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CHARACTERIZATION OF HOMOLOGOUS INDUSTRIAL STRAINS USING CONTINUOUS CULTIVATION TECHNIQUES TO UNDERSTAND PROCESS PERFORMANCE VARIATION IN A PLATFORM FED-BATCH PRODUCTION PROCESS

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A platform fed-batch fermentation process for drug substance manufacture was applied across several homologous industrial strains for production of a multivalent vaccine. Significant process performance variability was observed during development and commercialization necessitating type-specific empirical process optimization of several fermentation process parameters. To better understand the underlying mechanism of process performance variability despite the high degree of strain homology, the researchers applied a small-scale continuous cultivation technique to assess how certain type-specific strains adapted to process perturbations that were designed to mimic manufacturing scale fed-batch cultivation conditions (i.e. continuous substrate feeds). Strain characterization information garnered from these studies was then used to provide technical justification for the process parameter ranges and control strategies derived from empirical optimization