PDA®
Parenteral Drug Association

PDA Officers and Board of Directors 2016 Election Guide

Online voting open

Vote: www.pda.org/vote

Polls: Open Aug. 21, 2015
Close Nov. 15, 2015 at 11:59 p.m.

Open to PDA members in good standing as of midnight on Aug. 11, 2015.

PDA members have the opportunity to choose volunteer leadership for 2016. You may select three officers and four board members who will take seats on the PDA Board of Directors. Members in good standing can vote online from the PDA website and at conferences that will be held between Aug. 21 and Nov. 15 in the United States and Europe. The open seats are for the following officers: Chair-elect, Treasurer and Secretary. Eight people are running to fill four director seats.

Voting Details:

The Board of Directors election is open to **members in good standing as of midnight on Aug. 11, 2015. Balloting opens Aug. 21, 2015 and closes at 11:59 p.m. EST on Nov. 15, 2015. 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 in Europe or in the U.S.:

Particles in Injectables | Sept. 10-11 | Berlin, Germany
Pharmaceutical Freeze-Drying Technology | Sept. 15-16 | Munich, Germany
8th Workshop on Monoclonal Antibodies | Sept. 22-23 | Berlin, Germany
2015 PDA/FDA Joint Regulatory Conference | Sept. 28-30 | Washington, DC
Pharmaceutical Cold & Supply Chain Logistics | Oct. 6-7 | Amsterdam, The Netherlands
PDA 10th Annual Global Conference on Pharmaceutical Microbiology | Oct. 19-21 | Bethesda, MD
PDA Visual Inspection Forum | Oct. 26-27 | Bethesda, MD
The Universe of Pre-filled Syringes & Injection Devices | Nov. 3-4 | Vienna, Austria
PDA Metrics Conference | Nov. 9-10 | Bethesda, MD

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

Candidates Running for Officer Positions

4 BECKY DEVINE, PhD – CHAIR ELECT

5 MICHAEL SADOWSKI – TREASURER

6 JETTE CHRISTENSEN – SECRETARY

Candidates Running for Director Positions

8 ERIC DRAPÉ

9 ZENA KAUFMAN

10 MARTY NEALEY

11 G.K. RAJU, PhD

12 DR.-ING. STEPHAN RÖNNINGER

13 ANIL SAWANT, PhD

14 SUSAN SCHNIEPP

15 MELISSA SEYMOUR

Meet the Candidates

Board Officer Candidates

BECKY DEVINE, PhD – CHAIR ELECT

Rebecca (Becky) Devine, PhD, is an independent regulatory consultant with over 30 years of experience in the regulation of biological products. She began consulting after leaving the *U.S. FDA*. She joined the *FDA* in 1979 as a Microbiologist, and held various positions in the Center for Biologics Evaluation and Research (CBER) throughout her 20-year FDA career. Prior to leaving *FDA*, she was the Associate Director for Policy at CBER. In that position, she was responsible for the development and implementation of all regulations, policy and guidance for biological products. Throughout her career, she has been involved in the regulatory aspects of biopharmaceutical license applications, inspections, compliance, and quality of vaccine, therapeutic, and biotechnology derived biological products. Dr. Devine earned her BS and PhD degrees in microbiology from the University of Maryland. She is Treasurer of the PDA Board of Directors and Board Liaison to the PDA Biotechnology Advisory Board. She has been a member various technical report task forces including TR No. 38, TR No.42, TR No. 14, TR No. 60 and TR No. 69.

Candidate Statement

For many years now, I have been a part of the PDA community and have valued the friendships, working relationships and opportunities to contribute to PDA's important activities. As Secretary and Treasurer, I learned much about the organization. Building on this experience, I am very honored and excited to be nominated to continue to serve on the PDA Board of Directors. As Chair Elect, I will support implementation of the Strategic Plan initiatives to allow PDA to continue to serve our membership in many important areas. I believe the strength of PDA lies in its members, and I will strive to assure continued member satisfaction, support the advancement of PDA into cutting-edge areas such as cell and gene therapy, vaccines and biotechnology products, and continued excellence in our core areas, including aseptic processing and sterile manufacturing technologies. Globalization creates many new challenges for PDA members; therefore, PDA must also be a global organization. Working to serve members in many areas of the world will strengthen the association. Along with the excellent PDA staff, I would work hard to assure that we continue to succeed in providing sound scientific guidance and education, excellent networking and volunteer opportunities that serve the global pharmaceutical community. I look forward to what lies ahead for PDA.

MICHAEL SADOWSKI – TREASURER

Michael Sadowski is the Director, R&D Sterility Assurance and leads a Team of Engineers and Scientists at the *Baxter Healthcare Corporation* located in Round Lake, IL. He is 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, he 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, IN.

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 recent term as Secretary on the PDA Board of Directors, and I am honored to be nominated as Treasurer.

During my participation 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. The level of operational success is ultimately a result of the caliber and contributions of everyone; the staff, leadership, volunteers and members exemplify the highest level of core values. That same strong passion for science, in the endeavor to share and drive best demonstrated practices, advances the state of 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.

JETTE CHRISTENSEN – SECRETARY

Jette Christensen works at *Novo Nordisk A/S* where she has held several different positions. She currently serves as the Compliance Specialist 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 several activities. She has presented at several conferences and has been member of PDA planning committees and task forces. Currently, Jette is involved in the Points to Consider Aseptic Processing and the Sterile Manufacturing GMP Comparison task forces. She is also a member of the PDA Science Advisory Board and Board of Directors.

Candidate Statement

Being a part of the PDA Board of Directors is honorable and very interesting and it is an honor to be nominated as Secretary for the Board of Directors.

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.

As the pharmaceutical and biopharmaceutical world develops, PDA must continue choosing the right strategies and focusing on the right themes and issues within science and technology.

As Secretary, I will continue my work for PDA to strengthen the creation of substantial value for our members.

Meet the Candidates

Board Director Candidates

The next candidates are running for four open seats on the board. Candidates are listed in alphabetical order.

ERIC DRAPÉ

After his graduation as a Pharmacist from Paris University, Eric specialized in the field of Analytical Chemistry and, after several years of professional experience, obtained an Executive MBA from SIMI/Copenhagen Business School.

Eric's professional experience led him to various functions in analytical development, QC, QA, site management, regional management, technical operations and, finally, to *TEVA* as Head of Global Quality and Biologics Operations.

He has developed his experience through roles with different companies and organizations, such as the *French Air Force R&D, Laboratoires Servier, Novo Nordisk, Ipsen* and *TEVA*, and he has spent most of his time working in an international environment.

Eric's passion is about developing organizations' and peoples' skills in a multicultural environment. The evolution of our business also requires finding the right balance between compliance and effectiveness in everything we do. Utilization of methods such as Lean 6 Sigma has now become a must – Eric brings 15 years of operational experience in that field.

Candidate Statement

I am very honored to be considered for PDA's Board of Directors.

PDA is one of the most famous and respected industry associations and is perceived as "the lighthouse" in many respects.

With about 30 years of experience in the pharmaceutical industry in various functions and geographies, I believe that I can contribute to the development of PDA.

With my combined background of Operations and Quality Assurance in a global environment, I am really excited at the idea of joining the Board of Directors of PDA. It is our duty to transmit our knowledge and prepare for the future; in that respect, PDA is certainly the right place to be.

ZENA KAUFMAN

Zena Kaufman has worked in the pharmaceutical and medical device industry for more than 20 years, primarily in the field of Quality. Starting as a bench chemist at *Alza Corp.,* she has held positions of increasing responsibility at *Searle, Pharmacia, Pfizer, Abbott* and *Hospira*, always leveraging quality within the business as a competitive advantage. Most recently, she has served as the Senior Vice President of Global Quality at *Hospira*, the world's leading provider of sterile generic injectables and a global leader in infusion technologies.

She represented industry on the group that developed the ICH Q10 document, *Pharmaceutical Quality Systems*, using that experience to share her passion for quality systems through presentations and training sessions with both industry and regulatory agencies. Throughout her career, Zena has been a strong supporter of PDA, first through involvement with the PDA Midwest Chapter, moving into roles with RAQAB and then serving a term on the Board of Directors. Currently, Zena is co-chair of the PDA Interest Group for Inspection Trends, working to develop innovative shared learning experiences, such as "483 Speed Dating."

Zena earned a Bachelor of Arts in Biology from CUNY Queens College and a Master of Science in Marine Environmental Sciences from SUNY at Stony Brook, NY.

Candidate Statement

I am delighted to be nominated for the PDA Board of Directors. PDA has been a strong part of my growth as a quality professional, teaching me the fundamentals of regulatory sciences, enabling me to interact directly with colleagues while continuing to advance regulatory science. What is unique to me about PDA is the constant focus on providing benefits and services to membership. If elected to the board, keeping the membership as top priority will always be my goal. PDA has an international reach and, I have worked to assure global representation on committees by including all voices from all parts of our industry from around the world. I think this global approach will continue to strengthen PDA's future as a respected source of science.

What started as a means of escaping putting the kids to bed has progressed to encouraging others within my organization to actively participate in PDA. I believe so strongly in the value that PDA brings to our industry and the patients receiving our medicine, that I am honored to be considered for the PDA Board of Directors.

To me, that is what being a member of the Board is all about; creating value for PDA members worldwide while assuring a scientific basis in quality and compliance.

MARTY NEALEY

Marty Nealey serves as Vice President, Operations for *Hospira's* Rocky Mount, NC facility where he is responsible for operations, manufacturing science and technology, engineering, environmental health and safety, validation, materials management, distribution, procurement and operational excellence functions.

Prior to his current role, over the past 26 years, Marty served in various leadership roles with *Burroughs Wellcome, Merck & Co., AstraZeneca*, and *Purdue Pharmaceuticals*. He has extensive experience in operations management, facilities management, engineering, technical services, supply chain, project management, new product launches and building robust quality systems and cultures. Marty has been a member of PDA for more than 12 years and has served on PDA's Quality Metrics/Quality Culture Sub-Committee for the past three years. He has presented and served as moderator for several PDA Meetings and Forums.

Candidate Statement

I am honored to be nominated as a prospective member of PDA's Board. I have been an active member of PDA for more than 12 years and I appreciate the staff's commitment and the organization's focus on key technical, quality, and operational challenges. I am so impressed with the caliber of technical and quality professionals involved in PDA. My membership and engagement with PDA have been extremely rewarding and a key element of both my personal success and that of the organizations with which I've been fortunate to work.

If given the opportunity to serve on PDA's Board, I would continue to build the technical and scientific foundation of the organization as we evolve into a 21st century leader – shaping pharmaceutical science, regulatory expectations and operational strategies for the industry. We are all "quality" through our commitment to patients; I'd like to find ways to bring a more significant "manufacturing" focus to PDA's discussions and conferences. I will continue to further the understanding of quality culture across operational and quality systems embedded in our industry. I am confident that I will continue to make a difference as a member of PDA, and will be honored if chosen to represent PDA on the Board of Directors.

G.K. RAJU, PhD

G.K. Raju, PhD, is the Chairman and CEO of *Light Pharma Incorporated*, a consulting and technology company focused on the pharmaceutical and biotechnology industry. G.K. has been the Executive Director for Manufacturing Initiatives at the MIT Program on the Pharmaceutical Industry for more than 10 years. He has been the Chairman of the Bio-Manufacturing Steering Committee at the Center for Biomedical Innovation at MIT and has been involved in teaching the graduate course on the Pharmaceutical Industry at MIT for more than 15 years. For 10 years, he served on a number of FDA Advisory Committees. G.K. has also been the Adjunct Professor of Industrial Pharmacy at Purdue University and Executive Director of the Consortium for the Advancement of Manufacturing of Pharmaceuticals for 10 years. G.K. obtained his MS in Chemical Engineering from MIT, his MBA from the MIT Sloan School of Management and his PhD in Chemical Engineering from MIT.

Working at the interface of industry, academia and government for more than two decades, G.K. has focused on elucidating the strategic role of pharmaceutical development and manufacturing and enabling its performance. He has benchmarked the pharmaceutical and biotechnology industry's manufacturing practices and has been involved in multiple transformation initiatives. His areas of interest include new technologies, regulation, benefit-risk analysis, manufacturing science, operational excellence, systems dynamics process analytics and performance metrics. He is a recognized thought leader on quality, risk and knowledge management, and an author of several publications and book chapters.

Candidate Statement

For many years now, I have been involved with PDA as a member of planning committees and as a presenter at PDA meetings. I have experienced the value that PDA creates from the science, technology and regulatory information and education that it helps provide to the community.

I see a tremendous opportunity for PDA to enhance and sustain this value and would be excited to be part of doing so. I feel honored and excited to have been nominated to serve on the PDA Board of Directors. I share PDA's vision.

If elected, I would attempt to leverage my experience working closely with industry, academia and government (including the FDA's 21st century quality initiative) to help PDA achieve its vision and mission. As a member of the Board, I would seek to further PDA's strategic plan(s) and enable progress consistent with its mission elements. This would help enhance and sustain value for PDA's nearly 10,000 members.

DR.-ING. STEPHAN RÖNNINGER

Stephan Rönninger holds a PhD and engineering degree in organic chemistry from the Technical University of Darmstadt, Germany. He is leading the External Affairs department on *Amgen's* operational policy outreach. He collaborates with stakeholders including authorities, associations and competitors, and manages GMP/GDP intelligence and commenting on topics regarding quality management, good manufacturing and distribution practice (GMDP) internally. He also represents *Amgen* in the European industry association EFPIA and represented EFPIA in ICH Q9, ICH Q-IWG and ICH Q7.

Following his postdoctoral studies, from 1992-2013, Stephan worked for *Roche* in an API manufacturing site with responsibilities for laboratory and project management, and served as a production manager within the Quality Assurance and Quality Management department. In 2003, he joined the *Roche* Global Quality organization with responsibilities for the *Roche* Global Quality System and external collaborations. He has received numerous awards, including the 2011 FDA CDER Leveraging & Collaboration Award for collaboration in developing a web-based knowledge base used for industry and regulatory briefings on ICH Q9, Quality Risk Management and a Certificate of Appreciation/Recognition by PIC/S and Health Canada.

Candidate Statement

It is an honor to be nominated for re-election to the PDA Board of Directors. I believe our industry can build on its strength and share practical approaches to managing future pharmaceutical quality and manufacturing matters. Appropriate risk management approaches, sound scientific advice and focused regulatory resources will drive better protection of patients. In these areas, PDA is the leading professional association, offering a neutral platform for discussion and understanding among regulators, industry, scientists and other stakeholders.

I'm convinced we can overcome the challenges posed by changes in the environment and globalization with the support of PDA, its members and volunteers. PDA is the right organization to help build trust through communication and collaboration.

I am committed to continue supporting PDA in its role as the highly respected, influential and trusted organization it has become. I will help ensure that PDA continues to be recognized as the leader to advance bio/pharmaceutical manufacturing science and regulation, so PDA members can better serve stakeholders and patients. I will support PDA as it becomes an even higher performing organization, using my experience and skills in the international environment with different cultures. In this leadership position, I can help support positive and sustainable manufacturing and supply of quality medicines.

ANIL SAWANT, PhD

Anil Sawant, PhD, has more than 25 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 from injectables to topical, and various product types of drugs, vaccines, medical devices, and consumer products. Currently, Anil is Vice President, Global Quality Management Systems and External Affairs at *Merck*, with responsibility for ensuring effectiveness of Quality Management Systems at all Human and Animal Health supply chain sites worldwide.

Prior to joining *Merck*, Anil served in executive positions at *Johnson & Johnson* and *Wyeth Pharmaceuticals* (now *Pfizer*).

A PDA Member and volunteer since 1992, Anil currently serves on PDA's Regulatory Affairs and Quality Advisory Board. He was the lead for PDA Technical Report No. 55 on musty odor taints of pharmaceutical products and co-lead for the PDA Technical Report No. 67 on objectionable microorganisms. He currently leads PDA's Task Force on Particulate Matter in Oral Dosage forms, is the Co-Lead for the Task Force on Data Integrity and is a member of the Quality Metrics Task Force. Anil is a frequent speaker at PDA conferences and local chapter meetings.

He holds a BSc Honors and an MSc Honors Degree in Microbiology & Biochemistry from Panjab University, India, and a PhD in Microbial and Biochemical Sciences from Georgia State University. He is recipient of the GSU Distinguished Alumni Achievement Award and serves on the Board of Directors of GSU Alumni Association.

Candidate Statement

It is an honor to be nominated for election to the PDA Board of Directors. For the past 23 years, PDA has played a major part in enriching my professional life, and I am thankful for being part of such a great organization. Over the years, PDA has been the "go to" organization to address technical issues our industry faces, a watering hole for the best scientific minds in our industry and the publisher of timely, high-quality technical reports. I am committed to work diligently to promote science-based compliance and patient-centric policies. I am interested in ensuring that PDA plays a major role in preparing our industry for human microbiome- based products, and in promoting harmonization of quality standards by supporting PDA's International activities, especially in emerging markets. I am especially committed to developing technical reports, training, and a voluntary code of conduct for the most basic and fundamental issue plaguing our industry: Data Integrity.

SUSAN SCHNIEPP

Susan Schniepp has 35 years experience in Quality Assurance and is currently a Distinguished Fellow at *Regulatory Compliance Associates, Inc.* She was previously Vice President of Quality and Regulatory Affairs for *Allergy Laboratories, Inc.* and *OsoBio Pharmaceuticals, LLC,* where she oversaw the activities of the Quality Assurance, Quality Control and Regulatory Affairs operations for the companies. She has had responsibilities for laboratory analysis, method validation, complaints, labeling, investigations, compendial affairs, and other quality systems during her 35 years in the industry.

As an active member of PDA, Sue served on the Board of Directors from 2011-2014 and has been a member of the PDA/FDA Joint Regulatory Conference since 2001, chairing the conference in 2007 and co-chairing it from 2010 through 2015.

In addition to her involvement with the PDA/FDA Joint Regulatory Affairs Conference, Sue is Chair of PDA's Regulatory Affairs/Quality Advisory Board and has presented at many PDA venues. She has received numerous awards from PDA, including the Distinguished Author Award (2007), Distinguished Service Award (2008), Gordon R. Personeus Award (2009) and the Frederick J. Carleton Award (2015). Sue is a member of the *PDA Letter* Editorial Advisory Board and authors a quarterly column for *Pharmaceutical Technology Magazine*. Sue was Chair of a USP Monograph Development Expert Committee from 2005-2010.

Candidate Statement

It is an honor to be considered for 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 creating a creative and nurturing environment for its members, PDA also has its pulse on the scientific advancements and regulatory activities that play such an important part in our industry. PDA Technical Reports are some of the most quoted and respected scientific documents used by the industry.

It is because I believe in the activities and goals of the PDA that I wish to serve on the Board of Directors. I want to contribute by helping PDA maintain its uniqueness as an industry leader addressing scientific and regulatory issues that are so critical to our industry.

MELISSA SEYMOUR

Melissa Seymour is the Vice President of Corporate Quality for *Biogen, Inc.,* assuming responsibility for global compliance and quality systems, including management of Quality Systems, Internal and External Auditing and Global Affiliate GMP oversight. 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 20 years of experience in the quality arena, including quality positions at *Novo Nordisk* pharmaceuticals and *GlaxoSmithKline*.

Melissa has been highly active in the Southeast chapter of PDA for the last 5 years as a member of the local board, serving as Vice-President, President, and, most recently, Past President. She has also worked with the national PDA on conferences, including the *2013 PDA/FDA Investigations Workshop*. Additionally, Melissa has authored and reviewed PDA Technical Reports, most recently authoring sections of PDA TR No. 65 Technology Transfer.

She is currently involved with PDA training in developing a new and robust training program for investigations as well as serving on the task force for post approval changes. Melissa is an ASQ Certified Quality Engineer, Certified Quality Auditor and Certified Quality Manager, and has previously served on the Board of Directors for the Rx-360 Consortium focused on supply chain security.

Candidate Statement

I am humbled and honored to be nominated to serve on the Board of Directors for PDA. I have been blessed to have been an integral part of the local chapter in the Southeast, seeing the many benefits that this organization provides both locally and globally through training, education, conferences and collaboration with regulators.

Additionally, I find the volunteers, membership and leadership at the PDA to be truly focused on patients and enabling industry to provide the best quality care to those in need. It is this dedication to science and the improvement of pharmaceutical technology that has continued to keep me involved in this outstanding organization. The pharma industry is fast paced and ever changing with new technologies coming at a never before seen pace.

As a member of the Board, I would work to ensure that PDA can continue to meet the challenge of advancing pharmaceutical science and development of new technologies as well as providing unparalleled training and conference opportunities for the industry. I am sure that, in collaboration with the talented team of volunteers and exceptional staff at PDA, we can continue to contribute to advance PDA's mission. I am thankful and appreciative to have the opportunity to serve in this capacity.

Let Your Voice Be Heard!

Vote at **www.pda.org/vote**
by Nov. 15, 2015 at 11:59 p.m.

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


PDA
Parenteral Drug Association