

**Unleashing the Full Potential of Biomolecule Characterization:  
Purification and Analysis Strategies**

The high-resolution analysis of biomolecules is of increasing importance, especially in the pharmaceutical industry, where the market dramatically changed from small molecules to protein-based drugs and antibodies. Biomolecules are chemically and structurally diverse and include proteins, peptides, carbohydrates, lipids, amino acids, and nucleic acids. Due to the inherent structural complexity and broad chemical composition of these biomolecules, multiple separation modes, column chemistries and detection techniques are required for full characterization. In addition, the need to consider biological activity of the therapeutic as well as strategies to minimize sample matrix effects are equally important for analytical scientists.

In this seminar, we discuss several aspects for the purification, analysis, and characterization of biomolecules, with a particular focus on monoclonal antibodies (mAbs) and oligonucleotides (oligos). Utilizing unique resin and membrane technology, novel approaches to mAb purification will be presented detailing how rapid and efficient purification protocols can be developed. Afterwards, an examination into methods for determining critical quality attributes of the mAb and antibody-drug conjugate (ADC) therapeutics will be highlighted, with particular attention being given to aspects of peptide mapping, intact and middle-up analysis, and glycan characterization. Finally, the story of the Oligo-6 standard used not only for column comparisons but also for monitoring HPLC analysis and purification of oligonucleotides will be shared. After attending this seminar, the engaged audience member will have new information on unique approaches in purifying and analyzing complex biomolecules.

## Biography

**Egidijus Machtejevas** was born in Kaunas, Lithuania where he studied chemistry, biotechnology and separation sciences (1991-2001) at Kaunas University of Technology, Lithuania. Also, as a research student spend a year in Prof. Stelan Hjerten laboratory in Uppsala University (Sweden). After gaining his PhD in analytical chemistry 2001-2007 he worked as a post-doc with Prof. Klaus Unger at Mainz University, Germany. Also two years spent at AstraZeneca (Sweden) where he set up and validated several various multidimensional systems for peptidomic analysis of different biological fluids. He joined the R&D Department at Merck KGaA in Darmstadt in 2008, in 2009 took marketing manager position for North America, 2010 - 2018 product manager for chromatography. Currently he is a Senior Technical Advisor in Analytical Chromatography Workflows group. Egidijus Machtejevas has twenty-five scientific papers and thirteen book chapters to his name, and his major focus areas include chromatography, multidimensional liquid chromatography, proteomics and mass spectrometry

During his diploma and Ph.D. thesis in Chemistry, **Frank Michel** developed, optimized and evaluated new stationary phases for HPLC. At Bernina Biosystems, a biopharmaceutical company in Munich/Germany, he developed and validated analytical HPLC and other methods for Active Pharmaceutical Ingredients (APIs), including excipients and drug products. Frank was responsible for marketing of analytical services and reference standards at HWI Analytik, an analytical service provider for the pharmaceutical industry. During his time at Sigma-Aldrich (since Nov. 2015 Merck), he held various roles in Analytical Chemistry. In 2022 Frank took over responsibility for training and scientific education as well as for sustainability for whole chemistry franchise.

**Cory E. Muraco** is the Biomolecule Workflows Manager at MilliporeSigma, the life science business of Merck KGaA, Darmstadt, Germany. After finishing his graduate studies at Youngstown State University (Youngstown, Ohio, USA), Cory started his career at MilliporeSigma in 2013. After holding several roles in both R&D and Marketing functions, in 2022, Cory assumed his current role as the Biomolecule Workflows Manager where he is tasked with designing, developing, and executing the marketing and R&D strategies around MilliporeSigma's bioanalytical initiative. Cory is the author of several manuscripts appearing in trade magazines and has delivered over 100 presentations at international conferences, round table symposia, and at various pharmaceutical and biopharmaceutical companies.

Dr **Pierre F. Potier** is responsible at Merck-Sigma for the Manufacturing of Complex Nucleic Acid structures, small and large scale. He has more than twenty years of experience in the field of oligonucleotides manufacturing and developing new processes for their synthesis, purification and characterisation. In his Ph.D. thesis at the University of Strasbourg, France he developed the synthesis of oligonucleotides modified by polyamine chain and their use in the stabilization of double stranded DNA helices. In 2000 he did a post-doctoral fellowship at the California Institute of Technology working on a gene correction strategy involving DNA-minor groove binder chimeras. He joined Proligo in 2003, then Sigma-Aldrich (part of Merck KGaA) and has since then been responsible for the Technological Development and the Operations of custom manufacturing of many of nucleic acid structures. He has been at the forefront of the development of improved products for PCR, RNA-interference, Next Generation Sequencing or gene editing, among various other applications.

Dr. **Michael Schulte** is responsible at Merck Millipore for Research and Development of new chromatographic materials including polymeric and silica-based beads as well as adsorptive membranes. He has more than twenty years of experience in the field of preparative HPLC. In his Ph.D. thesis at the University of Münster, Germany he developed new chiral stationary phases for chromatographic enantioseparations. In 1995 he joined Merck and has since then been responsible for research and development in the area of preparative chromatography, including the development of new stationary phases, new separation processes and the implementation of Simulated Moving Bed-technology at Merck. He is co-editor of the book "Preparative Chromatography" published in its 3<sup>rd</sup> edition by Wiley-VCH in 2020 and is the co-author of more than 50 scientific publications.