PDA
Parenteral Drug Association

pda.org/vote

PDA OFFICERS AND BOARD OF DIRECTORS

2024 Election Guide

Online voting open

Vote: *pda.org/vote*

POLLS OPEN **05 Sept. 2023**
POLLS CLOSE **15 Nov. 2023 at 11: 59 p.m.**

Open to PDA members in good standing as of midnight on 31 Aug. 2023.

CONNECTING PEOPLE SCIENCE AND REGULATION®

PDA members have the opportunity to choose volunteer leadership for 2024.

You may select three officers and three 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 05 Sept. and 15 Nov. in the United States, Europe, and Asia Pacific. The open seats are for the following officers: Chair-Elect, Treasurer, and Secretary. Six people are running to fill three director seats.

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.

Voting Details

The Board of Directors election is open to members in good standing as of midnight on 31 August 2023. Balloting opens 05 September 2023 and closes at 11:59 p.m. EST on 15 November 2023. Ballots received or requests to vote after this date and time cannot be accepted.

Vote online or vote when you attend one of PDA's fall in-person meetings:

2023 PDA BioManufacturing Conference
12-13 Sept. | Seville, Spain

2023 PDA/FDA Joint Regulatory Conference
18-20 Sept. | Washington, DC

2023 PDA Mastering Deviations Workshop
21-22 Sept. | Washington, DC

2023 PDA Pharmaceutical Microbiology Conference
02-04 Oct. | Washington, DC

2023 PDA Microbial Data Deviation Investigations Workshop
04-05 Oct. | Washington, DC

2023 PDA The Future of Drug Delivery Workshop
16 Oct. | Gothenburg, Sweden

2023 PDA Circular Economy in the Pharmaceutical Industry Workshop
16 Oct. | Gothenburg, Sweden

2023 PDA Universe of Pre-Filled Syringes and Injection Devices Conference
17-18 Oct. | Gothenburg, Sweden

2023 PDA Aseptic Processing of Biopharmaceuticals Conference
31 Oct. – 01 Nov. | Incheon, South Korea

2023 PDA Quality and Regulations Conference
07-08 Nov. | Antwerp, Belgium

2023 PDA Visual Inspection Workshop
14 Nov. | Berlin, Germany

CANDIDATES RUNNING FOR
Officer Positions

CANDIDATES RUNNING FOR
Director Positions

MEET THE CANDIDATES

Board Officer Candidates

MELISSA SEYMOUR, MBA
CHAIR-ELECT

Melissa Seymour is the Chief Quality Officer for Bristol Myers Squibb. In her current role, Melissa leads the GPS Quality organization in setting the quality compliance strategy, implementation of quality processes and systems, and development of talent to ensure the highest level of quality and compliance in the pharmaceutical industry. Prior to this, Melissa served as the CQO at Biogen. She has had prior roles providing oversight for QC laboratories and additionally spent several years as the Vice President of Corporate Quality with responsibility for global compliance and quality systems as well as in-market Quality.

Melissa holds BS degrees in Biological Sciences and Biochemistry from NC State University and an executive MBA from Duke University. She has more than 25 years of experience in the quality arena, including quality positions at Novo Nordisk pharmaceuticals and Glaxo Smith Kline.

Melissa has been involved in the influencing of regulatory guidance through her participation on non-profit Boards of PDA from 2016 to present, as well as Rx-360, a consortium focused on supply chain security vis-à-vis public health concerns and patient safety. She has been an advocate for simplification of Post Approval Change processes, participating in industry forums, writing articles, and interacting with regulators.

CANDIDATE STATEMENT

I am once again, humbled and honored to be nominated to serve as Chair-Elect of the Board of Directors for PDA. I have been blessed to have been an integral part of the global Board, seeing the many benefits that this organization provides in a time of unprecedented change through training, education, conferences, and collaboration with regulators.

My interactions with the volunteers, membership, and leadership at PDA heightens my determination to maintain 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 continually changing via technological advancements and novel treatments, at an extraordinary pace. As Chair-Elect, 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 our valuable mission. I am thankful and appreciative to have the opportunity to serve in this capacity.

EMMA RAMNARINE, PhD
TREASURER

Emma Ramnarine is Head of Product Management, Development Operations, and Innovation for US BioPharma Operations at Boehringer-Ingelheim.

She has 24 years of global experience in pharmaceutical, biotechnology, and medical device companies in Product Management, Outsourcing & External Collaborations, Analytical Science & Technology, Risk Management, QC, and Quality Management Systems. She is a recognized expert on risk-based applications and continues to provide QRM expertise and training for regulatory authorities and industry. She is Co-lead for the Industry One-Voice-of-Quality Initiative for Post Approval Changes (1VQ for PAC), an initiative sponsored by Chief Quality Officers of more than 25 global pharma companies.

Emma has been active with PDA for 20+ years. She has been serving on the PDA Board of Directors for eight years and is currently serving as Secretary. She has additionally served on PDA's Regulatory Affairs and Quality Advisory Board (RAQAB), and has led several PDA Task Forces, Interest Groups, and Technical Report teams.

She holds a PhD in Pharmaceutical Sciences from TU Dublin, an MS in Pharmaceutical Sciences from the University of Connecticut, an MS in Medicinal & Pharmaceutical Chemistry, and a BS in Pharmacy, both from University of Indore, India.

CANDIDATE STATEMENT

I am honored and grateful to be nominated for the position of Treasurer on the PDA Board of Directors. PDA's vision and leadership in connecting people, science, and regulation has always motivated me, especially regarding the collaborations between industry and health authorities on diverse technical, quality, and regulatory topics. PDA's strength lies in its membership, and I am fortunate to be a part of this network of strong professionals. PDA has become stronger in establishing industry practice by providing high-quality, state-of-the-art, scientific, practical solutions through technical reports, standards, and industry dialogue.

I remain committed and eager to drive PDA's strategy and expand PDA's influence from the board level – particularly in advancing manufacturing science, innovation, new technologies, and practical application of science and risk-based approaches. I want to support PDA members in the unique opportunity PDA offers to be exposed to and contribute to influencing the direction of the industry and regulations – this has always been energizing, rewarding, and an invaluable part of my professional career journey! I am excited about the continued opportunity to be a part of PDA's leadership in making a difference for our industry, and beyond that, the patients.

BETTINE BOLTRES, PhD

SECRETARY

Bettine Boltres is a Director Scientific Affairs & Technical Solutions, Glass Systems with West Pharmaceutical Services, Inc. Her career focuses on addressing technical and regulatory challenges of drug package and delivery systems – at West with elastomer and glass components, and previously as a Product Manager at Schott AG, with glass components. She has shared her knowledge in several articles, including the book, *When Glass Meets Pharma*.

She is well recognized in the industry through the committee positions she is holding: USP Packaging and Distribution Expert Committee, European Pharmacopoeia Commission Group of Experts 16 (elastomers), GLS Working Party (glass), and ISO TC76/WG 4 (elastomers) and WG 2 (glass).

She has presented as frequent speaker and has chaired and moderated several conferences and technical trainings for PDA. Additionally, she is actively involved in writing different PDA Technical Reports and different PDA Interest Groups (IGs). As a longtime member of the Program Planning Committee for the Parenteral Packaging Conference, she is each year highly motivated in assembling a compelling program. In 2016, she was rewarded with the PDA Distinguished Service Award, which strongly motivated her to continue her contribution. Her scientific base is a diploma in chemistry (University Frankfurt) and a PhD in biochemistry (University Cologne).

CANDIDATE STATEMENT

It's in rough times, when you recognize a strong foundation.

We have all gone through a very challenging time this year. For PDA, this meant a complete rethinking of the daily business and the regular workflow. Now more than ever, it is important to stick together and to promote scientific exchange in order to ensure the best possible support for the world's population based on the best possible science. This has been done by connecting the pharmaceutical industry in numerous webinars, online trainings, and virtual conferences.

To sustain this much-needed communication, it is crucial to adapt to the new circumstances, which will change our working environment henceforth.

One indispensable part of this journey is represented by young professionals. In addition to the above-mentioned goals, I will therefore strongly support PDA's growth in involving these new talents and helping them grow into our industry by providing you and young professionals with a platform to foster your careers and expand your scientific horizons.

I am determined to continue supporting PDA in this process of mastering the challenge, which is eventually leading us into a new era of Connecting People, Science, and Regulation®.

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.

ANDREW CHANG, PhD

Dr. Andrew Chang is a multifaceted quality and CMC leader with 25 years of well-rounded medical product regulatory and industry experiences. He is the chair of the PDA Biopharmaceutical Advisory Board (BioAB) and a member of the board of directors for CASSS-Sharing Science Solutions. In his current capacity as a Vice President, Quality and Regulatory Compliance, Novo Nordisk Quality, Novo Nordisk, Inc., he is responsible for external affairs, providing strategic advice and solutions for quality and regulatory related issues, and expert support to inspections.

Andrew has substantial industry and ICH experience. He has represented Novo Nordisk at several work groups in industry trade organizations, such as PhRMA and BIO, to advocate patient and industry's interests by developing position papers and participating in liaison meetings with regulatory authorities. For ICH, he served as the FDA deputy topic leader for developing the ICH Q5E guideline and, most recently, he represented PhRMA as an expert and topic leader to ICH Q12 EWG and IWG, respectively.

Prior to industry, Andrew served more than 11 years in the U.S. FDA, most recently as an Associate Director for Policy and Regulation, Acting Deputy Director, Lab Chief and Senior Regulatory Scientist in the Division of Hematology, CBER.

CANDIDATE STATEMENT

I have 25 years of well-rounded medical product regulatory and industry experiences in the pharmaceutical field, including active engagement with PDA. Since 2000, I have served as the Chair for the PDA Biopharmaceutical Advisory Board (BioAB), a member of PDA Portfolio Steering Committee, the speaker or session chair/moderator for PDA conferences/workshops, and an author of PDA Technical Reports and the *PDA Letter*.

I am qualified to serve as a PDA Board member based on my track record of service, experience in both the regulatory Agency and the regulated industry, and my passion for public health and patients' access to safe, effective, and high-quality medicinal products.

I would like to take on following top priorities and challenges facing PDA if I become a member of the Board of Directors:

1) Continue our partnership with regulatory agencies to advance regulatory science and technology innovation in pharmaceutical manufacturing and quality
2) Expand PDA's presence in major global markets and play a role for a steady supply of innovative and high-quality medicines to patients globally
3) Position PDA to serve as a new type of platform for education and training to attract new talents/professionals to the field.

JAVIER CAMPOSANO, MBA

Javier Camposano is the Chief Operations Officer at Lifera, a PIF owned and funded company in Saudi Arabia, focused on localizing the manufacturing of key, life-saving medicines. His role includes overseeing the construction of three manufacturing facilities dedicated to Plasma and Fractionation, Vaccines, and Sterile Injectables while supporting operations at its Saudi Bio Insulin packaging facility. Prior to Lifera, Javier worked for Celltrion, South Korea, as Head of Global Expansion, Drug Product Division. He started his career in Baxter Bioscience, USA.

Javier has more than 25 years of manufacturing experience working in engineering and manufacturing leadership roles. He has been involved with PDA as a member, Chair of the APAC region, and a member of the Board of Directors since 2020.

Javier earned his MBA from Pepperdine University, California, and his BS in Mechanical Engineering from the University of California at Davis.

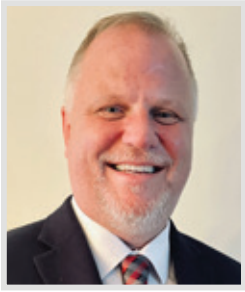
CANDIDATE STATEMENT

I am quite humbled and honored to be nominated for a second term as a member of the PDA Board of Directors. As a BoD member, I will continue to support PDA's vision to connect people, science, and regulation within the pharma industry, ensuring patients are better served by skilled, knowledgeable, and innovative professionals.

My many years in the biopharmaceutical industry, and as a member of the PDA, have reassured me that the PDA, as an organization, provides an essential service to the industry via targeted conferences, seminars, and expert-developed Technical Reports.

In 2020, my passion for promoting the PDA values led me to accept the PDA APAC Korea Chapter chairmanship. For three years, with a dedicated steering committee, the Aseptic Processing of Biopharmaceuticals Conference continued to attract professionals from Korea and neighboring countries seeking to improve their knowledge in aseptic filling and supporting operations. The conference continues to this date. Early this year, my career has taken me to Saudi Arabia. Drug substance and drug product operations are new to this region. I see this as a perfect opportunity to promote and expand the value PDA brings to the pharma industry in the Middle East.

Thank you for your consideration.



KEN PADDOCK

Ken Paddock is a Quality Sterility Assurance Director at Baxter Healthcare. Ken is responsible for leading a global team of Regional Sterility Assurance Representatives to create and carry out a unified SA strategy plan across Baxter as the Global Sterility Assurance (SA) Lead within the quality department. The team is also responsible for regional sterility assurance compliance and offers quality management for facility-level microbiological control and cleanroom practices. Ken has more than 25 years of experience in the pharmaceutical sector, with expertise in environmental monitoring systems, product/process development, and terminal sterilization (ethylene oxide, moist heat, and radiation) for both drug and device products.

Ken is a current member of the PDA Midwest Chapter Board and has served the chapter in a number of elected capacities since 2010. These include President, President-Elect, Treasurer, Secretary, and Member-at-Large. In addition, he serves on the PDA Science Advisory Board, a diverse group of leading bio-pharmaceutical industry experts setting strategic direction for the PDA on technical topics associated with pharmaceutical manufacturing and quality. He also serves as the co-chair for the 2023 and 2024 PDA Annual Meetings.

CANDIDATE STATEMENT

I am honored to be nominated for the PDA Board of Directors. PDA is a unique organization as it excels in connecting people, science, and regulation, as it pledges to do. I am proud to be a member of an organization that values both individual contributions and collaborative team efforts to accomplish a common objective.

During my 20-year PDA membership, I have collaborated with many knowledgeable people who have shared valuable experiences and promoted PDA's vision for the pharmaceutical and biopharmaceutical community. I am fortunate that PDA helped establish my foundation and contributed significantly to my passion for science.

As our community continues to evolve through digitalization, adhering to regulation changes, and adopting new technology, PDA continues to strengthen their position as a global leader by providing technical documents, offering expertise training, and successfully providing regulatory influence. My goals focus on complementing PDA's strengths, such as engaging the science behind the progression of our industry, membership engagement, ensuring strategic alignment with our community to share, and advance best demonstrated practices, all while being patient centric.

I am delighted for this opportunity to contribute to PDA's leadership and to have a positive impact on our industry and the patients we serve.

BRIGITTE REUTTER-HAERLE

Brigitte Reutter-Haerle personifies two decades of pharmaceutical industry experience, currently serving as Vice President Product Management & Marketing for Vetter. Her portfolio of experience positions Brigitte to offer new perspectives to PDA, driven by a commitment to its growth and success. Brigitte has comprehensive knowledge of manufacturing and packaging of biologicals, specifically pre-filled syringes and devices from a CMO perspective, but also of industry issues, priorities, and challenges. Her focused communication background enables her to always deliver PDA messages in a manner attuned to reaching technical and mainstream audiences with clear, compelling, and accessible language.

Brigitte joined PDA in 2005. She has been Vice Chair of the Marketing Advisory Board, Leader of PDA's Pre-Filled Syringe Interest Group/Europe, an active member of the PDA Task Force Combination Products, a three-term Chair of the PDA UPS Conference, and a member of the Program Planning Committee since 2007. In 2014, Brigitte received the PDA Distinguished Service Award and, in 2017, the PDA Europe Service Appreciation Award for her long-standing contributions to PDA. Her experience, personality, commitment, and spirit will uplift PDA members to accomplish more than ever before.

Brigitte earned a BA and a degree in Business Administration from Baden-Wurttemberg Cooperative State University.

CANDIDATE STATEMENT

I come to PDA with in-depth, technical expertise in the fields of injectables and equipment, garnered through decades of work at Vetter. This is balanced with a marketing background that shapes my thinking about how we communicate on behalf of our organization. Coupled with my longstanding involvement with PDA, I bring a unique lens into our position and possibilities. Together, let's investigate how we can do even more to prepare our industry and emerging professionals for the future we envision. This is vital for PDA, so we sustain our profile for leadership, our reputation for excellence, and our distinction for knowledge and innovation. My expertise affords me an opportunity to propose improvements in the way we communicate, especially through our owned channels where our messages are spared from media editorializing. My marketing perspective may also provide a valuable blend of creativity with our shared technical expertise thus increasing our impact. Such combined talent and capability can make our PDA Board empowered for member development and engagement, industry stewardship, and heightened recognition. I commit to supporting our growth, realizing our potential, and fostering our future, always with the kind of energy and enthusiasm for which I am known.

OSAMU SHIROKIZAWA

Osamu Shirokizawa is President and CEO of Life Scientia Ltd., an engineering consultancy firm specializing in pharmaceutical, biopharmaceutical, and ATMP manufacturing industries. He has more than 30 years of experience in providing a variety of engineering and compliance services to the industry. These include microbial control strategy, product sterility assurance, and cleaning validation.

Osamu has been an active PDA member for more than 25 years and currently serves on the PDA Board of Directors. He has been a representative of the PDA Japan Chapter (JPDA) since 2019. He is the current chair of the Kansai Study Group (KSG), which is one of the subcommittees of JPDA. He is a member of a task force for updating PDA Technical Report No. 29, *Science and Risk Based Cleaning Validation*, with the ongoing experience of developing several ASTM standard guides relating cleaning validation. He is one of the authors of *PDA Points to Consider for the Engineering of Manufacturing of ATMPs* as well.

Osamu has also been working in multiple volunteer activities led by the Pharmaceuticals and Medical Devices Agency (PMDA) of Japan. He took a key role in establishing and revising Japanese guidance documents for sterile products.

CANDIDATE STATEMENT

I am honored and grateful to be nominated to the PDA Board of Directors for a second term. Since I joined PDA about 25 years ago, I have always been impressed by its commitment to science and quality. It is truly a value to the industry and patients. During my first tenure, I continued working with wonderful people in PDA in a variety of opportunities, and that allowed me to create an unexpectedly wider and stronger network, which was extremely beneficial in my service on the BoD.

As the COVID-19 pandemic has shown us, collaboration among key stakeholders, such as the industry, regulatory authorities, and academia, is called for to provide better service to patients. I believe, therefore, PDA's science and quality-oriented mindset is needed now more than ever. If I am elected to the Board again, I will most thoroughly use all my knowledge and skills to support PDA in providing valuable services to our members and to advance all aspects of its mission. In particular, I will work on increasing diversity of the membership, addressing upcoming technologies, and promoting science and risk-based approaches.

ART VELLUTATO, JR.

Art Vellutato, Jr. is President/CEO of Veltek Associates, Inc. (VAI) and the President/Senior Consultant of Aseptic Processing, Inc. (API). A frequent speaker and PDA member for more than 38 years, he has also authored more than 75 industry publications, holds more than 256 worldwide patents, and is one of the leading contamination control consultants in the industry. Since 2002, Art has conducted routine training on Contamination Control for the FDA, EMEA, Health Canada, TGA, and the Kazakhstan Regulatory Agencies.

Art is one of the original and continuing faculty members of PDA's Aseptic Processing Course and the coordinator/trainer for PDA's Contamination Control Course. He is the Chair of the PDA Cleaning and Disinfection SIG, the Chair and technical writer for PDA TR70, and was a member of the PDA TR13 technical report team. He received the James P. Agalloco Award in 2011, PDA Excellence in Training Award, and the 2017 PDA Gordon Personeus Award. He has been a Faculty Member for USP <797> Workshops, Past President of the PDA Delaware Valley Chapter, Past Chair of the PDA Exhibit Committee, Past Chair of PDA Chapter Council and served on several Program Committees for PDA Annual Microbiological Conferences.

CANDIDATE STATEMENT

After many years of involvement with PDA and the industry, I've learned that information exchange is one of PDA's most valuable assets to GMP organizations, regulatory agencies, and GMP professionals. Interaction between professionals who have common goals is invaluable. Many times, success in this venue does not come from just attending sessions or joining an interest group and goes deeper into personal relationships. The relationship development, coupled with the utilization of learning tools such as those provided by PDA Education, can provide all levels of management with the ability to ascertain best practice and regulatory expectations. As a PDA Board Member, I will strive to make the relationship between members, the learning experience, and the realization of best practice in conjunction with regulatory agencies a foremost priority.

Let Your Voice Be Heard!

Vote at *pda.org/vote*

by 15 Nov., 2023 at 11:59 p.m.

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- Carefully read the instructions for each question before you make your selections.
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