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# Development of a first generation perfusion process and medium for continuous processing based on existing fed-batch platform media

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# DEVELOPMENT OF A FIRST GENERATION PERFUSION PROCESS AND MEDIUM FOR CONTINUOUS PROCESSING BASED ON EXISTING FED-BATCH PLATFORM MEDIA

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Process intensification leveraging perfusion offers tremendous potential for yield improvement over fed-batch processes for the production of monoclonal antibodies. In the context of continuous processing, the goal is to achieve highly intensified perfusion processes that allow substantial footprint reduction and enable flexible adaptation in new facilities. However developing a perfusion process and medium without prior technology requires leveraging the existing fed-batch platform knowledge. Evolving a medium for perfusion relies on designing suitable mixtures of basal and feed media that serve as adequate starting points for development. Focus on optimization of the medium to decrease byproduct waste, reduce unnecessary cell growth and enhance specific productivity is critical. Doing so would allow a more robust and controlled process, and allow steady-state to be more attainable which will aid in maintaining consistent product quality for continuous processing. Moreover, reducing medium utilization hence the ability to operate under lower cell specific perfusion rate was important in order to have a more economical and nimble process. In order to overcome the conventional perfusion medium bottlenecks of equipment capacity, liquid handling, transfer and storage, a different strategy to managing large bulk volume had to be undertaken in order to make fit for an existing small pilot plant. The approach to establishing a first generation perfusion process starting from a fed-batch platform will be shared. Examples demonstrating continuous perfusion and volumetric productivity of > 1 g/L-day under low CSPR will be discussed.