EU Regulatory

Your Trusted Partner for Navigating Compliance

For pharmaceutical and biotechnology industries, where regulations are stringent, a well-crafted regulatory strategy is vital for successful market introduction and managing global market intricacies. Our comprehensive service portfolio offers insights and solutions necessary to meet global regulatory requirements, boost compliance, and ensure successful product approvals.

Strategic Competences

- Guidance and assistance on regulatory filings
- Due diligence/gap analysis for strategic mergers and acquisitions
- Assistance with reviewing agreements and contracts to ensure the adequacy of regulatory provisions
- Evaluation and resolution of complex scientific and regulatory compliance issues
- Communicating with regulatory agencies
- Attending Agency meetings on our clients' behalf
- Regulatory Intelligence Services
- Regulatory CMC consultation
- Tailored strategies to streamline drug development timelines

Pre-submission Phase Activities

- CT Application Compilation and review
- Preparing Agency meeting requests and requisite briefing packages
- EU CTR/CTIS Submission (EU)
- Eligibility Request Submission
- Letter of intent and scheduling
- NRG submission
- Pediatric Plans and Orphan Designation
- Gap analysis and mitigation strategies
- Expedited programs request submission
- Labelling & Artwork Management
- Drafting SmPC, PILs, Investigator's Brochures (IB)

Submission & Evaluation Phase

- Drafting and review of MAA
- User readability studies
- Regulatory Publishing
- Regulatory Submission
- Application Validation query support
- Responses to scientific queries
- Translation phase support

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Post Approval Phase

Drafting, review, compilation, publishing and submission of

- Variations (Type 1a, 1b, II)
- Renewals
- Line extensions
- Transfers
- Safety labeling updates
- SPC updates

Specialized Expert RA services

- Legal entity service
- NBOp application
- Nitrosamine Impurity Risk Assessment Submissions
- Environmental Risk assessment

PEOPLE

- In-house Team of Regulatory Experts and International Regulatory Contact Points

CAPABILITIES

- Experience in Range of Products Medicine-Generic/Branded, Biologics, Combination Products, class I device

PLATFORM

- Inhouse eCTD & SAS

SOLUTION

- From Development products till Post-Approval & Divestment

CLIENTELE

- Working with 8 different clients (EU, China & USA)

VOLUME SUPPORTED

- 530+ eCTD Publishing, 350+ query responses, 85 CO & NCO (2.4 & 2.5), 45 moderate and minor variations, 15 Safety Labelling Changes, 11 scientific advices, 8 Major variations, 04 Biologics MAA, 04 Biologics CT Application, 04 MA Transfer & renewals, 01 NBOp application

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