

NEXT GENERATION PROCESSES: SINGLE USE TECHNOLOGY AND KEY ENABLERS

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Key Words: process intensification, perfusion, cell retention, next generation bioreactors, product development

The biopharma industry faces significant challenges. Among these are increased cost pressure on medicines from society and biosimilar manufacturers, the pressure to reduce the time to approval as well as more targeted patient populations resulting in smaller batch sizes and use of multi-product facilities.

This pressure forces companies to develop the next generation processes, i.e. more intensified processes with higher productivities, smaller footprint in agile plants and at a lower cost. Single-use technology is one of the key enablers for this next generation of intensified processes.

This presentation describes different strategies for next generation processing, where perfusion is an integral part of all these intensified upstream processes. These include both the seed train and the production bioreactor. We highlight, how recent technology developments support these strategies, especially with respect to high performing bioreactors and cell retention devices. Furthermore, we describe product development strategies including in-silico design like CFD, extensive verification and characterization. In addition, process and performance data will be presented for each strategy together with an estimation of the impact on plant productivity and process economy. The results provide useful insights for biomanufacturers who are considering the value of process intensification and single-use technology to address some of the challenges of the industry.