Case Study : Registration of Class II Medical Device in Australia, Brazil, China, India, Pakistan and Russia

Client

A US based medical device company.

Products

A hemostatic valve

Product Category

Class II Medical Device

Countries of Interest

Australia, Brazil, China, India, Pakistan and Russia

Service Provided

Regulatory Intelligence

Regulatory strategy

Device classification for each country

Device registration following harmonized approach

Client Situation

The Client is a US based medical device company that has registered its class II medical devices in USA, Canada and EU. Client wanted to get approval for its products in international markets. Client's expertise and geographical locations were limited to North America and was seeking a strategic partner to help expand its global market base.

GRP Solution

GRP's team brings decades of experience with registration of medical devices worldwide across LATAM, Europe, Asia, Africa, Middle East and North America. GRP's offices in these regions makes GRP standout as a partner of choice for devices companies seeking a Global Regulatory Partner. GRP conducted strategic workshops with Client's commercial and regulatory teams to assess their commercial markets of priority and provide a regulatory landscape based on their current status of registration.

The strategy was based on device's potential class in global markets of interest to develop a harmonized approach.

USA	Canada	Australia	Brazil	China	India	Pakistan	Russia
Class II	Class II	Class IIb	Class IIb	Class II	Class C	Class C	Class IIb
		2-3 Months	5-6 Months	12-20 Months	9-18 Months	6 Months	18 Months
← Approved		→ ← Potential Markets Global Strategy					→

Keywords: Medical device registration, medical device Class II registration in different countries Pakistan, India, Australia, China Brazil Russia, Regulatory Strategy for medical device class II registration, regulatory intelligence for class II registration in Pakistan, India, Australia, China, Brazil and Russia, gap analysis for hemostatic valve registration in brazil, gap analysis for hemostatic valve registration in china, harmonization of registration of class II in Asia and Latam.

GRP's Harmonized approach

Regulatory Intelligence	Regulatory Strategy	Dossier Preparation	Dossier Submission and Approval	License Maintenance
✓ GRP collected the regulatory requirements for the device in the 6 target countries	✓ GRP defined the regulatory strategy for the registration of the device in each one of the 6 target countries. ✓ The regulatory strategy defined the regulatory requirements and timelines for the device registration in each one of the 6 countries.	✓ GRP prepared a Core Dossier using regulatory requirements from target markets ✓ GRP defined priorities based on commercial plans and complexities ✓ Consider testing requirements ✓ GRP identified the risk s and complexities related to each device prior its registration	✓ GRP submitted the core dossier to different health authorities and provided support till product approval. ✓ GRP supported in Conducting local testing where required ✓ Submission as per Regulatory Charter ✓ GRP responded to queried and received approval ✓ Efficient project management for consistent communication and timely submission	✓ GRP provided post-marketing support by maintaining the licenses as needed.

Key Highlights

- Client could benefit from GRP right from planning stage where GRP's team worked with Client's commercial and regulatory teams in providing inputs on global regulations and help prioritize the markets
- An efficiency project plan was put in place considering client's current regulatory document status and potential requirements for countries of interest
- A one-stop-shop for all of Client's needs driven by Client focus and ownership
- GRP expertise in managing global and regional projects.
- GRP expertise in harmonizing the regulatory processes when needed to reduce the regulatory timelines and increase efficiency.

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