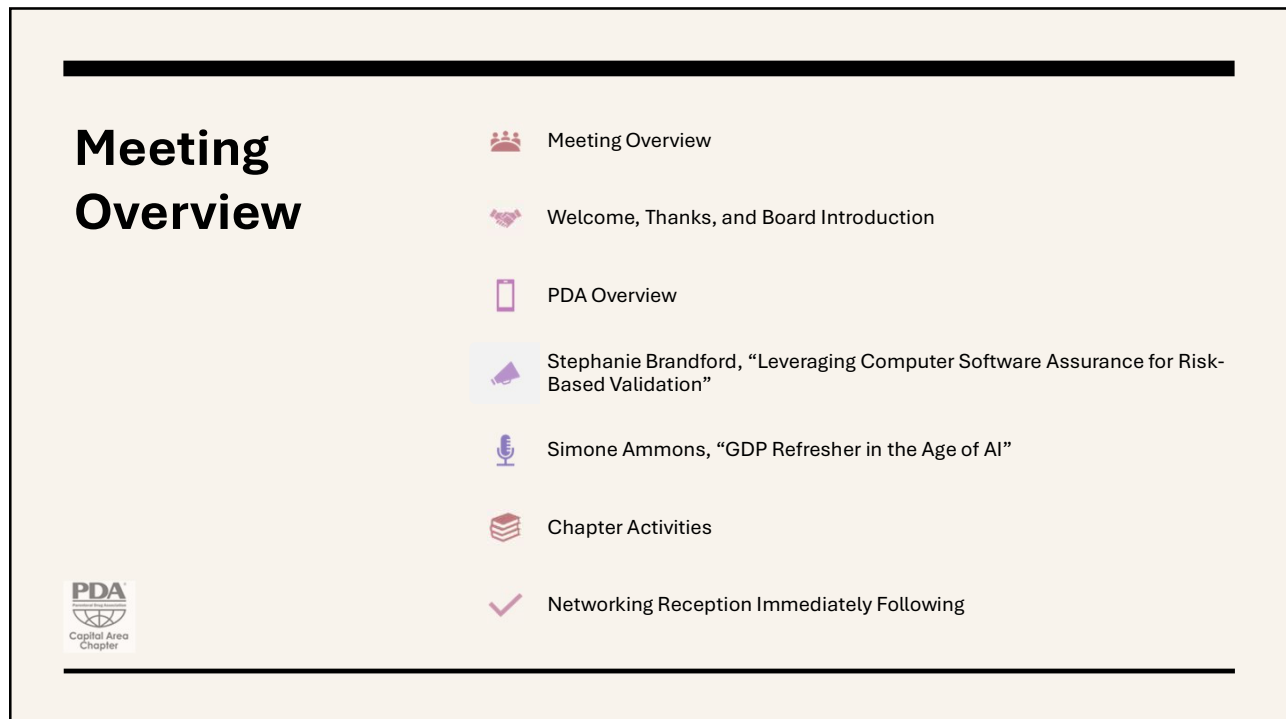


The slide features a background with a soft, abstract blend of purple, pink, and blue. On the left, the PDA Capital Area Chapter logo is displayed in a white box. The logo includes the text 'PDA' in large blue letters, 'Parenteral Drug Association' in smaller blue text, a blue stylized dome icon, and 'Capital Area Chapter' in blue text. To the right of the logo, the text 'PDA CAPITAL AREA CHAPTER' is written in large, bold, white capital letters. Below this, the meeting details are listed in a smaller, white, sans-serif font: 'Q1 QUARTERLY MEETING', '22 APRIL 2025', and 'BETHESDA, MARYLAND'. A small speaker icon is located in the bottom right corner of the slide.

**PDA CAPITAL
AREA
CHAPTER**

Q1 QUARTERLY MEETING
22 APRIL 2025
BETHESDA, MARYLAND

1



The slide has a light beige background with a thick black horizontal line at the top. On the left, the title 'Meeting Overview' is written in a large, bold, black sans-serif font. To the right of the title is a list of seven items, each preceded by a small icon. The items are: 'Meeting Overview' (people icon), 'Welcome, Thanks, and Board Introduction' (handshake icon), 'PDA Overview' (phone icon), 'Stephanie Brandford, "Leveraging Computer Software Assurance for Risk-Based Validation"' (megaphone icon), 'Simone Ammons, "GDP Refresher in the Age of AI"' (microphone icon), 'Chapter Activities' (stack of books icon), and 'Networking Reception Immediately Following' (checkmark icon). In the bottom left corner, there is a small PDA Capital Area Chapter logo. A thick black horizontal line is at the bottom of the slide.

Meeting Overview

- Meeting Overview
- Welcome, Thanks, and Board Introduction
- PDA Overview
- Stephanie Brandford, "Leveraging Computer Software Assurance for Risk-Based Validation"
- Simone Ammons, "GDP Refresher in the Age of AI"
- Chapter Activities
- Networking Reception Immediately Following

2

**Special
Thanks to
Our Event
Sponsor**

VALSOURCE

Innovative Solutions. Sustainable Results.



3

**Additional
Thanks to
Our Event
Contributor**

Lilit Café
GOURMET FOOD & FINE WINE



4

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, Validation Consultant, Brayerst Validation Consulting - *Social Media / Communications Committee Chair*

Board Members at Large and Committee Chairs

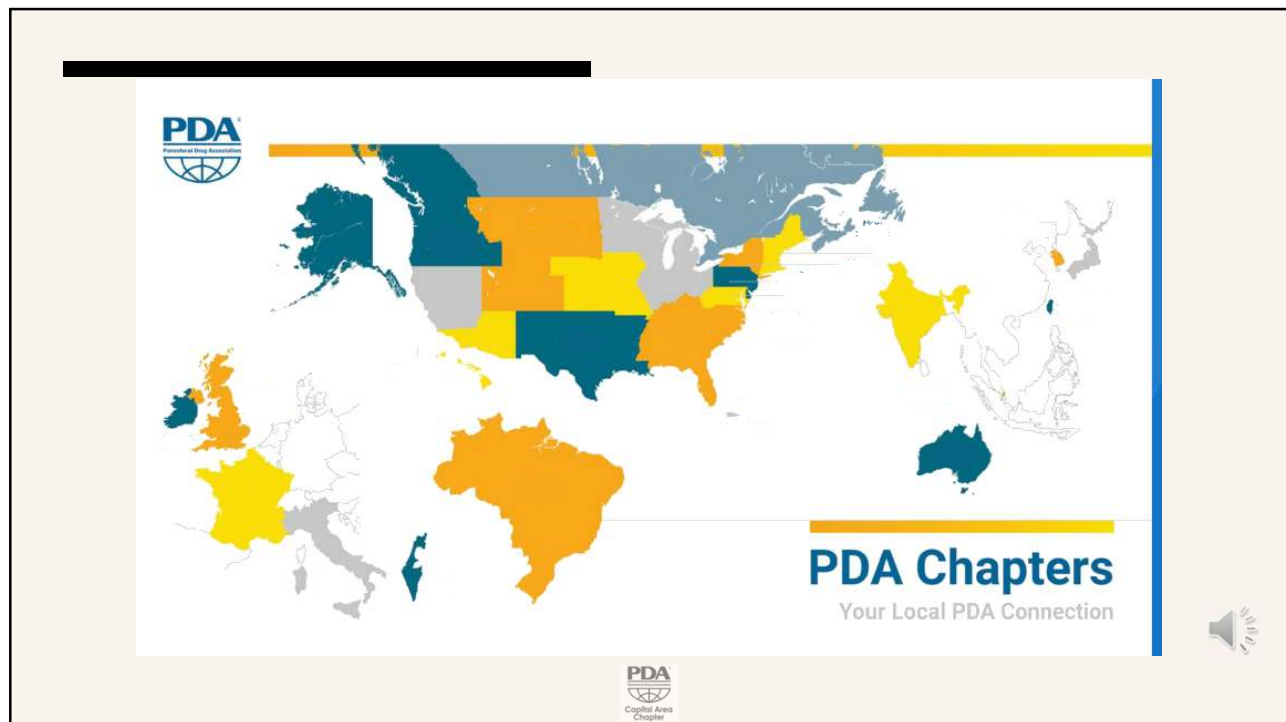
- Julie Barnhill, Senior Consultant, Pace Life Sciences -- *Global Pharmaceutical Student Network & Early Career Professionals Committee Chair*
- Dina El-Emary, Site Quality Head, Sanofi
- Ezekiel Kelly, Vice President of Engagement and Growth, Frederick Innovative Technology Center, Inc. (FITCI) -- *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

5

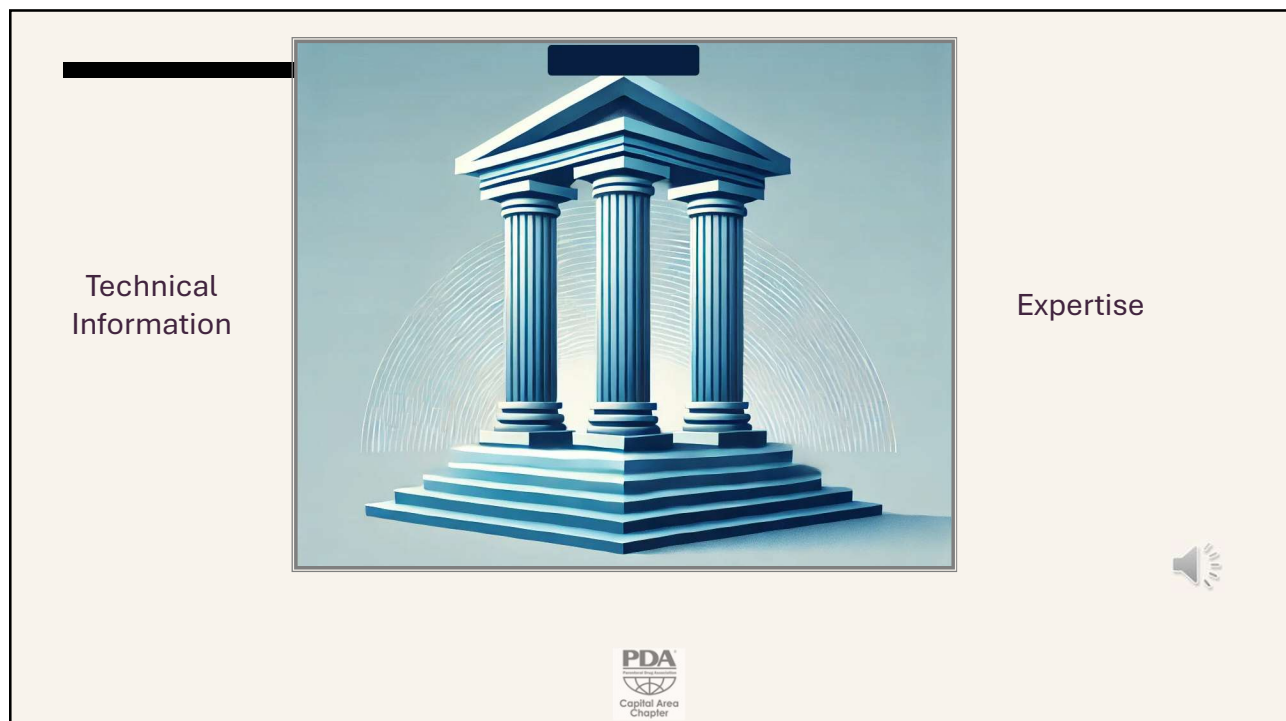
Parenteral Drug Association (PDA) Overview



6



7



8

Technology



Pharmaceutical
&
Biopharmaceutical





9

Collaboration &
Innovation




Highest Standards






10

Organization



Strategies



11

JOIN PDA TODAY!

Quality



Safety



12

Membership Benefits - Publications

Accessible through Bookstore
(Technical Publications Portal) or
direct submenu link on website

- PDA Technical Reports
- PDA Points to Consider
(commonly included within Technical Reports)
- PDA/ANSI Standards
- Research
- Books

Publications submenu links

- PDA Letter
- PDA Journal
- PDA Catalog of Technical Documents
(downloadable PDF list of available Technical
Reports, Points to Consider and Standards)



13

Recent Publication Topics

PDA
Technical
Reports

Technical Report No. 41: Virus Retentive
Filtration, provides a summary of best
practices for utilization

Technical Report No. 46: Guidance for
Good Distribution Practices for
Pharmaceutical

Technical Report No. 68: 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



14

Recent Publication Topics (cont'd)



PDA Points to Consider

- Points to Consider No. 11: Development, Classification, Manufacture, Control, and Testing of Plasmids and Vectors
- Points to Consider No.9: Lessons Learned from the COVID-19 Pandemic

PDA/ANSI Standards

- PDA/ANSI Standard 06-2025: Assessment of Quality Culture Guidance Documents, Models, and Tools
- PDA/ANSI Standard 03-2025: Standard Practice for Quality Risk Management of Aseptic Processes

Books

- Global Sterile Manufacturing Regulatory Guidance Comparison & Assessment Tool

15

Recent Publication Topics (cont'd)



PDA Letter

- What is the Best Way to Control Contamination on the Hands?
- Breaking point: Assessing and Addressing the Risk of Auto-Injector Failure
- From Lab to Market -- How Digital Transformation is Accelerating Drug Development and Delivery
- Ethical Dilemmas in Pharma: Pharma's Toughest Decisions

PDA Journal


- {Research} Definition of Particle Visibility Threshold in Parenteral Drug Products—Towards Standardization of Visual Inspection Operator Qualification
- {Case Study} Visual Inspection of Topical Ophthalmic Formulations Packaged in Opaque and Semi-Transparent Containers: Working Towards Alignment with USP<790> Visible Particulates in Injections
- {Reviews} A Risk Assessment and Risk-Based Approach Review of Pre-Use/Post-Sterilization Integrity Testing (PUPSIT)

16

	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

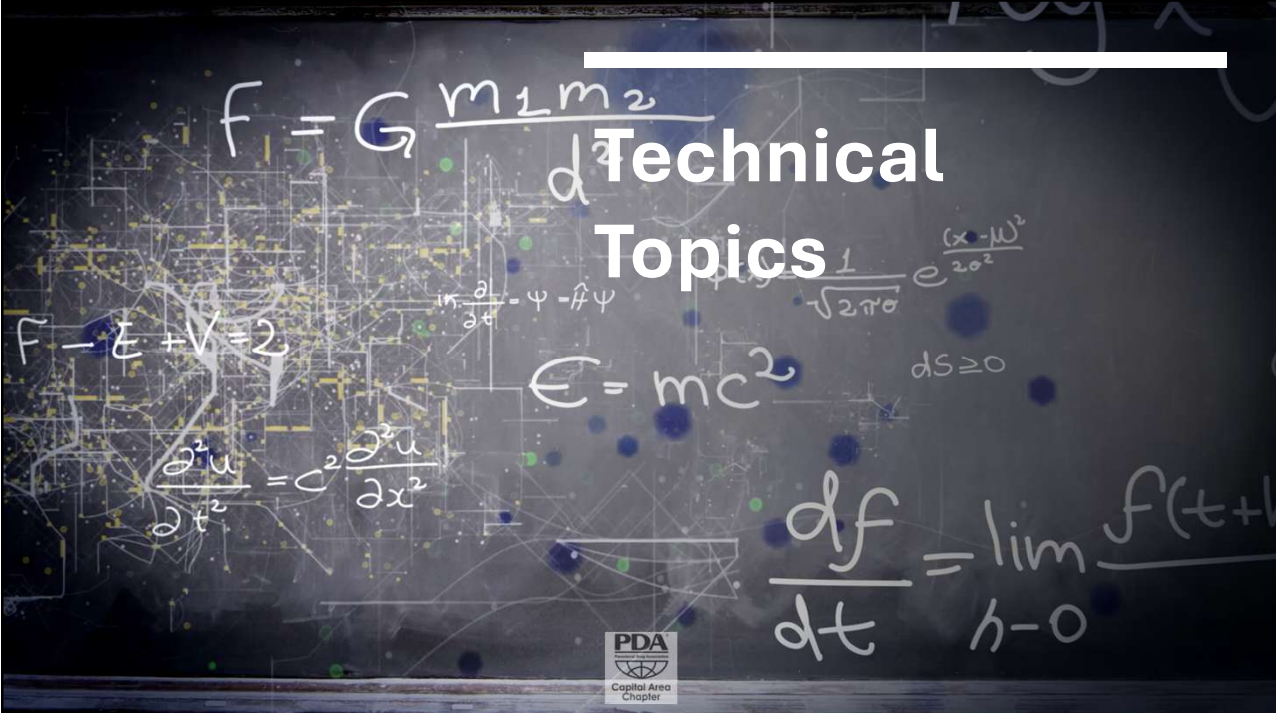
Member Types and Tiers

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



17

Technical Topics



$$F = G \frac{m_1 m_2}{d^2}$$

$$F - E + V = 2$$


$$\frac{\partial^2 u}{\partial t^2} = c^2 \frac{\partial^2 u}{\partial x^2}$$

$$i\hbar \frac{\partial}{\partial t} \psi = \hat{H} \psi$$

$$E = mc^2$$

$$\frac{df}{dt} = \lim_{h \rightarrow 0} \frac{f(t+h) - f(t)}{h}$$

$$ds \geq 0$$



18

Leveraging Computer Software Assurance for Risk-Based Validation



Founder and Validation Consultant
BRAYEARST VALIDATION CONSULTING



Stephanie Brandford is a Carnegie Mellon-trained chemical engineer with a career rooted in process improvement, regulatory compliance, and technical documentation. She began her journey in the chemical industry, applying statistical process control to drive operational efficiency and meet environmental standards.

Her path led to the medical device sector, where she advanced into validation engineering and earned a Six Sigma Black Belt. Stephanie became known for translating complex regulatory requirements into clear, auditable processes; strengthening quality systems and accelerating time-to-market for FDA-regulated products.

Today, as the founder of **Brayeardst Validation Consulting**, Stephanie leads a firm dedicated to empowering Life Sciences organizations through structured validation training, targeted document reviews, and process-driven optimization strategies. Her proprietary CAGESSM framework and deep understanding of compliance requirements position Brayeardst as a trusted partner for companies seeking sustainable validation practices and inspection-ready documentation.



19

GDP Refresher in the Age of AI



Process Engineer & Technical Writer
ELUCINIÈRE, LLC



Simone Ammons has 15+ years of experience as a Process Engineer in the oil & gas, chemicals and pharmaceutical industries. She has an impressive track record, having worked for Fortune 500 companies including GSK (GlaxoSmithKline), BASF, Dupont, Dow Chemical, Unilever, Alcon, and Novartis.

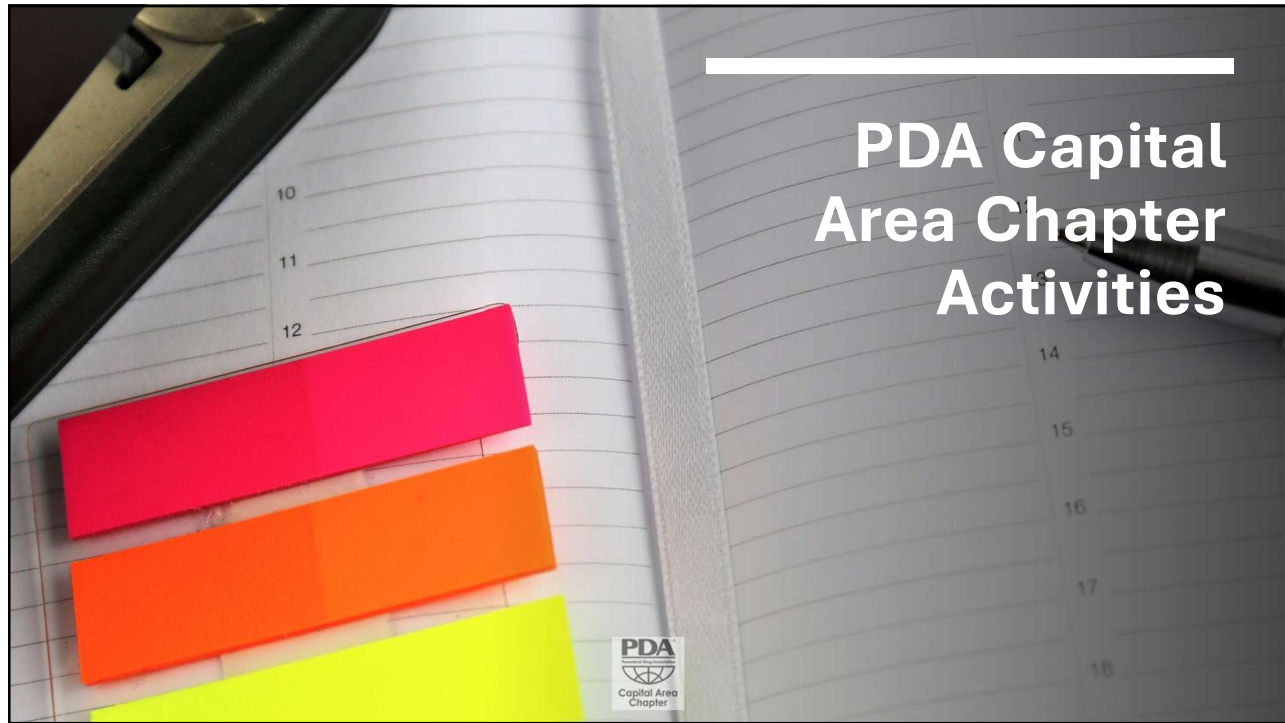
Simone's experience includes leading equipment design, procurement, installation, and commissioning, encompassing a diverse range of systems, from heat exchangers to bioreactors. Simone also excels in developing SOPs, validation and commissioning protocols for complex manufacturing systems.

Simone started her company **Eluciniere, LLC** in April 2022 as a provider of expert technical writing services, where she leverages her deep engineering expertise with her passion for writing. Her goal is to help companies effectively reach their end users, both internal and external, with effective, clear and impactful documentation.

Simone holds a B.Sc. in Chemical Engineering from Texas Tech University and a M.Sc. in Biomedical Engineering from University of Texas - Arlington.



20



21

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 Enjoy Ourselves While Continuing to Deliver Great Service.
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22

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

23

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)



24

Planned Events



DATE	TYPE	LOCATION	TOPIC/THEME
May 2025 Day TBD	Social Event	In-Person	PDA Chapter Social On Location Trivia Night!
June 17	Networking & Technical	In Person / Virtual	Q2 Chapter & Membership Quarterly Meeting - Technical Presentation and Member Networking
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	Technical Discussion	In Person / Washington, D.C.	Capital Area Chapter Hosts Roundtable Discussion Topic TBD
September 9	Signature Event	In Person / Washington, D.C.	Networking Reception Event – Theme TBT 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

25

Questions and Comments?



26

Thank You!



We appreciate your time and attention;
please complete our survey

