FACILITY DESIGN CONCEPTS FOR ADOPTIVE T-CELL IMMUNOTHERAPY

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Autologous chimeric antigen receptor T-cells (CAR T-cells) have been proposed as a possible treatment for multiple oncology indications. In order to overcome some of the challenges associated with autologous processes such as high COG, batch-to-batch variability and complex logistics there is increasing interest in developing allogeneic CAR T-cell products. The manufacturing process of allogeneic CAR T-cell products includes a 2-step genetic modification and magnetic purification in order to integrate the target CAR into the T-cells and to minimize the chances for graft versus host disease (GvHD). This presentation describes a detailed economic analysis of different facility design concepts for the commercial scale manufacture of allogeneic CAR T-cell products: fed-batch versus perfusion cell culture and centralized versus decentralized manufacture. This analysis was carried out using an advanced decisional tool developed at University College London. The case study assesses the impact of fed-batch versus perfusion cell culture on current limitations of DSP technologies for magnetic purification of CAR T-cells. The key cost drivers across these scenarios were identified through a detailed sensitivity analysis. A detailed NPV analysis was carried out with the aim of capturing the potential economic and technical benefits of using a single centralized facility compared to multiple facilities for the manufacture of allogeneic CAR T-cell products over several years.