Mark E. Arnold, Ph.D., FAAPS, is owner and principal of Bioanalytical Solution Integration, LLC. He consults with biotechnology and pharmaceutical companies to advance their portfolios and bring new therapies to patients in need. In that role, he collaboratively develops the bioanalytical scientific and regulatory strategy to meet current and future client needs for ligand-binding, cell-based, and liquid chromatography-mass spectrometry assays to quantify drugs and metabolites, anti-drug antibodies, and biomarkers in animal and clinical biological samples to support pharmacokinetic and pharmacodynamic assessments.

He received a Bachelor of Science in biology from Indiana University of Pennsylvania and a doctorate in pharmacology from the University of Pittsburgh. Arnold started his career as a bench scientist developing new bioanalytical methods for high-performance liquid chromatography and gas chromatography-mass spectrometry supporting animal and clinical studies. Over the years, he developed and expanded his scientific scope and responsibilities, becoming executive director of the Bioanalytical Sciences Department of the Bristol-Myers Squibb Co. Subsequently, Arnold was site director for LabCorp’s West Trenton Laboratory and then director of science for the Scientific Affairs Department of LabCorp Drug Development, where he advised bioanalytical and clinical laboratories.

During his career, Arnold has successfully led teams and departments of various sizes through times of growth and transformation. He accomplished this by monitoring and adapting to changes in science, global regulations, and business direction, and by providing his staff opportunities to learn and implement new technologies and science to support the evolving environment. To encourage his staff’s development, he fostered a culture that supported individuals’ research, presenting, and publishing. Arnold continues to mentor scientists at various stages of their career.

For 39 years, Arnold has been involved in the application of bioanalysis to developing new therapies, including the review and interpretation of regulations and guidance as they apply to the evolving science of bioanalysis in bioanalytical and clinical laboratories. Besides his corporate obligations, Arnold has been active in the external scientific community. He was co-chair of both the AAPS Crystal City V and VI Workshops on the ‘FDA Draft Revised Guidance on Bioanalytical Method Validation’ and ‘Biomarkers’, respectively. He has been actively involved in the Land O’Lakes Bioanalytical Conference (predecessor to the Summer Scientific Forum), Clinical and Pharmaceutical Solutions through Analysis, was a co-founder of the Global Bioanalysis Consortium, and has participated in IQ Consortia working groups.

Arnold has been a member of AAPS since 1988 and has held a variety of committee positions including 2023–2024 Scientific Advisory Committee chair, 2021 PharmSci 360 Scientific Programming Committee chair, 2018 PharmSci 360 Bioanalytical Track chair, and is an AAPS Fellow (2014). Arnold has written 3 book chapters and over 115 peer-reviewed publications and has numerous invited podium presentations. He is on the editorial advisory board of two journals and is an active peer reviewer for several journals.
Why are you interested in serving AAPS in the capacity of president-elect and how has your experience prepared you to lead AAPS?

“Advancing the pharmaceutical sciences to drive prevention and cures’ is AAPS’ vision—a vision that I believe in and have pursued throughout my career. Like so many of our members, my career path has been varied, full of learning and contributions to the development of new therapies with positions in large pharmaceutical companies, contract research, and now as a consultant, supporting a spectrum of companies. As a member of AAPS since 1988 and in collaboration with other AAPS members, I have contributed to fulfilling that vision. Together, we have developed and shared new science, influenced regulators, and provided educational forums. My roles in AAPS have included focus group and section leadership, U.S. Food and Drug Administration-AAPS Workshop co-chairs, Community leadership, 2018 PharmSci 360 Track chair, 2021 PharmSci 360 Scientific Programming chair, and today, I serve as chair of the Scientific Advisory Committee. I sought those roles based on my belief that AAPS delivers on its mission, and that I could contribute to it. It has certainly not been a one-way street; I have benefited immensely from what I have learned from other scientists and leaders in the organization, and along the way have made many new friends.

“These are exciting times in the pharmaceutical industry with all of the new therapeutic modalities and AAPS is energized to advance science and benefit its members as they improve patients’ lives. I want to take the passion I have for developing the pharmaceutical sciences to guiding AAPS as its president to ensure current and future members have the opportunity to reach their full potential. My experiences across the industry as a scientist, collaborator, and leader have provided a breadth of knowledge and the skills needed to serve as president. The president and the Board of Directors’ function is to ensure AAPS achieves its mission, now and in the future, by maintaining a perspective of its current health, integrating new therapy sciences, and understanding the influence current and future regulations and economic change. By prudently applying governance that drives the organization forward to deliver its mission for the members, partners, and collaborators, the board is able to succeed most importantly for the patients who need the new therapies our members develop. And that is what I am prepared to do and why I seek to be president—I want to ensure AAPS provides developmental opportunities to our members that result in therapies that improve patients’ lives.”