GLOBAL REGULATORY PARTNERS

# Case Study 118:
# Registration of API in China

**Client**
The client is state owned public company and is subsidiary of the south African nuclear energy corportion. It supplies commercial radiopharmaceuticals and distributors of key medical radioisotope molybdenum-99 and radioisotope based diagnostic imaging and therapy products including iodine-131 and lutetium-177.

**Products**
DMF

**Product Categories**
Drug

**Countries of Interest**
China

**Services Offered**

- ✓ Gap analysis
- ✓ DMF writing
- ✓ DMF submission to NMPA
- ✓ Local representation in China
- ✓ DMF annual report

**Key Highlights:**

- ✓ The DMF was prepared in 2 months
- ✓ **Zero queries** received post submission
- ✓ **Standardized checklists and templates** for China DMF for quick setup and turnaround
- ✓ Well defined process and project charters for sustained submission and lifecycle maintenance
- ✓ **100% compliance** maintained
- ✓ GRP continues to be **Strategic Partner in China** for Client

***Keywords:***
*China, NMPA, API.*

## Client Situation

Client is a multinational company, leader in the production and supply of APIs for radiopharmaceuticals and radioisotopes. The company received many requests from Chinese pharmaceutical companies, who were interested in buying one of its APIs and use it in their drug product's formulation.

To protect the confidential information related to the manufacturing process of its radioactive APIs, the client decided to register first the DMF of its API in China, then authorize other companies to reference it when they submit their ANDA to NMPA. As the client didn't have any presence in China, he was looking for local partner who can guide them through the process and help them register their DMF with Chinese health authority NMPA.

## GRP Solution

Through its affiliate in China and many years of experience, GRP has built a core team of regulatory professional in China, who is specialized in medical writing, compiling, translating and submitting the Chinese DMF to NMPA.

GRP has created a detailed checklist of regulatory requirements of DMF in China, that is used to track all the regulatory deliverables for the DMF and their timelines. The DMF was prepared in English language first before being translated into Chinese. That way, GRP gave the opportunity to the client's review and approve the English version of the DMF before being translated into Chinese and submitted to NMPA.

Using agile project management and tracking, the team was able to prepare and submit successfully the DMF to NMPA 45 days after receiving the required documents from the client.

GRP is currently acting as Client's local representative in China and assuring the maintenance of DMF as required by Chinese regulations.

For additional information,
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