PDA Capital Area Chapter

Q1 Meeting

23 April 2024

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PDA Parenteral Drug Association

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Meeting Overview

- Welcome and Board Introduction
- PDA Overview
- Speaker Janie Miller, MBA - Amgen
- Speaker Stephanie Brandford - Brayearst Consulting
- Questions and Answers
- Networking Reception Immediately Following

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Meet the Chapter Board Members

President

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

Treasurer

- Sapan Patel, Associate Director - Quality Assurance, AstraZeneca

Secretary

- Julie Barnhill, Senior Consultant, Pace Labs

Members at Large

- Krystian Gonzalez-Vasquez, CQV Engineer II, Integrated Project Services, LLC
- Dina El-Emary, MEng., MBA
- 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

Past-President and Chapter Advisor

- Tita Tavares, Chief of Staff, PDA

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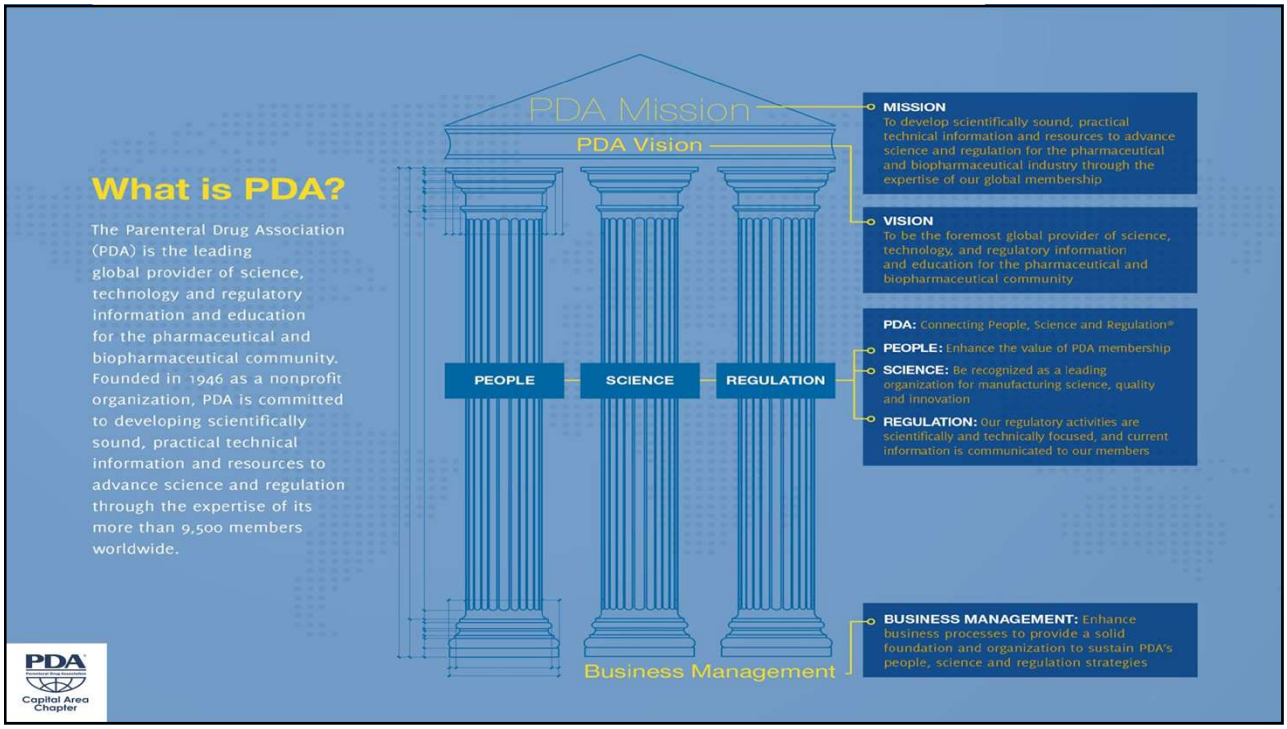
What is PDA?
The Parenteral Drug Association (PDA) is the leading global provider of science, technology and regulatory information and education for the pharmaceutical and biopharmaceutical community. Founded in 1946 as a nonprofit organization, PDA is committed to developing scientifically sound, practical technical information and resources to advance science and regulation through the expertise of its more than 9,500 members worldwide.
PDA Mission
PDA Vision
PEOPLE
SCIENCE
REGULATION
Business Management
MISSION
To develop scientifically sound, practical technical information and resources to advance science and regulation for the pharmaceutical and biopharmaceutical industry through the expertise of our global membership
VISION
To be the foremost global provider of science, technology, and regulatory information and education for the pharmaceutical and biopharmaceutical community
PDA: Connecting People, Science and Regulation®
PEOPLE: Enhance the value of PDA membership
SCIENCE: Be recognized as a leading organization for manufacturing science, quality and innovation
REGULATION: Our regulatory activities are scientifically and technically focused, and current information is communicated to our members
BUSINESS MANAGEMENT: Enhance business processes to provide a solid foundation and organization to sustain PDA's people, science and regulation strategies
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Parenteral Drug Association
Canada
Pacific Northwest
Mountain States
Midwest
New England
Korea
Japan
Taiwan
Metro
Delaware Valley
West Coast
Missouri Valley
Capital Area
India
Texas
Southeast
Southern California
Puerto Rico
Singapore
United Kingdom
Ireland
Australia
France
Brazil
Italy
Israel
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Member Benefits Summary

View the full library of **Technical Resources** in our online TR Portal for free!

Network with regulators and industry experts through PDA events and volunteer opportunities

Read the latest **research** on the *PDA Journal of Pharmaceutical Science and Technology* website

Catch up on industry and Association news with the *PDA Letter*

Grow **your local network** and learn about issues affecting your region through chapter involvement

Gain access to **professional resources** like our Online Membership Directory and PDA Career Center

Take advantage of **discounts** on conferences, courses and books

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PDA Technical Report Portal

PDA Members have 24/7 access to more than 70 active technical resources in the PDA TR Portal.

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Member Types and Pricing

TIER SELECTION			
Select Your Membership Tier Level:	**Essential**	**Plus**	**Premium**
Standard	☐ $150	☐ $250	☐ $350
Academic, Early Career Professionals, Emerging Economy	☐ $75	☐ $125	☐ $245
Health Authority, Students, Retired	☐ Free	☐ Free	☐ $175
Membership Directory	●	●	●
Vote in PDA Elections and on Proposed Bylaws Changes	●	●	●
PDA Letter Online	●	●	●
PDA Connect®	●	●	●
PDA Volunteer Opportunities	●	●	●
Members-Only Discounts	●	●	●
PDA Technical Publications Portal – *View and annotate the full collection of TRs and PtCs online*		●	●
PDA Journal – Limited Access – Current and previous volume year included, earlier articles available for purchase		●	●
Download New TRs/Surveys/PtCs for Free within 30 Days of publication release date			●
PDA Technical Reports – *1 free download of your choice from the existing TR/Survey/PtC library per year*			●
PDA Journal – Unlimited Access – All issues in the library are included			●

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Chapter Metrics

- Region
  - Washington, D.C.
  - Maryland
  - Northern Virginia
  - West Virginia
- Total # of Members in Region: ~ 525
- # of Active Members: < 50
- Target # of Members to Reclaim and Reactivate: 10 %

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Life Science Process Validation Guidance

- Presented by
  Stephanie Brandford
  Validation Consultant, Founder of
  Brayearst Validation Consulting

Email: sbrandford@brayearst.com

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Life Science Process Validation Guidance

- Stephanie Brandford, the founder of Brayearst Validation Consulting, delves into the critical aspects of process validation in the life sciences sector. With over two decades of experience and a strong foundation in Six Sigma-driven optimization and FDA compliance, Stephanie will guide attendees through the importance of adhering to regulations, enhancing operational efficiency, and improving product quality through effective process validation. This session is essential for professionals in medical device and pharmaceutical manufacturing, offering practical insights drawn from real-world applications in chemical manufacturing. Discover the roles and phases of process validation, the integration of guidance for medical devices and drugs, and post-validation considerations. Enhance your understanding of quality management systems and prepare for commercial-scale manufacturing with expertise that bridges theory and practice.

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Inspection Observation Trends 2023 & Planned FDA Guidance Agenda 2024

- Presented by

Janie Miller, MBA
Director of Quality & Compliance, External Affairs
Amgen Inc

Email: Jmille11@amgen.com

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Inspection Observation Trends 2023 & Planned FDA Guidance Agenda 2024

As a Director of Global Quality and Compliance in External Affairs for Amgen, Jahanvi primarily oversees activities within the Americas (North, Central & South), in addition to Canada, China, and Singapore. She is a conjugate in developing and shaping global policy/regulations which are consistent with industry and Amgen's best practices and shares these practices throughout her organization. She also engages with internal and external stakeholders to meet and implement global regulatory expectations throughout the product-life cycle (incl. early-warning signals).

She is the current co-Chair of the PDA Zero Defects for Visible Particles workstream and Co-chairs the QMM playbook workstream. She has supported presentations at multiple PDA events as well as developed training for the PDA Training and Research Institute. She is the Chair of the PhRMA quality workstream and is a member of the IPEC Quality and Regulatory Advisory Board. She is also the co-Chair of the ISPE Quality and Regulatory CoP and speaker at the 2024 Biotech conference. Over her 2- years in industry years she has published many articles and technical documents and has served on multiple technical committees.

Jahanvi comes to Amgen GQC (Global Quality Compliance) with over 20 years of industry experience. Prior to Amgen, she was with PDA (Parenteral Drug Association) where she was responsible for all activities and initiatives globally of the Science Advisory Board. She worked collaboratively with PDA members and governing bodies to facilitate the production of PDA Responses to Draft Regulatory Guidance Documents, Technical Reports, Points to Consider Guidance's, Training Courses and Strategic Plans. Prior to joining PDA in 2012, Jahanvi worked as a clinical manager for Otsuka, an account director at OneWorld, and 10 years in multiple capacities at Johnson & Johnson. Jahanvi holds a Bachelor of Science Degree in Biomedical Sciences and a Master's Degree in Business Management.

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Upcoming Events Calendar

Date	Type	Location	Topic/Theme
TBD	Networking & Membership	In-Person	PDA Chapter Social On Location: D.C. Tidal Basin 5K Run & Walk!
June 04	Networking & Technical	In-Person/Virtual	Q2 Chapter & Membership Quarterly Meeting Technical Presentation and Member Networking
September 10	Signature Event	In Person	Whisky Reception Event - On Tuesday evening of Joint PDA/FDA Regulatory Conference
September 24	Networking & Technical	In-Person/Virtual	Q3 Chapter & Membership Quarterly Meeting Technical Presentation and Member Networking
October 29	Networking & Membership	In-Person/Virtual	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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American Cancer Society Every Cancer, Every Life

The American Cancer Society is a leading cancer-fighting organization with a vision to end cancer as we know it, for everyone. We are improving the lives of people with cancer and their families as the only organization combating cancer through advocacy, research, and patient support, to ensure that everyone has an opportunity to prevent, detect, treat, and survive cancer.

can help people find hope and support online through our **Cancer Survivors Network℠**.

could help put **free cancer education** in the hands of those who need guidance.

can help people facing breast cancer connect with trained survivors through our **Reach To Recovery®** program.

could help 1 person find **free answers** and much-needed support through our **24-hour helpline**.

can help provide **1 free ride** to treatment through our **Road To Recovery®** program.

can help provide **1 free night's stay** at a Hope Lodge® community for people with cancer and their caregivers.

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COMMENTS & QUESTIONS

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Thank you!
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