Member-at-Large Candidate

Mark E. Arnold, Ph.D., FAAPS
Labcorp Drug Development

Mark E. Arnold, Ph.D., FAAPS, is director of science for Labcorp Drug Development in the Scientific Affairs group. In this role, he collaboratively develops and delivers innovative scientific and regulatory strategy to meet current and future client needs. This includes the application of ligand-binding, cell-based, qPCR and LC-MS/MS assays to quantify drugs and metabolites, anti-drug antibodies and biomarkers in animal and clinical biological samples for pharmacokinetic and pharmacodynamic assessments. Arnold first joined Labcorp to lead the bioanalytical laboratory in West Trenton, NJ, prior to moving to his current role. Arnold was previously with Bristol-Myers Squibb Co. where his career took him from bench scientist to executive director of the Bioanalytical Sciences Department where he was responsible for both immunochemistry and LC-MS capabilities in support of the development pipeline, including outsourcing to partner CROs. There, he also had a secondment in the CMC Analytical department as part of his leadership development.

Arnold received a bachelor's in biology from Indiana University of Pennsylvania and doctorate in pharmacology from the University of Pittsburgh. For 37 years, Arnold has been involved in developing new therapies with his work in the field of bioanalysis and contributions to the review and interpretation of regulations and guidance.

Arnold has been a member of AAPS since 1988 and has held a variety of leadership and volunteer positions within Focus Groups and Sections, prior to leadership roles in the Communities. Other roles include co-chairing of both the AAPS Crystal City V and VI Workshops on the "FDA Draft Revised Guidance on Bioanalytical Method Validation" and "Biomarkers", respectively. Arnold was on the programming committee for the Land O'Lakes Bioanalytical Conference from 2004 to 2021 and was conference chair in 2010. Arnold was chair of the Bioanalytical Track programming committee for the first PharmSci 360 conference. He was chair for the Abstract Screening Committee (2020), chair for the 2021 PharmSci 360 Scientific Program Committee and is currently chair for this year's Rapid Fire Committee. He is a member of the Scientific Advisory Committee and is an AAPS Fellow (2014). Outside of AAPS, Arnold was a co-founder of the Global Bioanalysis Consortium and an active participant in the Clinical & Pharmaceutical Solutions through Analysis Conference, leading the "Four Corners Initiative" for the past 5 years.

Arnold's contributions to the pharmaceutical scientific community include 100+ peer-reviewed publications and 3 book chapters on innovative science and regulations, and numerous invited podium presentations at both national and international conferences. He is a frequent peer reviewer for several journals and serves on the editorial boards of *The AAPS Journal* and *Bioanalysis*.

Why are you interested in serving AAPS in the capacity of member-at-large and how has your experience prepared you to lead AAPS?

"A patient's success story with a life-saving drug refined my career focus to delivering new therapies to patients in need. During the past 33 years as an AAPS member, I've received many benefits from the organization that have expanded my horizons on the breadth of drug development across the industry and helped me contribute to the development of new medicines. Those benefits range from learning leading edge science to technology and regulations in my area of expertise and across pharmaceutical development, to networking opportunities, and soft

skill development through various positions within the organization. I've seen how AAPS has made an impact on my career, for other members, and with the regulatory community through its interactions: AAPS makes a difference. The various positions within AAPS I've held have been my way giving back to the membership and the organization.

"Being a member-at-large will enable me to continue to strengthen the organization, the offerings that develop its members, and promote AAPS' mission of advancing the innovative science of drug development. I want to focus on expanding the learning and participation opportunities for members since investing in developing our scientists has an exponential impact on the advancement of science. The recent growth in cell and gene therapies are an example of where I will look for new learning opportunities to develop members so they can accelerate the advancement of these new therapies.

"My positions in pharma, CRO, and as a consultant have been at a number of levels and roles including independent contributor, team member, manager, initiative leader, department executive, and site leader. This breadth of experience includes developing and implementing strategies that maintain vibrant organizations, developing staff, driving change, budget development/management, collaboration, leading cross-functional teams, as well as understanding drug development from those different organizational perspectives. I have learned from these experiences how to interact within organizations and team environments to successfully achieve goals and champion ideas. Each of these positions has provided a different perspective on the pharmaceutical industry that allows me to relate to the AAPS membership and understand their needs. Those perspectives are essential within the member-at-large role and will enable me to continue to converse with the members on their diverse science and interests, and effectively work with the Board of Directors to develop a landscape of offerings that include in-person and virtual participation events, presentation and publishing opportunities, and on-demand learning opportunities."