GLOBAL REGULATORY PARTNERS

Case Study 30:
Registration of API DMF and In-Country Care Taker Services in Japan

Client
A European API manufacturer based in Switzerland.

Products
API of drug used in the treatment of neurological diseases

Product Categories
API

Country of Interest
Japan

Solution Offered
- ✓ API DMF in Japan
- ✓ ICC in Japan

Key Highlights:
- ✓ Client was driven by its commercial teams to ensure approval of DMF in certain timelines and it did not have any expertise with Japan market. They did not have local presence and therefore needed a strong partner with required regulatory, technical experience with sensitivity to commercial imperatives.
- ✓ Client was successful in obtaining timely approval in Japan, their immediate priority market and was ready to expand in China and Japan with their portfolio of ingredients.

Key Phrases:
API, Excipient, Active Pharmaceutical Ingredients, Japan, DMF API registrationl, PMDA, ICC, Local Agent, DMF maintenance. In country care taker for DMF.

Client Situation

The Client is a European manufacturer of API and wanted to register the DMF of one of its APIs in Japan before selling its API to a drug manufacturer in Japan. Client was seeking a partner who could support him in Japan by preparing and submitting the API DMF and communicating regularly with the drug product manufacturer in Japan that will be using the API.

GRP Solution

GRP with its teams based locally in Tokyo, was a partner of choice for Client combined with GRP's experience in successfully registering 20+ DMFs in Japan. GRP helped the Client in planning their DMF registration in Japan based on Client's commercial plan and to obtain the DMF approval as scheduled.

1 DMF Planning

- ✓ GRP worked with Client's Commercial and Regulatory teams to understand their timelines to be in market.
- ✓ GRP prepared a charter for Japan and a detailed project plan for Japan registration.
- ✓ GRP educated Client's teams with requirements for ICC in Japan, For 42, obtaining Form 43 post approval from PMDA to enable a coherent project execution.

2 Submission and Approval

- ✓ GRP reviewed Client's existing documentation for gaps and helped prepared complete submission package as per PMDA requirements.
- ✓ The documents included ingredient properties, manufacturing methods, quality, safety and non-clinical data, test methods, analytical procedures, storage methods, stability data and other information as applicable.
- ✓ GRP was the ICC for Client in Japan.

3 Maintenance

- ✓ Post approval, GRP continues to maintain Client's DMF in Japan including responding to HA queries, amendments, changes and notifications as applicable.
- ✓ GRP further expanded Client's presence in China by getting approval for their DMF.

For additional information,
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