

6th International Conference and Exhibition on **Analytical & Bioanalytical Techniques**

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Importance of analytical methods to understand the complexity and diversity of protein aggregation

In this 4 to 6 hours course the attendees will learn, based on biopharmaceutical case studies, about the complexity and diversity of the aggregation of peptide and protein drugs and on strategies to overcome these issues.

The workshop will have the following parts:

Part 1: Examples of protein aggregation mechanisms

Part 2: Available techniques for detection of aggregation and impurities (leachables) and how these methods can be applied. Combining analytical methods to ensure detection of aggregates across a range of particle sizes. New technologies for characterization of aggregates will be presented.

Part 3: Strategies for developing stable peptide drug formulations. High-throughput analysis (HTA) and high-throughput formulation (HTF) platforms will be presented. Using case studies, potential causes of aggregation and prevention strategies will be discussed.

Part 4: Aggregation of biopharmaceuticals in human plasma depends on formulation: a new development and research field

Part 5: Regulatory aspects and concerns

Biography

Tudor Arvinte, PhD received his academic training in physics at the University of Jassy, Romania, and his PhD in biophysics from the University of Düsseldorf, Germany. He performed his doctoral work and postdoctoral stage at the Max-Planck-Institute West Germany and held numerous research positions in Europe and the USA: at C.N.R.S., Orléans, France, at Cornell University, New York, at Texas A&M University, and at the Biophor Corporation, College Station, Texas, USA. In 1989 he joined Ciba-Geigy Pharmaceuticals in Horsham, England, and in 1994 he moved to Ciba-Geigy in Basel, Switzerland. Until 2002 he worked as Head of Exploratory Formulation, Novartis Biotechnology Development & Production, Basel. He worked on the characterization and formulation of more than 130 protein and peptide drugs. He has over 80 publications and holds 13 patents on formulations of proteins: one patented formulation for hirudin is used in the marketed product. Since 2001 he is invited Professor at the School of Pharmacy, University of Geneva, Switzerland where he is teaching a post-graduate course on "Formulation and delivery of protein biopharmaceuticals". He is also Visiting Professor at the Department of Pharmacy, School of Health and Life Sciences King's College London, UK. In 2003 T. Arvinte co-founded Therapeomic, Inc., a biotech company focused on developing formulations for biopharmaceuticals in collaborations with pharmaceutical companies.

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