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Abstract:

The Keytruda® drug substance manufacturing process was transferred and scaled up from a donor manufacturing site (12,500 L bioreactor WV) to two additional recipient sites (12,000 L and 22,000 L bioreactor WV) to further expand drug substance production capacity of Merck's novel monoclonal antibody against PD-1. Process facility fit into the recipient manufacturing facilities was required due to differences in equipment and operation as compared to the donor site and therefore upstream process performance comparability needed to be demonstrated (regulatory requirement). A three-level comparability approach was used, whereby upstream intermediate product quality (Level 1), cell culture performance KPAs (Level 2) and cell culture performance profiles (Level 3) data of the two recipient sites were compared with data of the donor reference process. In this case study, the author will present the comparability approach and (statistical) acceptance criteria applied, upstream process performance attributes selected and discuss key comparability results and conclusions.