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Glycosylation of therapeutic proteins: Functions and analytical innovation

Glycosylation is a critical quality attribute of therapeutic glycoproteins, including monoclonal antibodies (mAbs), which can directly affect product safety and efficacy. However, the complexity of protein glycosylation poses a daunting analytical challenge. The current methods for glycan analysis (e.g., mass spectrometry) consist of laborious enzymatic digestion protocols and analyses of the resulting free glycans and aglycosylated proteins. This presentation describes an innovative lectin-based microarray approach for high throughput glycan analysis of native proteins. Case studies of commercial therapeutic glycoproteins will be discussed to highlight the applications of the lectin microarray platforms for the characterization of biotechnology products.

Biography

Baolin Zhang is a Senior Investigator and Review Team Leader in the Office of Biotechnology Products of the Center for Drug Evaluation and Research (CDER) at the US Food and Drug Administration (FDA). He has 15 years of FDA experience regulating biotechnology drug product applications, including monoclonal antibodies and biosimilars. He also directs a research program on advancing analytics for biotechnology products. He has published over 80 original studies in high profile journals and presented at numerous scientific and regulatory conferences. He has received numerous awards for excellence in scientific achievement and for mentoring junior scientists including FDA Excellence in Laboratory Science and Excellence in Leadership.

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