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Toward development of continuous bioprocesses: Comparison of fed-batch and perfusion upstream production processes in early development

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TITLE: TOWARD DEVELOPMENT OF CONTINUOUS BIOPROCESSES: COMPARISON OF FED-BATCH AND PERFUSION UPSTREAM PRODUCTION PROCESSES IN EARLY DEVELOPMENT

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Continuous Processing is an exciting development in the field of bioprocessing. The potential for quick response to market demands, decrease in infrastructure, increased flexibility and consistent product quality has resulted in a growing interest in Continuous Processing for production of all types of protein drugs (high or low volume, stable or unstable). Sanofi is developing a novel Integrated Continuous Manufacturing platform for biologics that utilizes an upstream perfusion process. While cell culture perfusion processes offer substantial benefits for commercial biologics production, implementation may present challenges in early development, where speed to first in man studies is critical. Here we present a comparison of candidate Phase I fed-batch and perfusion processes resulting from our upstream development work for a monoclonal antibody. The report focuses on process productivity, product quality attributes, and development timelines. Assessment of the advantages and challenges for both processes informs strategy for Continuous Process platform development.