COST AND LIFE CYCLE ASSESSMENT OF UPSTREAM MONOCLONAL ANTIBODY PRODUCTION

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The demand for biopharmaceutical products in modern societies has been rapidly increasing to address diseases like cancer, and more recently COVID-19. Optimizing production processes is now necessary to avoid bottlenecks and to cope with shrinking free capacity at production facilities. Ideally, process developments should lead to lower costs, environmental impacts with increased production efficiency. However, the introduction of new technologies can often lead to tradeoffs in the desired objectives. The development of a comprehensive assessment framework (**Fig. 1**) is therefore necessary for the decision-making process [1]. The environmental impact of pharmaceutical production is more difficult to assess due to the lack of available data and is therefore still largely unclear. In this work, we compared the costs and impacts of continuous monoclonal antibody production in perfusion mode with traditional fed-batch systems. In addition to an assessment of operating costs, an extended life cycle assessment was also conducted with 15 environmental categories. A dynamic cultivation model developed based on data from a pilot-scale facility in Japan was used as the basis for the analysis. A case study is presented for commercial scale production. The use of single use (SUT) equipment was investigated in comparison to traditional stainless steel multi-use (MUT) bioreactors. In total four scenarios were compared for the different operating modes and equipment configurations. The results showed trade-offs between operating costs and the human health impacts, represented by the disability adjusted life years (DALY) (**Fig.2**) [2]. Continuous production was shown to have a higher operating cost, mainly due to the higher consumption of cultivation media, but a lower impact on human health. A sensitivity analysis is also presented to show the impact of the assumptions made in the study.

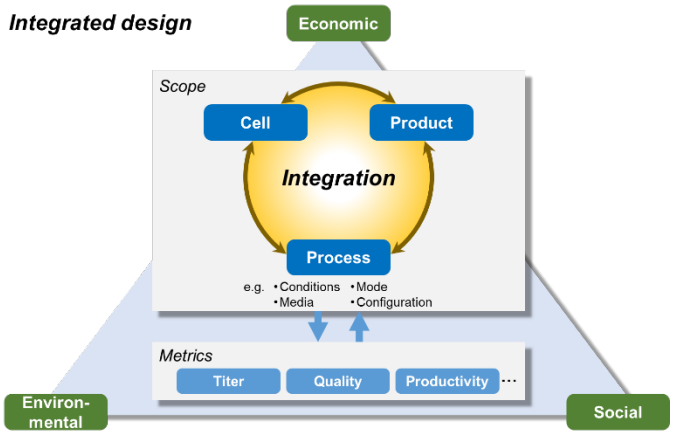

Figure 1 – Integrated sustainability assessment framework [1]

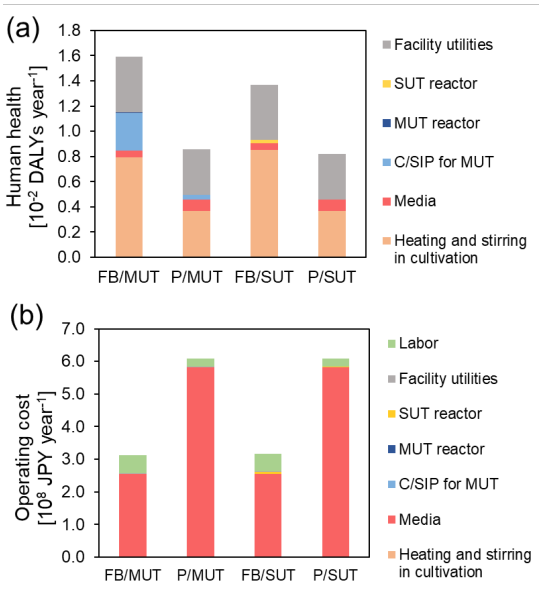

Figure 2 – Comparison of human health and operating costs at different cultivation modes [2]

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[2] Amasawa, E.; Kuroda, H.; Okamura, K.; Badr, S.; Sugiyama, H. Cost–Benefit Analysis of Monoclonal Antibody Cultivation Scenarios in Terms of Life Cycle Environmental Impact and Operating Cost. ACS Sustain. Chem. Eng. 2021, 9 (42), 14012–14021.