Topic: - **Development of Biosimilar Drugs, Opportunities and Challenges**

Abstract: - Changes in production method of a biological product may necessitate an assessment of comparability to ensure that these manufacturing changes have not affected the safety, purity, or efficacy of the product. Depending on the nature of the protein or change, this assessment consists of a hierarchy of sequential tests in analytical testing, preclinical animal studies and clinical studies. Differences in analytical test results between pre- and post-change products may require functional testing to establish the biological or clinical significance of the observed difference. Although manufacturing is not the most common case of product failure, product quality issues can delay antibody development. Applying product knowledge proactively to manufacturing may allow greater flexibility and maintain or improve product quality. However, the ability to compare biological materials is solely dependent on the tests used, since no single analytical method is able to compare every aspects of protein structure or function. With the recent introduction of regulatory pathways for follow-on versions of complex biologics, the role of analytical technologies in comparing biosimilars with the corresponding reference product is attracting substantial interest in establishing the development requirements for biosimilars. Here, we discuss the current state of the art in analytical technologies to assess three characteristics of protein biopharmaceuticals that regulatory authorities have identified as being important in development strategies for biosimilars: post-translational modifications, three-dimensional structures and protein aggregation.