

PROCESS INTENSIFICATION – SO MUCH MORE THAN CONTINUOUS BIOPROCESSING

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Over the past decade, continuous bioprocessing has been mentioned as a game changer in manufacturing biopharmaceuticals, poised to unlock significant improvements in production cost. Today, solutions exist to enable continuous bioprocessing for nearly every step in the overall biomanufacturing process flow. However, despite the promise of significant cost savings, implementation of fully integrated continuous bioprocessing platforms is limited.

The slower adoption curve suggests one of two things: either continuous bioprocessing is not a game changer for production costs, or the decision to implement innovative manufacturing solutions involves much more than financials. Indeed, regulatory aspects, flexibility, simplicity, and sustainability are often considered equally important in the decision-making process. Continuous bioprocessing cannot be the goal for all scenarios. Instead, it should be viewed as one tool in the toolbox of solutions for modern, intensified processing. Its suitability and output should be evaluated for the individual process needs and objectives.

Within this context, we reviewed the impact of various combinations of a toolbox for intensified connected bioprocessing. We assessed the overall costs, simplicity, regulatory challenges, and sustainability. Depending on the operational needs and boundary conditions, the optimization leads to different combinations of solutions—performance materials (such as filters and adsorbents), technological solutions (repetitive batch processes, multicolumn chromatography solutions, etc.) and automation solutions. This review is not limited to the primary process flow (the sequence of unit operations); it also involves supporting functions, such as the supply of buffers and consumables and the digital aspects of an intensified connected bioprocessing platform. Also, we considered the process portability (scale-up/scale-down and technology transfer).

