Karlsruhe Institute of Technology

MAB
PROCESS ENGINEERING IN LIFE SCIENCE

Institute of Process Engineering in Life Sciences
Section IV: Biomolecular Separation Engineering

Model predictive process control for pharmaceutical downstream processes

Master‘s Thesis
Starting date: **As soon as possible**

Real-time quality assurance in pharmaceutical manufacturing processes requires precise **process control** strategies. Herein, **Process Analytical Technology (PAT)** tools provide valuable insights into process performance, by measuring **critical quality attributes (CQAs)**. The integration of PAT data with mathematical models, then allows for **predictive control** of the process, leading to improved product quality and operational efficiency. A hybrid modeling approach, combining **mechanistic and statistical models**, could provide increased process understanding and allow for proactive process adjustments. By establishing an **integrated framework**, consisting of the operating system, the PAT sensors and a model pipeline, advances can be made towards **automated** process control in real-time.

Research Objective

The proposed project aims to establish an in process control using a predictive modeling pipeline. Herein, a PAT model is to be integrated in a Server-Client architecture and a machine-to-machine communication framework is to be established. Afterwards, a downstream process unit operation is to be regulated using control engineering approaches.

Methodology

Experimental	Computational
Äkta-based Chromatography	• Data-driven modeling (Python)
PAT (UV/Vis, Raman, MIR,…)	• Server-Client architectures/ Machine communication frameworks
Offline-Analytics (HPLC-SEC, HPLC-IEX, CE-SDS,…)	• Control Engineering

Timeline

	Month #1	Month #2	Month #3	Month #4	Month #5	Month #6
Literature review						
Model + Control engineering setup						
Machine-to-machine communication framework						
Validation runs						
Thesis writing						

Requirements

- Interest in Python and statistical modeling
- Knowledge of data-driven modeling
- Knowledge of Äkta-based downstream processing

Applications of interested applicants can be sent to **doil.yun@kit.edu**