THE JOURNEY FROM TECH TRANSFER TO BLA SUBMISSION: CASE STUDY OF A NS0 CELL CULTURE PROCESS FROM 2000L STAINLESS STEEL BIOREACTOR TO 2000L DISPOSABLE BIOREACTOR

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A case study of NS0 cell culture process transfer from 2000L stainless steel bioreactor (SST) to 2000L disposable bioreactor (SUB), and through to process validation and BLA submission is reported for production of an antibody therapeutics in this poster. Initial attempts in growing the NS0 cells in the small scale 2D bags yielded non-satisfactory results, as growth was impacted by bag material type as well as by different suppliers of the same bag material type. However, 3D bags of 50L and above proved to be supportive of the NS0 cell line growth.

Process characterization (PC) and process validation (PV) efforts were initiated after successful scale up to the 2000L SUB. Scale down model (3L) was qualified using bench top glass bioreactors, and PC studies identified several critical process parameters (CPPs). Successful process performance qualification (PPQ) campaign followed and BLA was submitted in 2017.