

INTEGRATED CONTINUOUS BIOPROCESSING: COSTS OF GOODS VERSUS COST OF DEVELOPMENT

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A significant benefit of continuous manufacture is the potential to provide higher productivities compared to traditional batch processes. Smaller facilities with single-use technology could become preferable offering reductions in the capital expenditure. Hence, continuous bioprocessing could offer savings in the cost of goods (COG). However there are other cost factors that need to be considered when evaluating bioprocess facilities in addition to the COG. The cost of development (COD) is a key cost driver that could affect the decision to adopt new manufacturing methods.

This study aims to carry out a holistic financial assessment of introducing continuous bioprocessing strategies by considering both the COG and the COD. To be able to perform this level of analysis a decisional tool was developed at University College London to evaluate the cost of implementing traditional batch or continuous bioprocessing (end-to-end and hybrid) at various stages of the drug development pathway. A range of scenarios investigated the economics of different manufacturing strategies at various demands, company sizes and stages of manufacture (pre-clinical, clinical and commercial). Therefore, through the analysis it was possible to determine whether the apparent benefits of continuous bioprocessing translate into cost savings, focusing on the development and commercialisation of monoclonal antibodies.