depth Filters
- **TR 48** Moist Heat Sterilizer Systems: Design, Commissioning, Operation, Qualification and Maintenance
- **TR 50** Alternative Methods of Mycoplasma testing
- **TR 51** Biological Indicators for Gas and Vapor-Phase Decontamination Processes: Specification, Manufacture, Control and Use.
- **TR 53** Guidance for Industry: Stability Testing to support Distribution of New Drug Products.
- **TR 59** Utilization of Statistical Methods for Production Monitoring
- **TR 60-2** Process Validation: A Lifecycle Approach Annex 1: Oral Solid Dosage/Semisolid Dosage Forms
- **TR 61** Steam In Place
- **TR 76** Identification and Classification of Visible Nonconformities in Elastomeric Components and Aluminum Seals for Parenteral Packaging
- **TR 63** Quality Requirements for the Extemporaneous Preparation of Clinical Trial
- **TR 81** Cell-Based Therapy Control Strategy
- **TR 82** Low Endotoxin Recovery
- **PtC** Points to Consider for Aging Facilities



PDA Chapters

Your Local PDA Connection

PDA Korea Chapter Election Announcement

- **We are looking for Chapter Officers for 2025-2026:**
 - ❖ President-Elect
 - ❖ Secretary
 - ❖ Treasurer
 - ❖ Members-at-Large
- **Elections** will be held in **Nov/Dec**, and new officers will start in **January 2025**

Education...Innovation...Impact

PDA Offers Specialized Training with Cutting-Edge Solutions

- ⌘ Hands-on Training at PDA Training and Research Institute (TRI)
- ⌘ Customized Onsite Training
- ⌘ Interactive Virtual Training

TOPIC AREAS

- Aseptic Processing
- Biopharmaceuticals
- Cleaning
- Compounding
- Environmental Monitoring
- Facilities
- Filtration
- Human Factors
- Lyophilization
- Parenteral Packaging
- Quality and Compliance
- Quality Risk Management
- Sterilization
- Visual Inspection