



Editorial

Preface of the special issue “Cell Manufacturability”



This special issue of Regenerative Therapy contains original papers and review articles for the manufacturing technologies toward therapeutic applications of regenerative medicine and cell therapy. The research for cell manufacturing covers not only creation of novel technologies but also development of operational skills providing the operational stability to keep both the consistency of the production and the aseptic conditions to prevent contamination.

Manufacturing cells and tissues for regenerative medicine and cell therapy require interdisciplinary activities ranging from medicinal and biological sciences to manufacturing engineering, and the chemical engineers who are experts for manufacturing makes great contribution to this field. “Design for manufacturability (DFM)” is known to be the general engineering art of designing products in such a way that they are easy to manufacture. This concept exists in almost all engineering disciplines, but the implementation differs widely depending on the relevant manufacturing technology. In cell and tissue productions, DFM should also lead to facilitation of the consistency and robustness of the process as well as the reduction of the cost. However, there are many imprecise and unknown factors in manufacturing therapeutic cells. Therefore, it is necessary to consider such specificities in cell manufacturing and to construct a new concept to optimize the process.

The “Cell Manufacturability” is proposed to be the new concept for the discipline of cell production as follows.

Definition of “Cell Manufacturability”; capability of cell manufacturing through the process(es) by bridging between biological and engineering aspects.

Design for “Cell Manufacturability”; manufacturing design of cell-based products in such a way that they are easy to manufacture through simple, safe and efficient (cost-saving) process with stable product quality and that they should be secured to the customer by considering transportation and preparation outside factory.

Action of design for “Cell Manufacturability”; practical actions of the system optimization for the efficiency and stability of the process by understanding the gaps in the requirements between

biological and engineering aspects, reducing output fluctuation and leading to cost saving of the products through the process simplification and governing the kinetics of cell behavior.

The persistent efforts of the systematization, which is one of the critical actions for cell manufacturability, will have conducted to prepare the manufacturing process mainly by chemical engineers, leading to high quality of cell-based therapy.

This issue provides a survey of the diverse scope of this new concept that is expected to realize effective processes for cell manufacturing. It is the hope of the editors of this special issue that the articles contained herein can not only educate related researchers but can also accelerate the social implementation of the technologies.

We believe that the readers of this special issue will feel the practical senses for design of cell manufacturing process through greater knowledge and synergy of ideas concerning “Cell Manufacturability”. We also hope that the readers will enjoy this special issue. Finally, we thank all of the contributors as well as the reviewers.

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