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INFLUENCE OF CULTIVATION PARAMETERS OR SUPPLEMENT ON PRODUCT QUALITIES AND
CULTURE PERFORMANCES DURING PERFUSION

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Perfusion processes have been developed with technological advances in single-use bioreactor and cell retention device. Perfusion has advantages such as high cell density culture in compact facilities and media change or culture parameter shifts for protein production with desired qualities. Single use bioreactor (200L or 1000L) with ATF System was used for the clinical production. For the process development, the scale-down model was established with lab-scale (2L) bioreactor with ATF2.

A recombinant CHO cell line producing a fusion protein was cultivated using in-house serum-free media. Influence of insulin (0~3mg/L) on qualities was investigated in the established perfusion process using in-house serum-free medium and 2L scale-down model. The results showed that low concentration of insulin enhanced O-glycosylation and -2 charged N-glycan of fusion protein. Temperature (30~34°C) conditions, under no addition of insulin, were investigated to evaluate effect on qualities. High temperature enhanced O-glycosylation and -2 charged N-glycan of fusion protein.

To evaluate interaction among culture parameters (Temperature, pH, and Dissolved Oxygen) in the perfusion process, Central Composite Inscribed (CCI) was selected as design of experiment. 20 perfusion cultures were carried out in the 2L scale-down model. The results showed each parameter and interactions among parameters had an effect on qualities and culture performances.