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TITLE: Digital AI-driven methodologies to support and accelerate mAbs development in the biopharmaceutical industry

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ABSTRACT: Monoclonal antibodies (mAbs) are increasingly establishing themselves as effective treatment for immunological and oncological diseases. However, the development of new antibodies is a resource-intensive process that requires significant investments and long timelines, often exceeding 2 billion dollars and 10 years. Among the key stages of the development pipeline are the identification of the production cell line, which ensures robust performance and the desired quality attributes (i.e., productivity, stability, product quality, production consistency) in the manufacturing context, and the optimization of the culture process (Li et al., 2010). Both stages require extensive experimentation and substantial resource allocation. To accelerate drug time to market and reduce development costs and human intervention, pharmaceutical companies are exploring innovative digital and AI-driven modeling solutions to automate key development steps.
To address this challenge, we propose solutions targeting two fundamental problems in mAbs development: i) the automated identification of anomalous cell cultures and ii) the rapid identification of the optimal culture feeding schedules.
In this context, we developed a tool based assumption-free modeling to effectively identify anomalous experimental batches at the Ambr®15 scale and diagnose the root cause of non-standard behavior (Barberi et al., 2025). This tool is of paramount importance for accelerating the analysis of experimental batches and reducing the need for expert intervention.
Additionally, we proposed a methodology to optimize the mAbs culture feeding schedule of glucose and glutamine by partially virtualizing the experimental campaign through a hybrid semi-parametric model (Barberi et al., 2024). In this work, Design of Dynamic Experiments (DoDE) is used to plan an experimental campaign aimed at optimizing nutrient concentrations at different stages of the culture and generating the experiments required to train the hybrid model for in-silico experimentation. We demonstrated that the in-silico campaign performed through the hybrid model, trained only on nine experimental batches, identifies a feeding schedule leading to higher antibody titer than DoDE-based campaigns performed with both 9 and 31 experimental batches.

References

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BRIEF SPEAKER BIO: Dr. Gianmarco Barberi is a post-doctoral researcher at CAPE-Lab of the University of Padova where he got his Ph.D. in Industrial Engineering in 2023. Dr. Barberi's research focuses on the development of digital solutions using hybrid modeling and artificial intelligence to support and enhance production and development processes in the pharmaceutical and food industries. His areas of expertise include

machine learning, multivariate statistics, deep learning, reinforcement learning, and Design of Experiments (DoE) methodologies. He also has significant experience in the development and deployment of artificial vision systems and AI-based software. In addition to his academic work, Dr. Barberi is Co-founder and CEO of ProDig s.r.l., a spin-off of the University of Padova. ProDig develops and commercializes AI-driven digital solutions and hybrid modeling tools aimed at improving industrial processes in the pharmaceutical and food sectors.