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Logistics of Bioremediation

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Introduction

Due to the advantages of utilising living cells as therapeutic agents in several clinical investigations and trials, the area of cell and gene therapy has experienced fast expansion in recent years. In order to enable process optimization and lower production costs, bioprocess economic models (BEMs) are essential tools for decision-making in bioprocess design. These tools are particularly crucial for manufacturing decision-making and boosting the possibility that cell-based medicines will be accepted by the market, as they are frequently cost-prohibitive due to high resource and quality control expenses. Aside from this, their underlying bioprocesses' inherent biological unpredictability renders them particularly vulnerable to unanticipated expenses brought on by failed or delayed manufacturing batches [1].

Because it is thought that cell and gene therapy (CGT) has the potential to effectively treat a wide range of illnesses and potentially to cure previously incurable diseases, the field is currently going through a phase of rapid progress. This notion is well-founded because using living cells as therapeutic agents has a number of benefits over using traditional medications. They are able to respond to the cues provided by their particular environment and can carry out a variety of complicated biological tasks like aggressively targeting cancer cells, regulating the immune system, and rebuilding tissues. Additionally, genetic engineering or cellular hitchhiking can be used to improve the therapeutic characteristics of the cells themselves, opening up a world of diverse options [2].

The fundamental idea behind CGT is not as new as it first appears. In a clinical setting, cell therapy was first successfully used in 1956 after an allogeneic bone marrow transplant from a twin donor to cure leukaemia. In the ensuing decades, not only did bone marrow transplantation solidify its position as a critical medical procedure with obvious therapeutic advantages for a number of diseases, but further cases of cell therapy also started to emerge. The FDA approved its first cell therapy product (CTP) in 1997 with the goal of treating severe cartilage abnormalities. Subsequently, the FDA approved a number of CTPs for use as skin substitutes to treat burn wounds and ulcers.

But it wasn't until stem cell research that CGT started to excite the scientific community. The potential of CGT was enormously expanded by stem cells because of their innate capacity for self-renewal and cell-type differentiation. On the one hand, they made it possible to treat conditions like type I diabetes, heart failure, and neurodegenerative disorders that are linked with severe loss of cell types. However, they also demonstrated promise in lowering the high manufacturing costs and low efficacy of CTPs dependent on terminally differentiated cells, which are scarce and have a low proliferating potential [3].

Description

The challenge inherent in the creation of CTPs from stem cells is amply demonstrated by the dearth of viable CTPs. The molecular complexity that makes stem cells so promise for therapeutic uses also poses a significant obstacle to turning laboratory-scale research into dependable and affordable bioprocesses. The acquisition or production of the starting cell type, cultivation, modification, harvest, concentration, purification, formulation, fill, and finish are the several steps that make up these bioprocesses, which are typically complex operations. Current Good Manufacturing Practices (cGMP) must be strictly followed during each of these steps, and they must all be optimised to be profitable. Therefore, using deliberate and properly thought-out design approaches is essential for producing CTPs that work.

One of these technologies is in silico bioprocess economic models (BEMs). A bioprocess model, in its most basic form, is a group of interconnected equations that reflect the many stages of a given bioprocess. These equations take a set of inputs raw materials and operating parameters for the stage in question and transform them into one or more outputs, like the amount of finished product obtained or the anticipated quality of the finished product. A BEM is created by layering a bioprocess model with economic equations that determine the cost of the final product based on the consumption of key resources and the scale of production. A trustworthy BEM can be used to quickly and affordably conduct research.

The bioprocesses used to make CTPs frequently use fragile end products with short shelf life and highly variable cell-based basic ingredients. They must also follow strict rules in order to receive regulatory permission, which frequently results in expensive setbacks. This naturally results in long and onerous development lifecycles, and there is no guarantee that they will produce a marketable product that can be sold. Therefore, in order to assure the success of such endeavours, it is essential to adhere to a strategic framework for the development of cell therapy processes, preferably based on the idea of quality by design (QbD) and its emphasis on ongoing innovation and iterative refinement [4].

Given the lack of information on how the product will really behave in a clinical context, it is clear that the TPP of a CTP cannot be fully defined in the early stages of its development. Since this cannot be avoided, the foundation of QbD is the idea of iterative refining. The notion is that a process design space should be developed, depicting the numerous parameters that interact in such a way as to affect the CQAs, after basically establishing the TPP and CQAs. The TPP should then be iteratively improved by accruing knowledge about the product's mode of action from clinical trials and the CPPs through careful observation and data collecting during experiments [5].

Conclusion

Design of experiments (DOE) and computational modelling are two complementary methodologies that can be used to best drive iterative refinement. In order to understand the effects of these elements' interactions on the output of a particular bioprocess, a number of approaches are used in DOE. The information gathered from these precisely planned experiments can then be utilised to create a computational model that predicts how the bioprocess will behave in response to various input parameters. A similar model might be restricted to purely technical components or broadened to additionally take into account economic factors, as is the case with BEMs. The design space can then be explored and fine-tuned in silico using the model to determine which parameters are most promising.

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Conflict of Interest

There is no conflict of interest by author.

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