Eignapharma

Your leading consultancy & service provider for RA, PV, GXP & BD (EU & UK)

SUPPORTING OUR INTERNATIONAL PHARMA CLIENTS SINCE 2010

Contact us!

We're here to support you!

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4049-012 Porto (Portugal)

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Eignapharma

Regulatory Affairs

Preparation, submission & maintenance of marketing authorisations in the EU & UK

- Highly experienced Regulatory Affairs Team
- Tailored service support
- Expertise in Medicines for human use, as well as MDs & FSs
- Maximise your RoI with Eignapharma

Dossier Due Diligence reviews, Dossier preparations, submissions, Product Information (PI) & labelling translations, National Procedures (NP), Decentralised Procedures (DCP), Mutual Recognition Procedures (MRP), Centralised Procedures (CP),Certification of Suitability, Revisions, Renewals, Submission of variations, Submission of renewals, Variations typification, Portfolio Acquisition Due Diligences, MA transfers & more

Pharmacovigilance

Ensuring full EU & UK Pharmacovigilance Compliance

- Expert EU and local PV Teams
- Support & delivery of healthy & fully compliant Pharmacovigilance systems
- Expertise in EU & international drug safety regulations
- We embrace a drive for the highest Quality standards in the Pharma industry
- Switched on to latest changes affecting your PV system

EUQPPV Appointments • **PSMF** - Authoring and maintenance • **PV System Audits** • **RMP** - Authoring an • **LPPV** - Appointment of a local Qualified Person for PV • **XEVMDP** • **SDEAs** Prep, review, negotiation & execution • **RA & PV intelligence** Monitoring Global & Local regulations/guidelines • Signal Management • **PSUR** Authoring & subsequent submission to the EMA PSUR Repository • **PV training** • **Periodic reconciliations** of cases/PQCs/medical enquiries • **Medical information services** Handling of medical enquiries • **Social Media monitoring** Screening of social media accounts • **& more!**

GxPs

Meeting EU & UK GMP/ GDP standards

- GMPs for active substances, excipients & finished medicinal products, as well as for manufacturers of primary and secondary packaging materials worldwide
- GDPs for logistic operators, warehouses, distributors & transportation agencies
- Commercial partners/distributors, subsidiaries, ensuring compliance of the Pharmacovigilance Good Practices

Business Development & Matchmaking Services

Identifying best fit pharma business partners for FDF, APIs, CMOs, CROs

- In & out-licensing
- Co-development
- Contract manufacturing
- API sourcing
- M&As
- Regulatory & Pharmacovigilance support services
- Marketing support services
- Product launch management
- EU set up support consultancy services

Visit us: Eignapharma.com