SAGM-RRBP- Selecting appropriate glycoanalysis methods to reduce risk in biopharmaceutical production

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Glycosylation of therapeutic recombinant proteins is of particular 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 monosaccharide's 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. Choosing appropriate glycoanalysis methods 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 in order to ensure consistency, efficacy, and safety of therapeutic products.

Biography
Iva Turyan completed her PhD at the age of 27 years 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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