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適切な科学的規制による再生医療実用化促進

A Regulatory Endeavor using Sound Sciences towards Prompt and Safe Application of Human Cell-based Products for Regenerative Medicine

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Abstract

To make sure that regenerative medicines contribute more to human health care, it is essential that, based on sound scientific rationale and approaches at that point in time, suitable measures be taken by the regulatory authorities with respect to prompt and safe application of relevant cell-based products to the treatment of patients. For 15 years no efforts have been spared to implement sound regulation regarding regenerative medicine in Japan, which includes establishment of relevant legal frameworks (e.g., establishment of the Regenerative Medicine Promotion Law, the Act on the Safety of Regenerative Medicine and the Revised Pharmaceutical Affairs Law-renamed the Pharmaceuticals, Medical Devices, and Other Therapeutic Products Act), as well as development of various relevant guidelines. This paper describes background, scientific principle, and concepts of such regulatory endeavor and also represents core technical elements for product development, evaluation, and control of human cell-based products. It is expected that regenerative medicine in Japan can be advanced efficiently, effectively, and reasonably through the use of currently established regulatory mechanism and relevant guidelines. The newly proposed approach of Minimum Consensus Package together with the Add-on package in an individual case would be challenging.

はじめに

再生医療実用化推進と安全性確保には研究開発の推進と規制環境の整備が車の両輪である（**図1**）。規制環境の整備で最も重要なことは，まず患者さんの人権と便益の確保を最終的な目標とし，その目的に叶う科学的・倫理的妥当性と合理性を貫きつつ，効率的，効果的な再生医療推進と安全性確保をもたらす規制のあり方を追求することである。また，規制の制度的枠組みや行政上の運用は各国の独自の方策によるが，科学的妥当性・合理性の根幹部分に関しては国際的に通用するものでなければならない。そのような規制整備には，①再生医療に関する多様かつ先端的研究動向や内容について，把握・理解していること，また，関連する科学・医療分野にも通暁していること，②基礎・基盤研究段階，研究開発段階，臨床研究・治験段階，承認審