★CO-LOCATED SESSION

[C2] The 22nd Biopharmaceutical Forum

April 13(Thu), 10:10-15:30 / Rm.307

Biopharmaceuticals are different from chemically synthesized drugs as they originate from a biological source or living cell. Consequently, they are large, complex heterogeneous mixtures of proteins. Quality and safety are determined by the consistency of the manufacturing and purification process. This has implications on the way Biopharma products are developed and regulated. Key quality and safety issues include, but are not limited to, cell bank/virus seed and raw material characterization and purity testing, expressed protein/glycoprotein structural determination including post-translational modifications, biological activity, immunogenicity testing and stability. Thus, highly advanced precision analysis technology is required throughout the biopharmaceutical R&D and quality management process.

In this forum, we will discuss the recent global trends and existing and emerging analytical solutions for biosafety and product structural characterization to ensure the quality of biopharmaceuticals. Also we provide guidance on analytical program strategies according to the regulatory trends of overseas regulatory agencies (US FDA, EMEA) to strengthen the global competitiveness of Korean pharmaceutical and biotechnology companies.

Session 1. Enhancing Biopharmaceutical R&D and Quality with Advanced Protein/Peptide Analysis 10:10-15:30

Session Chair	Hun-Young So, (Former) Senior Researcher, (Former) KRISS (Korea Research Institute of Standards and Science)
Speakers	
10:10-10:50	**Analytical Strategies for Quality Assurance/Quality Control of Biotherapeutic Glycoproteins : Case Study and Practical Guide** Hyun Joo An, Professor, Graduate School of Analytical Science and Technology, Asia-Pacific Glycomics Reference Site, Chungnam National University
10:50-11:30	**Challenges for Analytical Characterisation of Biopharma products Novel, Biosimilar and Biobetter** Fiona Greer, Global Director, BioPharma Services Development, SGS Life Sciences
11:30-12:10	**Biosafety Testing : Characterisation of Cell and Virus Banks** Richard Adair, Team leader and Manager, Virology Technical Support, Vitrology
12:10-13:30	Session Break
Session Chair	Jin Woo Choi, Professor, College of Pharmacy, Kyung Hee University
Speakers	
13:30-14:10	**Antibody Quality Characterization in Drugs Discovery & Development** Yunfen He, Director Operations, Shanghai OPM Biosciences
14:10-14:50	**Introducing the Standardized Quantitative Protocol of Therapeutic Antibody Drugs in Blood and Cell Culture Profiling** Ichiro Hirano, Product Manager, Mass Spectrometry Business Unit, Shimadzu Corporation, Kyoto, Japan
14:50-15:30	**Establishing Biosimilarity : Evaluating Comparability of Primary and Higher Order Biotherapeutic Structure for Candidate Biosimilars** Scott J. Berger, Senior Manager, Biopharmaceutical Markets, Waters Corporation, Milford, MA, USA