GLOBAL REGULATORY PARTNERS

Case Study 4:
Regulatory Strategy & Registration of Otometric Devices in Japan for a European Device Manufacturer

Client
A global medical device conglomerate with annual revenue of USD 0.5+ Billion.

Products
Multiple devices including electroacoustic, otoscopic, testers for used for otology disorders.

Product Categories
Class I and II medical devices

Country of Interest
Japan

Solution Offered
- ✓ In-Country D-MAH
- ✓ Primary Contact for Local Authorities
- ✓ FMA Submission
- ✓ Quality & Safety Review of products
- ✓ QMS compliance with PMDA
- ✓ Adverse events reporting
- ✓ Custom clearance
- ✓ Medical Device Reimbursement Consulting
- ✓ Selection of Distributor & Product Release Criteria

Key Highlights:
- ✓ GRP defined the regulatory strategy for the market including clearly defined roadmap and expected milestones with timelines
- ✓ GRP became one-stop-shop for managing end to end process including translation and communication with PMDA authorities in Japanese language
- ✓ Product was approved successfully in timely manner, opening new commercial avenues for the client in the 2nd largest pharmaceutical and biotechnology market in the world with one of most challenging regulations.

Key Phrases:
Japan, Class I, Class I Medical Device, Otometry, electroacoustic, otoscope, custom clearance, PMDA, device registration, Designated MAH, QMS, safety reporting

Client Situation

Client was new to Japan market and needed end to end support right from strategy, product registration, legal representation, marketing authorization holder in country, custom clearance, distributor identification and post approval maintenance of product in Japan. Client did not want to invest initially in registering the company and employing staff, instead it was seeking a reliable partner to work with its distributors to ensure its global ISO standards of product quality in the market.

GRP Solution

GRP was right partner for client due to it local presence and tremendous experience of its experts in registering devices for otology as well as importation and ensuring safety and compliance of device as per Japanese regulations. GRP set up a specialized team at its regional office in Tokyo, that managed client's products right from pre-submission consultation, registration, importation and post approval safety assessment/adverse events reporting. GRP continues to act as trusted partner for client to continue to expand its business interests in the region. GRP had provided a detailed process involving all the steps in acquiring the approval, potential bottlenecks & remediation as well a comprehensive documentation roadmap to ensure seamless registration and safety reporting. GRP's expertise in Japanese language enabled seamless interaction with different stakeholders through the lifecycle.
Covid19 test kits were registered within 30 days instead of 6 months.

For additional information,
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