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Perspective Article

Importance to understand medical device regulations for accelerating clinical translation

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ABSTRACT

Clinical translation of medical devices is determined by many factors and is challenging for certain countries or regions as no regulatory body is available to approve related applications. They must rely on application for regulatory bodies of other countries or regions who have independent medical device regulatory systems, while the major markets regulatory process is different. For example, considering the market size and policy orientation, mainland China may be a good option for Hong Kong research organizations. Typically, China National Medical Products Administration (NMPA) has positioned innovation as a key growth engine and implemented various mechanisms to expedite the registration, including Marketing Authorization Holder policy (MAH), as well as the setting up of the NMPA's Guangdong-Hong Kong-Macao Greater Bay Area (GBA) Branch Office, type test reform and application for securing innovation channel application. However, there are still many challenges in the transitional process for Hong Kong universities or research institutions, to set up a company in mainland and then prepare many documental files from very beginning. In the future, taking advantage of NMPA reform and seeking cooperation with the NMPA to establish an independent regulatory body in Hong Kong to be recognized by NMPA is recommended as this alone will boost innovation in life sciences and boost in Hong Kong, and have a positive impact on the commercialization of medical devices in mainland China. Such example may also be relevant for many countries or regions who are seeking medical device approval in the designated regulatory systems.

1. Introduction

The successful clinical translation of medical devices is dependent on many factors or steps, including funding support and/or capital investment, technology itself, clinical trial(s), regulatory approval, and market demand or clinical needs. It is necessary to fully consider the actual situation of market demand and technical feasibility, as well as sound business model and market promotion strategy [1]. Successful translation rate refers to the percentage of medical devices that move from the research and development (R&D) phase to the final regulatory approval, and finally launch into the market for clinical applications. Unfortunately, the overall documented translational rate is very low in China [2,3].

Medical devices are classified and managed by regulatory bodies, therefore clinical trials, registrations and approvals in the translational roadmap are crucial for clinical applications of Class III medical devices or implants. Although there are variations among countries or regions in approval of medicines and medical devices, some regions may have special statues where innovation and clinical translation are promoted and supported by local policies, such as Hong Kong [4].

Historically, Hong Kong, as a Special Administrative Region (SAR) of China, has no independent regulatory body to approve local inventions or innovations related to biotechnology and medicine as well as medical devices, especially Class III medical devices or implants that require clinical trials. At present, applications to Hong Kong for regulatory approval of any marketing or clinical applications must rely on application for regulatory bodies of either PR China in Mainland, i.e. the NMPA or other countries or regions who have independent medical

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device regulatory systems [5,6].

This article is to analyze the regulatory landscape in the world's major markets for medical devices, including the US, Europe and China, and the suggestions for countries or regions where at moment they do not have their own regulatory bodies, such as Hong Kong.

2. Activities in R&D of innovative medical devices related to market volume

Market demand is important for companies to develop highly regulated medical products to meet unmet needs. The US and Europe are the largest markets for medical devices, and their demand for medical devices will continue to be impacted by cost control pressures, value-based healthcare, technological advancements, and demographic changes [7]. In particular, the most notable impact on Europe was regulatory reform. The Europe Medical Device Regulation (MDR), which came into force in May 2017, requires more stringent clinical evidence and quality management practices as a prerequisite for device approvals. It may make it less attractive to develop and launch new products in Europe, leading medical device companies to shift their focus to emerging markets such as China [8].

China's medical device market ranked the third with $42.5 billion in 2021 and is expected to reach $63.6 billion in 2025 at a compound annual growth rate of 10.60 % (Fig. 1). This trend is driven by demographic shifts, economic prosperity, and the evolving healthcare landscape, coupled with the rising prevalence of lifestyle-related diseases and the growing demand for healthcare treatment [7].

Besides marketing share, regulation system is also important to the success of research translation. In recent years, the NMPA has also conducted regulatory reform to encourage innovation, giving start-up companies more opportunities [9–11].

3. Regulatory framework in major markets

Regulation of the medical device is an essential step before a medical device goes to market for public use. Safety and effectiveness are two critical elements from a regulation perspective for new medical devices or implants. Regulatory oversight of medical devices is an important part of the process before a medical device is marketed for intended use by the public. Similar to three registration bodies in the United States, Europe and China, the first step is to ensure a clear device definition before regulatory submission, yet the registration path is different due to classification in FDA, European Medicines Agency (EMA) and NMPA [12].

The approaches in developing medical device regulations by the FDA, EMA and NMPA have fundamental differences (Table 1) [13]. While the FDA and NMPA aim to promote and protect public health through the supervision of medical products, the European System of Notified Bodies (an organization that has been accredited by Europe to conduct a conformity assessment under the relevant European Directives and issue CE (Conformité Européene) certificate) was developed as a broader initiative to reinforce innovation and industrial policy across Europe [14,15]. The FDA separates the registration review and quality management system (QMS) audit, which the QMS may be delayed, and they inspect the devices after they are placed on the market. Whereas EMA and NMPA put QMS assessment as one of the important sections for product registration [16].

In the US, most class I devices are exempt from requirement for premarket notification (510(K)). Class II devices normally need premarket notification 510(K). Class III devices have the greatest risk and require premarket approval (PMA). New medical devices are classified by comparison with existing medical device in terms of intended use and technology used. Another new path for new device which is not previously classified yet is de novo classification [17].

In Europe, medical devices are defined into four classes [18]. Class I (low risk) devices need only "self-declare" that they conform with the essential requirement in their country of origin. Class IIa & IIb (moderate risk) and Class III (high-risk) devices require clinical and/or nonclinical evidence to support approval [19]. The devices with CE marks (signifies that the product or device to which it is applied meets

Table 1
Comparison among FDA, EMA and NMPA for medical devices regulation.

System Feature	FDA	EMA	NMPA
Principle	Oversight of public health	Device approval through Notified Bodies	Oversight of public health
Centralization	Oversight of all device regulation by the FDA	Directives carried out by different Notified Bodies	Approved by NMPA and local representatives
QMS	Product registration review and QMS audit separate	QMS integration with product registration	QMS integration with product registration

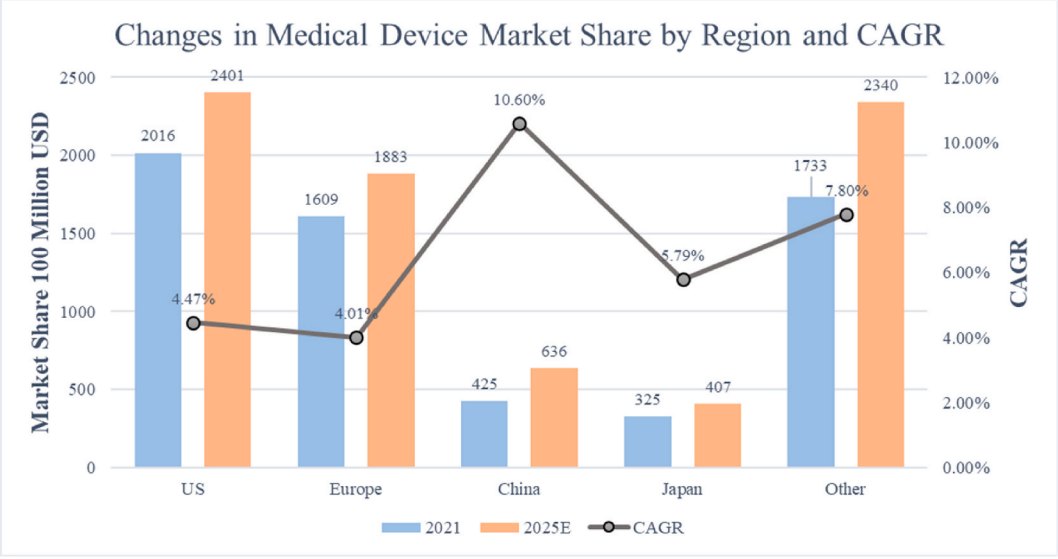

Fig. 1. Medical device market volume [7].

all essential requirements of applicable European directives) are ready to be vended in any nation within Europe [20]. The CE Mark process relies more on self-regulation and post-marketing surveillance. However, CE is only half-way mark because re-imbursement approval will still be needed for each individual country [21].

In China, all medical devices must obtain product and manufacturing licenses before they can be marketed and sold. According to the principle of approval, different classes of medical devices are approved by the mainland's hierarchical regulatory authorities.

Class I medical devices are filed at the NMPA of the municipal level government. Class II medical devices are registered and approved by provincial NMPA representatives. Class III and all imported medical devices need to be registered and approved by NMPA [22,23]. All the foreign manufacturers require a Chinese-based legal entity for medical device registration, and this is also applied to Hong Kong, such as one from the Chinese University of Hong Kong with members who have already registered start-up companies in Shenzhen, for developing innovative Mg-based hybrid system for fracture fixation and healing enhancement [24–27]. Type test is a special requirement and essential process to verify product technique requirement (PTR) in China [14]. Test methods follow the GB requirement which is also a reference from International Organization for Standardization (ISO) or American Society for Testing and Materials (ASTM) standard [28,29].

There is no difference from the regulation perspective among FDA, EMA and NMPA system if it is related to Class I medical devices (Fig. 2). Among all the regulation processes, it may quickly get an approval by FDA if the new device is similar to the existing one. Once the US pre-approval notification is achieved it would be easier to go for indirectly to many other countries of the world and simultaneously apply for EMA and NMPA [30]. On the other hand, if substantial equivalence is not possible/cannot be proved, PMA could be lengthy, expensive, and generally requires a clinical study conducted in the US. The overall review time for PMA is 180 working days, including primary review, substantive review, panel meeting and executive decision [31,32]. Then it may be easier to go for a CE Mark as also plan a US clinical study in guidance with FDA. If it is an innovative product, NMPA will have special review process and dedicated officer to support the whole regulation process (Fig. 2) [9]. With the introduction of innovative medical devices, the cooperation among the China government, academia and industry increased, giving more opportunities for the medical devices translation.

Taken an innovative Intramedullary Nails as an example, the applicant can finish product design, test and manufacture under QMS requirement, and submit to NMPA for registration by the help of officer after type test and clinical trial in China. While in FDA without predicates, the PMA and clinical trial is needed before registration (Fig. 3) [17,31].

4. NMPA reform and harmonization for Hong Kong

For research organizations and universities in Hong Kong that are committed to the development of medical device "Approval by Hong Kong, Benefit to the World", they face the difficulty in translating their products to the clinical market due to different regulation systems. In mainland China, medical devices approved by NMPA can be launched for sales. But in Hong Kong, there is currently no independent regulatory body for medical devices and drugs. The Medical Devices Division (MDD) of the Department of Health (DH) is responsible for the implementation of the Medical Devices Administrative Control System (MDACS) and the development of a long-term statutory regulatory framework for imported medical devices but does not have the authority to approve new medical devices [33].

Strategically, considering the market size and policy orientation, choosing the mainland for translation may be a good choice for Hong Kong research organizations, especially NMPA has positioned innovation as a key growth engine, implemented various mechanisms to expedite the registration and utilization of cutting-edge technologies, including MAH policy, as well as the setting up of the NMPA's GBA Branch Office [34], type test reform and application for securing innovation channel application.

4.1. Medical device Marketing Authorization Holder (MAH) Policy

In 2021, The newly revised on "Regulations on the Supervision and Administration of Medical Devices" of the State Council have been fully implemented. The medical device product license and production license enter into separation management mode, in short, the marketing authorization and the production license are independent of each other (Fig. 4) [35].

MAH policy was published under the background to encourage

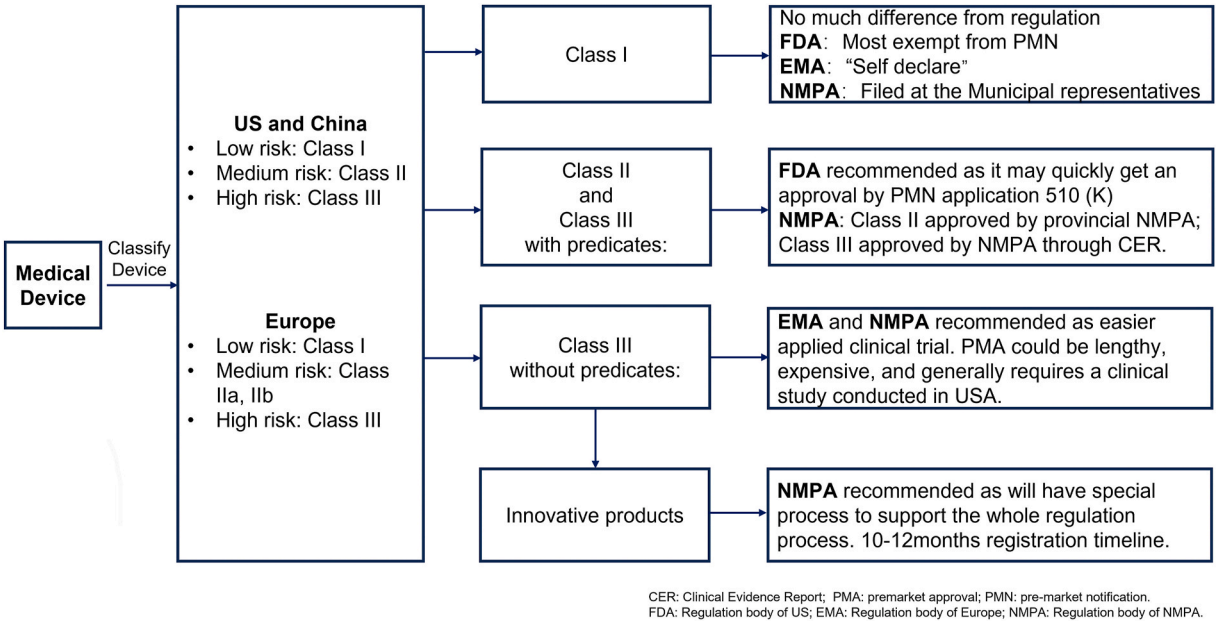

Fig. 2. Registration path for medical device of different regions [17,23].

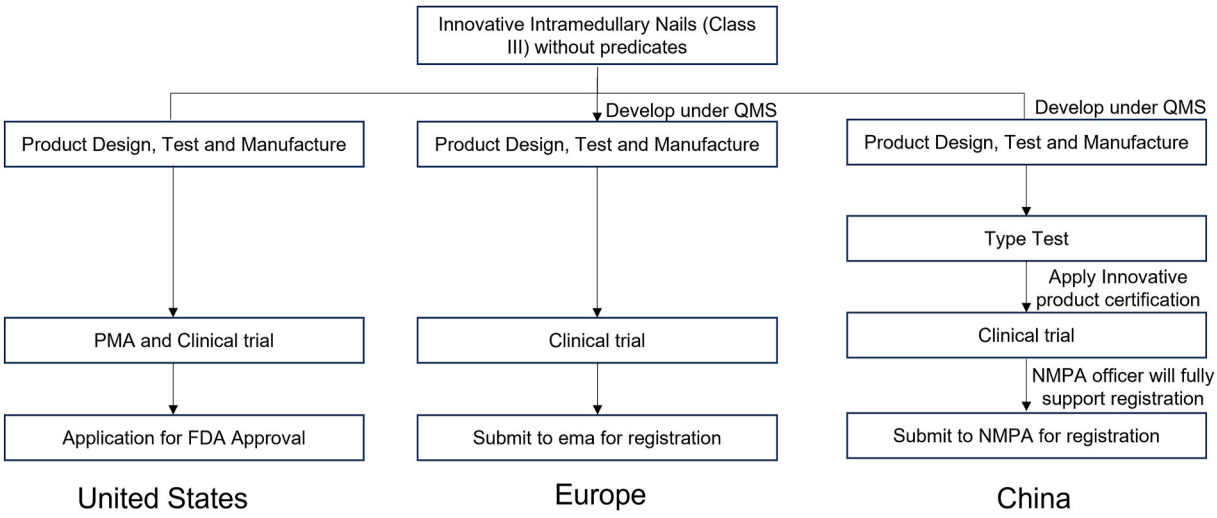

Fig. 3. Illustration of registration paths in different regions.

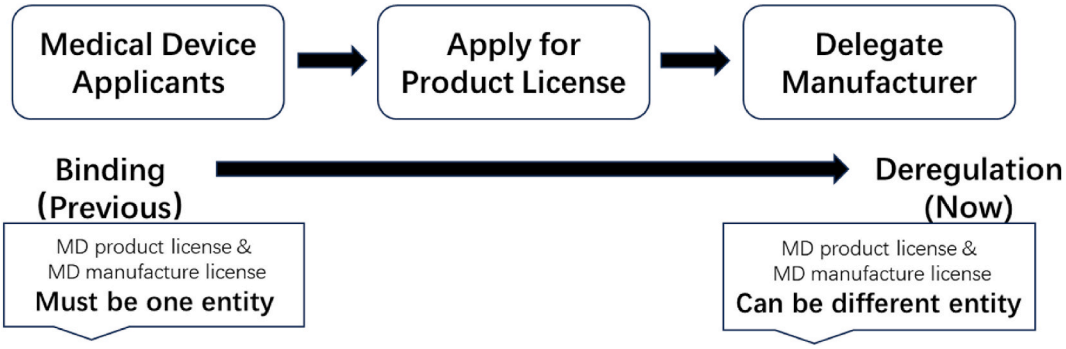

Fig. 4. Changes of MAH policy [35].

innovation, optimize resource allocation, promote industrial concentration, and strengthen whole-process management [36]. The new MAH policy implies that the product owner (mostly for encouraging innovation from inventors from universities or research institutions) does not need to setup a manufacturing site with full of equipment and Good Manufacturing Practice (GMP) compliance requirement at the beginning. The inventor(s) can focus more the clinical value of their innovations and their safety verification. The new regulation has laid down an excellent foundation for "university-industry collaboration" and solves the problem of the "stuck neck" of innovative products towards clinical translation and bedside applications [9]. In order to strengthen the supervision of medical device production and ensure the safety and effectiveness of medical devices, NMPA also published the category (high-risk) that forbidden to apply MAH policy in 2022 [37].

4.2. *The establishment of the NMPA's GBA branch office*

The NMPA's GBA Branch Office was established officially in Futian District, Shenzhen City on 23 Dec 2020. The main responsibilities are to assist the Center for Medical Device Evaluation (CMDE) of NMPA in pre- and in-process communication and guidance, as well as relevant inspections for medical device review and other technical work assigned by the CMDE of NMPA in the GBA [38]. To assist Hong Kong and Macao medical industry development is also one of the tasks for the GBA branch office. The pre-communication of medical device evaluation also extends to Hong Kong and Macao to benefit clinical translation of innovative medical products [39]. Till Dec 2024, the GBA branch office received 4000 rounds pre-communication and guidance. The center is also active in supporting innovative products translation, and as an example, all 49 innovative products in GBA area were received registration guidance from GBA center at that time point [40].

4.3. *Medical products or devices for seeking regulatory tests (in short: type test)*

In China, the registration of medical devices requires the submission of a type test (registration test) report, which provides important assessment data for the validation of the medical device design. The type test report is a critical milestone to finalize the product design. In previous practice, all class III medical devices type test shall be done by a few dedicated governmental test centers. Depending on the capacity of the test center, the entire timetable takes between 6 and 9 months and consequently extends the entire product development cycle [23].

The Regulation on Supervision and Administration of Medical Devices (2021) stipulates that type testing can be done by the applicants or an accredited third party (Table 2), which can shorten a lot of time for the testing and follow up actions.

4.4. *Innovative medical devices regulation*

Given the successful practice of the US medical device companies and the FDA's driving force to innovation [44], NMPA published a similar regulation "innovative medical device" to encourage research and innovation of medical devices in China. It is also expected to boost the application of innovative technologies and promote the development of the medical device industry [9]. Once the device is considered as

Table 2
Type test requirement change [41,42].

Regulation for the Supervision and Administration of Medical Devices		
2014	Type test report must be provided by authority institute	The main authority institutes for your reference: • Beijing Medical Device Quality Supervision and Inspection Center: Comprehensive. • Shanghai Medical Device Quality Supervision and Inspection Center: Comprehensive. • Tianjin Medical Device Quality Supervision and Inspection Center: Implants and Physical Therapy Equipment. • Jinan Medical Device Quality Supervision and Inspection Center: Medical infusion, Blood transfusion and Injection devices. • Guangzhou Medical Device Quality Supervision and Inspection Center: Extracorporeal circulation equipment, Dentistry, and Disinfection. • Liaoning Medical Device Quality Supervision and Inspection Center: X-ray equipment. • Hangzhou Medical Device Quality Supervision and Inspection Center: Medical optics and lasers. • Wuhan Medical Device Quality Supervision and Inspection Center: Ultrasound equipment.
2021	Besides authority institute, type test report can also be provided by applicants or 3rd party	The applicants or third-party test center requirement: • China National Accreditation Service for Conformity Assessment (CNAS) certification [43]. • Test capability requirements: test engineer, equipment and environment, method, sample and record management. • Medical device QMS requirement.
Summary	To improve China's medical device system and further release the development potential. **Including two aspects**: • Strengthen whole life-cycle management. • Encourage innovation.	

an innovative product, an officer from NMPA will work together with the applicant(s) in an early stage for product registration, which becomes an effective way to reduce registration risk and shorten the product registration time or cycle.

According to the Medical Device Evaluation Center of NMPA, more and more innovative products have been applied recently. From 2014 to 2023, there are 250 innovative medical devices were approved. In particularly, NMPA approved 61 in 2023, an 11 % increase compared with 2022 [45].

There are three criteria for review and approval of innovative medical devices [46].

(1) About the intellectual properties: The applicants own the invention patents in China for the core technology or claim, or they have obtained the right of invention patent in China through a legal transfer, or the invention patent for the core technology has been published by the patent administration department under the State Council.
(2) The main working principle/mechanism of the product is the first documented one in China, or the product performance or safety has been fundamentally improved compared with similar marketed products, and the technology is international leading, and has significant clinical application value.
(3) The applicant has completed the preliminary research of the product, and the research process is true and controlled, and the research data is complete and traceable.

More even, the government have made a lot of efforts to drive medical cost efficiency through Volume-Based Procurement (VBP) to balance access, quality and innovation. For example, the NVBP price of orthopedics' implants has dropped 70%–80 % after implementation of the Pilot Program of the Centralized Procurement and Use of Drugs Organized by the State [47], but the officially approved innovation products are exempted from this policy. Domestic applicants shall apply for special approval of innovative medical devices to the provincial NMPA where they are located, while the overseas applicants shall apply to the NMPA. The documents to be submitted include the application form for special approval of innovative medical devices and product related documents [46].

With the continuous implementation of the new regulation system and reform, more and more safe and effective innovative medical devices will be approved by NMPA and be an advantage to patients. Parallelly, global medical device companies can import more attractive products into the Chinese market where Hong Kong may play a bridging role for international collaborations. There are two stages for the overseas companies to enter the Chinese market through Hong Kong. In current stage, the overseas company may setup a trading company for product commercialization in China. After "Hong Kong FDA" harmonizing with NMPA, the overseas companies may establish a Hong Kong-based legal entity with more functionality, including R&D, regulatory, quality, etc.

5. Medical device registration in Hong Kong

As mentioned above, the Hong Kong MDD under the DH is responsible for implementing the MDACS and the supervision of medical devices in Hong Kong. However, like some other small countries or regions, Hong Kong does not have an independent medical device regulatory body to approve local innovation, especially biological products, drugs and Class III medical devices or implants, which is unfavorable for nurturing local institutions or companies to realize their innovation/invention and clinical translation inside of Hong Kong as Hong Kong is not part of NMPA system.

Taken Hong Kong as an example, Hong Kong applicants need to set up a mainland company for product registration and selling per current situation policy [48] (Fig. 5). There are still many challenges in the transitional process for Hong Kong universities and research institutions, to set up a company in mainland, and all the product development, test and NMPA registration processes must be repeated over again. It could be strange to Hong Kong applicants and does not meet the current needs of Hong Kong research institutions.

In the future, taking advantage of NMPA reform and seeking cooperation with the NMPA to establish an independent regulatory body in Hong Kong to be recognized by NMPA is much recommended as this alone will boost innovation in life sciences and medicine in Hong Kong and also move R&D centers from overseas to Hong Kong for the first phase as Hong Kong implements Common Law that most of the leading countries in innovation and technology transfer are using the same law system for handling legal issues. Such initiation would definitively benefit innovation and clinical translation of relevant medical products in Hong Kong and the establishment of R&D centers of overseas' companies and institutions for their medical products registration in Hong Kong and then future marketing in mainland China as well. This would definitively be favorable for establishing an international innovation center in Hong Kong, Hetao, and the GBA in China as a national development strategy promoted by the State Council of China [49].

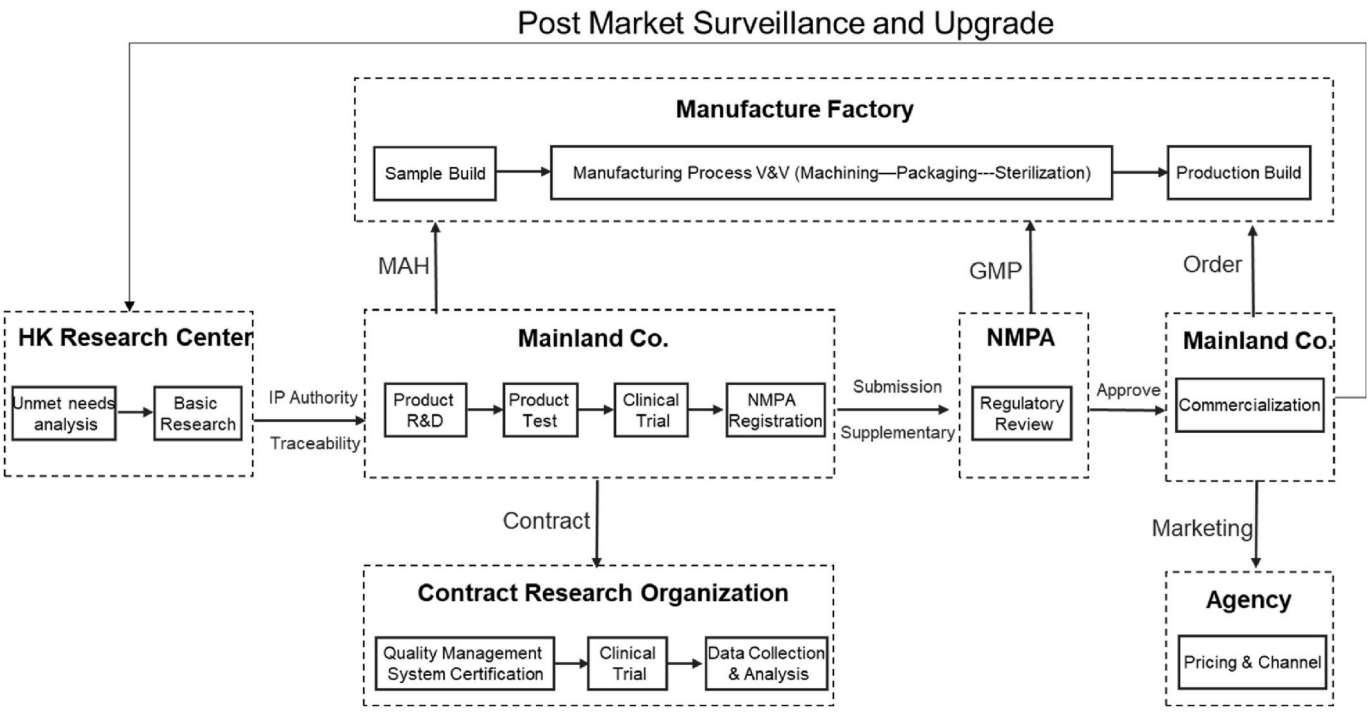

Fig. 5. Translation flow of medical products to be registered in Mainland Chinese NMPA for applicants from Hong Kong universities or research institutions.

6. Recommendations for Hong Kong centre for medical products regulation (CMPR) ("Hong Kong FDA")

On October 25, 2023, the Chief Executive of the Hong Kong Government clearly stated that Hong Kong would use its medical advantages and establish the preparatory office of CMPR in 2024 to make suggestions and steps for the establishment of CMPR. This would defectively simplify the registration and approval procedures for drugs and medical devices developed in Hong Kong, and eventually also directly approval for drugs and medical devices in Hong Kong based on clinical data in the future [5,6]. However, this would mainly be limited to Hong Kong without direct conversion of NMPA recognition for clinical application in Mainland China [5].

6.1. CMPR leverages GBA and cooperates with NMPA to facilitate clinical trial

Hong Kong should take advantage of NMPA reform of the "Evaluation and Approval Systems and Encouraging Innovation on Drugs and Medical Devices" [36], and actively cooperate with the NMPA, especially with NMPA's site office in GBA for Medical Device Evaluation and Inspection. According to the "Hong Kong and Macao Medicine and Equipment Connect" policy in 2021, imported medicines and medical devices already launched in Hong Kong and Macao can be used in designated medical institutions of the GBA for urgent clinical use [50]. In addition, according to the implementation plan for "Supporting Hong Kong and Macao Medical Device Registrants to Produce Medical Devices in the Nine Mainland Cities of the Greater Bay Area" issued by the NMPA in June 2022, nine cities are allowed to carry out cross-border commissioned production pilots, providing a higher degree of freedom for medical device MAHs in the arrangement of licensing and production [51]. Both above policies mitigate the gap between domestic and imported products in terms of regulatory requirements. As a bridge window, the proposed Hong Kong CMPR will make it more convenient and faster for devices (here refer to market available medical devices imported and used in Hong Kong) to enter the mainland market in the future.

Clinical trial is one of the most important stages for medical device translation. In this process, it is also necessary to seek advice from NMPA. For example, it is hoped that devices that have passed the Hong Kong CMPR certification with the permission statement can carry out clinical trials in the certified clinical departments for medical products registration by NMPA in the GBA (consider multi-centers in Hong Kong and the GBA) after completing the national filing and recognize the validity of these clinical trial data.

Furthermore, based on the filing acceptance of GBA branch office of NMPA, the medical device certified by the Hong Kong CMPR can be used in Hong Kong and mainland China. The risk can be controlled through the post-market surveillance model, which is more convenient and saves time and resources than a series of processes such as setting up a company on the mainland. Once it is completed, it will play a more active role in the Hong Kong CMPR and share the workload of NMPA in reviewing products certificate applications and make full use of Hong Kong's medical resources.

6.2. CMPR cooperates with NMPA to accelerate innovation

Benefiting from Hong Kong's mature judiciary (common law) and language advantages, and as a 'super connector' linking the mainland with the world, the Hong Kong CMPR can function as a hub connecting the NMPA with other national regulatory bodies, allowing China's medical products to be more efficiently used globally.

Simultaneously, if Hong Kong has a similar policy guidance to the "Boao Pilot Zone in Hainan", the products which have been approved by the Hong Kong CMPR can enter a green channel in mainland China [52]. By establishing Hong Kong CMPR that would enjoy the same statues of NMPA in terms of mutual recognition, it would definitively help attract more global medical device companies to setup R&D centers, conduct clinical trials, and build capabilities and recognition at the international innovation center in Hetao, primarily at Hong Kong park or eventually also at Shenzhen park to ensure that the device approval is mutually recognized and the approved medical devices could be marketed in both Hong Kong and Mainland China. CMPR can also reduce the NMPA's evaluation pressure, accelerate marketing evaluation and approval, and

align the goal of encouraging innovation on drugs and medical devices.

6.3. The importance of CMPR to the commercialization of mainland enterprise in Hong Kong

The establishment of the Hong Kong CMPR not only benefits invention/innovation and clinical translation for Hong Kong research institutions or enterprises, but also has a very positive impact on the commercialization of medical devices in the mainland. After official opening of the Hong Kong CMPR in the near future, Hong Kong can be the place of "first-tier approval" and "first in human use" for medical enterprises of mainland China. At the same time, Hong Kong CMPR certified products might be more easily to be assessable internationally attributed to the independent regulatory body.

7. Conclusions

This article illustrates or compares the medical device regulatory process in the United States, Europe and China. Typically, China NMPA has implemented several reforms to facilitate the innovative development of medical devices and to improve the efficiency of registration. In the case of counties or regions or special administration regions without their own independent regulatory body but also devoting to innovation of drugs and medical devices, such as Hong Kong, it is difficult to realize the clinical translation of their own innovation for clinical applications.

Overall, it will be a good opportunity for research universities and institutions, enterprises and patients in both mainland China and Hong Kong to establish Hong Kong CMPR under NMPA reform. For enterprises, in the future, various Chinese mainland entities might use Hong Kong as a window to accelerate the "going global or globalization" or to enable global products to enter the mainland market faster through Hong Kong to deepen medical resource utilization and business integration. For patients in mainland and Hong Kong, they are more likely to have the opportunity to cure diseases with rather easy access to newly approved and more effective medical products.

Declaration of competing interest

The authors have no conflicts of interest to disclose in relation to this article.

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