ASSESSING THE COST AND VALUE DRIVERS OF AUTOMATION IN CELL AND GENE THERAPY MANUFACTURING: A DECISION GUIDE

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INTRODUCTION

Contrary to off-the shelf therapies, autologous solutions cannot benefit from economies of scale[1]. One option to make the process more efficient is to automate different steps in the procedure. This assessment looks at the key parameters that should be considered when taking this decision.

METHODOLOGY

Qualitative interviews were conducted through a third party with academia and biotech companies active in the field of cell and gene therapy to clarify the different cost and value drivers for automation vs. manual manufacturing process in both cell expansion and final formulation[2]. A literature search and data on file were used to complement these findings.

RESULTS

Patient-specific considerations, manufacturing costs and the weight of value drivers should all be assessed when considering automation.

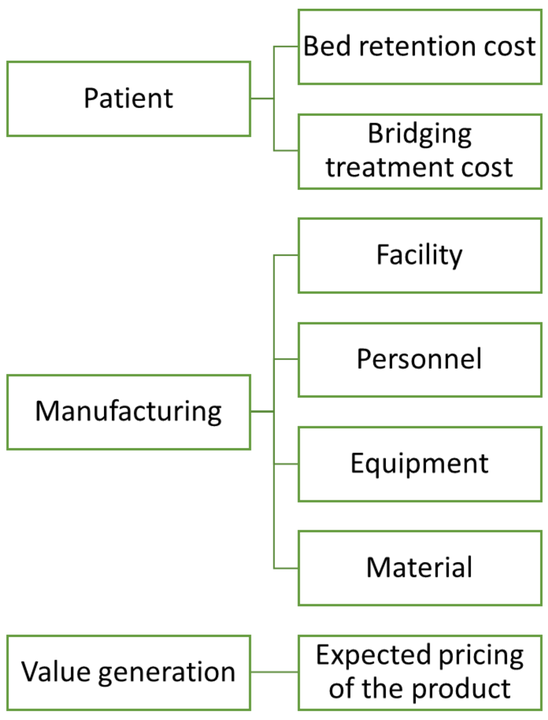

Figure 1. Components for decision-making on automation

RESULTS (continued)

Patient-specific considerations include waiting time for the treatment[3] from the moment of cell collection to the administration of the therapy, translated into bed retention and alternative treatment cost. Furthermore, number of patients served should be considered.

Manufacturing costs include facility, personnel, equipment, and materials[2,4]. Facility costs would consider the grade of the clean room[4]. In terms of personnel, the number of FTEs, their qualification as well as training time would need to be measured[2]. In addition, product runs per FTE should be looked at[4]. Capital equipment and disposable costs are another differentiating factor[4]. Starting materials as well as failure rates due to human error should be factored in, as these may result in a loss of raw material[2].

Finally, the value drivers of automation should be weighted. These include the potential for commercialization and the expected value of the final product[5].

CONCLUSIONS

The decision to automate the cell and gene manufacturing process should take into account a broader number of factors than simply equipment costs in order to assess its true value.

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