# How to Market
# your
# Medical Devices in Japan

## S.K.I.Net Inc.

# The Roles of S.K.I.Net

- Medical Device Registration/approval Process
- Either Marketing Authorization Holder **(MAH)** or Designated Marketing Authorization Holder **(D-MAH)** Representation
- Regulatory Affairs (RA) Consultancy and,
- All related regulatory affairs (RA)

# How to Market Your Device

- Introduction
- One of the most difficult aspects of introducing a medical device to the Japanese market is KNOWING WHERE TO BEGIN i.e., what are the steps for marketing and in what order they are to be taken.
- Essentially, medical devices are subject to the Japanese regulatory affairs law that is Japanese pharmaceutical and medical device act (**PMD Act**).
- These controls are the baseline requirements that apply to all medical devices necessary for marketing, proper labeling and monitoring its performance once the device is on the market.

# 3 Steps of
# Medical Device Registration Process

1) Identification of Device Classification
2) Manufacturer Registration
3) Product Registration and QMS compliance

# 1st step
# Identification of Device Classification

- S.K.I.Net can and will support you by correctly identifying the classification of your product in Japan where device classification system is based on GHTF and that is slightly differs from USA, China and Korea where all device classified into three class i.e., class I, II & III.
- GHTF device classification is derived from EU classification, therefore, Japan and EU are similar and classified into four class i.e., class I, II,III & IV.
- Once correctly identified, in order to market your product in Japan, a **M**arketing **A**uthorization **H**older (**MAH**) must register the product by following the process depending on the classification.

# 1st step (continued)
# Depend on the Classification

- **Class I** (General MD) : Premarket Notification **(Todoke)**
  - MAH need to submit a Todoke to PMDA
- **Class II** (Designated Controlled MD): Premarket Certification **(Ninsho)**
  - MAH need to submit a Ninsho to the Registered Certification Body (RCB). This process is comparable to the European CE Marking using Notified Body.
- **Class III & IV** (Specially Controlled MD): Premarket Approval **(Shonin)**
  - MAH must submit a Shonin to PMDA and obtain its approval. Class II devices that are not designated to Specified Controlled Devices are also subject to the Shonin.

# 2nd step
# Manufacturer Registration

- Appointing us as your **MAH** brings peace of mind to you by knowing that we handle all your Japanese regulatory activities associated with your registered product and by giving you flexibility to smoothly change your local distributor if it is necessary.
- All medical device manufacture in foreign manufacturing facilities are required to obtain **foreign Manufacturer registration** prior to product registration defined in Article 36 of PMD Act enforcement regulations.
- We can and will obtain your registration in timely and efficient manner.

# 3rd step
# Product Registration

- As a government-licensed type 1 Market Authorization Holder (MAH), we can submit your product registration and its registration name **on behalf of** you in timely and efficient manner.
- We have an affluent of experience both in medical device development and in regulatory affairs in all classes including Class IV and have thorough understanding of revised PMD Act.
- PMD Act requires that the product registration process has to be handled by appropriately licensed MAH according to your device classification.
- Generally it is not advisable to appoint a distributor as your MAH, as you will face a challenge in case you wish to **switch your distributor** to someone else.
- For that purpose we can take a role as a **D-MAH** on behalf of you so that you maintain your right to execute those right.

# 3rd step Product Registration Japanese QMS compliance

- We can support you in modifying your existing Quality Management System in order to meet Japanese quality management system, that differs slightly from ISO 13485.
- PMD Act and Ministerial Ordinance 169, issued by Ministry of Health, Labour and Welfare **(MHLW)** define the requirements on quality management system in Japan.
- Those manufacturers with ISO 13485 will find meeting Ordinance 169 requirements fairly straightforward.
- We can assist you in dealing with those additional requirements and retention of relevant records and facilities.

# Japanese QMS compliance (continued)

- We are well qualified to support you meet the extra QMS requirements that are demanded by Ordinance 169, so that you can engage with the process of obtaining approval to market your products from the Japanese Pharmaceutical and Medical device Agency **(PMDA)**.
- The Device Master File (**Seihin Hyojun Sho**) of your product is a critical element in successfully receiving approvals to sell your products in Japan.
- The Device Master File (Seihin Hyojun Sho) is similar to the European Technical File except additional information such as labeling, packaging and document retention period amongst others, required by PMD Act.

# Marketing Authorization Holder **(MAH)** Representation

- We are government-licensed independent Marketing Authorization Holder **(MAH)**.
- As MAH, we are licensed to carry out necessary regulatory matters for all medical devices between class I to IV.
- All marketing application must be submitted through **MAH**.

# Marketing Authorization Holder (**MAH**) Representation (continued)

- Requirements for **MAH**
  - MAH must be licensed by the government and employ people with relevant qualifications.
  - Marketing Supervisor–General, responsible both for QA and RA
  - Quality Assurance Manager
  - Safety Control Manager

# Designated Marketing Authorization Holder (**D-MAH**) Representation

- MHLW allows foreign manufacturers to own the registration of their product under their own name, instead of the MAH's name. In this case, the manufacturer bears full responsibility as MAH, and the appointed MAH is referred to as a designated MAH (D-MAH), as they do not own your device registration.
- Your D-MAH carries some of the same responsibilities that foreign manufactures are deemed unable to adequately perform, such as shipment release judgments and vigilance.

# Designated Marketing Authorization Holder (**D-MAH**) Representation (continued)

- Communicating with your storage manufacturer to develop Quality Agreement and indicating to prepare Device Master Files (Seihin Hyojun Sho) for labeling and storing where applicable.
- Conducting audits of your facilities, where applicable.
- Ensuring marketing, and safety standards of products in the Market.
- Obtaining PMD Act certificate and other documentation for each of products from the Japanese authorities and forward them to the manufacturer.
- And many other job roles that is required as a **MAH**.

# Regulatory Affairs Consultancy

- Consultation on Japanese device classification, product registration, and import procedure.
- Audit, research & guidance over operational matters for Manufacturers, and local distributors & retailers.
- As we are based at he heart of Japanese medical device industry here in Hongo district in Tokyo we can bring valuable insights of the Japanese market and can introduce you to our extensive network of well-qualified local distributors and retailers.

Thank you for your attention