Case Study: Registration of Glucometer (Class III In-Vitro Diagnostic) in Japan

Client
A South Korea based medical devices manufacturer

Products
Glucometer, In-Vitro Diagnostics (IVD)

Product Categories
Class III

Countries of Interest
Japan

Services Provided:
- Product Classification
- Regulatory Intelligence
- Foreign Manufacturer Accreditation
- Conformity Assessment of QMS
- Preparation and Submission of Registration Dossier to PMDA
- D-MAH Representation

Client Situation

The Client is a South Korea based medical devices manufacturer who has developed a glucometer that it wanted to launch in Japanese market. Client had no experience with Japanese PMDA regulations and was not clear with product's classification and applicable regulations, studies and documentation required for registration of the device.

GRP Solution

GRP has successfully registered medical devices in Japan under different classes. GRP was retained as a partner of choice by the Client to help navigate applicable PMDA regulations on their device, develop a regulatory strategy and help register the product successfully in the market with GRP being the D-MAH for client in Japan. GRP's high-level approach for overall product's registration included the following:

GRP's Approach:

Strategy	Implementation	Post-Approval Maintenance
▪ GRP had engaged with Client to present and discuss the strategy for registration of Glucometer in Japan and documentation required ▪ GRP clearly presented the roadmap, expected outcomes, potential challenges and mitigation strategies for registration	➢ Prepared, participated in Consultation meeting with PMDA and advice on next steps post meeting ➢ Assist with Local Testing based on already discussed expected outcomes ➢ Preparation and submission of registration dossier to PMDA ➢ Address PMDA queries till approval ➢ Receive approval ➢ DMAH Representation	GRP continues to maintain the license for Client in Japan by submitting annual reports and safety reports as applicable

Keywords: invitro diagnostics registration in japan, ivd registration japan, ivd registration pmda, invitro diagnostics registration pmda, glucometer regulations japan, glucometer registration pmda, class iii devices regulations japan, class III device registration pmda guidelines, ISO 13485 QMS Japan, DMAH services japan, In Country Care-taker japan, DMAH Pmda requirements

GRP's Services:

1. **Determination of Product Classification in Japan**

   Self-blood glucose measuring device are considered high risk, Class Ⅲ devices in Japan.

2. **Foreign Manufacturer Accreditation (FMA/FMR)**

   Japan's Pharmaceuticals and Medical Devices Act (PMD Act) requires both domestic and foreign companies to register applicable manufacturing facilities in Japan before registering their products in Japan. As D-MAH of Client, GRP obtained an accreditation for manufacturing sites.

3. **Conformity Assessment of Quality Management System (QMS)**

   For medical devices and in vitro diagnostics, PMDA conducts on-site and document-based inspections of the registered manufacturing sites (of products under review or approved products) located in Japan or overseas, in order to ascertain whether their manufacturing facilities and manufacturing and quality controls comply with standards such as the Quality Management System (QMS), and whether the manufacturing sites have a system for manufacturing products of adequate quality.

   The Japanese Quality Management System requirements are similar to ISO13485 but have additional requirements including the role of the MAH are included as well. GRP submitted a pre-approval QMS inspection to PMDA and assisted the Client during the inspection process.

4. **Preparation and Submission of the Registration Dossier to PMDA**

   After completion of the clinical trial, GRP prepared and submitted the registration dossier to MHLW. As a Class III IVD in Japan, the content of the pre-market approval application followed the STED format.

Key Highlights

- GRP's past experience with similar IVDs helped client develop an optimum regulatory strategy for Japan and validate the strategy with PMDA through consultation meeting
- GRP's network and experience with clinical trials enabled client plan and conduct studies in timely manner for successful submission of registration dossier

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