

Workshop: " New aspects in regulated Bioanalysis "

The workshop will cover new aspects in the understanding of immunogenicity including novel advanced medical therapies such as gene therapies. Due to the current and future advancements in technologies which allows a very sensitive detection of anti-drug antibodies a deep understanding of the concepts of induced immune responses is required. In addition, novel treatment options and drug modalities will lead to a further complexity in assay performance and data interpretation. Novel Biomarkers will help to interpret the clinical relevance of immune responses which may require different levels of regulations.

Date:

Friday, 28 June 2019, 9:00 – 14:00

Location:

IZB (Innovations-und Gründerzentrum Biotechnologie)
Conference Room Ellipse 1/2
Am Klopferspitz 19
82152 Planegg/Martinsried

Program

8:30	Welcome of the attendees
9:00	PD Dr. Arno Kromminga Understanding Immunogenicity – Concepts and Clinical Relevance
10:00	Dr. Lydia Michaut Immunogenicity in Gene therapies
11:00	Tea and Coffee
11:30	PD Dr. Arno Kromminga Biomarker analysis – Exploratory or regulated?
12:30	Lunch
14:00	End

Speakers and Biographies

PD Dr. Arno Kromminga

Arno Kromminga is a certified Specialized Immunologist and Biochemist with 25+ years expertise in regulated bioanalysis covering the entire cascade of assay strategy and characterization of immune responses against biological therapeutics. He is the co-founder of IPM Biotech which was acquired by BioAgilytix in 2016 for which he serves as Global Chief Scientific Officer. He leverages his knowledge and expertise as a board member of the European Immunogenicity Platform (EIP), core member of the European Bioanalysis Forum (EBF) and member of multiple other scientific societies including the American Association of Pharmaceutical Scientists (AAPS), German Society of Immunology (DGfI), German Society of Clinical Chemistry and Laboratory Medicine (DGKL). As a world-leading authority in the area of immunogenicity, he is invited to speak at numerous international scientific conferences and has authored multiple peer-reviewed scientific publications in journals and text books. Dr Kromminga is an esteemed senior expert in immune mediated diseases including autoimmunity, allergy, oncology. His interest is in the integrated interpretation of clinically meaningful immunogenicity, PK and Biomarker data.

Dr. Lydia Michaut

Lydia Michaut has over a decade of experience in regulated PK/PD and Immunogenicity bioanalysis supporting the development of biologics and gene therapy drugs. She is involved in several initiatives from the European Bioanalytical Forum (EBF), the European Immunogenicity Platform (EIP) and the AAPS (American Association of Pharmaceutical Scientists). Lydia holds a Ph.D. in Immunology from the University of Strasbourg (France). After ten years in academic research on the genetic control of eye development, aging and disease, she joined Novartis in 2008. Since 2019, she acts as a Scientific Officer at BioAgilytix.