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## Comparison of different approaches for quantitative N-, O-linked glycan and monosaccharide composition analysis in biopharmaceutical production

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Glycosylation of therapeutic recombinant proteins is of importance due to its potential impact on solubility, bioactivity, pharmacokinetics and immunogenicity of glycoprotein pharmaceuticals. Detailed characterization of glycans present on recombinant glycoprotein remains an important challenge in the development and production of biotherapeutics. Analytical strategies for characterization of N- and O- glycosylation and monosaccharides analysis will be presented. These include comparison of HILIC-FLR, MALDI-TOF MS and CE-LIF for N-glycan analysis, choice of a method for quantitative and non-selective release of O-linked glycans, and selection of a method for monosaccharide composition analysis. In this seminar, I will discuss appropriate glycoanalysis methods which allowed detecting changes in glycosylation parameters. A case study will be presented that highlights glycoanalysis techniques useful for gaining understanding of the relationship between process inputs (raw materials) and product quality attributes. The findings confirm that the glycosylation profile of therapeutic antibodies needs to be monitored through development to ensure consistency, efficacy, and safety of therapeutic products.

### Biography

Iva Turyan has her expertise in characterization of N- and O-glycosylation and monosaccharide analysis at the level of released glycans and intact therapeutic recombinant protein. She has completed her PhD from St. Petersburg University and Postdoctoral studies at The Hebrew University of Jerusalem. She is currently an Analytical Development Scientist at Biogen, Cambridge, MA. She has published more than 45 papers in reputed journals, and has been awarded 6 patents.

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