

**AAPS**
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EXPERTS

ASK THE EXPERTS INTRODUCTION TO BIOMARKERS

AAPS' Introduction to Biomarkers eCourse will walk you through the fundamentals of biomarkers assays and their applications in clinical trials. The eCourse focuses primarily on the discussion of technologies, key issues in assay development and some regulatory considerations to ensure continuity of experience and best practices, sharing institutional knowledge and making literature more accessible.

In this virtual session, our biomarker experts will be on hand to answer all of your questions. If you completed the eCourse or still have questions, this is your chance to ask us anything!

Learning Objectives: Gain a high-level overview for the role of biomarkers in clinical development; Identify regulatory framework for biomarkers in drug development; Learn the unique aspects and considerations that apply to biomarker assays.

Live, 1-hour Discussion Thread in the AAPS Community

June 7, 2023 | 11:00 am–12:00 pm ET

Email your questions before the event to axlers@aaps.org or post them live in the AAPS Community during the event. [Join the conversation here.](#)

[Access the Introduction to Biomarkers eCourse today.](#)

**This course is free to all AAPS members!
Not a member? Join today!**

MEET THE EXPERT PANELISTS



Abbas Bandukwala

Abbas Bandukwala graduated from Vanderbilt University as a Biomedical Engineer. He then served five years as a United States Naval Officer. He completed his Master's degree in chemical engineering from University of Maryland. He joined the Food and Drug Administration in 2009 in the Center of Devices and Radiological Health (CDRH), and reviewed pre-market applications for light based devices. He was commissioned as an engineering officer in USPHS in 2010. In 2017, he moved from CDRH and became part of the Center Drug Evaluation and Research (CDER) Biomarker Qualification Program (BQP).

Carmen Fernández-Metzler

Carmen Fernández-Metzler, Ph.D., graduated from MIT with a S.B. in chemistry. After earning her Ph.D. in chemistry from the University of Pennsylvania, Dr. Fernández-Metzler joined the Department of Drug Metabolism at Merck & Co. in West Point, PA where she was a group leader, scientific mentor, and project team representative over the course of more than 18 years. In the fall of 2010, Dr. Fernández-Metzler left Merck to become President of PharmaCadence Analytical Services, LLC, a professional analytical services organization serving the pharmaceutical and life sciences fields with expert LC-MS services. Since joining AAPS in 2010, Dr. Fernandez-Metzler has been the Past-Chair for the AAPS BFG Topic Team on LC-MS/MS Biomarker Assay Validation and founding member and current leadership team member of the AAPS Biomarkers and Precision Medicine Community.



Steven P. Piccoli

Steven Piccoli, Ph.D., joined Sun Pharmaceutical Advanced Research Center, SPARC, in 2020 as Head of Clinical Biomarkers. Prior to that, he was Senior Director of Precision Medicine and Head of Clinical Biomarkers at GlaxoSmithKline. He is recognized as an expert in clinical biomarkers and precision medicine with extensive contributions to in vitro diagnostics and clinical chemistry and has led clinical and analytical teams in the pharmaceutical, biotechnology, and medical/companion diagnostics industries, including at Johnson & Johnson and Bristol-Myers Squibb. He obtained degrees in chemistry, biochemistry and molecular biology from Carnegie Mellon University, Washington University in St. Louis, and Princeton University.



Yan Ni

Yan Ni, Ph.D., is an Executive Director of Biomarkers and Precision Medicine at Passage Bio. The Biomarkers and Precision Medicine team is responsible for the overall biomarker strategic planning and execution for all clinical and preclinical programs in the Passage Bio research portfolio. Before Passage Bio, Yan was an Associate Director at the Precision Medicine Group of Regeneron Pharmaceuticals and was responsible for clinical biomarker planning and implementation for multiple disease areas from First-in-human to phase III. She actively volunteers for the American Association of Pharmaceutical Scientists (AAPS) and is a founding member on the Leadership teams of the AAPS Biomarkers and Precision Medicine Community and the Gene and Cell Therapeutic Products Communities.

