ASSESSING THE SUSTAINABILITY OF FED BATCH AND CONTINUOUS PROCESS FORMATS FOR MAB MANUFACTURING VIA BIOPROCESS MODELING

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In recent years, the biologics industry has been moving towards adoption of continuous manufacturing for mAbs and other therapeutics to reduce costs, decrease cycle times, and increase flexibility. The industry has also been challenged with improving sustainability to help mitigate the effects of the global climate crisis. Since continuous manufacturing provides opportunities for intensifying the process and shrinking facility footprint, we sought to compare the sustainability of an intensified, continuous process to a fed batch process as part of a larger sustainability effort within NIIMBL. BioSolve©, a bioprocess modeling tool, was used evaluate the relationships between or among different sustainability-related impact categories, such as water, raw materials, and consumables usage, for single use and stainless-steel processing modes. These outputs, along with facilities and energy requirements, have been assessed for environmental sustainability impact across various damage categories using life cycle assessment (LCA) methodology. Data has been generated for mAb manufacturing using a fed batch process with single use technologies, a primarily stainless-steel fed batch, and a single-use fully continuous base case scenario. Within each of these scenarios, process changes impacting sustainability, such as removal of unit operations or reuse of process consumables, as well as facility design improvements, are assessed to help guide technology development efforts to more environmentally sustainable operations.