

## **President-elect Candidate**

Gopi Shankar, Ph.D., M.B.A., FAAPS
Janssen R&D LLC (Johnson & Johnson)



Gopi Shankar, Ph.D., M.B.A., FAAPS, is vice president and head of Biologics Development Sciences at Johnson & Johnson. He earned a master's in molecular biology from Oklahoma State University, a doctorate in immunology from University of Kentucky, a certificate in biomedical regulatory affairs from the University of Washington, and an executive Master of Business Administration from Drexel University. Following a brief post-doctoral tenure, Shankar managed Quality Control & Immune Monitoring at Northwest Biotherapeutics (Seattle, WA) from 1999 to 2002. He then joined Centocor (Malvern, PA) as a senior scientist overseeing clinical immunogenicity and methods development. Subsequently he assumed greater responsibilities for immunogenicity and the bioanalytical laboratory, supporting biologics development at Janssen (Spring House, PA). He leads a global department of about 175 scientists who contribute to scientific and operational deliverables for Johnson & Johnson's biotechnology therapies across the areas of discovery translational research, bioanalytical sciences, and GLP compliance, from preclinical through post-market studies.

Shankar is a globally recognized subject matter expert in the field of immunogenicity and has published in the areas of basic immunological research and strategic and regulatory best practices. He has led or contributed to several highly cited articles, including six industry whitepapers and a chapter in the United States Pharmacopeia. During his career, Shankar has focused on the development of fit-for-purpose solutions to scientific problems. He built consensus and harmonized scientific practices pertaining to clinical immunogenicity and laboratory science, many of which have been adopted by regulatory agencies in their public scientific guidance documents. His research, consensus-building efforts, and best-practice publications, both independently and via AAPS, have transformed the thinking and tactical processes related to immunogenicity around the globe. In recognition of his contributions to pharmaceutical science, AAPS conferred on Shankar it's Fellow status in 2015. He is also an adjunct professor at the University of Tennessee Health Sciences Center.

Shankar joined AAPS in 2003 and it has since become his professional home. He has been an active member in a variety of leadership roles. Starting with a discussion group on immunogenicity methods, he contributed to various committees of the Bioanalytical Community, proposed content for AAPS meetings, presented and led sessions at meetings, co-founded the Therapeutic Products Immunogenicity Community, and led the Biotechnology section for four years. In that role, he managed the revision of section bylaws, clarified policies and responsibilities, developed consistent practices, and coached focus groups to meet their objectives. At the 2015 Leadership Retreat, Shankar had the opportunity to contribute to AAPS' revised mission statement—*To advance the capacity of pharmaceutical scientists to develop products and therapies that improve global health*. His contributions to the Annual Meeting/National Biotechnology Conference (AM/NBC) Task Force led to his appointment as chair of the Integrated Meeting Planning Committee (2016–2017) that conceptualized the PharmSci 360 Conference and created its motto *Advancing Pharmaceutical Sciences, Careers, and Community*. Shankar led the 2018 Scientific Programming Committee and served as chair of this new flagship meeting. He currently serves on the AAPS Board of Directors as a member-at-large and participant on several committees.

## Why are you interested in serving AAPS in the capacity of president-elect and how has your experience prepared you to lead AAPS?

"AAPS has played a critical role in my professional growth; I have benefitted greatly from numerous learning experiences through my volunteer work and opportunities to serve the organization in diverse leadership roles.

"As a mid-career scientist member, mentor, and leader at various levels (including AAPS committees, focus groups, the Biotechnology section, the AM/NBC Task Force and conference chairmanship), I have gained deep knowledge of AAPS' products, strategies, sustainability risks, and its overall strengths and weaknesses. While on the Board I served on the Audit, Communities, Ethics, Fellows, and Fellows Appeals committees. Over the years I have also developed excellent working relationships with AAPS staff and have championed change—from designing and leading the first PharmSci 360 conference to drafting the roles and responsibilities of the various Scientific Programming Committee positions. I also participated in the development and implementation of both the 2016-2020 and the 2021–2026 strategic plans, which have driven bold transformations to sustain AAPS and meet the evolving needs of its members and business partners. These included optimizing the conference and year-round programming, transforming digitally to improve global reach, and investing in improved business and member engagement strategies while simultaneously working and evolving to stabilize its revenues and membership. I am proud of AAPS for navigating the challenges of the pandemic successfully without losing member engagement. And, as most of the educated global workforce discovered that work and knowledge exchange could be managed remotely, AAPS developed newer strategies for member-to-member engagement. While these were successful and placed AAPS ahead of the curve in relation to many comparable organizations, I think we can do even better. As president-elect I believe I can catalyze future momentum that enables AAPS to grow in global membership, collaboration, diversity, and brand recognition.

"My experiences in leadership roles at AAPS and Johnson & Johnson over the past two decades have prepared me well to serve as president-elect. I am a learner with a continuous improvement mindset, have insight and experience with both organizational strategy and operations, and am strong in change management and communications. I have a practical, 'open and real' and inclusive communication style that should help me interact with members and optimally collaborate with the AAPS board and staff. Together we shall ensure that AAPS continues to be a globally trusted and influential society that is valued by members because of its resolute and unrivaled focus on advancing pharmaceutical sciences, careers, and community."