Regulatory House

„Ensuring Regulatory and Pharmacovigilance Compliance“

Medicinal Human and Veterinary Products

Registration Procedure

- All types of submission (Nat, MRP/DCP, CP)
- Compilation and evaluation of the partner file (Due Diligence)
- Completeness and quality check
- Creating Module 1
- Full maintenance during whole life cycles
- Local contact
- Translation service
- Mock-up creation

Post-Registration maintenance

- Management /strategy of grouping/consolidation of variations
- Communication with authorities, MAH
- Renewals managements
- Sunset clause monitoring and solving
- Archiving the documents
- Monitoring of local legislation
- Product information checking, correction
- Reporting

Other service

- Creating eCTD dossiers
- CESP submission
- Product information translation/correction to/from national languages

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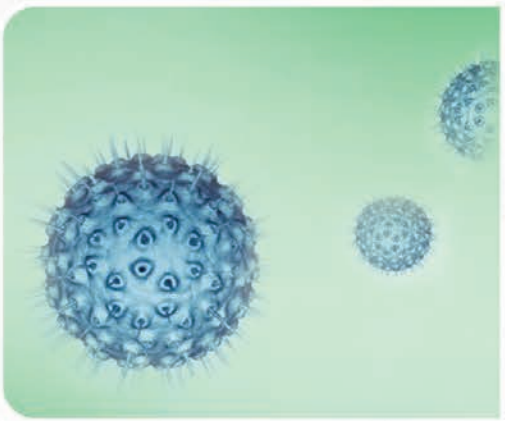
Pharmacovigilance service



Establishment of a new valid PhV system

- Preparing of all demanded documents (SOP, PSMF, PhV database,..)
- Access to Eudravigilance (ICSR, art. 57, EVDAS)
- Setting the functional reporting and information exchange

Evaluation and update of current PHV system

- Preparing of all demanded documents (SOP, PSMF, PhV database,..)
- Access to Eudravigilance (ICSR, art. 57, EVDAS)
- Setting the functional reporting and information exchange

Regularly maintenance

- Complex service of EU QPPV and deputy
- Non-stop services for receipt of AE signals (24/7/365)
- ADR's reporting
- Proprietary PHV database
- Regularly reconciliations
- Monitoring of legislation
- Evaluation of monitored literature
- PSUR and RMP supervision, preparing, submission

Literature search service

- Local literature monitoring
- Worldwide literature monitoring

Special request

- Translation of documents, correction/revision of text in local languages
- Dear doctor letter locally

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