Bionical Emas

Fact Sheet

Bionical Emas: Pharmacovigilance

Post-Marketing Pharmacovigilance at Bionical Emas enables our clients to effectively monitor the safety of their products by utilising our highly experienced team combined with tried and tested processes to deliver a cost effective solution to outsourced safety activities.

The Capabilities

- Setup Global Pharmacovigilance Systems
- UK based case processing
- Signal Risk Management
- Database Validations
- Regulatory Submissions
- PBRER/PSUR authoring and management
- Risk Management Plan authoring
- Licensed Partner PVG Audits
- PSMF Creation
- PVG SOP suite creation
- Safety Data Exchange Agreements
- EU QPPV and Network of LQPPV
- Established suite of SDEAs to meet client requirements

The Benefits

- Tailored hands-free PVG
- Single point of contact via Project Manager
- A cost-effective business model tailored to providing all or components of post-marketing PVG system
- Autonomous PVG systems service offering
- Consolidation of safety information for effective risk management

The Experience

20 years
Experience working with pharmaceutical companies in US, Europe and Asia

5 years
Minimum Project Manager Post-Marketing Experience

99%
Annual ICSR reporting compliance

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