A Process Systems Engineering approach for accelerated, sustainable pharmaceutical manufacturing and distribution

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Abstract:

Pharmaceutical process and product development rely primarily on time- and cost- intensive experimentation. In recent years, computer-modelling tools have been gaining increasing interest as means to inform, accelerate, and optimise the industrial workflow. In this talk, we will discuss how such tools can enable adaptive process design, sustainable operation and optimal process performance, harnessing the power and economical sustainability of computer-based experiments. We will focus on how model-based tools can: (1) accelerate and inform decisions related to material and process conditions and (2) support decision-making during process scale up to ensure continuous, global supply. Starting from process development, we will present a model-based framework for bioprocess design and optimisation that, beyond the traditional Key Performance Indicators (KPIs), features sustainability metrics. The presented cases studies include biopharmaceutical separation processes, including informed selection of process conditions, as well as a workflow and model-based tools for quantitative comparison of different design options, such as the type of resin.
To complement process development, we will demonstrate a model-based framework that can guide decision-making during scale up. We will showcase how computer-modelling tools can be used and embedded in industrial practices to support manufacturers across the product lifecycle, from clinical trials to commercialisation. In that respect, we will discuss how process uncertainties can be identified quantified and we will illustrate case studies where we evaluate different equipment and scale options with respect to productivity, economic feasibility and environmental sustainability.