TOWARDS IMPLEMENTATION OF NOVEL SINGLE-USE DEVICES IN INTEGRATED PROCESSES FOR BIOPHARMACEUTICALS

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Depending on how labile therapeutic proteins are they can be difficult to manufacture in traditional fed-batch processes due to their unstable nature, unfavorable upstream conditions, and degradation by host cell proteases[1,2]. Integration of the protein capture step with the upstream process, in a continuous or semi-continuous operation, could offer a solution by rapidly recovering the target product or removing unwanted impurities in a flow-through mode. In this context, single-use devices for protein capture, such as membrane chromatography devices and functionalized chromatography resins, are attractive tools suitable for such processes[3,4]. We investigate new strategies for the evaluation of novel single-use devices for their implementation in an integrated process, bridging the gap between the device development and process development.

We evaluate to what degree membrane chromatography devices and functionalized chromatography resins could accommodate different upstream processes with respect to media composition, the presence of compounds interfering with protein binding, as well as the lifetime of the devices. A key element of the ongoing work is to establish new feasible process development approaches, which do not require the production of a large number of single-use devices but still provide an insight into the integration of protein recovery and impurities removal directly from the fermentation process. Therefore, scale-down fermentation systems have been used in the experimental work, as well as microcultivations for holistically optimizing fermentation and binding conditions specifically for resin-based capture technologies.

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