

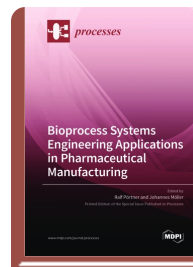
Special Issue Reprint

Bioprocess Systems Engineering Applications in Pharmaceutical Manufacturing

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Biopharmaceutical and pharmaceutical manufacturing are strongly influenced by the process analytical technology initiative (PAT) and quality by design (QbD) methodologies, which are designed to enhance the understanding of more integrated processes. The major aim of this effort can be summarized as developing a mechanistic understanding of a wide range of process steps, including the development of technologies to perform online measurements and real-time control and optimization. Furthermore, minimization of the number of empirical experiments and the model-assisted exploration of the process design space are targeted. Even if tremendous progress has been achieved so far, there is still work to be carried out in order to realize the full potential of the process systems engineering toolbox. Within this reprint, an overview of cutting-edge developments of process systems engineering for biopharmaceutical and pharmaceutical manufacturing processes is given, including model-based process design, Digital Twins, computer-aided process understanding, process development and optimization, and monitoring and control of bioprocesses. The biopharmaceutical processes addressed focus on the manufacturing of biopharmaceuticals, mainly by Chinese hamster ovary (CHO) cells, as well as adeno-associated virus production and generation of cell spheroids for cell therapies.

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