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Hybrid Modeling based process development in Cell Therapy, Gene Therapy and mRNA Processes

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Hybrid modeling has emerged as a cost-effective and time-saving approach for process modeling, significantly advancing model-based process development within the biopharmaceutical industry. By integrating mechanistic and data-driven modeling techniques, hybrid models provide a comprehensive framework that enhances process efficiency and scalability. This combination leverages the strengths of both mechanistic insights and data-centric methods, allowing for more accurate and reliable predictions of process behavior under varying conditions.

A key advantage of hybrid modeling in the pharmaceutical industry is its ability to generate robust models with relatively less data compared to purely data-driven approaches. This is particularly beneficial because data collection in the industry is not only expensive but also time-consuming. Consequently, hybrid models contribute to accelerating the development of new products by minimizing the experimental workload while maintaining model accuracy.

In this work, we explore the application of hybrid models to accelerate the development of critical bioprocesses, particularly focusing on upstream processes for cell and gene therapies, as well as the in vitro transcription (IVT) process used in mRNA production. These bioprocesses often involve complex interactions and dynamic behavior, making them challenging to model using conventional techniques alone.

We present a series of case studies to demonstrate the practical application of hybrid models in optimizing bioprocesses. In the context of cell and gene therapy, hybrid models are used to model cell growth, productivity, and quality attributes, enabling more precise control over critical process parameters. Similarly, in IVT processes, hybrid models facilitate the prediction of yield and quality, streamlining process development and ensuring consistency across production batches.

Our findings underscore the versatility of hybrid modeling in addressing the unique challenges of cell therapy, gene therapy, and mRNA-based processes. By reducing development timelines and improving process performance, hybrid models hold great potential to support the rapid development of advanced biopharmaceutical products.

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