GLOBAL REGULATORY PARTNERS

Case Study 63:
Registration of Vaccines with Anvisa in Brazil

Client
Asia based large vaccine manufacturer.

Products
Multivalent vaccines for diphtheria, tetanus, pertussis, hepatitis, influenza

Product Categories
Vaccines, Biologics

Countries of Interest
Brazil

Services Offered

- ✓ Vaccine Regulatory Strategy
- ✓ Consultation with ANVISA
- ✓ Dossier Preparation
- ✓ GMP Certification
- ✓ Local Representation
- ✓ License Renewal
- ✓ License Maintenance
- ✓ Importation
- ✓ Pharmacovigilance

Key Highlights:

- ✓ GRP's over two decades of experience with biologics and vaccines in Brazil had helped Client get started early with registration activities with right guidance
- ✓ Client could reduce the time to market by fast tracking vaccine registration process using GRPs strategy validated by ANVISA
- ✓ Client had a trusted local partner to manage end to end vaccine registration, importation and distribution of vaccine

Keywords:
vaccine registration in Brazil, vaccines registration Anvisa, Brazil vaccine regulatory guidelines, Brazil biologics registration, gmp certificate biologics Brazil, local representation in Brazil biologics, biologics consultation meeting Anvisa, registration dossier vaccines, registration dossier biologics, regulatory strategy vaccines Brazil, regulatory strategy biologics Brazil.

Client Situation

The Client is an Asia based global vaccine manufacturer with products marketed in 50+ countries. Client's management had decided to expand its presence in Latin American countries, with initial focus on Brazil. Client needed a partner with regional presence in Brazil and experience in vaccines or biologics products registration in the country. Considering the business impact of multi-million USD, Client needed a partner that could provide end to end regulatory services.

GRP Solution

GRP was identified and retained by the Client as a partner of choice to meet its expansion needs in Latin America, starting with Brazil. GRP, with its local offices in Brazil has helped several biologic, vaccines products registration with ANVISA. Vaccines are registered as biologics in Brazil. GRP performed a thorough assessment of available studies and clinical data on the products, (the products were not registered in USA or Europe) and drafted an optimum regulatory strategy for their registration in Brazil. Client was interested in evaluating opportunities to reduce the time to market and identifying options for fast-track registration of vaccine in Brazil. Based on GRP's experience, the appropriate options were recommended to the client to register its vaccines in Brazil following the fast track pathway. GRP scheduled a consultation meeting with ANVISA to validate the proposed regulatory strategy for fast track. GRP prepared the meeting package working with Client teams and led the consultation meeting with ANVISA. Upon validation of strategy, GRP prepared the registration dossier in Portuguese and submitted it successfully to Anvisa for review. GRP further assisted client with applying for GMP audits by ANVISA and supported the client to be ready for such audits by performing GMP mockup audits. GRP's office in Brazil was used as local representative for the application and primary distributor of vaccines in Brazil. Since GRP has authorized warehouse in Brazil, GRP supported Client with importation and storage of vaccine for further distribution through their marketing partners. GRP continues to act as Client's local representative in Brazil, managing the life cycle of the vaccines and performing pharmacovigilance activities as well.

For additional information,
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