GLOBAL REGULATORY PARTNERS

Case Study 121:
Regulatory Strategy for Class IV MD (Regenerative Medicine) in Brazil

Client
An Australian company specialized in the development and commercialization of regenerative medicinal products wanted to commercialize its products in Brazil and needed support from a regulatory expert in Brazilian regulations to establish the RA strategy for the product registration in Brazil.

Products Category
Class IV medical device.
Implant orthodontic medical device

Country of Interest
Brazil

Solution Offered
- ✓ Gap Analysis
- ✓ Regulatory Strategy
- ✓ Project management

Key Highlights:

- ✓ Client benefited from GRP strong RA local expertise in medical device registration in Brazil.
- ✓ Standardized checklists and templates for medical device assessment in Brazil.
- ✓ Expertise with ANVISA.
- ✓ **100% compliance**
- ✓ GRP continues to be **Strategic RA in Brazil** for Client

Keywords:
Medical device Class IV, registration, ANVISA, Gap analysis, Regulatory Strategy for Brazil, Market Access Brazil

Client Situation

An Australian company specialized in the development and commercialization of regenerative medicinal products wanted to commercialize its products in Brazil and needed support from a regulatory expert in Brazilian regulations to establish the RA strategy for the product's registration in Brazil.

The product is a collagen based medical device that facilitates tissue repair and healing in a variety of orthopedic. The devoce is considered very high risk in Brazil and classified as Class IV in Brazil.

GRP Solution

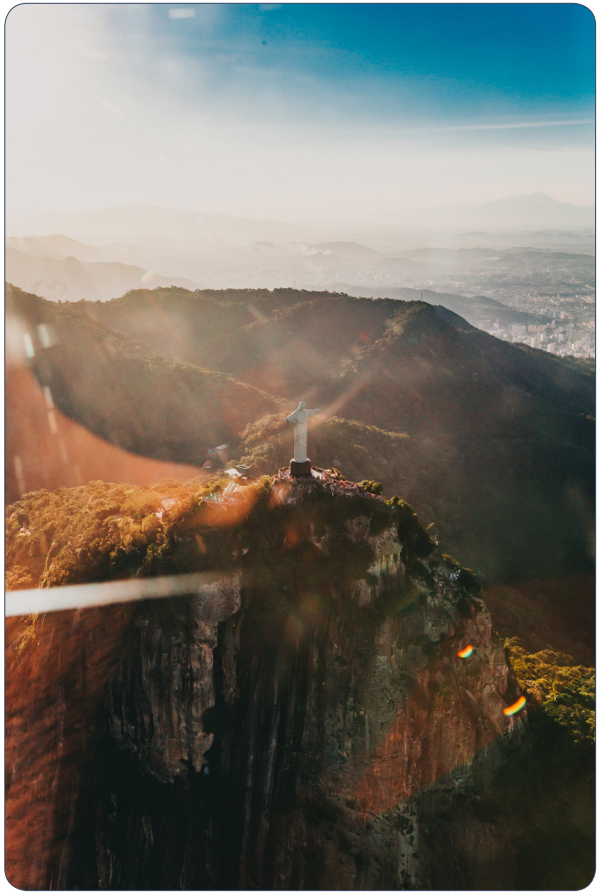
GRP regulatory team in Brazil has many years of experience in defining the Regulatory strategy and registering Class IV medical devices in Brazil. The team provided the following services:

1 GAP Analysis

- ✓ GRP identified all Anvisa regulations that apply to the device.
- ✓ GRP identified similar medical devices that were registered in Brazil by other companies.
- ✓ GRP conducted a gap analysis of the original technical file of the device and identified the missing information based on Anvisa requirements.
- ✓ GRP generated a gap analysis reports.

2 RA Strategy

- ✓ Based on the results of the gap analysis, GRP proposed the best RA strategy for introducing the device into Brazilan market.



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Brazil Agent | RA Strategy | Gap Analysis