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Digital AI-Driven Methodologies to Support and Accelerate Mabs Development In the Biopharmaceutical Industry

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ABSTRACT

Monoclonal antibodies (mAbs) have become a cornerstone in the treatment of immunological and oncological diseases. Nevertheless, bringing new antibody therapeutics to market remains a costly and time-consuming process, often requiring more than 10 years of development and investments exceeding 2 billion dollars. Critical stages of the development pipeline include the identification of a robust production cell line, capable of ensuring key quality attributes such as productivity, stability, product quality, and production consistency, as well as the optimization of the culture process (Li et al., 2010). These steps typically rely on extensive experimental campaigns and significant resource allocation. As a result, pharmaceutical companies are increasingly investigating digital and AI-driven approaches to streamline development workflows and accelerate drug time-to-market. In this work, we address two key challenges in mAb process development: i) the automated detection of anomalous cell culture experiments and ii) the efficient identification of optimal feeding strategies. First, we developed an assumption-free modeling framework to automatically detect anomalous experimental batches at the Ambr®15 scale and diagnose the underlying causes of abnormal culture behavior (Barberi et al., 2025). This approach supports faster interpretation of experimental campaigns and reduces reliance on manual expert analysis. Second, we introduce a methodology for optimizing glucose and glutamine feeding strategies by partially virtualizing the experimental campaign through a hybrid semi-parametric model (Barberi et al., 2024). Design of Dynamic Experiments (DoDE) is employed to structure the experimental campaign, enabling the generation of informative data for training the hybrid model and conducting in-silico optimization. Results show that a model trained on only nine experimental batches can identify a feeding strategy that achieves higher antibody titers than DoDE-based campaigns performed with both 9 and 31 experimental batches.

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