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Current analytical techniques for characterization of carbohydrate biosimilars.

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Abstract

The analysis of the N/O-glycan portions of glycoproteins has become important for all comparability studies and in the quality control of biosimilar recombinant glycoproteins. We will describe current mass spectrometry methods and procedures that are commonly used for glycoprotein analysis in order to obtain regulatory approval. Details will be given on the pros and cons of certain methods from regulatory stand point. We will discuss procedures necessary for the complete structural elucidation of any *N/O*-glycan mixture found in glycoprotein products as well as sites of glycosylation. Examples of the methodologies will include data needed in different phases of the study. In addition currents analysis of biosimilars will be discussed.

Biography

Dr. Azadi is currently the Director of the Analytical Services where she oversees and manages the analytical services and training at the Complex Carbohydrate Research Center. The service program enables glycoconjugates to be analyzed on a fee-for-service basis for the research facilities, pharmaceutical and biotechnology industries. She has been involved in structural elucidation of many pharmaceutical products and has acted as a consultant for pharmaceutical companies with carbohydrate-based products and regulatory compliance projects. She has also been annually teaching courses/and organizing workshops on glycoprotein and polysaccharide isolation and characterization for the last fourteen years. Dr. Azadi received her B.Sc. in Chemistry in 1987 from University of North London, UK and her Ph.D. degree in biochemistry in 1991 from Imperial College of Science and Technology, University of London, studying structural characterization of carbohydrates and glycoproteins by mass spectrometry. She was a senior scientist at M-Scan LTD, a mass spectrometry consultancy company prior to joining the Complex Carbohydrate Research center.