ATOP

PHARMA SOLUTIONS

SERVING STRATEGIC EXCELLENCE TO THE PHARMACEUTICAL WORLD

ABOUT THE COMPANY

Atop Pharma solutions is a global leader in regulatory, pharmacovigilance, legal and translation services. We support pharmaceutical companies to meet their regulatory requirements in all the key markets like Europe, North America, Asia, Africa and Latin America. We believe in helping pharmaceutical companies to accelerate their growth and provide diversification. We provide high-quality services trusted by pharma companies across the globe.

SERVICES

REGULATORY

- Regulatory due diligence and strategy
- Gap analysis
- MAA dossier – review and compilation of modules 1 to 5
- eCTD/NEES publication services
- Product information preparation – SPC, PIL and labelling
- Readability Testing and Bridging report
- Translation of product information text (and harmonisation for generics)
- Local regulatory support (e.g., local representative, preparation of locally required documentation)
- Services of EU QPPV and country specific local QPPV
- Deficiencies management
- Compilation of Major and Minor variation
- MA duplication procedure
- Regulatory services for specific countries e.g. LATAM, CIS + ex members, ASEAN, South Africa, ANZ, Botswana, Switzerland, etc.
- DMF preparation

IMPURITY

- High quality analytical impurities and working standards
- Providing complete set of data HNMR, 13CNMR, Mass, HPLC, IR, TGA, COA along with products.
- Provide technical and analytical support to clients.
- Customise synthesis of product on request.

PHARMACOVIGILANCE

- Signal detection – adverse reaction
- Drafting and submission management of PSUR, PBRER, PADER, Clinical Overview and DSURs: Comprehensive Pharmacovigilance Service packages for ROW region
- Establishment of PSMF and drafting of Risk management plan
- Literature search-Global/local literature search and review for reports of adverse events for all types of products, using standard terms
- Monitoring of literature for aggregated reports and safety information
- Scientific and medical writing: Drafting of Clinical/Non-clinical report or overview, narrative, IMPD with all regulatory compliance of EMA/any country.

INNOVATOR SAMPLES:

- Supply of innovator samples

PATENTS

- Patent Prior Art Search
- FTO Report
- Infringement Analysis Report
- Patent Drafting and Filing in India, USA
- PCT Application Filing
- PCT National Phase Application Prosecution
- Post Grant and Pre Grant Oppositions
- Patent Infringement Suits

TOXICOLOGY

- Preparation of Toxicology reports
- Calculation of PDE and NOAEL
- Cleaning Validation and MACO calcul tion

COPYRIGHT

- Copyright Filing in India and USA
- Copyright TM-C certificate prosecution
- Copyright Opposition
- Copyright Infrigement Strategy
- Legal Notice and Seizures
- Copyright Litigation

TRADEMARK

- Trademark Country Specific Search
- Trademark Filing- India, Uk, USA
- Trademark Filing- Madrid Protocol
- Trademark Prosecution
- Trademark Opposition
- Trademark Infringement
- Trademark Litigation

TRANSLATION

Translation of following pharmaceutical documents:

- Dossiers
- Product information – SPC, PIL, PI, artwork text as per country specific requirements
- Validation protocols and reports
- Administrative documents
- Clinical study documents
- Bioequivalence documents
- Guidelines
- Queries

GET IN TOUCH

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