GLOBAL REGULATORY PARTNERS

Case Study 61:
Pharmacovigilance Outsourcing: Literature Screening in China and Macao

Client
A multinational pharmaceutical company with affiliate in china was looking for a partner in china to which it can outsource the pharmacovigilance activities of 27 legacy drugs in China.

Products
27 legacy drugs

Products Categories
Prescription drugs

Country of Interest
China, Macao

Solution Offered

- ✓ Post-marketing Pharmacovigilance
- ✓ Local PV regulatory Intelligence
- ✓ Literature screening in china and Macao (142 local medical journals and 23 medical databases)
- ✓ Evaluating safety information collected from literature

Key Highlights:

- ✓ Client benefited from GRP strong PV local expertise in China and Macao and was able to outsource this activity with no issues within 15 days. Client was able to rely 100% on GRP to perform PV post-marketing activities of a portfolio of 27 legacy drugs in China and Macao.
- ✓ Standardized checklists and templates for Literature screening and Reporting in China and Macao, allowed efficiency in screening process of local literature and databases and on time reporting.
- ✓ Expertise and ability to handle a portfolio of many drugs from different therapeutic areas.
- ✓ 100% compliance maintained
- ✓ GRP continues to be Strategic PV Partner in China and Macao for Client

Keywords:
China , Macao, Pharmacovigilance, Literature screening, Literature Screening reports, Adverse Event Assessment, Literature Search, NMPA, Annual Report, DSUR, ICSR China, post-marketing PV.

Client Situation

The Client is a multinational pharmaceutical company with affiliate in china, that was looking for a qualified PV service provided in China, to whom it can outsource the post-marketing activities of 27 legacy drugs sold china and Macao.

GRP Solution

GRP PV team in China has significant experience in providing pharmacovigilance services in both china and Macao, according to NMPA requirements. The provided services:

1 PV Regulatory Intelligence

- ✓ Regular (monthly) monitoring of local regulatory changes and reporting them to the company.
- ✓ Interpretation and implementation of changes in PV legislation
- ✓ Participation in industry groups
- ✓ Translation in English of changed regulations (including QC)

2 Local Literature Surveillance and Screening

- ✓ Conducting search on a weekly basis of new journal issuance
- ✓ Evaluating suspected cases or other important safety information and reporting them where appropriate.
- ✓ Translating to English suspected ADR information from journal review.
- ✓ Reconciliations

For additional information, please contact us at
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