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## Speeding Up Development for Upstream and Downstream Processes using Bioprocesses Modelling and Smart Experimental Design

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Introducing new bio products to market involves numerous challenges, including the risk of product dropout during lab-scale stage and competitive pricing compared to existing products. Design of experiments (DoE) methodology is used to solve these problems, which assesses the influence of critical process parameters (CPPs) on critical quality attributes (CQAs). Nevertheless, this process can take a lot of time, and the high cost of production drives up the final prices.

Time-resolved bioprocess models offer a solution to this problem by enabling increased process understanding, process predictions and online monitoring. Applying process modelling strategies makes it possible to save up to 70% of experimental effort during development. Moreover, it provides a better process understanding which can be transferred during scale-up and used for process monitoring and control.

We will present use cases from both upstream and downstream to demonstrate how smart experimental design and streamlined workflows lead to bioprocess models for understanding, monitoring, and prediction and how digital twins can be used to directly control the process unit. We will discuss how reduction of experimental design can be implemented for microbial and mammalian cultivation processes to find optimum conditions for highest yields and downstream for the optimization of ultra- and diafiltration processes.

### Biography

I'm a Bioprocess Modelling Engineer with experience in mathematical modelling, process optimization, and data science. I've worked on developing and evaluating bioprocess models, collaborating with clients, and driving innovation in biotech. I've got experience in research, regulatory affairs, and R&D, with hands-on work in cell culture, chromatography, and biotechnological solutions. I'm skilled in tools like Python, Minitab and Mat lab. I value teamwork, creativity, and continuous learning, always seeking new challenges to advance the biotech industry. I'm a Bioprocess Modelling Engineer with experience in mathematical modelling, process optimization, and data science. I've worked on developing and evaluating bioprocess models, collaborating with clients, and driving innovation in biotech. I've got experience in research, regulatory affairs, and R&D, with hands-on work in cell culture, chromatography, and biotechnological solutions

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