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A systematic approach to process understanding: Accelerating bioprocess development

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Shortening development times, maximizing product yield and increasing batch success rate are the primary goals of all industrial bioprocessing organizations. In future, QbD principles should ensure and, via PAT, predict product quality. However, QbD is increasingly questioned in its benefits, as it is perceived to be laborious and require additional experimentation. The contribution aims at reviving QbD by demonstrating a systematic methodological approach to process understanding along the depicted Task Cycle. The methods start with an inverse analysis approach, analyzing the effect of bad data quality on decision making in process development tasks such as screening, optimization and set up of a control strategy. Subsequently, a path for deriving understanding von historical data sets is developed and methods to reduce data to scalable information are proposed. We demonstrate that this approach yields to a reduced number of experiments and accelerates process development. Following the predictive processing path, the mechanistic hypothesis are entered in a systematic approach for mechanistic modeling using methods for assessing observability of the model as well as sensitivity and identifiability of parameters. Finally we show an observer strategy for model based bioprocess control. The Task Cycle approach leads a systematic generation and implementation of process understanding, reducing experimental effort and increasing process control capabilities.

Biography

Christoph Herwig, process engineer, worked in industry in the design and commissioning of large chemical facilities prior to enter his interdisciplinary PhD studies at the University of Technology EPFL Switzerland, in the field of bioprocess identification. Subsequently, he positioned himself at the interface between bioprocess development and facility design of biopharmaceutical facilities working in different companies from process development over engineering services to biopharmaceutical production. Since 2008, he is full Professor for Biochemical Engineering at the Vienna University of Technology, with more than 80 papers and is Founder of the spin off Exputec.

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