Contribution ID: **35** Type: **not specified**

Knowledge transfer for biopharmaceutical production: data analysis of different process development campaigns

Friday, 30 May 2025 16:05 (20 minutes)

Background
Monoclonal antibodies (mAbs) are highly specific proteins used in personalized therapeutics, with applications ranging from cancer treatment to autoimmune disease management. In this study, we focus on the production of 86 monoclonal antibody (mAb) molecules, each potentially having unique production characteristics.
Due to the confidential nature of proprietary data in the biopharma industry, obtaining experimental data for all 86 mAb molecules is challenging. Many companies are unwilling to share such data, and this lack of transparency limits the ability to develop generalized models for mAb production processes. Therefore, alternative approaches that can simulate production processes and predict mAb yield are essential to advance our understanding and optimize production methods.
Aims and Objectives
This study aims to develop methods that can enhance the transfer of knowledge across various process development campaigns in the biopharma industry. By leveraging available data and creating synthetic datasets where necessary, we aim to fill gaps in knowledge regarding monoclonal antibody production and improve predictive capabilities. Specifically, the study aims to:
1. Develop dynamic simulation models for mAb production.
2. Use synthetic data generation to compensate for the lack of experimental data.
3. Create a hybrid modeling approach that combines empirical data with knowledge-driven structures to simulate the production processes more accurately.
Methods
The primary tool used for developing the simulation model is Python, with the scipy.integrate module for solving ordinary differential equations (ODEs). The model focuses on defining kinetics constants and rates that govern the production of mAbs and use of aminoacids within the system. The approach involves solving ODEs that describe the behavior of the system over time.
Furthermore, a simple use of Logistic Regression from the sklearn module is employed to assign low titer and high titer to the different mAbs based on factors such as the frequency of amino acids in their sequences and their overall production characteristics.
Results
The results of this study include the development of Python code capable of reading commercial mAb sequences and simulating the production process. The code also accounts for high titer and low titer mAbs, providing insights into how variations in the amino acid sequence can impact production outcomes.
Furthermore, synthetic datasets were generated to visualize the time-course behavior of species within the system, allowing for the observation of changes in mAb concentration and the related biochemical processes over time. These visualizations provide insights into the dynamics of mAb production and the factors that influence titers in different scenarios.
Future Work
The next step involves using the synthetic data generated in this study to train the hybrid model. This will help to improve the model's predictive accuracy, enabling it to handle real-world, incomplete data scenarios typical in biopharma production. By doing so, we aim to develop a more robust and versatile tool for optimizing monoclonal antibody production processes across various biopharmaceutical platforms.

Through this approach, we hope to contribute to the ongoing efforts in the biopharma industry to enhance the efficiency of mAb production while reducing costs and time to market.

Type of presentation

Contributed Talk

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Session Classification: Session

Track Classification: Spring Meeting