

わが国アカデミアで加速化する革新的医療機器の開発

永井 洋士^{*1}, 西村 秀雄^{*1}, 川本 篤彦^{*2}, 菊地 克史^{*1}, 福島 雅典^{*1}

Acceleration of Innovative Medical Device Development in the Japanese Academia

Yoji NAGAI^{*1}, Hideo NISHIMURA^{*1}, Atsuhiko KAWAMOTO^{*2},
Katsushi KIKUCHI^{*1} and Masanori FUKUSHIMA^{*1}

Summary

To realize the revolution of current treatments for intractable diseases, the global competition to develop new drugs and medical devices is increasingly intense. To construct infrastructure of R&D on medical technology, the Japanese government has made substantial investments to the academic sector during the past decade, leading to the formation of core structure to promote such R&D. However, as for medical devices, despite abundant new technologies nurtured in the academia, the industrial competitiveness of our nation is far from strong, whereby plausible remarks that medical device development is stagnated in Japan are irrelevant. We must recognize the simple fact that success in the development cannot be accomplished unless it is executed under the pharmaceutical affairs law. Indeed, negligence of the righteous legal approaches could have been the essential reason for the delay of medical device development. Recently, with the researchers' mind altered by the governmental R&D promotion programs, kinds of innovative medical devices are being developed in accordance with the judicial processes. This article explains the current status of medical device pipeline in the Japanese academia, and introduces certain examples of innovative devices born in the academia.

Key words

Medical device, Translational research, Regulatory science, Clinical trials