Karlsruhe Institute of Technology

MAB
PROCESS ENGINEERING IN LIFE SCIENCE

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

Implementation of Mechanistic Modeling for Enhanced Process Understanding and Control

Master's Thesis
Starting from **Sept 2025**

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.

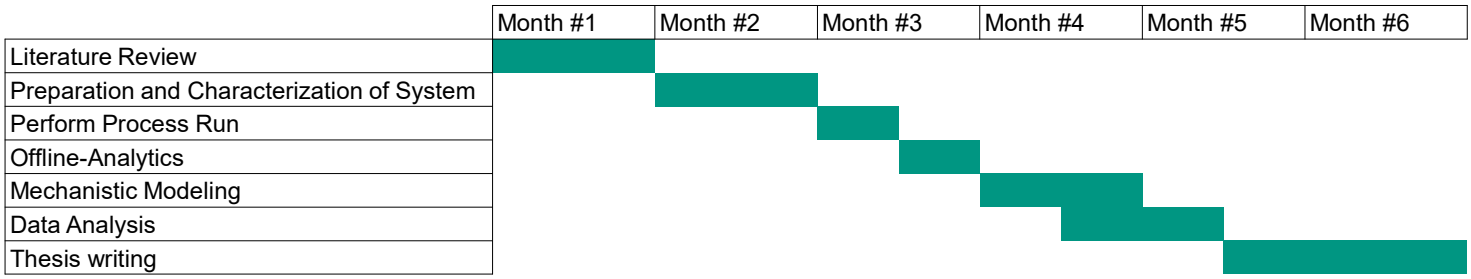
Research Objective

The proposed project aims to mechanistically model the CQAs of a multimodal downstream process for Nanobodies. The predictive performance of the model will then be compared to data acquired from offline analytics. In addition, the suitability of PAT sensors for inline process monitoring will be tested.

Methodology

Experimental	Computational
• Äkta-based Chromatography	• Data Science (Python)
• UF/DF	• Mechanistic Modeling (CADET)
• Offline-Analytics (HPLC-SEC, HPLC-IEX, CE-SDS,…)	
• PAT (UV/Vis, Raman, MIR,…)	

Timeline



Requirements

- Interest in Python and Mechanistic Modeling
- Experience w/ Äkta systems or Offline-Analytics
- Knowledge of downstream processing

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