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DIGITALIZATION PLATFORM AND SUPERVISORY CONTROL OF AN INTEGRATED CONTINUOUS BIOPROCESS

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Project Summary: Recently, there has been an increased interest in continuous and integrated biopharmaceutical manufacturing. However, there is a vast gap towards an efficient implementation of process analyzers, a centralized data storing combined with the online use of advanced modeling techniques and the implementation of a supervisory control. In this work, a digital platform was developed for a process consisting of a perfusion bioreactor, a continuous protein A capture step, followed by virus inactivation, and two chromatographic polishing steps. Automated at-line HPLC systems give insight into critical process parameters without the necessity of manual sampling. Moreover, the potential of Raman spectroscopy was investigated in USP and DSP, for which a flow cell and spectral modelling approach were developed, enabling crucial real-time information of process-relevant parameters. The results show the importance of a hierarchical control system to handle process perturbations and drifts, facilitating robust product yield and quality. The concept provides a fundamental basis to intensify the advantages of continuous manufacturing and follows the trend of industry 4.0.

CV. Fabian Feidl started his studies in pharmaceutical biotechnology at the UoAS Biberach and subsequently enrolled into the TU Munich to conduct his master studies in molecular biotechnology. Since June 2015 he has been pursuing his Ph.D. in the Morbidelli-Group, from which he co-founded the ETH spin off DataHow AG.