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Toolbox needed for structural characterization and comparability studies of glycan biosimilars

Production of high-quality pharmaceutical recombinant therapeutic glycoprotein with consistency in glycan quality is still challenging. Since glycans are responsible for bioactivity, solubility, immunogenicity, and clearance rate from circulation, it is vital to have detailed map of glycans in therapeutic glycoproteins. However, due to the enormous diversity of carbohydrate structures and their heterogeneity, this still remains one of the bottlenecks of full structural characterization. Detailed glycoprotein structural analysis has to be able to identify the peptide sequence where the glycans are attached, as well as the structure of the glycan portion, including oligosaccharide sequence and glycosyl linkages. We will detail methods for mass spectrometry (MS) experiments on both released glycans (“glycomics”), as well as on intact glycopeptides (“glycoproteomics”) using EDT, HCD and CID fragmentation pathways that are needed for quantitation and full elucidation of the structure of glycoproteins. Additional data will be shown where a combination of 2D-NMR, glycosyl composition and glycosyl linkage analysis, will provide information on the glycan topology as well as detection methods for potential non-human modifications that could arise from mammalian expression systems such as Gal α 1-3Gal and N-glycolylneuraminic acid (NeuGc). Our consolidated experiments will outline all the necessary information pertaining to the glycoprotein, including glycan fine structure, attachment site, and glycosylation degree to be obtained pharmaceutical recombinant glycoproteins.

Biography

Parastoo Azadi received her BSc in Chemistry in 1987 from University of North London, UK and her PhD Degree in Biochemistry in 1991 from Imperial College of Science and Technology, University of London, UK studying structural characterization of carbohydrates and glycoproteins by mass spectrometry. She is currently the Executive Director of the Analytical Service and Training at the Complex Carbohydrate Research Centre, USA where she oversees and manages the analytical services and training of glycoconjugates such as glycoproteins, polysaccharides and glycolipids. She was a Senior Scientist at SGS prior to joining the Complex Carbohydrate Research Centre in 1994.

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