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Scientific aspects of biopharmaceutical PTM characterization

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The characterization of biotherapeutic monoclonal IgG1 antibodies regarding post-translational modifications (PTM) has become routine analytical work due to the fact that these represent the vast majority of therapeutic proteins developed in the past two decades. However, in-depth research on pathophysiological pathways as well as recombinant protein expression and production, facilitated an increase in the number of developed therapeutic proteins beyond IgG1, requiring non-routine PTM characterization. This lecture gives insight how industrial development of new therapeutic proteins challenges biopharmaceutical analytics demanding individually tailored solutions. One such example is gonadotropins, which are heavily glycosylated. Characterization of the glycome requires in-depth glyco-analytical development involving glyco-profiling, linkage analysis and site-specific quantification of glycan structures. Complex patterns of disulfide bridges require method development to generate specific dipeptides for verification of the assumed disulfide bridge formations. PTMs like deamidation and oxidation require identification of sites of biological relevance that show increased levels of modifications in a first step. Secondly, methods have to be developed that allow for unambiguous site-specific identification and quantification of the specific modification. Despite the fact that much individual method development is necessary for protein characterization, some solutions were developed so far that facilitate (semi-)automated characterization of PTMs beyond IgG1 mAb. One example is presented, which is automated glyco-profiling of proteins facilitating identification and quantification of hundreds of glycan structures of different proteins within a few minutes.

Biography

Sven Bahrke is a leading Scientist at Glycotope GmbH since 2007. As a Specialist in Glycobiology, he was responsible for the establishment of the Glyco-Analytic Department at where he implemented all necessary technologies for high standard glycan profiling as well as for MS based protein analysis. Currently, he manages projects in PTM analytics and therapeutic protein development. He studied Chemistry at the University of Potsdam and gained experience in the fields of Glycobiology and Instrumental Analytics during his PhD and Post-doctoral Fellowship in the Departments of Chemistry, Biochemistry and the Interdisciplinary Center for Mass Spectrometry.

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