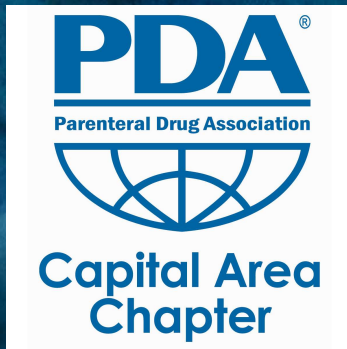


PDA CAPITAL AREA CHAPTER



Q2 QUARTERLY MEETING

17 JUNE 2025

FREDERICK, MARYLAND



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- Meeting Overview
- Welcome, Thanks, and Board Introduction
- PDA Overview
- Jaspreet Seth, Ph.D., "Building Quality by Design (QbD) into Early-Phase Development"
- Fehmida Kapadia, Ph.D., "Get Ready to Pitch! Crafting Your Startup Investment Pitch"
- Chapter Activities
- Networking Reception Immediately Following

Meeting Overview



2

Special Thanks to Our Event Sponsors



3

Special Thanks to Our Event Sponsors



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



4

Additional Thanks

HOST PARTNER



FOOD AND BEVERAGE SPONSOR

VALSOURCE



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Meet the Chapter Board Members

President

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

President-Elect

- Krystian Gonzalez-Vasquez, CQV Engineer II, Integrated Project Services, LLC -- *Programs & Events Committee Chair*

Treasurer

- Ben Bhattarai, Medical Assistant/Coordinator at Bowie Town Behavioral Services -- *Finance and Budgeting Committee Chair*

Secretary

- Stephanie Brandford, CAGES® Framework Steward, Brayearst Validation Consulting -- *Social Media / Communications Committee Chair*

Board Members at Large and Committee Chairs

- Julie Barnhill, Senior Consultant, Pace Life Sciences -- *Global Pharmaceutical Student Network & Early Career Professionals Committee Chair*
- Dina El-Emary, Site Quality Head, Sanofi
- Ezekiel Kelly, Vice President of Engagement and Growth, Frederick Innovative Technology Center, Inc. (FITCI) -- *Chapter Sponsorship Committee Chair*
- Janie Miller, Director, Quality Strategy & Business Ops External Affairs, Baxter International Inc. -- *Chapter Membership Committee Chair*
- Sapan Patel, Associate Director - Quality Assurance, AstraZeneca

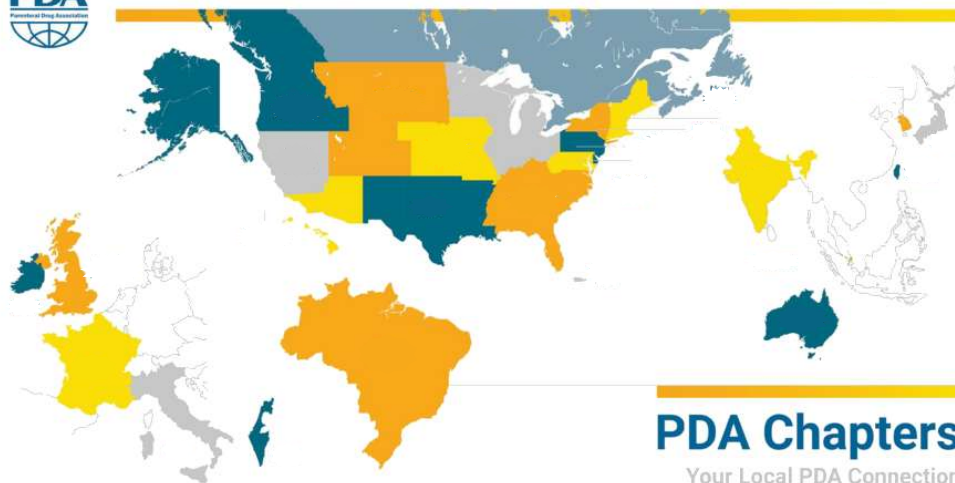


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PARENTERAL DRUG ASSOCIATION (PDA) OVERVIEW



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PDA Chapters
Your Local PDA Connection



8

Technical
Information



Expertise



9

Technology



Pharmaceutical
&
Biopharmaceutical



10

Collaboration & Innovation



PDA MISSION


PDA VISION

PDA
Capital Area Chapter

Highest Standards

11

Organization



PDA MISSION

PDA VISION

PEOPLE SCIENCE REGULATION

PDA
Capital Area Chapter

Strategies

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JOIN PDA TODAY!

Quality



Safety



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Membership Benefits – Publications Review



PDA Letter Online

Provided to all members:
Essential, Plus, and Premium



PDA Journal

View access to current and
prior year for Plus members
Download access to current
and full archive for Premium
members



PDA Technical Reports and Points to Consider

View access for Plus members
Download access within 30
days of release for Premium
members
Download access for one (1)
selected item per year for
Premium members



PDA Bookstore

Purchase availability for
standards, books, and other
publications



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Membership Benefits – Volunteering

Ways You Can Contribute

- Technical Committees & Expert Panels – Develop standards, reports, and regulatory guidance.
- Conference & Workshop Planning – Design cutting-edge educational programs.
- Advisory Boards – Provide strategic guidance on key PDA initiatives.
- Leadership Roles – Serve as Interest Group Leaders, Chapter Officers, or on the PDA Board.
- Specialized Workgroups – Tackle emerging industry challenges.
- Editorial Roles – Write or review for PDA Letter and the PDA Journal.



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Membership Benefits – Volunteering (cont'd)

Current Opportunities

- QRM Task Force (TR 54) – Task Force – Apply by June 30, 2025
- Author for PDA Letter – Writing – Apply by Dec 31, 2025
- Be a Quality Champion – Leadership, Mentoring – Apply by Dec 31, 2025
- Tech Document Reviewer – Document Review (Virtual) – Apply by Dec 31, 2025
- Submit to PDA Journal – Writing – Ongoing
- Peer Reviewer – PDA Journal – Writing (Virtual) – Apply by Dec 31, 2025



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ATMP AB (Advanced Therapies)

Focus: Cell, gene, tissue therapies
Topics: Manufacturing science, quality systems, comparability, analytics, supply chain

BioAB (Biopharmaceuticals)

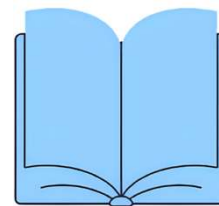
Focus: Biotech manufacturing & quality
Topics: Materials, upstream/downstream, biologics QC, emerging technologies

RAQAB (Regulatory & Quality)

Focus: Regulatory lifecycle, advocacy
Topics: Harmonization, guidance, data integrity, QRM, metrics, culture

SAB (Science AB)

Focus: Pharma manufacturing & testing
Topics: Aseptic processing, packaging, analytics, data science



Volunteering – Join a PDA Technical Advisory Board

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Membership Benefits - Connect Through PDA Interest Groups



Ways to Participate

- Join IG LinkedIn pages to meet peers and experts
- Attend virtual meetings (PDA members only)
- Join in-person meetings at PDA conferences
- Sign up online to get IG updates and invites

Interest Group Topics

- Biopharmaceuticals: Vaccines, ATMP, Digitalization
- Regulatory & Quality: QRM, GMP, Data Integrity
- Manufacturing Science: Annex 1, Sterile, Water Systems
- Industry Membership: Early Career Professionals



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MEMBER TYPES AND TIERS

Visit 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	\$155	\$260	\$360
Academic, Early Career, and Emerging Economy	\$78	\$130	\$250
Health Authority, Retired	Free	Free	\$180
Students	Free	Free	Free
Membership Directory	X	X	X
Vote in PDA elections and on proposed bylaws changes	X	X	X
PDA Letter Online	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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TECHNICAL TOPICS



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BUILDING QUALITY BY DESIGN (QBD) INTO EARLY-PHASE DEVELOPMENT



Jaspreet Seth, Ph.D.
President/COO, QuRA Solutions



Jaspreet Seth, Ph.D., is a seasoned expert in Quality and Regulatory Affairs, with over 20 years of leadership across the Life Sciences and Medical Device industries. Her deep experience spans ISO 13485 and cGMP compliance, with a strong focus on In Vitro Diagnostics (IVDs), Research Use Only (RUO) products, Laboratory Developed Tests (LDTs), breakthrough devices, and 510(k) submissions. She also brings extensive expertise in clinical compliance, ensuring alignment with ethical standards and regulatory requirements across human subject research and clinical testing environments.

Jaspreet has held key roles at global leaders like QIAGEN, innovative molecular diagnostics firms such as Molecular Designs, and nonprofit research institutions including the Henry M. Jackson Foundation. Her cross-sector experience spans biotech, MedTech, and pharmaceutical environments, allowing her to navigate complex regulatory frameworks, such as 21 CFR 820, 210/211, 45 CFR 46, and 32 CFR 219, alongside ISO, ICH, and USP standards.

An expert in Quality Systems Regulations, Clinical Research Compliance, and CAP accreditation, Jaspreet brings a practical, results-driven approach to implementing and managing Quality Management Systems (QMS). She has led QMS oversight across biotech, MedTech, and pharmaceutical organizations, ensuring continuous audit readiness and regulatory alignment. Her leadership has resulted in multiple successful inspections, including FDA, CAP, GCLP, and ISO audits, with zero observations or findings. Jaspreet is also highly experienced in addressing FDA 483s through thorough root cause analysis, effective CAPAs, and comprehensive SOP revisions.

As a dynamic presenter and strategic advisor, Jaspreet translates regulatory complexity into actionable insights that drive organizational excellence



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GET READY TO PITCH! CRAFTING YOUR STARTUP INVESTMENT PITCH



Fehmda Kapadia, Ph.D.
*Founder & President,
Kapamed Consulting / Amplify MedTech*



KAPAMED CONSULTING
Innovate | Build | Market

Fehmda Kapadia, PhD is a highly accomplished professional renowned for her expertise in entrepreneurship, business strategy, and innovation. As the Founder and President of Kapamed Consulting and Amplify MedTech, Fehmda provides invaluable support and coaching to inventors, founders, and startups on the intricacies of technology commercialization. With a robust technical background and expertise in commercialization, Fehmda offers profound product and business insights; and strategic guidance to empower startups to build and scale.

Over the last 20 years, Fehmda has worked with over a hundred entrepreneurial projects, facilitating their successful progression in their startup journey. Her versatile roles as an entrepreneur-in-residence, consultant, project manager, mentor, and educator underscore her multifaceted contributions to the entrepreneurial ecosystem. Through her adeptness in marketing, strategy formulation, and product development, as well as her extensive experience and leadership roles, Fehmda is widely recognized as a trusted expert in business and entrepreneurship.

Fehmda is passionate about training and supporting the next generation of entrepreneurs. She has taught technology entrepreneurship at Case Western Reserve University and was awarded a Fulbright scholarship to teach entrepreneurship in health sciences in Brazil. Fehmda further extends her mentorship to startup companies through her affiliations with the Maryland Tech Council and Johns Hopkins Technology Ventures. As the Executive Women in Bio Vice Co-Chair for the Capital Chapter of Women in Bio, she is actively helping to create a supportive environment for women in the life sciences arena.

With a PhD in Biochemistry from The Ohio State University and a master's in Biotechnology Entrepreneurship from Case Western Reserve University, Fehmda Kapadia brings a wealth of knowledge to her work. Her specialty areas encompass strategy formulation, value proposition development, fundraising, strategic partnerships, team building, and biomedical product development, including regulatory and reimbursement strategy. As a leader and mentor, Fehmda continues to make indelible contributions to the entrepreneurial landscape, empowering startups to thrive and succeed in a dynamic business environment.



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Chapter Priorities

01 Prioritize Early Career Professionals and Students Active Participation in Chapter Events.	02 Increase active Chapter Member Participation.	03 Prioritize Planning Events and Activity (Social, Technical, Membership Meetings)	04 Develop Support Structure and Backups for Chapter Leaders	05 Fulfill Chapter Council Requirements – Reporting, and Activity	06 <u>Enjoy Ourselves</u> While Continuing to Deliver Great Service.
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Committees – Newcomers Welcome!

Programs & Events - contribute to impactful events that inform members, foster community, and strengthen chapter success

Social Media / Communications - drive engagement by keeping members informed, connected, and aligned with chapter activities and updates

Chapter Sponsorship - secure vital support that enables events, enhances member experiences, and sustains chapter growth

Chapter Membership - strengthen the community by welcoming new members and fostering lasting connections within the chapter

Finance and Budgeting - ensure financial health to support chapter initiatives, events, and long-term sustainability

Early Career Professionals (ECP) / Global Pharmaceutical Student (GPS) Network - cultivate future leaders by engaging students and early-career professionals in meaningful chapter opportunities



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Sponsorship Tiers Available

BENEFIT	PREMIER (\$7,000)	PLATINUM (\$5,000)	GOLD (\$3,000)	EVENT SPONSOR (\$1,000)
Complimentary Tickets for regular Chapter Events.	10 per event	8 per event	6 per event	5 for sponsored event
Promotional Table at Events	Flagship event 4 quarterly meetings 2 selected social/technical	3 quarterly meetings 2 selected social/technical	2 quarterly meetings 1 selected social/technical	Sponsored event only
Company Name on PDA Capital Area Webpage	Premier Sponsor	Platinum Sponsor	Gold Sponsor	N/A
Entertainment/Amenity Sponsorships and Complimentary Tickets at Flagship Event	Included at No Additional Cost	Optional Add-On (\$2,500)	Optional Add-On (\$3,000)	Optional Add-On (\$3,500)



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Planned Events

DATE	TYPE	LOCATION	TOPIC/THEME
June 23-26 Day - TBD	Social Event	In-Person	TBD - PDA Chapter Social On Location Trivia Night!
July 2025 Day - TBD	Social Event	In-Person	TBD - Trivia Night or Social Networking Event
August 9 (16 th Rain out Date)	Networking & Membership	In Person	PDA Chapter Social On Location: "PDA 5K Walk – Stride Against Cancer" (D.C. Tidal Basin 5K Walk)
September 07 16:00 – 17:30	Technical Discussion	In Person / Washington, D.C.	Capital Area Chapter Hosts Roundtable Discussion – FDA Complete Response Letters: A Growing Industry Challenge with Big Impacts
September 9	Signature Event	In Person / Washington, D.C.	Networking Reception Event – Tuesday evening during PDA/FDA Regulatory Conference)
October 7	Networking & Technical	In Person / Virtual	Q3 Chapter & Membership Quarterly Meeting - Technical Presentation Students and Members Networking
October 21	2025 Chapter Planning	In Person / Virtual	Capital Area Chapter 2026 Planning Meeting – Open to New and Existing Members
November 13	Networking & Membership	In Person	PDA Chapter Social On Location Trivia Night!
December 2	Networking & Technical	In Person / Virtual	Q4 Chapter & Membership Quarterly Meeting - Technical Presentation and Member Networking



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Upcoming Partner Event

A WORKSHOP FOR SCIENTISTS

FROM SCIENCE TO STARTUP: THE ENTREPRENEURIAL JOURNEY.

June 26-27, 2025 | Earn 2.0 CEUs

This **two-day workshop** equips you with entrepreneurship skills to leverage your background in bioscience and biotechnology.

Identify funding opportunities, create a business plan and commercialize your research. Featuring guest speakers, case studies and hands-on exercises, you will learn to translate scientific discoveries into viable business ventures and earn a digital badge credential.

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Thank You!

We appreciate your time and attention;
please complete our survey



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