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Enabling Near-Real-Time N-Linked Glycosylation Monitoring of Monoclonal Antibodies during Upstream biomanufacturing

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The <u>biopharmaceutical industry</u> is transitioning towards continuous biomanufacturing processes that require advanced analytical tools to monitor and control bioprocesses to produce high-quality biologics. Post-translational modification of therapeutic proteins, such as N-linked glycosylation, are critical quality attributes that affect biologics safety and efficacy, requiring close monitoring during biomanufacturing. We have developed an analytical toolkit, called <u>N-GLYcanyzer</u>, to monitor monoclonal antibody N-linked glycosylation. Here we highlight this PAT system and provide examples of its use for monitoring an upstream process for producing a commercially relevant Trastuzumab biosimilar.

Biography

Dr. Áron Györgypál is a Post-doctoral Fellow at Harvard Medical School and The Massachusetts General Hospital, in Boston (Massachusetts, USA) working on glycoengineering of antibodies and to understand the role of antibody glycosylation in health and disease. Dr. Gyorgypal completed his undergraduate degree in Chemical Engineering at the New Jersey Institute of Technology (NJIT) and his Ph.D. in Chemical and Biochemical Engineering at Rutgers, the State University of New Jersey.

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