

A collaborative academic vision for Hong Kong's medical device regulatory transformation

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Hong Kong has a unique position as a financial hub connecting East and West. With support from the Greater Bay Area (GBA), there has been a significant local and regional drive to innovate in Hong Kong, and the city's startup ecosystem is thriving. In 2024, the number of startups in Hong Kong grew by 10% to more than 4600, employing 17 651 people.¹ Supported by a top-tier healthcare system and skilled professionals, Hong Kong has the opportunity to develop as a medical technology innovation hub. A key element in supporting this ambition is a regulatory framework that is currently undergoing an important transformation.

Academic research: informing a renowned regulatory framework

Hong Kong hosts numerous leading institutes in Asia, with five institutes ranked among the top 100 in the region according to the QS World University Rankings 2025.² Furthermore, The University of Hong Kong and The Chinese University of Hong Kong, home to the only two local medical schools, are ranked among the top three in medicine in Asia.³ These academic powerhouses possess the essential ingredients to foster the development of a medical technology hub. From research that innovates and commercialises, to expertise across healthcare, engineering and life sciences, and academic environments that support and facilitate the translation of research into practice, all these elements will support the development of a regulatory framework that promotes innovation, research translation, and commercialisation in Hong Kong and the broader GBA.

Education and training: building a skilled workforce

This medical device regulatory framework is important in reinforcing Hong Kong's ambition to become a hub for medical device innovation, creating novel technologies that will transform healthcare and benefit patients worldwide. To support this, we must build capacity and attract the right talent to develop a workforce that can sustain this regulatory framework and disseminate its principles. These goals are supported by the talent admission schemes

implemented by the Hong Kong SAR Government, and by our world-renowned tertiary institutions which serve as a hotbed for talents. With these critical elements in place, we have the support to develop the people needed to transform medical device regulation.

Regional and global collaboration: positioning Hong Kong as a leader

Hong Kong's strategic location and its 'One Country, Two Systems' framework position it as a super-connector between the Chinese Mainland and the rest of the world. Supported by two world-renowned medical schools, Hong Kong is well positioned to lead in the medical device realm. For example, the Multi-Scale Medical Robotics Centre, established by The Chinese University of Hong Kong at the Hong Kong Science Park and opened in 2019, collaborates with ETH Zurich, Imperial College London, Johns Hopkins University, and the Technical University of Munich, driving research and development of medical robotics through international partnerships.⁴ This collaborative environment in Hong Kong has fostered the development of important startups such as Cornerstone Robotics, which develops safe and accessible surgical robots; Agilis Robotics; and EndoR Surgical, which produces endoluminal surgical robots. It has also enabled the translation of pioneering technologies into clinical application, such as magnetically actuated microcatheters for patients with acute ischaemic stroke, strengthening Hong Kong's position as a leader in medical device innovation under an efficient regulatory environment.

Innovation and entrepreneurship: driving technological advancements

The Hong Kong SAR Government has strongly supported the development of healthcare technology. The 2024 Policy Address set out plans for a HK\$10 billion Innovation and Technology Industry-Oriented Fund to channel capital into, but not exclusively, life and healthcare technology.⁵ Furthermore, the InnoLife Healthtech Hub is being established in the Hong Kong–Shenzhen Innovation

and Technology Park, which offers extensive support structures for medical device innovation.⁶ With these monumental infrastructures in place, our world-class universities are empowered to translate research from bench to bedside and commercialise successful medical device technologies.

Public engagement: building trust and awareness

With the infrastructure to support innovation, there is a need to enhance the robustness of the medical regulatory framework. Currently, Hong Kong's framework is underpinned by a voluntary listing system maintained by the Medical Device Division of the Department of Health.⁷ There is a plan to establish the Hong Kong Centre for Medical Products Regulation by the end of 2026 and to introduce a statutory framework for the regulation of medical devices.⁸ This strategic shift will strengthen pre-market controls for the safety, performance and quality of medical devices, alongside enhanced post-market surveillance systems and product information dissemination. These reforms are timely, given the rapid emergence of innovative medical devices. A stronger regulatory system will build public trust, cultivate a favourable healthcare innovation environment, and position Hong Kong as a leading global hub for medical device development.

Conclusion

Hong Kong is evolving into a healthcare innovation hub, with the medical device sector at its core. With this in mind, it is vital to develop an internationally recognised regulatory framework that lends credibility to innovation while continuing to foster its growth both locally and across the GBA.

Author contributions

All authors contributed equally to the conception, preparation, and editing of the manuscript. All authors approved the final version for publication and take responsibility for its accuracy and integrity.

Conflicts of interest

JYK Chan is a co-founder of Agilis Robotics Ltd. PWY Chiu is a board member of Cornerstone International Holdings Limited and its subsidiaries, and a founder of EndoR Surgical Limited. He holds stock options in both companies but does not have direct equity ownership. HC Yip has declared no conflicts of interest.

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