



PDA Board of Directors 2017 Election Guide

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

Polls: Open September 6, 2016
Close November 16, 2016 at 11:59 p.m.

Open to PDA members in good standing
as of midnight on August 25, 2016.

PDA members have the opportunity to choose volunteer leadership for 2017. You may select four board members who will take seats on the PDA Board of Directors. Members in good standing can vote online (pda.org/vote) and at conferences that will be held between Sept. 12 and Nov. 16 in the United States and Europe. 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. 25, 2016**. Balloting opens **Sept. 6, 2016** and closes at 11:59 p.m. EST on **Nov. 16, 2016**. 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.:

- 2016 PDA/FDA Joint Regulatory Conference** | Sept. 12-14 | Washington, DC
- Washington - 2016 PDA Data Integrity Workshop** | Sept. 14-15 | Washington, DC
- 9th Workshop on Monoclonal Antibodies** | Sept. 20-21 | Rome, Italy
- Pharmaceutical Freeze Drying Technology** | Sept. 27-28 | Strasbourg, France
- Dublin - 2016 PDA Workshop: Current Challenges in Aseptic Processing, Potential Changes in EMA/PIC/S Annex 1 Revision** | Oct. 5-6 | Dublin, Ireland
- 2016 Pharmaceutical Cold & Supply Chain Logistics** | Oct. 11-12 | Amsterdam, The Netherlands
- 2016 PDA Universe of Pre-filled Syringes & Injection Devices** | Oct. 17-18 | Huntington Beach, CA
- 2016 PDA Drug Delivery Combination Products Workshop** | Oct. 19 | Huntington Beach, CA
- 11th Annual PDA Global Conference on Pharmaceutical Microbiology** | Oct. 24-26 | Arlington, VA
- Visual Inspection Forum** | Oct. 25-26 | Berlin, Germany
- Arlington - 2016 PDA Workshop: Current Challenges in Aseptic Processing, Potential Changes in EMA/PIC/S Annex 1 Revision** | Oct. 26-27 | Arlington, VA
- 2016 PDA Outsourcing/CMO Conference** | Nov. 3-4 | Washington, DC
- Berlin - 2016 PDA Data Integrity Workshop** | Nov. 8-9 | Berlin, Germany
- PDA Europe Outsourcing & Contract Manufacturing** | Nov. 15-16 | Barcelona, Spain

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 +1 (301) 656-5900.



Candidates Running for Director Positions

4

BARBARA M. ALLEN, PhD

5

JOYCE E. BLOOMFIELD

6

VÉRONIQUE D. DAVOUST, PharmD

7

GHADA HADDAD, MBA

8

STEPHAN O. KRAUSE, PhD

9

MORTEN MUNK

10

MARTY R. NEALEY

11

BRENT WATKINS

Meet the Candidates

These nominees are running for four open seats on the board and are listed in alphabetical order in the following pages.

PDA Board of Directors



BARBARA M. ALLEN, PhD

Barbara Allen, PhD, is Sr. Director for Global Quality Systems for *Eli Lilly & Company*, where she is responsible for quality standards and practices as well as external monitoring for Lilly Quality Systems across research, development, manufacturing, distribution and sales and marketing.

Barbara has more than 20 years of experience in the pharmaceutical industry, including technical services, validation, new product introduction and quality assurance, both in Ireland and in the United States. In addition, she was a member of the expert working group for International Council for Harmonization Quality Guideline for Pharmaceutical Quality Systems (ICH Q10). Barbara received a Bachelor of Science degree in Chemistry from University College Cork, Ireland and a Doctorate in Chemistry from University College Dublin, Ireland. A portion of her doctorate was undertaken at the Universite de Paris.

Barbara is an active member of PDA and has been involved in planning many conferences, as well as presenting at multiple PDA events on topics including quality management, supplier quality management, process capability and knowledge management. In 2013 she received the PDA Distinguished Service Award from the Board of Directors in recognition of her contributions to PDA.

Candidate Statement

PDA has helped me to learn and develop as a professional in the pharmaceutical industry. Since attending my first PDA meeting, to participating at and planning PDA events, along with accessing PDA publications, my scientific and regulatory knowledge has broadened and deepened. The interactions with other members have provided meaningful and thought-provoking discussion and debate, as well as providing a professional network and many valued friendships.

As an organization, PDA plays a key global role facilitating the development of pharmaceutical professionals and contributes significantly to the advancement of science and technology as well as associated regulations for this sector. It provides many opportunities, including task forces, local chapters, conferences, meetings and committees, through which to learn, engage with and advance topics and to develop personally. Serving on the PDA Board of Directors would allow me to ensure the successful PDA mission continues and to shape the future to meet the needs of each of the members.



JOYCE E. BLOOMFIELD

Throughout my 25 years in the Sterile Pharmaceutical Sciences, I have been truly fortunate to work with the very best leading scientists, manufacturing, quality and compliance experts, regulators and educators in the industry. As a quality and compliance leader, I have always strived to put the patient first in all of my roles, including as an FDA Investigator and Compliance Officer for the Center for Drug Evaluation and Research, as a Senior Consultant to the pharmaceutical industry with PAREXEL Consulting, as a pharmaceutical Executive in Global Quality Assurance at Cardinal Health and, most recently, at Merck, Sharp, and Dohme.

Most rewarding to me personally and professionally has been my many years of service as a PDA volunteer. I learn something valuable every day from our PDA members and volunteers. I currently serve as the Chair of PDA's Science Advisory Board; as the Co-Chair and ongoing contributor and speaker/moderator to multiple conference Program Planning Committees and Steering committees; as a leader in the areas of quality systems for sterile drug and biologics manufacturing, glass quality and quality metrics; and as an author for the *PDA Letter*. I also currently serve as a Director on the PDA Board of Directors. I have a BA degree from Murray State University and I am a certified Medical Technologist.

Candidate Statement

My personal mission is to do all that I can do to lead the advancement of medicine and manufacturing technology in order to facilitate availability of medicine to patients everywhere. That is why I volunteer at PDA. I'm honored to work for PDA's members and volunteers and continue to be energized by their vision and passion for manufacturing science. I'm humbled to be considered for a second term by my peers and colleagues as a Director on the PDA Board of Directors. I'm committed to continue to embrace and lead the advancement of PDA's mission and goals and sincerely grateful to have been given this opportunity to further serve our membership.



VÉRONIQUE D. DAVOUST, PharmD

Véronique Davoust has over 20 years' experience in the pharmaceutical industry, in Regulatory Affairs and Manufacturing, for *Pfizer Inc.* She is responsible for the monitoring and analysis of European emerging regulations and guidelines, focusing on Good Manufacturing & Distribution Practices, and the Quality section of Marketing Authorization dossier throughout the product life cycle, as well as global topics such as Serialization, Drug Shortage and Quality Culture. Furthermore, she ensures the communication and implementation of the guidelines and regulations within the firm, and coordinates responses to proposed regulatory documents. Vero has been an active member of the PDA for more than 15 years. She is a member of the current Board of Directors and co-chaired the PDA Paradigm Change in Manufacturing Operations (PCMO) project. She contributed to various PDA documents, including Technical Report 54 and Points to Consider for Aseptic Processing. Vero is an active member of the Regulatory Affairs and Quality Advisory Board (RAQAB) and is a frequent lecturer at PDA conferences and meetings. She completed a one-year secondment at the European Federation of Pharmaceutical Industries and Associations (EFPIA), supporting the Technical and Development Operations Committee. Véronique earned a Doctorate in Pharmacy at the University of Rouen in Normandie, France.

Candidate Statement

Through my participation as a PDA member, I recognize the high value and support offered by the organization. I have been fortunate to be on the planning committee for the PDA/EMA Joint Conference at its creation in 2006, continued to work diligently on PDA events, and in 2016, was happy to contribute to the first PDA Europe Annual Meeting and to co-chair the 2016 PDA Manufacturing Science Workshop. The more I am involved with PDA, the more I appreciate the interaction with other members. PDA is an excellent forum for networking and sharing valuable experience with industry, thus making PDA a scientific partner of choice for regulators and for establishing sound regulations and guidances. It is a real honor to be re-nominated for the PDA Board of Directors. I look forward to contributing even more actively to the success of PDA by enhancing PDA's activities in influencing regulations in the Quality/GMP arena. I am thankful to be part of this great organization and to work with such fine staff, volunteers, members and leaders, and I am excited to have the opportunity to help further enhance PDA's position as the premier organization for connecting people, science and regulation.



GHADA HADDAD, MBA

Ghada Haddad is currently a Director at *Merck & Company*, leading the Global Quality Risk Management (QRM) Center of Excellence. She holds a chemistry degree and an MBA with more than 18 years of experience. She has worked in the biotech, pharmaceutical and virus industries, starting with Hewlett-Packard, Agilent Technologies, Genentech, Roche and now Merck in the areas of Qualification and Validation, QRM, Quality Systems and Regulatory, including research, process development, auditing, regulatory agency inspection and change control. Ghada is a member of the PDA Science Advisory Board, liaison to the Biologics Advisory Board and is currently leading a PDA task force for QRM for the Design, Qualification and Operation of Manufacturing Systems and co-leading the Aging Facility Task Force. She was the Task Force leader of the Paradigm Change in Manufacturing (PCMO) initiative for TR 54-2, QRM in Packaging and Labeling, a member of TR 54-3, QRM in the Manufacturing of Pharmaceutical Drug Products and a contributor to TR 54, Implementation of QRM for Pharmaceutical and Biotechnology Manufacturing Operations. Ghada is also a Faculty member for PDA Education and a frequent speaker at PDA conferences and has been a member of the PDA Annual Meeting Program Planning Committee for the past three years. Ghada is a mother of two young ladies, one of whom is attending Pharmacy College.

Candidate Statement

I am honored to have the opportunity to serve as a member of the Board of Directors of the PDA. The PDA, as an organization devoted to not only advancing science but also reaching out to its members and connecting across research, operations and regulatory authorities, is essential to addressing the challenges facing the pharmaceutical and biopharmaceutical industry. I am fortunate to have been involved in many aspects of the PDA, speaking at Signature Events, participating in Workshops, being both a member and a leader of Task Forces writing Technical Reports. I hope that, with your vote, I will be able to devote greater service to the PDA and its members by working to ensure quality, accuracy and relevance to the Technical Reports, the programs and training events.

As a member of the Science Advisory Board, as well as liaison to the BioAB, I have had the opportunity to participate in the development of resources that are valuable and timely to the membership, including leading the teams that prepared several Technical Reports on Quality Risk Management. I look forward to the continued role in listening to and understanding the needs of the membership.



STEPHAN O. KRAUSE, PhD

Dr. Stephan O. Krause is Director of QA Technology for *AstraZeneca* in the commercial biologics operations in Maryland, USA. Stephan has a PhD in analytical biochemistry from the University of Southern California and has fulfilled leading roles in QA/QC and RA for clinical and commercial manufacturers for the last 17 years. His many publications and presentations reflect his broad experience in risk management, validation, tech transfer and control

strategies. His book on risk-based method validation strategies won the 2007 PDA Distinguished Author Award.

Stephan has numerous publications in the *PDA Letter* and *PDA Journal* and he is the primary author and Task Force leader of PDA TR 57 (2012). He is co-author of PDA TR 65 for Tech Transfer (2014), PCMO's Task Force leader for IMP Specification Setting (2015), and PDA Task Force co-leader for Biosimilars. He has been a member of PDA's Biotechnology Advisory Board since 2014.

Stephan often serves as chair and lecturer at major conferences worldwide and has taught multiple courses for PDA. In 2012 and 2015, Stephan was recognized for his work on PDA TR 57 and was invited by the FDA to present an industry perspective to the CMC reviewer teams at FDA's headquarters.

Candidate Statement

I have worked with several associations and industry groups in the past but have not found any other group to be as rewarding and fun to work with as PDA. Because I really like working with my PDA colleagues, the task forces, committees and boards, I have steadily increased the projects with which I have been involved.

I am very proud of being nominated among the other highly qualified candidates for the Board of Directors. This potential opportunity comes at a great time for me as I am ready to invest even more of my time with PDA. After having worked with PDA Task Forces and Committees for more than 10 years to improve industry standards, I have learned hands on which processes work well.

PDA has great leadership and is committed to executing PDA's strategic 2020 plan. PDA has become a leader for advances and acceleration in technology innovation (manufacturing and analytics) and has been expanding from traditional pharmaceuticals to biologics and other novel therapies. As my career objectives and values are aligned with PDA's goals, I believe that I will accomplish many more good things as a board member.



MORTEN MUNK

Morten Munk's career comprises of 30 years of experience within the global biopharmaceutical industry. One common denominator has been to ensure a holistic and broad perspective on biomanufacturing challenges from idea to established facilities. His key focus is to ensure compliant and cost-effective production through the optimal use of all relevant and available knowledge and technologies, such as single-use systems and continuous processing. Morten combines his technological expertise with a thorough business understanding and a great personal interest in and practical understanding of stakeholder relations and change management.

Morten frequently gives technical presentations at international conferences and he is highly motivated by sharing knowledge and experiences in how to meet the key objectives of the pharmaceutical industry. Furthermore, he prioritizes and appreciates being a member of scientific committees for various international conferences, as well as a member of the Biotechnology Advisory Board, CMC Biologics Technical Advisory Committee and the Advisory Board for Master studies at Copenhagen University. Morten joined *NNE Pharmaplan* as Global Technology Partner in 2015. In 2001, he co-founded CMC Biologics, after working 14 years at Novo Nordisk.

Candidate Statement

I am honoured to be nominated to join the PDA Board of Directors and I hope you will support me in continuing the impressive development of PDA, which is a result of PDA's member and staff commitment.

Though I gained my 30 years of experience through my work at two different companies – NNE Pharmaplan (a Novo Nordisk subsidiary) and CMC Biologics – the focus has always been the same: Integrated involvement in process development and facility design for manufacturing of high-quality, life-saving pharmaceutical products.

My membership in PDA has offered invaluable support and inspiration in my daily work and I will do my utmost to ensure that all members have the same experience from their PDA membership. PDA supports a strong, knowledge-based network that offers valuable resources, including Technical Reports (TRs). I am pleased to have taken part in the development of numerous TRs, including TR 66 on Single Use Systems where I served as co-chair of the TR Task Force for a group of brilliant experts from the PDA network.

My focus is to continue the proud traditions of PDA, including organizing high-quality educational conferences, meetings and training events. As a PDA board member, I will do my best to support the organization's efforts to improve and expand its offerings.



MARTY R. NEALEY

Marty Nealey serves as Vice President, Operations, for *Pfizer's* Rocky Mount, NC facility where he is responsible for operations, quality, 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 27 years, Marty has served in various leadership roles with *Burroughs Wellcome*, *Merck & Co.*,

AstraZeneca, *Purdue Pharmaceuticals* and *Hospira*. He has extensive experience in operations, facilities management, engineering, technical services, supply chain, project management, product launches and building robust quality systems and cultures. Marty has been a member of PDA for more than 13 years and has served on PDA's Quality Metrics Committee for the past four years. He has presented and served as moderator for several PDA Meetings and Forums.

Candidate Statement

I'm honored to be nominated as a prospective member of PDA's Board of Directors. An active member for many years, I appreciate PDA's focus on key technical, quality, and operational challenges. The caliber of technical and quality professionals involved in PDA creates an atmosphere of collaboration, learning and advocacy for our industry. My affiliation with PDA has been both rewarding and a key element of my personal success and the organizations with which I've worked. Given the opportunity to serve on PDA's Board, I would continue to support building 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. I will continue to further the understanding of quality culture across operational and quality systems linking continuous improvement to everyday thinking. 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.



BRENT WATKINS

Brent Watkins is a Technical Manager for *Veltek Associates, Inc.*, with more than 20 years of experience in the pharmaceutical industry. Beginning his career in 1995 with Abbott Labs, Brent held various manufacturing positions as a part of the small volume parenteral operation at the Rocky Mount, NC facility. After moving to Veltek in 2000, he joined the PDA in 2001. Brent joined the PDA Education faculty in 2007 and has taught a variety of contamination control

topics both at the PDA Training and Research Institute and onsite for PDA clients. For his efforts, Brent received the *James P. Agalloco Award for Excellence in Education* in 2014. In addition to his responsibilities with PDA Education, he also participated in the Task Force to develop Technical Report 70 on Cleaning and Disinfection and is the Vice Chair of the Education Advisory Board. He chairs PDA's Exhibit Committee and serves on the Membership Committee. Brent earned his Bachelor's degree in Chemistry from Wake Forest University.

Candidate Statement

I am humbled and honored to be nominated for a position on PDA Board of Directors. The ultimate goal of our industry is to better serve patients. PDA is the leading professional organization in our industry, facilitating the sharing of knowledge and encouraging discussion throughout its membership. PDA provides an invaluable link between regulators, industry and academia.

For the past 15 years, PDA has played a major role in enriching my professional life. Through my involvement with PDA, I have met exceptional, dedicated individuals who strive to improve the quality of products our industry creates and manufactures. We must always remember, the strength of PDA lies in its members and volunteers, dutifully supported by a staff and leadership team.

PDA programs, guidance and resources support a scientific-based approach to problem solving and are a vehicle for the sharing of information as we face an ever-changing environment. As a member of the Board, I would work to ensure that we remain true to our mission, growing our organization and doing our part to improve the lives of patients worldwide.

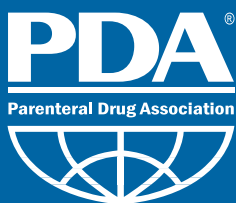
Let Your Voice Be Heard!

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PDA Global Headquarters

Bethesda Towers
4350 East West Highway, Ste. 600
Bethesda, MD 20814
Tel: +1 (301) 656-5900
Fax: +1 (301) 986-0296

PDA Europe gGmbH

Am Borsigturm 60
13507 Berlin
Germany
Tel: + 49 (0) 30 43 655 08-0
Fax: + 49 (0) 30 43 655 08-66

www.pda.org