Regulations and Approval/Certification Process of Medical Devices

- There are two regulatory authorities responsible for regulation of medical devices in Japan, MHLW (Ministry of Health, Labour and Welfare) and PMDA. MHLW is responsible for the administrative actions such as guidance or decision of product approval pursuant to the Law on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical devices (hereinafter, PMD Act) as well as judgment on whether or not the product is considered as medical devices, while PMDA undertakes application review and post-market safety measures based on the relevant data.

  < PMD Act >

  http://www.japaneselawtranslation.go.jp/law/detail/?id=2766&vm=04&re=02&new=1

- In Japan, medical devices are classified into four classes based on the risk level; Class I (Extremely low risk), Class II (low risk), Class III (medium risk) and Class IV (high risk). In order to market medical devices in Japan, a foreign manufacturer has to obtain approval/certification or submit notification, depending on the classification, pursuant to PMD Act, through a Japanese Marketing Authorization Holder (MAH) or a Japanese manufacturer appointed by such foreign manufacturer. Required procedures for each device classification are shown below.

  Class I devices:
  Notification to PMDA

  Class II devices
  - for those certification standards exist:
    Certification by registered certification body

  - other Class II devices:
    Approval of MHLW

  Class III devices
  - for those certification standards exist:
    Certification by registered certification body

  - other Class III devices:
    Approval of MHLW

  Class IV devices:
  Approval of MHLW

Regardless of the Class of the medical device, the MAH of such device must ensure efficacy, safety and quality thereof based on the evidence before submission.

- For devices that require “Certification by registered certification body”, the product must be certified by a Registered Certification Body.

  List of Registered Certification Bodies (available only in Japanese):
  http://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryou/iyakuhin/touroku/index.html

- For devices that require “Approval of MHLW”, PMDA will verify scientific evidences in the review. Regulatory requirements of individual products are assessed on a case-by-case basis and answered in PMDA's consultations (fees applicable).

  If you seek an opinion from us Japanese regulatory authority regarding necessary regulatory procedures for your product requiring approval of MHLW, we would advise you to make product-specific information available and apply for PMDA's consultations.

  Http://www.pmda.go.jp/english/review-services/consultations/0002.html
  http://www.pmda.go.jp/review-services/f2f-pre/consultations/0003.html
  (only in Japanese)

  Consultation service on R&D or regulatory submission involves consultation fee, but what can be discussed in such consultations may be clarified free of charge in a pre-consultation meeting.

  Consultation fees and other user fees are shown in Table 13 of PMDA’s Annual Report. Please note that fees may be changed without notice.
  http://www.pmda.go.jp/files/000221481.pdf

  If you intend to enter into Japanese market, we strongly recommend you to appoint a Japanese MAH and have PMDA’s consultation service by the intermediary of such MAH. When you are requesting the free pre-consultation meeting only, accompanying an interpreter instead of the appointed Japanese MAH may be acceptable.

Scope of approval/certification of medical devices and basic rules of evaluation criteria for medical devices are provided in the following web page (available only in Japanese);
http://www.pmda.go.jp/review-services/drug-reviews/about-reviews/devices/0004.html