IQVIA

Regulatory Affairs and Pharmacovigilance Services by IQVIA

Regulatory services

- Strategic and operational support in all phases of registration for national and European procedures: from the preparation of the dossier to the granting of MA.
- Life cycle management of medicinal products.
- Support in the drafting and/or revision of Standard Operating Procedures (SOP).

Pharmacovigilance

- Out-sourcing or ad-hoc pharmacovigilance support, ADRs assessment, reporting and Eudravigilance management.
- Preparation of PSUR, line listing, PSMF, RMP, SOPs, SDEA.
- Internal audits, preparation for regulatory authority inspections.
- PV training in house and/or at the customer's site.
- Pharmacovigilance during Clinical Studies (SAE management, SUSAR and DSUR preparation).

Medical scientific information and Medical compliance

- Compliance with Art.126 of Law 219/06, regional, local and deontological regulations, management of accreditations of Sales Representatives, assumption of responsibility of Scientific Service.
- Support for regulatory requirements in promotional activities (congresses and promotional materials).
- Compliance in the field of consultancy, advisory boards, sponsorships, donations, market research, investigator meetings, hospital meetings, public affairs.
- Internal audit activities, support for Farmindustria audit and SOP preparation to guarantee a Medical Scientific Information quality system.
- Medical Scientific Information Training.

Conferences and meetings

- Evaluation of the sponsorship of conference events and the relevance of the event with the products marketed by the Company.
- Support activities for managing contacts with organizational secretariats and providers.
- Assumption of the role of Representative for Conferences and Congresses.
- Complete management of AIFA authorization procedures through the Front End portal for the authorization of Conferences and Congresses (ACC): from the request for authorization to the final accounting of event expenses.

Medical device

- Preliminary regulatory assessment focused on the classification of the device and support in the analysis of the new regulatory requirements to define their impact on the economic operators involved, outlining all the responsibilities of the manufacturer, the authorized representative, the importer and the distributor, and the person responsible for regulatory compliance.
- Support in the activities necessary for the launch/ maintenance of the product on the market (review/ drafting of technical file, PSUR, post-marketing surveillance reports) and resolution of any critical issues.
- Interaction with the competent Health Authorities and Notified Bodies.

Diligence and GAP analysis

- Support for Due Diligence and Gap Analysis of medicinal dossiers during Mergers&Acquisition processes or for new Business Development strategies of its products.
- In-depth analysis of pre-clinical, clinical and quality documentation to assess compliance with the latest regulatory requirements, industry regulations and current guidelines and any information gaps that could compromise the outcome of new registrations and therefore new business.
- Worldwide assessments for different types of products (e.g. new chemical entities, biological medicinal products, orphan drugs, generic drugs, OTC, herbal medicines, homeopathic medicines) thanks to a consolidated global partner network.

Start-up

- Support to companies during the various life stages of a medicinal product, from registration (set-up and pre-marketing activities) to the entire product life cycle (launch and post-marketing activities).
- Support in ensuring compliance with European and local requirements for placing on the market.
- Support in registering on the platforms required by law in the role of Marketing Authorization Holder (MAH) and in identifying all the figures necessary in order to comply with legal requirements.
- Support in the management of mandatory activities expected during the product launch phase and during the post-marketing phase to guarantee the maintenance of a medicinal product on the market after its authorization.

Regulatory update and press review

- Daily or weekly newsletter which provides a collection and a complete overview of regulatory updates and news published on the websites of the Health Authorities and pharmaceutical magazines, allowing the Customer a timely update on the most relevant news to adapt and act promptly to satisfy the updated legislation.

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