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From observation to control: Using cell culture automation for enhanced product quality optimization

Cell Culture Engineering XV, 2016, Palm Springs

Sven Markert

In this talk we will present an overview of our findings on influencing and controlling product quality attributes of different antibody derived biopharmaceuticals like standard IgGs, bispecifics, glycoengineered and antibody cytokine fusion proteins.

We used the Roche in-house developed automated cell culture system which is based on shaken multi-well plates and a fully automated process workflow. More than 600 fed-batch cultivations can be handled in parallel enabling the screening of a wide range of process conditions. Combining the automation technologies in the fields of cell culture and product quality analytics enables the high throughput screening of a broad range of product quality attributes which makes this technology ideal for the process development of complex molecule formats. The resulting high information density enables the identification of general levers for product quality attributes that can be used to control product quality or adjust it to a desired pattern. Furthermore the know-how can be used for the process development of new pipeline molecules. We could demonstrate that the results from the automated multi-well plates are predictive for the bioreactor and we established the system for the routine use of product quality optimization.

Several case studies from active early and late stage portfolio projects identifying levers for product quality attributes of different molecule formats will be presented in this talk. We focused on the glycosylation pattern, charge distribution, product aggregation, and trisulfide levels. Furthermore an outlook to future activities will be given that include the linking of (1) metabolic data using the Roche CHO metabolomics network model and (2) cell physiological data to product quality.