

PROCESS INTENSIFICATION: MODELING THE IMPACT OF TECHNOLOGY AND PROCESS SCENARIO SELECTION ON COST, THROUGHPUT, FACILITY VOLUME, FOOTPRINT AND SUSTAINABILITY

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As the current biological product pipelines become more diverse, product demand and cost pressures are increasing. Process Intensification (PI) is one-way industry is exploring to overcome these challenges. PI can either be applied to an individual unit operation or set of unit operations across upstream and downstream. These applications can enhance several measures such as: accelerated drug development, increased productivity, reduced footprint, flexibility, improved drug quality.

Although many advances have been understood when implementing PI in upstream, downstream often poses several challenges. First and foremost is choosing the primary purification process in downstream which connects seamlessly to upstream PI. Then integrating the different steps in downstream to run them in an intensified batch Vs connected Vs continuous mode need to also be considered in order to obtain additional cost, productivity, footprint and sustainability gains to the overall process.

In this presentation, through cost modelling tools, we will highlight how technology and eventual process choices can impact cost, facility footprint and sustainability, especially PMI (process mass intensity). Analysis indicates with the right process choices one can reduce overall COGS by upto 50% and decrease the facility footprint by upto 20% while keeping the throughput the same. Another impact that intensification does is on sustainability matrix, where both PMI and Carbon footprint can be reduced to upto 30% thus leading to a more sustainable manufacturing.

This type of analysis could be a powerful tool for Innovators/ CDMO biomanufacturers in understanding very early how the 'correct' upstream and downstream intensification strategy selection and implementation can have a positive impact to the manufacturing facility, thus reducing pressure on developmental and scale-up activities.