# A CDMO PERSPECTIVE TOWARD THE IMPLEMENTATION OF CONTINUOUS BIOPROCESSING STAND-ALONE AND INTEGRATED OFFERINGS

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The challenge involved in integrating unit operations for continuous bioprocessing is a significant impediment to implementation of the technology in the industry. The benefit of continuous bioprocessing can be better understood when the components of the technology are analyzed under multiple factors including modalities, protein quality attributes and stability, specific productivity and overall cost-benefit of implementation and operation of the technology. Contract Development and Manufacturing Organizations (CDMO) need to provide a portfolio of offerings that cover the needs of diverse groups and process needs. For example, processes with lower productivity and unstable molecules can benefit from a perfusion system while more stable molecules with high productivity may need to focus on the benefits of a continuous capture to address a potential bottleneck on the downstream.

In this work, we present Catalent's road map and rationale of the step-wise approach we are using toward the implementation of continuous bioprocessing. Our approach will facilitate the integration of the appropriate technology components tailored for each process in a timely and cost-effective manner. Modeling and simulation data will be presented to support the soundness of the approach using selected stages in a typical process for the production of monoclonal antibodies.

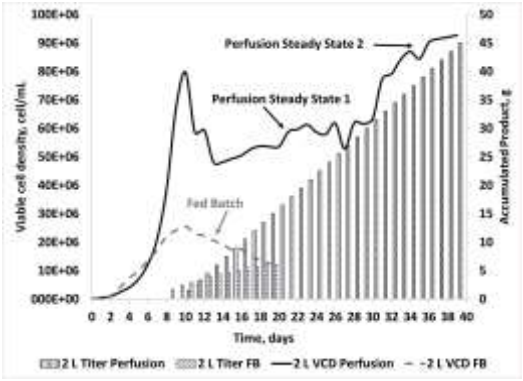


*Figure 1 – Optimization of Steady State conditions for increased productivity in a perfusion bioreactor*

As an example of the optimization of independent components of the technology, we will present results from experimental studies developed at bench and pilot scale. Figure 1 shows the results obtained when process parameters in the bioreactor were manipulated to achieve different steady states while maintaining titer and product quality for a production perfusion bioreactor.

Additional studies at bench and pilot scale will be presented to demonstrate proof of concept of other components including N-1 perfusion and continuous capture.

The results are allocated to present a combination of scenarios that will guide the use of specific and combined components of the continuous bioprocessing technology based on modality and process needs.