

ECONOMIC AND OPERATIONAL APPRAISAL OF ALLOGENEIC CAR T-CELL BIOPROCESSES

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Allogeneic CAR T-cell therapies face a variety of challenges from a processing point of view. Pressures to deliver cell therapies at affordable prices demand the development of efficient and cost-effective manufacturing strategies and process technologies for the manufacture of such products. Consideration must be paid to both financial and operational aspects of bioprocess designs from the early stages of product development. This work presents the application of a decisional tool to a case study which describes the manufacture of an allogeneic CAR T-cell therapy. The tool, developed at University College London, is able to quantitatively evaluate bioprocess designs from both a financial and an operational perspective. In this instance the tool has been used to carry out mass balances and equipment sizing calculations in order to compute resource utilisation and cost of goods (COG) for a range of bioprocess designs. Scenario analyses have been used to pinpoint future process improvements that result in feasible manufacturing COG. Furthermore, multi-attribute decision making (MADM) has been employed in order to allow the appraisal of optimal bioprocess designs from both a financial and an operational perspective. The tool outputs provide COG breakdowns for bioprocess designs at a range of annual demands and dose sizes. MADM has been used to provide quantitative output values to key financial and operational performance metrics. Further to this, key process bottlenecks and economic drivers have been identified; these provide a basis for the focus of future process improvements. This work presents a computational technique that can be used to drive effective decision making early on in the development of allogeneic CAR T-cell therapy bioprocesses.