



2018 PDA Officers and Board of Directors Election Guide

Online voting open
Vote: www.pda.org/vote

POLLS: Open September 5, 2017
Close November 15, 2017 at 11:59 p.m. EST.

Open to PDA members in good standing
as of midnight on August 24, 2017.

PDA members have the opportunity to choose volunteer leadership for 2018. You may vote for three officers and three directors who will take seats on the PDA Board of Directors.

Voting Details:

The 2018 PDA Officers and Board of Directors election is open to members in good standing as of midnight on **August 24, 2017**. Balloting opens **September 5, 2017** and closes at 11:59 p.m. EST on **November 15, 2017**. Ballots received or requests to vote after that date and time cannot be accepted.

Vote online or vote when you attend any of PDA's fall meetings:

2017 PDA/FDA Joint Regulatory Conference

September 11-13 | Washington, DC

2017 PDA PAC iAM Workshop

September 13-14 | Washington, DC

Pharmaceutical Freeze

Drying Technology

September 19-20 | Cologne, Germany

Particles in Injectables Conference

September 26-27 | Berlin, Germany

10th Workshop on Monoclonal Antibodies

September 26-27 | Berlin, Germany

2017 PDA Annex 1 Workshop

October 2-3 | Washington, DC

2017 PDA Container Closure, Devices and Delivery Systems: Compatibility and Material Safety Workshop

October 2-3 | Washington, DC

Pharmaceutical Cold & Supply Chain Logistics

October 10-11 | Prague, Czech Republic

12th Annual PDA Global Conference on Pharmaceutical Microbiology

October 16-18 | Bethesda, MD

2017 PDA Endotoxins Workshop

October 18-19 | Bethesda, MD

2017 PDA Visual Inspection Forum

October 23-24 | Bethesda, MD

The Universe of Pre-filled syringes and Injection Devices

November 7-8 | Vienna, Austria

How to Cast Your Ballot

- Log on to www.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? Email: vote@pda.org or call (301) 656-5900.



Candidates Running for Officer Positions

- 3** JETTE CHRISTENSEN – CHAIR-ELECT
- 4** MICHAEL SADOWSKI – TREASURER
- 5** STEVEN LYNN – SECRETARY

Candidates Running for Director Positions

- 7** MASAHIRO AKIMOTO
- 8** AARON R. GOERKE, PhD
- 9** KERRY INGALLS
- 10** IVY LOUIS
- 11** MARY OATES, PhD
- 12** EMMA RAMNARINE

Board Officer Candidates

The open seats are for the following Officer positions: **Chair-elect, Treasurer, and Secretary**

JETTE CHRISTENSEN



Jette Christensen works at Novo Nordisk A/S where she has held several different positions. She currently serves as the Scientific Director of Compliance and QMS in the Diabetes Finish Product section. Jette works with sites located in Denmark, France, the U.S., Brazil, and China, and has a global view on authority requirements, manufacturing processes, and culture.

Jette has been an active PDA member since 1998 and has been involved in many activities. She has presented at several conferences and has been a member of PDA Program Planning Committees and Task Forces. Currently, Jette is involved in the Annex 1 Task Force and has recently been involved in preparing the PDA Points to Consider for Aging Facilities. She is a member of the PDA Science Advisory Board and is Secretary for the Board of Directors and, thereby, also part of the Executive Committee.

Candidate Statement

It is an honor to be nominated as Chair Elect of the PDA Board of Directors. During my years in PDA, I have met many, very great and knowledgeable people, and I welcome the opportunity to continue being part of the PDA Board of Directors with this significant responsibility.

PDA is the leading global provider of science and technology information and education for the pharmaceutical and biopharmaceutical community, and PDA connects people, science, and regulation with great success.

The pharmaceutical and biopharmaceutical world develops, and PDA must continue supporting this development by choosing the right strategies and focusing on the right themes and issues within science and technology.

As Chair Elect, I will continue my work for PDA to strengthen the creation of substantial value for the members, among others by:

- Focusing on and supporting the scientific approach that is our base
- Ensuring that dialogue between regulation and industry are scientifically, risk-based, and technically focused
- Focusing on engaging members to take part in PDA work and on member/volunteer diversity
- Ensuring that PDA activities cover the latest trends and development in the pharmaceutical and biopharmaceutical industry

MICHAEL SADOWSKI



Michael Sadowski is the Director, R&D Sterility Assurance for the Baxter Healthcare Corporation and leads a team of engineers and scientists located in the U.S., China, and Belgium. He and his Team are responsible for international Sterility Assurance programs in support of pharmaceutical products and medical devices. Mike has more than 25 years of experience with drug and device sterilization methods, including moist heat, ethylene oxide, radiation, and aseptic processing.

In addition to participation as an author on the Task Force to revise PDA Technical Report No. 1 on Moist Heat Sterilization, Mike was also Chairman of the Task Force for the revision of PDA Technical Report No. 30 on Parametric Release. Mike has served on the Board of Directors since 2008. He is a member of the Science Advisory and Education Advisory Boards and is a member of the PDA Education faculty, in which capacity he enjoys sharing his knowledge of the sterilization sciences. He is a published author and has given presentations and training sessions on sterilization and parametric release to industry professionals and regulators across the globe. Mike received his BS Degree in Microbiology from Purdue University in West Lafayette, Indiana.

Candidate Statement

It has been a great privilege and an extremely valuable experience for me personally and professionally to serve the PDA membership during my current term as Treasurer on the PDA Board of Directors. I am honored to be nominated to complete another term as Treasurer.

During my 10 years on the Board, it has been exceptionally rewarding to see PDA continue to grow ever stronger with quality products and services at an unmatched level that further distinguish PDA's superior value proposition. This level of operational success is ultimately a result of the caliber and contributions of everyone; the staff, leadership, volunteers, and members who exemplify the highest level of core values. That same strong passion for science, to share and drive best-demonstrated practices, advances our industry and maximizes the benefit to the patients we serve.

Scientific principle is at the core of the PDA Strategy, supporting both our mission and vision. Our passion for science will continue to strengthen our position as the foremost provider of best practice for the industry, and this virtue sets us apart from all other organizations. I feel very fortunate and truly appreciate the opportunity to fulfill my passion for science while contributing to the future successes of PDA.

STEVEN LYNN



Steve Lynn is currently the Global Head of Group (Corporate) Compliance and Audit for Novartis International, where he leads the corporate GxP compliance and audit functions across the brand, generics, and Alcon device divisions. Previously, Steve was the Vice President of Global Quality Compliance at Mylan, before which he spent many years with the U.S. FDA, most recently as Director of CDER's Office of Manufacturing and Product Quality (OMPQ) within the Office of Compliance. In this role, he led multiple major domestic and international drug programs designed to assure compliance with Current Good Manufacturing Practices. Through his other roles at FDA, Steve set up operations for the new Office of Pharmaceutical Quality; worked closely with the Assistant Commissioner for Operations regarding medicinal products and tobacco, including investigatory operational issues and inspection programs; and oversaw the planning, development, and implementation of ORA's inaugural organization-wide formal Quality Management System.

Steve received his 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. He is also an ASQ Certified Manager of Quality/Organizational Excellence.

Candidate Statement

I am honored and humbled to be a nominee to the PDA Board of Directors. PDA is a wonderful organization that I've come to greatly value for science, technology, and regulatory information.

My first major interaction with PDA was during my tenure at the U.S. FDA, when I came to rely on PDA as a reliable resource for technical knowledge and continuing education and as a strategic partner for the Agency's outreach activities. After returning to the private sector, I've come to further rely on PDA for valuable information and education.

When invited, I eagerly accepted the nomination to become a member of PDA's Regulatory and Quality Advisory Board (RAQAB). The past three years on the RAQAB have helped me gain a much better understanding of PDA and the value proposition this organization creates for us as members.

If elected to the Board of Directors, I will strive to further strengthen PDA's value proposition. As PDA constituents, you deserve the best. We are living in times of great disruptive change in our industry, and I believe PDA is at the forefront of helping to advance the vital scientific, technical, and regulatory information that arises as a result.

Thank you for your consideration.

Board Director Candidates

The following six candidates are running for three open seats on the Board.

According to the recent change in PDA's bylaws, the Directors that fill these three open seats will be elected by the PDA membership. A fourth Director will be appointed by the Board of Directors.

Candidates are listed in alphabetical order.

MASAHIRO AKIMOTO



Masahiro Akimoto is the senior manager of the R&D and Quality Assurance Division at Otsuka Pharmaceutical Factory, Inc., responsible for supervising the quality assurance and ensuring regulatory compliance for innovative product development.

In his approximately 25 years in the field, Masahiro has been involved with CMC development, strategic quality planning for CTM production of both sterile and oral-solid dosages, technical transfer managements to U.S. and EU CMOs, preparation of the quality sections of the marketing authorization dossier, and quality assurance for system audits for regulatory compliance, and continuous improvement.

Masahiro earned his master's degree in pharmaceutical science (physical chemistry) from the graduate school of the Pharmaceutical Institute, Tohoku University in 1987. He has been a registered pharmacist and an ASQ certified quality engineer.

An active member of PDA for 20 years, Masahiro has been a member of the Board of the Japan Chapter since 2009 and the Annual Meeting Program Planning Committee since 2012. He was instrumental in arranging speakers for successful collaborative meetings with the PDA-EU Chapter and PDA Global. He is also a member of PDA's Science Advisory Board (SAB), the Aseptic Processing Points to Consider Task Force (2016), and the Sterile Product GMP and development QA committees of the Japan Chapter.

Candidate Statement

It is a great honor to be nominated to the PDA Board of Directors.

PDA is the leading professional facilitator of science, technology, and regulatory information. In expanding globalization and innovation of pharmaceutical industries, I have realized the power of the strong PDA global network, which has become more beneficial in providing solutions related to manufacturing technology, GMPs, and quality systems.

If I have the privilege of being re-elected, I am committed to continuing to assist PDA to ensure its leadership role and highly respected mission, focusing on the patient first, as all roads to quality lead to patient safety.

I will contribute to broadening the value of membership and promoting the mission of PDA. I will continue to facilitate the sharing of PDA knowledge, among membership through interactive communication using my skill and experience. I would also be pleased to participate in or arrange to involve appropriate experts from my network in the development of valuable PDA resources, such as technical reports, particularly in cases where different points of view on quality culture, and business expectations would be beneficial.

AARON R. GOERKE, PhD



Aaron Goerke has more than 14 years of industry experience in supporting bio/pharmaceutical companies in process development, manufacturing, and quality systems. Passionate about PDA, Aaron has served on Planning Committees and the MSOP Steering Committee, chaired technical sessions, actively manages new manufacturing intelligence topics to PDAs focus, and is authoring PDA technical papers.

In various roles, Aaron has developed projects ranging from discovery to Phase III and managed internal and CMO Biologics and Vaccine manufacture. Aaron's most recent role as Head of Downstream Global Manufacturing at Genentech included responsibility for international technology transfers, maintaining Make-Assess-Release, and driving various network strategic initiatives. He developed the Roche Process & Product monitoring program, established a Global Performance Analysis program, and conceptualized an IT solution in the age of "big data" to capture insights across manufacturing.

Currently Head of Global Engagement and Deployment at Hoffmann-La Roche, Aaron focuses on managing resistance and driving change on key projects. External influencing has afforded Aaron opportunities to discuss topics with ROW Health Authorities. Aaron holds a PhD in Chemical Engineering from Stanford University and has published a number of peer-reviewed journal articles and patents, and given numerous external presentations. He continues to serve on national/international forums, and has won various academic and professional awards.

Candidate Statement

PDA provides invaluable insights that improve how I work and incredible opportunities to collaborate with the best minds in our industry. It's an honor to be nominated to serve on its Board of Directors. If elected, I will redouble my efforts to advance our agenda, using the energy and skills that helped me establish multiple Global groups at Roche. At PDA, we can partner to accomplish more.

My focus on manufacturing innovation and business intelligence is shaped by real-world experience. Many are swimming in data without actionable insights. Leaders, investors, regulators, and consumers need us to improve how we track quality, identify risks, and manage production. Why is it so hard?

Building manufacturing intelligence is difficult because organizations are complex. Engaging people, from the lab to executive level to the shop floor, is required to drive behavior change. Delivering innovative process and product improvement won't happen without connecting quality, regulatory, and manufacturing on both technical and human levels.

Partnering with others passionate about matching the science of continuous improvement with the art of managing large-scale change energizes me. I look forward to this relationship with PDA and its members, building these capabilities together, and engaging a new generation of professionals.

KERRY INGALLS



Kerry Ingalls joined Amgen in October 2009, serving as Vice President, Engineering until March 2011. He has since led manufacturing operations in Colorado and Ireland, and is currently Vice President of Site Operations for Amgen's largest manufacturing site, located in Juncos, Puerto Rico. He serves on the Manufacturing Science and Operations Program Steering Committee of the Parenteral Drug Association (PDA) and is a member of the Board of Directors for the Pharmaceutical Industry Association of Puerto Rico.

After graduating from the United States Naval Academy in 1983, Kerry served as a submarine officer for 26 years. His commands included the nuclear powered fast attack submarine USS ASHEVILLE (SSN 758) and Submarine Squadron NINETEEN, comprised of six OHIO-class ballistic missile submarines, two of which were converted during his tenure for conventional strike operations and delivery of Special Operations forces. Ashore, Kerry served as Plant Manager of a land-based reactor plant, Special Assistant to the Commander of US forces in the Pacific theater, Senior Member of the US Pacific Fleet Nuclear Propulsion inspection team, director of Political-Military affairs for coalition forces in Afghanistan, and Military Assistant to the Deputy Secretary of Defense.

Candidate Statement

I have devoted my professional life to public service, from protecting our freedoms to improving quality of life for patients with grievous illnesses.

I am living proof that PDA's mission matters. From personal training to annual conferences, at which I have both presented and moderated, PDA has been a very important resource for my personal growth and professional success. The Association has similarly benefited not just many of my colleagues but also, most importantly, the patients we serve.

Although my background is atypical for a biopharma executive, many of the skills and expertise I developed through intense military service are directly applicable to our work in the service of patients. For example, I am particularly passionate about people, teamwork, compliance, safety, quality, continuous improvement, and high reliability – essential elements for success across the many member organizations of PDA.

I am honored to be nominated for the PDA Board of Directors and hope that you will support me in applying my unique perspectives and experience to directly further PDA's mission. Thank you for your consideration.

IVY LOUIS



Ivy Louis is Founder Director of VIENNI TRAINING & CONSULTING LLP, an organization that builds excellence through training and consulting, while working with people and processes. Ivy's expertise in training emerges from her career as a teacher in pharmaceutical sciences, having worked in the manufacturing and quality domains in the pharmaceutical industry and having established a strong, credible validation and service vertical for Millipore while she headed the company's Technical Services in India.

She has been a forerunner in establishing validation and support services for pharmaceutical customers in research, production, and quality control/assurance areas, in India and parts of Asia, through propagating the science and importance of filtration and validation, significance of microbiology, contamination and control, its monitoring in aseptic processing, and its regulatory requirements.

In her current role, she assumes the responsibilities of making measurable differences to operational and assurance efficiency, at various pharmaceutical organizations, through services that offer practicality in implementation of learning.

Ivy holds a Master's degree in Pharmaceutical Sciences and an MBA in Human Resource Management. From the inception of the Chapter in India, she has been entrenched in leading all the activities of the Parenteral Drug Association Chapter, initially as the Treasurer, and currently as the President Elect.

Candidate Statement

It is an absolute honor to be nominated to the PDA Board of Directors, from India. That PDA plays a significant role in contributing to building assurances in quality of medicines, as the leading professional association, offering a rich network for deliberations and understanding among regulators, industry, scientists, and other stakeholders, is undoubted. PDA is endowed with the unique ability to enable pharmaceutical professionals in the industry to overcome challenges posed by a myriad of deficiencies, owing to the mission of connecting people, science, and regulation, and building trust through communication and collaboration.

The remarkable capacity to erect reliability, by sharing practical approaches in managing current and future operational, quality, and distribution impediments, is a hallmark for PDA, whose subject matter experts, comprehensive scientific guidance, the unparalleled resources of Technical Reports, the unrivaled educational resources, and the networking/volunteering opportunities remain ahead of its time.

I am deeply committed to the cause that the organization upholds while using my experience and skills to scale greater altitudes in altering lives of patients, worldwide. It will be a privilege to have this opportunity to represent PDA on the Board of Directors and contribute in this capacity.

MARY OATES, PhD



Mary Oates has more than 25 years of experience in the pharmaceutical industry in Operations, Quality, and R&D. She is currently Vice President of Innovative Operations and Network Excellence at Pfi er, where she is responsible for 19 Biotechnology and Consumer product manufacturing plants, Consumer External Supply, and operational excellence for the manufacturing division. Prior to this, Mary was the Global Quality Operations leader at Pfi er for eight years with responsibility for quality oversight of all clinical and commercial products made by or for Pfi er for all markets.

Mary has been an active contributor to industry organizations throughout her career. She is currently a member of an International Council for Harmonization (ICH) expert working group, developing a Quality Guideline on Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management (ICH Q12). She is also a member of the Pharmaceutical Research and Manufacturers of America (PhRMA) Global Quality and Manufacturing Work Group.

Mary holds an undergraduate degree in Biochemistry from Queens College and a PhD in Analytical Chemistry from the University of North Carolina in Chapel Hill.

Candidate Statement

Throughout my career, I have always been committed to putting patients first. If elected to serve on the PDA Board of Directors, I will work with PDA members, volunteers, and stakeholders in pursuit of PDA's mission, which is fully aligned with my own, to enable us all to better serve patients through the advancement of manufacturing science and regulation.

EMMA RAMNARINE



Emma Ramnarine is the Sr. Director, Head of Global Analytical Science & Technology at Roche Pharma. She is accountable for the strategic and technical leadership for analytical methods, specific tions, and technologies for Roche's commercial Biologics and Small Molecule products. This includes establishing and maintaining up-to-date, compliant and harmonized analytical control systems, proactive lifecycle management, technology innovation, method transfers, stability program, raw materials, and reference standards management.

She has 17+ years of experience in the pharmaceutical, biotechnology, and medical device industry in QC, Quality System Management, Quality Risk Management (QRM), validation, and change control. She is a worldwide-recognized expert on QRM, providing QRM leadership, expertise and training to regulatory authorities, and industry.

Emma has been active with PDA for 15 years in various volunteer and leadership roles. She has been on PDA's Regulatory Affairs and Quality Advisory Board (RAQAB) since 2013, is currently leading PDA's Post Approval Change Task Force, and PDA's QRM Interest Group. She led PDA's Task Force on Drug Shortages and also provided leadership for several PDA Technical Reports.

Emma holds an MS in Pharmaceutical Sciences from 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 a second term 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 and publications.

I remain committed and eager to drive PDA's strategy from the board level. Topics that I am passionate about and will continue to help expand PDA's influence are: post approval change management, enabling innovation and new technologies, quality risk management, drug shortage management, and practical application of science- and risk-based approaches. I want to support every PDA member 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 and rewarding for me! 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.

Let Your Voice Be Heard!

Vote at www.pda.org/vote
by November 15, 2017 at 11:59 p.m. EST.

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