Regulatory Affairs Services
for pharmaceutical and medical device industries

MEDICAL WRITING

- **Non-clinical modules (2.4, 2.6 & 4)** for drugs, **Biological Evaluation Plan (BEP)** & **Biological Evaluation Report (BER)** for medical devices.
- **Clinical modules (2.5, 2.7 & 5)** for drugs, **Clinical Evaluation Plan (CEP), Clinical Evaluation Report (CER), PMCF & PMS Plans, PMCF & PMS Reports** for medical devices.
- **Variation applications (safety, clinical, CMC)** & responses to Authorities questions.
- Periodic Safety Update Report (**PSUR**) for drugs and medical devices.
- Product information: **Summary of Product Characteristics** (SmPC), leaflet/IFU & labeling.
- **Risk management plan/report** for drugs and medical devices.
- Environmental Risk Assessment (**ERA**) for drugs.
- **Regulatory compliance** for promotional materials.

TECHNICAL WRITING

- **Quality modules** for MA file (M3 & QOS-2.3) and variation applications.
- **Gap Analysis** to evaluate impacts and write the variation applications to maintain regulatory compliance.
- **Manufacturing and validation** part of the EC marking Technical Dossier for medical devices according to MDR 2017/745-Annexes II & III.
- **Cosmetics**: Product Information File (PIF) including Part A & B.

POSITIONING & REGULATORY STRATEGY

- **Feasibility** and **regulatory positioning** for your portfolio of products.
- Regulatory **strategy:** status, regulatory pre-requisites, submission, etc…
- Support for the **development** of your products (development plan, selection of CMO/CRO…).

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Quality Assurance Services
for drugs, medical devices and cosmetics

AUDITS

- *« Exploitant » in France*, GMP & GDP
- ISO 13485:2016/A11:2021 & MDR 2017/745
- ISO 22716

QUALITY MANAGEMENT SYSTEM

- Optimization of your QMS
- Writing of documentation and QMS management (indicators, pilot meetings, management review)
- Implementation and training of teams in Quality, Risk Management, Change Control Management
- Process Pilot Training
- Preparing employees for inspections/audits

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