

LONG-TERM COST EFFICIENCIES LINKED TO AUTOMATED VS. MANUAL FILL AND FINISH PROCESS IN CELL AND GENE THERAPY MANUFACTURING

Timea ReziKato; Koenraad Dierick; Leda Sweerts

INTRODUCTION

Due to the high risk and variability in the final step of the cell manufacturing process¹, a large portion of the commercial segment is looking to automate. While there are several advantages to automation¹, this assessment aims to explore the long-term cost efficiencies linked to this decision.

METHODOLOGY

21 qualitative interviews were conducted with academia and biotech companies active in the field of cell and gene therapy focusing on both cell expansion and final formulation². We have coupled those findings with internal data on file and literature to assess the long-term cost efficiencies specifically related to the fill and finish step.

RESULTS

Long-term cost efficiencies in automating the fill and finish step of the cell and gene manufacturing process relate to two major parameters: facility and personnel.

Manual fill and finish generally takes place in a Grade A or Grade B clean room, whereas automated solutions allow this process to take place in a Grade C environment. According to some estimations, this can result in savings of approximately 46.000 USD upfront³.

With regards to personnel, it has been established that total estimated labor costs can be cut by 50% when using an automated final formulation system⁴. Our research shows that the long-term gains relate to personnel training and skill level. An operator can be trained to use an automated system in a day, whereas it takes 5-6 months to learn to work in a high-grade clean room. The latter can translate into an overall cost saving of 43.560 EUR⁵. Finally, operators working with an automated system require less training and education, translating into savings related to wages.

CONCLUSIONS

When deciding to opt for an automated fill and finish solution, it is important to take the long-term cost efficiencies into account as they can make a significant difference in upfront investment for the organization.

REFERENCES

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