PDA
Parenteral Drug Association

PDA BOARD OF DIRECTORS 2022 Election Guide

Online Voting Open

Vote: *pda.org/vote*

POLLS OPEN **Sept. 7, 2021**
POLLS CLOSE **Nov. 15, 2021 at 11:59 p.m. EST**

Open to PDA members in good standing as of midnight on 31 August, 2021.

CONNECTING PEOPLE SCIENCE AND REGULATION®

PDA members have the opportunity to choose volunteer leadership for 2022.

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 7 Sept. and 15 Nov. in the United States. The open seats are for the following officers: Chair-elect, Treasurer, and Secretary. Six people are running to fill three director seats.

Voting Details

The Board of Directors election is open to members in good standing as of midnight on 31 August, 2021. Balloting opens Sept. 7, 2021 and closes at 11:59 p.m. EST on Nov. 15, 2021. Ballots received or requests to vote after this date and time cannot be accepted.

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 Positions

CANDIDATES RUNNING FOR
Director Positions

Meet the Candidates

BOARD OFFICER CANDIDATES

ANIL SAWANT, PhD

Chair-Elect

ANIL SAWANT has more than 30 years of experience in the pharmaceutical industry in Quality & Compliance, Pharmaceutical Microbiology, Business Ethics and Compliance, Auditing, and R&D functions. He has worked on various dosage forms, and various product types of drugs, biologics, vaccines, and medical devices.

Currently, Anil is Sr. Vice President, Global Quality Compliance, Merck & Co. Prior to joining Merck, Anil served in executive positions at Johnson & Johnson and at Wyeth Pharmaceuticals (now Pfizer). Anil has been a PDA Member and volunteer since 1992. Currently, he serves on the PDA Board and Chairs the PDA COVID -19 Task Force. He has been the lead or co-lead on four PDA Technical Reports addressing the science and best practices pertaining to issues resulting in highly publicized FDA enforcement actions.

Anil is a frequent speaker at PDA conferences and local chapter meetings. He holds a BSc Honors and a MSc Honors in Microbiology & Biochemistry from Panjab University, India, and a PhD in Microbial and Biochemical Sciences from Georgia State University (GSU), Atlanta. He is a recipient of the GSU Distinguished Alumni Achievement Award. Anil serves on the Board of the non-profit Mind Your Brain Foundation and has served on the Board of Directors of GSU Alumni Association.

CANDIDATE STATEMENT

It is an honor to be nominated for election to serve as Chair-Elect. For the past 29 years, PDA has played a major part in enriching my professional life, and I am thankful for being part of such a great organization. PDA is the "go to" organization to address technical issues our industry faces, and the publisher of timely, high-quality technical reports.

I was honored to lead an agile and timely Coronavirus Task Force that conducted numerous webinars with Health Authorities on hot topics such as remote inspections and assessments to meet approval timelines, manufacturing and testing component shortages, and remote audits; developed podcasts and published a scientific paper on impact of the COVID-19 on manufacturing.

I am committed to working diligently to promote science-based compliance and patient-centric policies, as our industry evolves through pandemic and pricing pressures, using digital technologies and harmonized standards. PDA's strength is its focus on science and people, our volunteers. I will focus on creating opportunities for our global diverse demographic membership to participate and shape our industry through these changing and challenging times. As our industry transitions from paper to digital, analytics to machine learning, PDA is poised to be an enabler committed to build on its 75-year legacy of service.

MELISSA SEYMOUR, MBA

Treasurer

MELISSA SEYMOUR is Global Head of Quality and Chief Quality Officer for Biogen Inc. In her current role, Melissa leads the PO&T 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 Vice President of Global Quality Control, assuming responsibility for the comprehensive strategy and implementation of Global QC testing. Additionally, she spent several years as the Vice President of Corporate Quality with responsibility 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. She has more than 25 years of experience, including quality positions at Novo and GSK.

Melissa has been highly involved in influencing of regulatory guidance through participation on non-profit Boards of PDA from 2016 to present, as well as Rx-360, an international consortium focused on supply chain security vis-à-vis public health concerns and patient safety. Additionally, she has been an advocate for simplification of PAC, 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 Treasurer 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 organization 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 Treasurer 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.

EMMA RAMNARINE

Secretary

EMMA RAMNARINE is Executive Director, Global Head of External Development Collaborations at Genentech/Roche, managing the external network for development, manufacturing, and clinical collaborations of Roche's Biologics and Small Molecules development portfolio.

She has 20+ years of global experience in pharmaceutical, biotechnology, and medical device companies in Analytical Science & Technology, Risk Management, QC, and Quality Management Systems.

She is a highly recognized expert on Quality Risk Management, and continues to provide QRM expertise and training for regulatory authorities and industry. She is Co-lead for the Industry One-Voice-of-Quality (1VQ) Initiative on Post Approval Changes, an initiative sponsored by Chief Quality Officers of more than 25 global pharma companies.

Emma has been active with PDA for 18+ years. She has been serving on the PDA Board of Directors for six years, and is Secretary on the PDA Board Executive Committee. 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 is currently pursuing a PhD from TU Dublin. She holds 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 a second term as Secretary on the PDA Board of Directors Executive Committee. 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.

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.

MICHAEL BLACKTON, MBA

MICHAEL BLACKTON has worked for 30 years in the pharmaceutical industry in leadership positions at Eli Lilly, IDEC, Millennium, BioMarin, and Inhale Therapeutics. Currently, Michael is VP Quality at Adaptimmune LLC.

A volunteer at PDA since the 1990s, Michael has been a member of the PDA Board of Directors since 2018. He was presented with a Service Appreciation Award in 2020.

He has been a member of the Biopharmaceutical Advisory Board, and has contributed to several technical reports, including TR-60, *Process Validation A Lifecycle Approach*, TR 60-2, *Oral Solid Dosage/Semi-Solid Dosage Forms*, TR-61, *Steam in Place*, and TR-81, *Cell Based Therapy Control Strategy*.

Michael has helped to establish the ATMP focus at PDA, organizing multiple U.S.-based Cell and Gene Therapy conferences – a first for PDA. As part of his work advocating ATMPs, Michael co-created the Cell and Gene Therapy Interest Group and is currently the co-chair of the ATMP Advisory Board.

In addition to his PDA activities, Michael served on the Editorial Review Board for Cell and Gene Magazine and has presented at numerous conferences.

Michael holds a Bachelors in Biochemistry from The University of California San Diego, and an MBA specializing in Strategy, Finance, and Leadership from the NYU Stern School of Business.

CANDIDATE STATEMENT

It has been a great honor to serve on the PDA Board of Directors and I am humbly asking for your vote for a second term. Over 25 years as a member and a volunteer, I have gained many lasting friendships and professional collaborations that resulted in a deep and lasting passion for success of the organization. Since 2015 I have worked to advance ATMPs as a focus area at PDA, with the many U.S. conferences we organized, the establishment of the Cell and Gene Therapy IG, and the ATMP Advisory Board.

As a board member, it is deeply satisfying to participate in shaping the strategic direction of the organization in a way that brings the most value to our members and the industry.

Despite the progress, I feel my work is not finished. Serving on the PDA Board of Directors will allow me to continue the work I started years ago advancing the PDA mission, particularly around advanced therapies. I feel that PDA is the premier organization for pharmaceutical professionals, and I would be honored to be elected to continue working to shape the very bright future for the PDA.

MARC GLOGOVSKY

MARC GLOGOVSKY is a Senior Microbiology Consultant with ValSource, Inc., focusing on development and improvement of contamination control strategies, validation of rapid microbiological methods (RMMs), and establishing risk-based environmental monitoring programs.

Marc has more than 20 years of microbiology experience in the pharmaceutical industry. He has been an active PDA member since 2000, is currently serving on PDA's Science Advisory Board, where he is also the Interest Group Liaison, and is a member of both the ATMP and Education Advisory Boards. He is the North American chair of the Microbiology/EM Interest Group, has served on numerous Technical Report committees, and is co-chairing the Microbial Data Deviation Investigations and Environmental Monitoring Technical Reports and the ATMP Microbiology Points to Consider report.

Marc was a founding member of the PDA Mycoplasma task force and is an active advisor to the PDA Environmental Monitoring Task Force. In 2020, Marc received the James P. Agalloco award for his efforts at PDA's Training and Research Institute (TRI), where he has been a faculty member teaching EM training courses for more than 10 years.

Marc earned his BS in Biology from Monmouth University and his MS in Microbiology from Rutgers University.

CANDIDATE STATEMENT

I have been involved with PDA throughout my entire career and have enjoyed engaging with all members, who have proven to be industry and regulatory experts, committed to protecting patients. The ability to collaborate with and support PDA's various advisory boards, interest groups and local chapters has been immensely rewarding both personally and professionally. My years of interactions with other PDA members have led to many amazing debates, enlightening conferences, and, most importantly, lifelong friendships. I am honored and humbled to be considered along with the other nominees to serve as a member of the PDA Board of Directors.

PDA's involvement is essential in the ever-evolving pharmaceutical landscape as novel therapies, manufacturing technologies, and control strategies become reality in our future. As a board member, my passion for education, mentoring, and problem solving, together with my experience and dedication, will prove beneficial in meeting PDA's 2026 strategic plan, as well as any future goals and objectives. In this position, I am confident that we will continue to strengthen and expand PDA's role in scientific and industrial guidance and innovation while continuing to influence regulatory expectations to exceed the standards for product quality and patient safety.

Thank you for your consideration.

ANDREW HOPKINS

My career covers several areas over 40 years. Currently, I am a Director of Compliance at Abbvie, a role that includes Auditing of manufacturing sites, training and mentoring, guidance on the implementation regulatory guidance documents, and interaction with regulatory agencies.

Previously, I was an Inspector with the MHRA for nearly 14 years. This role included:

- Routine (and less routine!) inspections internationally, including joint inspections with several regulators (USFDA, TGA, TFDA and Health Canada) in several technical areas, including sterile products, biological products, blood components, and plasma
- Chairperson of the Inspectorates Compliance Management Team (working with marginally compliant companies to support them back to full compliance)
- MHRAs inspection Action Group (actions regarding non-compliant sites)
- Inspector training and mentoring
- Supporting the writing of regulatory guidance documents, including:
  - MHRAs Data Integrity guidance
  - EMA guidance on water systems
  - Chair for the working group for the revision of Annex 1
  - MHRA blog regarding the fragility of VHP
- Supporting technical monographs such as PDA TR1 and PHSS TM20.

Prior to MHRA, I worked for more than 20 years in several different areas and technologies in the pharmaceutical industry.

I have a BSC (Hons) in Microbiology with Genetics and a Post Graduate Diploma in Industrial Pharmaceutical Science.

CANDIDATE STATEMENT

As somebody who has worked in the pharmaceutical industry for 40 years and as a father and husband, I am proud of the work we do. In my 40 years, I worked in QC, as a Production Manager, Quality Assurance Manager, and set up validation teams, and have worked as a regulatory inspector. I have seen the industry evolve (not as fast as I think it could do) and have seen it from several perspectives (including different product types). I have had different objectives in my roles but the fundamental one, getting safe, effective product to the patient, has been common. I believe that the pharmaceutical industry must move forward, embracing new ways of thinking and working. I have been an advocate of more collaborative ways of working between industry, the regulators, and suppliers (we have shown we can do this during COVID); the many industry bodies, PDA specifically, have a major role in facilitating this. I hope that, if elected, I can indulge a personal pleasure of helping individuals grow and learn and I can use my knowledge and contacts to support a paradigm shift, so that we all work together in a more collaborative manner, embracing innovation, for the good of the patient.

STEPHAN KRAUSE, PhD

STEPHAN O. KRAUSE is Director of Product Quality for *AstraZeneca Biologics* in Maryland, USA. For the last 20 years, he has fulfilled leading roles in QA/QC and RA for clinical and commercial manufacturers. His many publications and presentations reflect his broad experience in risk management, validation, tech transfer, and control strategies. He won the 2008 PDA Distinguished Book Author Award, PDA's Fred Simon Award (2017), Distinguished Service Award (2018), and Service Appreciation Award (2019-20).

Stephan has numerous publications in the *PDA Letter* and *PDA Journal*, has co-authored several PDA technical reports, and was Task Force Leader for Analytical Method Validation, Investigational Medicinal Product Specification Setting, and Biosimilars. Currently, he serves on the PDA Board of Directors. Additionally, he volunteers as co-chair of the ATMP AB, member of BioAB and RAQAB, and chair of PDA/ANSI Standard (ANS-007) development.

Stephan often serves as chair and lecturer at major conferences worldwide. He is a course instructor for PDA Education, for which he has developed several successful training courses. In 2012 and 2015, Stephan was recognized for his contributions to advance industry best practices and was invited to present an industry perspective to the FDA at the agency's headquarters.

Stephan has a PhD in analytical biochemistry from the University of Southern California.

CANDIDATE STATEMENT

I worked with several associations and industry groups in the past but have not found any other group to be as rewarding and enjoyable to work with as PDA. I have steadily increased my time and involvement with this association because it provided me with a sense of greater purpose and fulfillment.

I am very proud of being nominated for my second term along with the other experienced candidates for the position of member of the Board of Directors. I am looking forward to dedicating more of my time to the PDA mission and sharing the hands-on experience I have through my two decades in the industry. As a board member, I believe that I can use my knowledge to support PDA's 2026 strategic plan effectively. I want to use the influence afforded by that position to further expand PDA's leading role in manufacturing and laboratory technologies and the development of novel therapeutic products.

Thank you for your consideration.

TONI MANZANO

TONI MANZANO is the co-founder and Chief Science Officer at Aizon, an AI software provider that transforms manufacturing operations in pharma and biotech industries using advanced analytics, artificial intelligence, and other smart factory technologies. For more than two decades, he has led software projects for international pharmaceutical companies covering the entire production process and supply chain.

Toni is co-chair for both the Biomanufacturing IG and the CPV of the Future initiatives at the PDA and leads the AI in Operations team within the Xavier Health Artificial Intelligence Initiative at Xavier University, which seeks to increase the predictive assurance of product quality across all pharma operations through the power of AI. He teaches artificial intelligence classes at universities (Universitat Autònoma de Barcelona and OBS Business School) and is a member of the Science Experts in the Spanish Parliament.

He has written numerous articles in the pharma industry and holds a dozen international patents related to the encryption, transmission, storage, and processing of large volumes of data for regulated environments in the cloud.

Toni holds an undergraduate degree in Physics, a Master's degree in Information and Knowledge Society, and holds a postgraduate degree in quality systems for manufacturing and research pharmaceutical processes.

CANDIDATE STATEMENT

I'm passionate about the mission of the PDA: to advance pharmaceutical/biopharmaceutical manufacturing science and regulation so members can better serve patients. My professional life has been dedicated to analyzing, understanding, and improving drug manufacturing processes by means of technology and I am devoted to this community. I bring the know-how acquired from decades of experience and hard work.

Since becoming a PDA member four years ago, I have known that this organization has all the ingredients to make the industry better for humankind, carrying out science, verifying facts, and improving patients' health. For this reason, I continuously and actively support PDA initiatives at conferences and workshops, contribute in papers, and actively participate in Interest Groups.

It would be an honor to support this great task and serve the community as a board member. As a member of the PDA Board of Directors, I would bring expertise from the technological sphere, generate transversality in regulation, research, manufacturing, and logistics with one main goal: serve patients.

AMY McDANIEL, PhD

AMY McDANIEL is the Senior Director of the Microbiology Center of Excellence at Bristol Myers Squibb. In this role, she leads harmonization of microbiology strategy and methods for small and large molecules, in process production material, drug substance, and final product.

She is part of the Analytical Strategy and Operations Division in the Pharmaceutical Development Organization, responsible for the production of clinical material and transfer of analytical assays to the commercial manufacturing sites around the world. She is also responsible for new technology implementation for the Clinical Supply Organization at the New Brunswick, NJ site, and the cascade of the technology globally across the company.

Prior to joining BMS, Amy was a microbiology reviewer in CDER's Division of Microbiology Assessment as a Generic Drug User Fee Act term position, a two-year position reviewing sterile small molecule filings for generic drugs. Prior to the FDA, Amy was in management roles at Pfizer for 17 years, which included QC Microbiology, Manufacturing Operations, Technical Operations, and Quality Assurance.

Amy has authored multiple articles and book chapters and presented on technical topics in rapid and traditional microbiology. Amy holds a Ph. degree in Microbiology and Molecular Genetics from Rutgers University.

CANDIDATE STATEMENT

I am honored to be nominated for the PDA Board of Directors. PDA has been central to my professional life for more than 20 years. I have volunteered throughout my career roles as a vendor, a site-based leader at a biotech manufacturing facility, a regulator, and a network microbiology leader.

These diverse technical experiences and the personal empathy gained in each of my roles will allow me to bring unique, creative, and broad strategic perspectives to the Board as it makes critical decisions to move into the future of bringing people, science, and regulation together.

Let Your Voice Be Heard!

Vote at *pda.org/vote*

by Nov. 15, 2021 at 11:59 p.m.

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