PAT and CFD for reduced-scale integrated viral inactivation and chromatography-based polishing

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Project description

Continuous processing is significantly changing the manufacturing landscape of biologics to meet high efficacy, quality and profitability standards. To this end, technological advances in process development strategies are pivotal, as well as automated monitoring and control of process parameters and product quality during long-term operations [1-2].

This PhD project is part of an academia-industry collaboration between TU Delft and Janssen Biologics. The aim is to contribute to intensified and/or continuous downstream processing (DSP, i.e. purification), by realizing a proof-of-concept reduced-scale viral inactivation (VI) step integrated with two chromatography-based polishing steps, including in-line conditioning and real-time monitoring and control.

A combination of process analytical technology (PAT), computational fluid dynamics (CFD) simulations, and statistical modelling in reduced-scale experiments will be implemented, which will provide a significant contribution to the transition towards integrated and continuous bioprocessing [3-4]. The required PAT will be selected based on an assessment of available technology and critical process/product parameters. Mixing and blending operations for VI and buffer preparation will be evaluated via CFD modelling. Furthermore, CFD simulations will be used to develop a rational mixing/blending development workflow and to improve in-line conditioning strategies.

References

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