PDA
Parenteral Drug Association

PDA.org/vote

PDA OFFICERS AND BOARD OF DIRECTORS

2020 Election Guide

Online voting open

Vote: PDA.org/vote

POLLS:

OPEN Sept. 9, 2019

CLOSE Nov. 15, 2019 at 11: 59 p.m. EST

Open to PDA members in good standing as of midnight on August 26, 2019.

CONNECTING PEOPLE SCIENCE AND REGULATION®

PDA members have the opportunity to choose volunteer leadership for 2020.

You may select three officers and t ee board members who will take seats on the PDA Board of Directors. Members in good standing can vote online at *PDA.org/vote* and in person at conferences that will be held between Sept. 16 and Nov. 13 in the United States and Europe. The open seats are for the following officer Chair-Elect, Treasurer, and Secretary. Six people are running to fil three director seats.

Voting Details

The Board of Directors election is open to members in good standing as of midnight on August 26, 2019. Balloting opens Sept. 9, 2019 and closes at 11:59 p.m. EST on Nov. 15, 2019. Ballots received or requests to vote after this date and time cannot be accepted.

Vote online or vote when you attend any of PDA's fall meetings in Europe or in the U.S.:

2019 PDA/FDA Joint Regulatory Conference
Sept. 16-18 | Washington, DC

2019 PDA Data Integrity Workshop
Sept. 18-19 | Washington, DC

2019 PDA Europe Pharmaceutical Freeze-Drying Conference
Sept. 24-25 | Munich, Germany

2019 PDA Europe Particles in Injectables Conference
Sept. 24-25 | Munich, Germany

14th Annual PDA Global Conference on Pharmaceutical Microbiology
Oct. 21-23 | Rockville, MD

2019 PDA Rapid Microbiological Methods Workshop
Oct. 23-24 | Rockville, MD

2019 PDA Europe Pre-Conference Workshops
Oct. 21 | Gothenburg, Sweden

2019 PDA Universe of Pre-filled Syringes & Injection D vices
Oct. 22-23 | Gothenburg, Sweden

2019 PDA Europe Outsourcing and Supply Chain Conference – A 360° View
Nov. 12-13 | Lisbon, Portugal

How to Cast Your Ballot

- Log on to ***PDA.org/vote***.
- You will need your PDA member ID and last name.
- Carefully read the instructions for each question before you make your selections.
- When you finish the ballot, check the Participant Consent Box and click submit.
- View and print your receipt and exit the voting system.

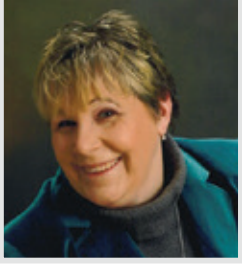
QUESTIONS? e-mail: vote@pda.org or call +1 (301) 656-5900.

Candidates Running for Officer ositions

Candidates Running for Director Positions

Meet the Candidates

Board Officer Candidat



PDA Board of Directors

SUSAN SCHNIEPP

Chair-Elect

SUSAN SCHNIEPP has 40 years of quality assurance experience in the pharmaceutical industry. She served in leadership roles at Allergy Laboratories, Inc.; OsoBio Pharmaceuticals, LLC; Searle; Abbott; and Hospira. She has earned several awards from PDA, including its Distinguished Author Award, Distinguished Service Award, and Gordon Personeus Award.

Sue's publications include the book, *Understanding the United States Pharmacopeia and the National Formulary: Demystifying the Standards-Setting Process*, for which she was awarded the 2007 PDA's Distinguished Author Award. She co-edited and contributed to the books *Pharmaceutical Outsourcing: Quality Management and Project Delivery* and *SOPs Clear and Simple for Healthcare Manufacturers*.

Serving as a volunteer in a number of capacities, she has served on the PDA Board of Directors from 2011- 2013 and from 2016- 2019. Sue has served on numerous planning committees, including the PDA/FDA Joint Regulatory Conference Planning Committee since 2002. She is currently working part of the working group writing a technical report relating to manufacturing data integrity issues and participating in PDA's standard setting activity regarding purchasing controls.

In addition to her PDA activities, Sue is an editorial advisory board member and columnist for *Pharmaceutical Technology* (since 2007) and *BioPharm International* Magazines. She holds a Bachelor of Science degree in Microbiology from Northern Illinois University.

Candidate Statement

It is an honor to be considered for the Chair-Elect of the PDA Board of Directors. PDA is a unique organization because it accomplishes what it claims to do: Connect people, science, and regulation. It is refreshing to be part of an organization that accepts and values individual contributions and cooperative team efforts to achieve a common goal. I have been involved with a number of activities for PDA and have recognized their value in advancing my knowledge base and allowing me to attain my career goals. I believe the organization helps people grow and achieve career success in a positive manner.

In addition to building a creative and nurturing environment for its members, PDA also has its pulse on the scientific ad ancements and regulatory activities that play such an important part in our industry. It is because I believe in the activities and goals of PDA that I wish to serve as Chair-Elect of the Board of Directors. I want to continue to contribute by helping PDA maintain its uniqueness as an industry leader addressing scientific and egulatory issues that are so critical to our industry.

GLENN WRIGHT
Treasurer

GLENN E. WRIGHT is currently the Head of Quality at Exelead Biopharma, responsible for all Quality operations. The company specializes in complex formulation and filling of sterile injectable orphan drug p oducts with a focus on pegylated enzyme and liposomal/lipid-based mRNA and small molecule formulations. Glenn has more than 25 years of experience in the pharmaceutical industry. Previously, he served in various technical and senior leadership positions at Eli Lilly, Amgen, and Pfi er. He has extensive technical, regulatory, and quality expertise in both small molecule and biologic drug substance manufacturing and sterile injectable drug product production.

Glenn has served on the PDA Board of Directors, Science Advisory Board, and Program Advisory Board. In addition, he has chaired numerous PDA meetings, including the PDA/FDA Joint Regulatory Conference and the PDA Annual Meeting. Glenn was the founding President of the PDA Southern California Chapter and has chaired many industry task force groups, including the PDA Aging Facilities Task Force and PQRI's Post Approval Changes for Aseptic Processing Working Group. He is a frequent speaker at PDA events and is an active member of the PDA Manufacturing Science and Operations Program Steering Committee. Glenn received his BS and MS degrees in Microbiology from Southern Illinois University.

Candidate Statement

It has been a great privilege to be an active member of PDA for more than 25 years. I still remember my first P A meeting, "Sterilization in 1990s," in August of 1990 in Washington, DC. How impressed I was with the work PDA was doing to advance the scientific principles of pharmaceutical manufacturing, and how much I could learn as an active member. PDA has been part of my DNA since that very first d y, allowing me to build my technical skills and providing me with a framework through which to contribute back to advance our industry.

Now approaching my 30th year as a PDA member, I continue to be excited by PDA's mission and the many ways PDA enables its members to contribute. Just as the industry evolves, so does PDA, with new interest groups, task forces, technical reports, training options, and outstanding events.

Science is at the core of PDA and its value to its members and ultimately the patients they serve. Being nominated to serve as Treasurer on the PDA Board of Directors is a great honor. As Treasurer, I will continue to work diligently to -promote PDA's mission and to serve the needs of our members.

PDA Board of Directors

MELISSA SEYMOUR, MBA

Secretary

MELISSA SEYMOUR is the Vice President of Global QC Operations for Biogen, Inc., responsible for the comprehensive strategy and implementation for Global QC testing of raw materials, drug substance, drug product, and finished goods worldwide. Prior o this, Melissa served as the Vice President of Corporate Quality, responsible for global compliance and quality systems.

Melissa holds BS degrees in both Biological Sciences and Biochemistry from North Carolina State University and an executive MBA from Duke University, and she is a recent graduate of the WIB Boardroom Ready program. She has more than 25 years of experience in the quality arena, including positions at Novo Nordisk Pharmaceuticals and GlaxoSmithKline.

Melissa has been highly active in PDA's Southeast Chapter for a decade, holding leadership positions on the Board. She is involved in multiple activities with PDA, serving on the Program Planning Committees for many PDA conferences, including serving as co-chair for the 2018 and 2019 PDA Annual Meetings. She is active on the PDA PAC iAM Task Force, co-chairs the Tech Transfer IG, and has authored and reviewed multiple PDA reports and articles.

Melissa is an ASQ Certified Quality Enginee , Quality Auditor, and Quality Manager, and served on the Board of Directors for Rx-360.

Candidate Statement

I am once again, humbled and honored to be nominated to serve as Secretary of the Board of Directors for PDA. I have been blessed to have been an integral part of the SE local chapter and the global Board, seeing the many benefits that this o ganization provides in a time of innovation and technology through training, education, conferences, and collaboration with regulators.

My interactions with the volunteers, membership, and leadership at PDA strengthens my resolve to truly focus on patients and enable the industry to innovate in ways that will provide quality care to those in need. It is this dedication to science, technology, and innovation that motivates me in my continued involvement with PDA.

The pharma industry is ever changing with new technologies and treatments coming at a never before seen pace. As Secretary of the Board, I would work to ensure that PDA can continue to meet the challenges of advancing pharmaceutical science and innovative technologies by providing unparalleled training and conference opportunities. I am sure that, in collaboration with the talented team of volunteers and exceptional staff at PDA, we can continue to contribute to the mission. I am thankful and appreciative to have the opportunity to serve in this capacity.

Meet the Candidates

Board of Director Candidates

The following nominees are running for three open seats on the Board. Candidates are listed in alphabetical order.

BARBARA ALLEN, PhD

BARBARA ALLEN is Sr. Director Global Quality External engagement for Eli Lilly and Company. For 14 years, she led the development and evolution of integrated quality standards and practices and IT systems for Lilly Quality Systems across research, development, manufacturing, distribution, and sales and marketing.

Barbara has more than 20 years of experience in the pharmaceutical industry, including quality management, technical services, validation, new product introduction, and quality assurance, both in Ireland and in the U.S. She sponsored the development of Lilly Quality Academy program for Quality professionals. Barbara is a member of the ICH Informal Quality Discussion Group, and represented industry on the expert working group for ICH Q10.

Barbara received a Bachelor Science degree in Chemistry from University College Cork, and a Doctorate in Chemistry from University College Dublin, Ireland, with a portion undertaken at the Universite de Paris, France.

Barbara is an active member of PDA and currently serves on the Board of Directors. She has participated on conference planning committees, and presented at multiple PDA events on quality, supplier quality, knowledge management, and process capability. Barbara co-leads a team working on data integrity in quality management systems. In 2013, she received a PDA Distinguished Service Award.

Candidate Statement

PDA has helped me to learn and develop as a professional in the pharmaceutical industry. My scientific and egulatory knowledge has broadened and deepened from attending PDA conferences and chapter meetings, participating at and planning PDA events, along with accessing PDA publications. The interactions with other members have provided meaningful and thought-provoking discussion and debate, as well as a professional network and many valued friendships.

As an organization, PDA plays a key global role in facilitating the development of pharmaceutical professionals and contributes significantly to the advancement of science and technology as well as associated standards for this sector. It provides many opportunities, to learn, engage with, and advance topics and to develop personally.

Serving on the PDA Board of Directors would allow me to continue ensuring the success of the PDA mission and shaping the future to meet the needs of each member.

JEFF BROADFOOT

JEFF BROADFOOT is currently the Site Head of Quality for Emergent BioSolution's Winnipeg, Canada site where they develop and manufacture sterile biologics, primarily protein therapeutics. He has oversight responsibilities for all GXP aspects of site activities, and is directly responsible for the Quality Assurance, Quality Control, and Compliance functions.

Jeff has been active within PDA for more than 15 years and has been a member of its Regulatory Affairs and Quality Advisory Board (RAQAB) for the last 10 years. He recently completed a 3-year term as Chair of the Advisory Board and is currently serving his 2-year term as immediate Past Chair. As a member of RAQAB, Jeff has participated on numerous regulatory commenting task forces, and has supported many others, including the Quality Culture/Quality Metrics Task Force, the PAC iAM Task Force, and the Data Integrity in Manufacturing Systems Tech Report team, among others.

He studied Bioengineering and Chemical Technology and is currently working to complete an MBA.

Candidate Statement

I know many current and past Board members. They're an awesome group of people, passionate about advancing the good and meaningful work that we have the privilege of doing in this industry and I am honored to have been nominated to stand for election to the Board.

My passion for this industry is driven by the impact it has made on my own family, just like so many of you. PDA has provided me with so many opportunities to grow personally and professionally, to connect with colleagues, and support our industry in ways that I never thought would be available to me. I'm eager to continue to support PDA and its members in advancing areas that impact on the quality and availability of medicines.

PDA Board of Directors

TIA BUSH

TIA BUSH is the Senior Vice President of Quality at Amgen. Prior to this, in her recent role as Vice President, Site Operations, she was responsible for all operations at Amgen's 75-acre West Greenwich, RI, campus where staff contribute to the manufacture of Enbrel and other clinical trial materials. She was also responsible for leading site operations for Amgen Woburn where she oversaw the manufacturing of IMLYGIC™, a genetically modified oncolytic vi al therapy. She started her career at Amgen in 1992 after obtaining her Biological Sciences and Chemistry degree from the University of Southern California. She was the recipient of Amgen's Excellence in Quality Award, Providence Business News "Women in Business – Industry Leader" Award, 2012 Healthcare Business Association Rising Star Award, 2017 Outstanding Mentor Award and 2018 Manufacturing Strategic Leadership Award, and the 2018 Ronald McDonald Women's Leadership award. In 2017, Rhode Island's State Governor Gina Raimondo and Million Women Mentors Rhode Island presented Tia with a Stand Up for Stem award.

Candidate Statement

I am honored to be nominated for the PDA Board of Directors. I am committed to delivering on the mission of PDA as we all work together to better serve patients.

I have been truly impressed with the scientific rigor and expe tise that PDA harnesses to help solve the industry's most difficult manufacturing and egulatory challenges. PDA provides leadership in a dynamic, global environment that makes a difference every day. As a board member, we have an opportunity to influence and simplify our complex regulated environment and ensure that we are focused on what is most important to the patient and product quality.

PDA has played an important role in my professional growth and development and shaped my approach to quality and compliance as an executive leader. I have actively participated with PDA as a student, advisor, volunteer, and taskforce leader. I am inspired by PDA's mission to serve patients by advancing manufacturing science and regulations. I look forward to bringing my experience to serve PDA and its members. I would be privileged to work with other Board members to progress PDA's strategic plan and to serve our industry and patients. I see this as my opportunity to give back to an organization that has made a positive difference in my professional growth.

GHADA HADDAD, MBA

GHADA HADDAD is currently an Executive Director at Merck & Co., leading the Global cGMP & Compliance Auditing Organization. She holds a chemistry degree, an MBA, and is a 2019 PhD candidate at TU Dublin. She has more than 20 years of experience working in the biotech, pharmaceutical, and vaccine industries at global companies. At Merck, she covers the areas of Qualification and alidation, QRM, Quality Systems, and Regulatory, including research, process development, auditing, regulatory agency inspection, and change control.

Ghada currently serves on the PDA Board of Directors and the PDA Science Advisory Board. An active volunteer, she has taken a lead role on multiple task forces, including the Paradigm Change in Manufacturing (PCMO) initiative for TR 54-2, and other Technical Report and Points to Consider teams.

Ghada is also an instructor for PDA Education, a frequent speaker at PDA conferences, and has been a member of the PDA Annual Meeting Program Planning Committee for the past fi e years, of which she served as co-chair for two years. Ghada has authored several scientific publications, two of which appeared in the *PDA Journal*. She is a mother of two young ladies, one of whom is will be graduating Pharmacy School in 2020.

Candidate Statement

It has been a great honor to represent you on the PDA Board of Directors, and I am humbly asking for your vote again to return to the Board of Directors for a second term. Through my work on many aspects of the PDA, including presenting at Signature Events, leading or being a member of Task Forces creating Technical Reports, and participating in Workshops, it is my hope that you are seeing value in your membership and would want me to continue service by working to ensure quality, accuracy, and relevance to the Technical Reports, the programs, and the training events.

With openness and approachability, I am always eager to hear your input on the direction the organization should take and the 'Hot Topics' that need to be addressed. I remain a big supporter of our young professionals' evolving role in the PDA family. As a member of the Board, I will continue to work to ensure that PDA can meet the challenge of advancing pharmaceutical science and development of new technologies as well as providing continuous education and conference opportunities for the industry.

IVY LOUIS

IVY LOUIS, a pharmacist with a focus on behavioral and value analysis of people, an MBA in Human Resources, and a total of 30 years of experience, finds w ys to challenge the limits of learning, education, and implementation.

As the Founder-Director of Vienni Training & Consulting LLP, Ivy believes that people and their understanding of *the-what*, *the-why*, and *the-how* play *'the'* crucial role in all bio and pharmaceutical operations.

Ivy has worked in the manufacturing and quality domains at CIPLA and the manufacturing line up of Astra-IDL. Her work in filt ation technology operations, and experience heading the Access Services℠ at Millipore India, have built her expertise in aseptic practices and filter alidation services.

She is a forerunner in creating benchmarks in the propagation and education of aseptic filt ation and validation and services for pharmaceutical customers in research, production, and quality control/assurance areas in India and Asia.

Currently, she helps companies achieve measurable improvements to operational and assurance efficiencies t ough practical and implementable learning and consulting services.

She has been a member of PDA for 15 years and was actively involved in the creation of the PDA India Chapter in 2013. She has been a Chapter Officer and is cu ently responsible for the activities of the Chapter as its President.

Candidate Statement

Knowing that PDA can become *"the"* key differentiator in amalgamating education, science, and regulations for improving lives of patients commits and propels me to advance this cause. My foremost priority will be to enhance the relationship between members and their learning experiences, to be distilled and realized as best practices, under the ambit of the regulatory expectations.

I will be delighted and privileged to have this wonderful opportunity to represent PDA on the Board of Directors and to serve in this capacity.

STEVEN LYNN

STEVE LYNN is currently the principal consultant/owner for Lynn Consulting, LLC, advising and working with life science sector company executives on pre- and post-market GxP issues. Prior to this, Steve was the Global Head of Group (Corporate) Compliance and Audit at Novartis AG, leading GxP compliance and audit functions for all Novartis pre- and post-market units. Before that, Steve was the inaugural Vice President of Global Quality Compliance at Mylan, Inc.

Steve also spent nine years working in multiple units at the U.S. Food and Drug Administration, in roles of increasing importance/responsibility in the Center for Drug Evaluation and Research (CDER), Center for Device Evaluation and Radiological Health (CDRH), and the Office of Regul ory Affairs. In his last role with FDA, Steve served as the Office D ector of CDER's Office of Manufacturing and oduct Quality (OMPQ) within the Office of Compliance, wh e, he was responsible for CGMP oversight of all drugs manufactured and/or imported into the U.S.

Steve received a BS in Biology from Bethany College in Bethany, WV, and an MS in Quality Systems Management from the National Graduate School in Falmouth, MA. He is a Senior Member of the American Society for Quality (ASQ) and is an Excellence in Government Program Senior Fellow.

Candidate Statement

I'm honored to be re-nominated to PDA's Board of Directors. Serving as the Executive Secretary of the Board of the past two years has allowed me to gain a much better appreciation of the valuable work PDA and its members conduct in service to our industry. PDA is a wonderful organization on which I have come to rely for great science, technology, and regulatory information.

Being a Board member, as well as now serving in my second term on PDA's Regulatory and Quality Advisory Board (RAQAB), has given me a robust perspective of where PDA is now and where we want to go in the future. If re-elected to the Board, I will continue to strive to further strengthen PDA's value proposition. As PDA constituent members, you deserve the best. I believe PDA delivers a valuable service to our industry and is at the forefront of helping to advance vital scientific, technical, and egulatory information. Thank you for your consideration.

How to Cast Your Ballot

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