

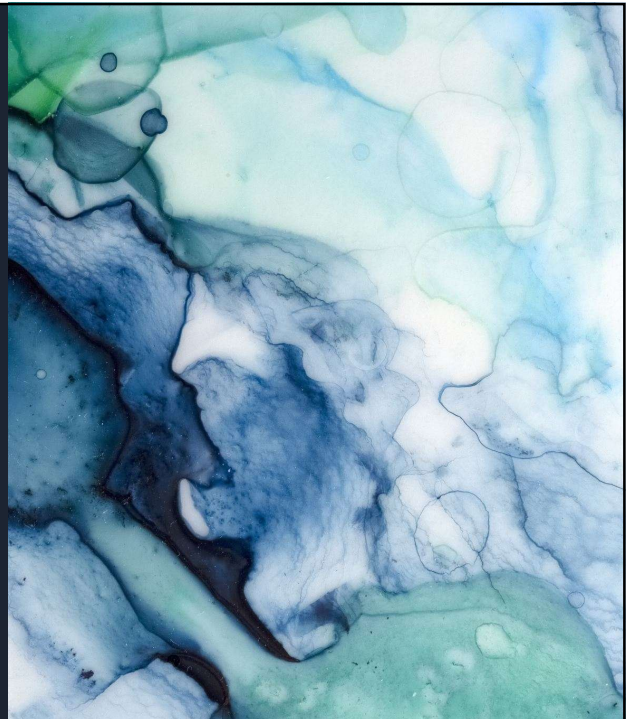
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# *PDA CAPITAL AREA CHAPTER*

## *Q3 MEETING*

*01 OCTOBER 2024*

*BETHESDA, MD*



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## *MEETING OVERVIEW*

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- Meeting Overview
- Welcome and Board Introduction
- PDA Overview
- Speaker Tom Hanney -- New Approaches to Annex 1 C&D Compliance
- Speaker Dr. Djikolngar (Djik) Maouyo -- Heterogeneity of Lipopolysaccharides: Redefining Endotoxins Based on Pyrogenicity
- Chapter Activities
- Networking Reception Immediately Following



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*SPECIAL THANKS  
TO OUR CHAPTER  
PREMIER  
SPONSOR*

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*ADDITIONAL THANKS TO OUR EVENT SPONSOR*

**BENCHMARK**  
PRODUCTS

**BENCHMARK**  
Bioprocessing Solutions

Innovative **solutions** for Life Sciences'  
critical manufacturing environments

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# MEET THE CHAPTER BOARD MEMBERS

## President

- Martin S. Jenkins, Sr. Consultant / Qualifications and Project Management, Circle MJ Consulting, LLC

## Treasurer

- Sapan Patel, Associate Director - Quality Assurance, AstraZeneca

## Assistant Treasurer

- Krystian Gonzalez-Vasquez, CQV Engineer II, Integrated Project Services, LLC

## Secretary

- Julie Barnhill, Senior Consultant, Pace Labs

## Board Members at Large and Committee Chairs

- Krystian Gonzalez-Vasquez, CQV Engineer II, Integrated Project Services, LLC
- Dina El-Emary, Site Quality Head, Sanofi
- Ben Bhattarai, Medical Assistant/Coordinator at Bowie Town Behavioral Services
- Stephanie Brandford, Validation Consultant, Brayearst Validation Consulting
- Janie Miller, Director, Director Quality & Compliance, External Affairs, Amgen – Capital Area Chapter Membership Chairperson

## Past-President and Chapter Advisor

- Tita Tavares, Chief of Staff, PDA

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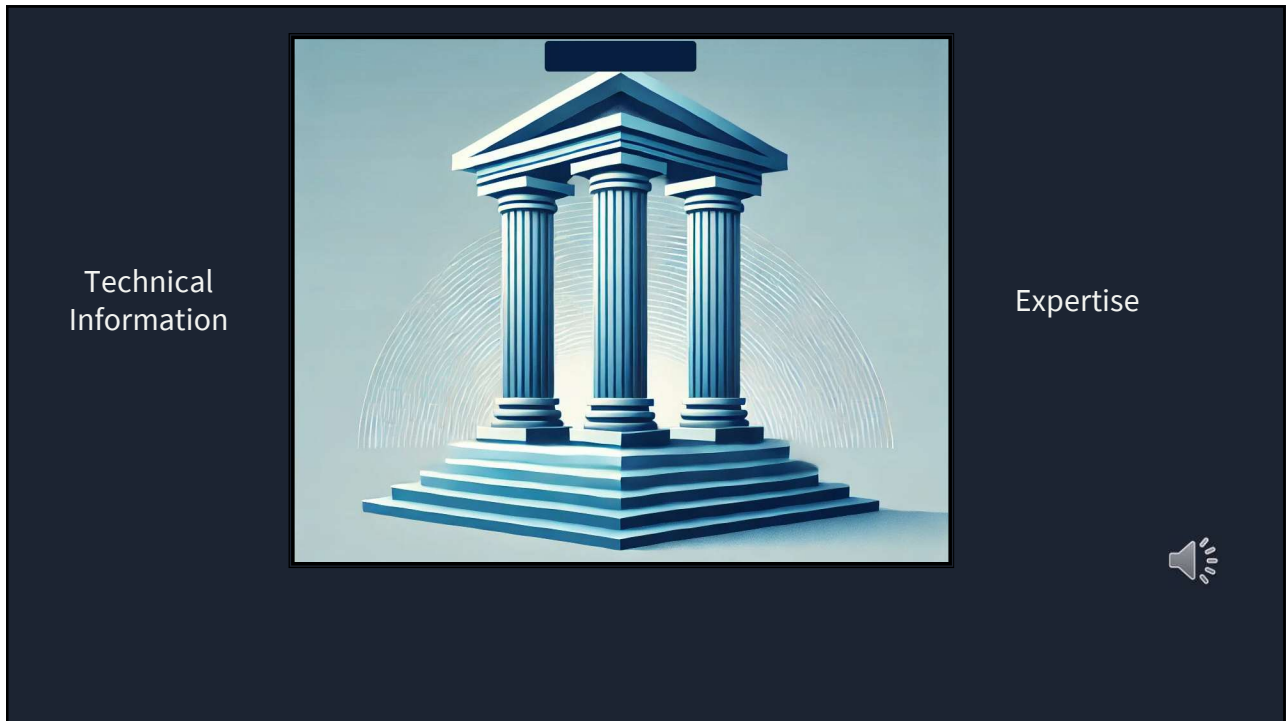
# PARENTERAL DRUG ASSOCIATION (PDA) OVERVIEW



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Technology

**PDA MISSION**



Pharmaceutical  
&  
Biopharmaceutical




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Collaboration &  
Innovation

**PDA MISSION**

**PDA VISION**



Highest Standards



10

Organization



Strategies



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*JOIN PDA TODAY!*

Quality



Safety



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# ESSENTIAL MEMBERSHIP BENEFITS

Membership Directory

Vote in PDA elections and on proposed bylaws changes

PDA Letter Online

PDA Connect

PDA Volunteer Opportunities

Members-Only Discounts

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# DIRECTORY

Search

Home / Directories / Search

Member Directory Search

Firstname:

Lastname:

Company:

State:

City:

Country:

Member	Company	City
	FDA	New Market, United States
	CDER, FDA	Silver Spring, United States
	PDA	Bethesda, United States
	NIIMBL	Gaithersburg, United States
	FDA	Berwyn Heights, United States
	USP	Rockville, United States
	NIAID/NIH	Poolesville, United States

Name: **PDA Admin**

Company:

Title:

Address: 4350 East West Hwy  
Bethesda, MD 20814-4410  
United States

Email: info@pda.org

Phone: 1 301 6565900 x

Fax:

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# VOTING

## Parenteral Drug Association

Welcome to PDA's online e-Ballot voting system for the 2025 Board of Directors Election. The elected candidates will fill their terms commencing on January 1, 2025.

To ensure you make the most informed decision, be sure to read the biographies and personal statements of each candidate. All the nominees have the expertise, experience, and capability to make a significant contribution as a member of PDA's governing body, but it is up to you to decide.

All votes are anonymous and e-Ballots have been numerically coded with your member ID to ensure authenticity. The system will only allow one vote per member.

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# DISCOUNTS – IN-PERSON LEARNING

## Validation of Moist Heat Sterilization Processes Training Course

Standard Registration	
Member Price	
<b>\$3,499</b>	
<b>Government</b> Member Only	<b>Health Authority</b> Member Only
\$2,449	\$2,449
<b>Academic</b> Member Only	<b>Non-Member</b>
\$2,449	\$4,199

## Essentials of Contamination Control Strategy Workshop

Standard Registration	
Member Price	
<b>\$999</b>	
<b>Government</b> Member Only	<b>Health Authority</b> Member Only
\$699	\$699
<b>Academic</b> Member Only	<b>Non-Member</b>
\$699	\$1,199

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# DISCOUNTS – PUBLICATIONS



**Technical Report No. 46 (Revised 2024) Last Mile: Guidance for Good Distribution Practices for Pharmaceutical Products to End Users**

PDF Single User

Member price: \$180.00  
Nonmember price: \$325.00



**ANSI/PDA Standard 02-2021: Cryopreservation of Cells for Use in Cell Therapies, Gene Therapies, and Regenerative Medicine Manufacturing (single user digital version)**

PDF Single user

Member price: \$180.00  
Nonmember price: \$325.00



**Global Sterile Manufacturing Regulatory Guidance Comparison & Assessment Tool, Second Edition**

PDF Single User

Member price: \$315.00  
Nonmember price: \$350.00

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## PLUS MEMBERSHIP BENEFITS

### Essential membership benefits

### PDA Technical Publications Portal

- View and annotate the full collection of TECHNICAL REPORTS online
- Recent titles include
  - Last Mile: Guidance for Good Distribution Practices for Pharmaceutical Products to End Users [TR 46]
  - Application of Medical Device Regulation Annex I Requirements for Staked Needle Syringes [TR 73-2]
  - Risk-Based Approach for Prevention and Management of Drug Shortages [TR 68]

### PDA Journal of Pharmaceutical Science and Technology

- Limited Access

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# PREMIUM MEMBERSHIP BENEFITS

## Essential and Plus membership benefits

### PDA Technical Publications Download

- New Technical Reports / Surveys / Points to Consider for free within 30 days
- ONE (1) free of your choice from the existing library per year

### PDA Journal of Pharmaceutical Science and Technology

- Unlimited Access

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## MEMBER TYPES AND TIERS

- Visit [pda.org/membership](http://pda.org/membership) for more information or to sign up
- Use the following code during checkout for a 20% discount  
chapter20

	Essential	Plus	Premium
Standard Member	\$150	\$250	\$350
Academic, Early Career, and Emerging Economy	\$75	\$125	\$245
Health Authority, Students, Retired	Free	Free	\$175
Membership Directory	X	X	X
Vote in PDA elections and on proposed bylaws changes	X	X	X
PDA Letter Online	X	X	X
PDA Connect	X	X	X
PDA Volunteer Opportunities	X	X	X
Members-Only Discounts	X	X	X
PDA Technical Publications Portal - view and annotate the full collection of TRs and PtCs online.		X	X
PDA Journal - Limited Access		X	X
Download new TRs/Surveys/PtC for free within 30 days			X
PDA Technical Reports - 1 free download of your choice from the existing TR/Survey/PtC library per year.			X
PDA Journal - Unlimited Access			X

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## NEW APPROACHES TO ANNEX 1 C&D COMPLIANCE



Tom Hanney, Director of Business Development, Benchmark Products

- >25 years of experience providing Products used in GMP Production areas.
- Focus on problem-solving to meet continuous changes in methods of manufacturing.
- Understanding of Regulatory requirements, combined with a practical understanding of needs, has led to the development of many product innovations in use today.
- Benchmark Products 2006-present
- Temple University Fox School of Business Graduate

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## HETEROGENEITY OF LIPOPOLYSACCHARIDES: REDEFINING ENDOTOXINS BASED ON PYROGENICITY



[Djikolngar Maouyo, Ph.D., Managing Director and President, PyroDex LLC](#)

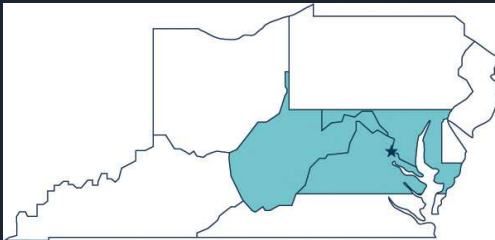
Before founding PyroDex LLC in February 2017, Dr. Maouyo was a Senior Scientist at Lonza Bioscience in Walkersville, MD, for more than 9 years, leading R&D teams focused on rapid microbial detection (including universal bacterial and fungal, mycoplasma, and endotoxin detection) based on Limulus amoebocyte lysates and the recombinant Factor C. Dr. Maouyo previously held faculty positions at the University of Maryland School of Medicine and Johns Hopkins University as well as postdoctoral fellowships at Johns Hopkins and the University of Montreal. His Ph.D. in biology (concentration in integrative animal physiology) is from the University of Sherbrooke in Quebec. In 2019, Dr. Maouyo joined the European Task Force on the Monocyte Activation Test (M.A.T). A leading expert on monocyte activation testing, he often consults on alternative (non-animal) test methods.

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# CHAPTER METRICS



- Region
  - Washington, D.C.
  - Maryland
  - Northern Virginia
  - West Virginia
- Membership
  - Total member count in region
    - Approx. 525
  - Active member count
    - Approx. 50
  - Target for member reclamation and reactivation
    - 10%

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# UPCOMING EVENTS CALENDAR

Date	Type	Location	Topic / Theme
October 15	2025 Chapter Planning	In Person / Virtual	Chapter Planning Meeting – Open to New and Existing Members
October 29	Networking & Membership	In Person	PDA Chapter Social On Location Trivia Night!
December 10	Networking & Technical	In Person / Virtual	Q4 Chapter & Membership Quarterly Meeting - Technical Presentation and Member Networking

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**PDA CAPITAL AREA CHAPTER**

**PDA**  
Professional Development Association

**2025 CHAPTER PLANNING**

**INCLUDING NEW MEMBERS INFORMATIONAL SESSION**  
Discover our vision for the future and how you can get involved! Join us for an engaging session where we'll outline our goals for 2025 and welcome new members. Whether you're looking to make a difference or simply learn more about our chapter, this is the perfect opportunity!

**TUESDAY, OCT 15, 2024**  
5:00 - 6:00 PM - Bethesda, MD

**AGENDA**

- Chapter Plan for 2025 Goals
- New Member Information
- Network

SCAN QR Code to fill out Member Interest Form

REGISTER NOW

# 2025 CHAPTER PLANNING MEETING

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# COMMENTS & QUESTIONS



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# THANK YOU!

→ We appreciate your time and attention;  
please complete our survey

