GLOBAL DRUG REGULATORY SERVICES

DDReg

Consulting

Global Regulatory Services

Market Access

Regulatory Compliance

"Your doorway to world-class drug regulatory expertise "

DRUG PRODUCT AUTHORIZATION

- ⇒ Review of Technical Data on Finished Formulations as per country requirements
- ⇒ Gap Analysis and Remediation Advisory
- ⇒ Authoring of Technical Sections of Dossiers
- ⇒ Dossier authoring, compilation & ePublishing
- ⇒ Labeling document reviews
- ⇒ Submission to Agency

REGULATORY DUE DILIGENCE & GAP ANALYSIS

- ⇒ Regulatory framework and technical capabilities of target companies
- ⇒ Drug Product & API documentation review of the target companies/brands
- ⇒ Regulatory & quality due diligence of API suppliers & CMO/ CDMOs
- ⇒ Vendor audit (Technical)

"Global Drug Regulatory Services that make the difference"

WE MAKE YOU ACHIEVE GO-TO-MARKET MUCH FASTER

DDReg is your consultant, service provider, interface with EMA/US FDA/ UKMHRA/SFDA, strategist since 2009 that delivers "Quality" in everything it does for you. Our regulatory experts work with you throughout the product life cycle. providing consistently high quality and flexible services to ensure smooth regulatory processes and maintaining in-market compliance all the time.

DDReg is an astute Regulatory Affairs guide for new market authorizations / initial submissions to global clients, for all types of products (New Chemical Entity (NCE), Generics, Medical Devices, Active Pharmaceutical Ingredient (API) / Bulk Drugs, Over the Counter (OTC) / Consumer Healthcare products) and Formulations (solid oral, liquid oral, parenteral dosage forms, biologicals etc.).

DDReg has gained expertise in pre-submission technical Data reviews, gap analysis, dossier compilation, Regulatory content authoring, validation and final submission of various global new product authorization applications.

There are many good reasons for global pharmaceutical organizations to prefer DDReg as its partner. Key ones are*:*

Functional Expertise

- Standard Operating Procedures & Working Guidelines that define global Regulatory standards
- Consistent monitoring & tracking of global Drug Regulatory Guidelines

Operational Excellence

- Strong Quality Management System
- Process Consistency, Robust Templates, Proven Project Management

Compliance to Global Drug Safety Requirements

- Processes developed in line with requirements of Global agencies e.g US FDA & EMA
- Strong Reference base of various agencies requirements & Guidelines of US FDA, EMA, Saudi FDA WHO, ICH etc

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REGULATORY & MEDICAL WRITING

- ⇒ Clinical Overviews & Summaries
- ⇒ Non- Clinical Overviews & Summaries
- ⇒ Development of Product labels, SPC, CCDS, PIL, PIs
- ⇒ Investigator's Brochures
- ⇒ Product Monographs

POST APPROVAL LIFE-CYCLE MANAGEMENT

- ⇒ Gap Analysis and Remediation
- ⇒ Response to agency queries/ notices on marketed products
- ⇒ Variations
- ⇒ Advisory on CMC data generation for successful filing
- ⇒ Manufacturing Site Transfers

REGULATORY STRATEGIES FOR GTM

ePUBLISHING & SUBMISSION

DDREG TEAM

- Led by Experts with combined experience of ~ 100 years in handling global Drug Regulatory & Medical writing work
- Efficient Organizational Structure for Regulatory Function with experienced groups handling each stage of Drug Regulatory Affairs
- Extensive trainings on all critical aspects of Global Regulatory Guidelines & Regulations (e.g ICH, US-FDA, UK MHRA, Saudi FDA, WHO PQ etc.)

DATABASE & IT INFRASTRUCTURE

- IT tools with the functionality to create any submission format (eCTD, NeeS, ACTD and paper) as well as comply with dynamic country-specific guidelines.
- A central platform for multi-site collaboration on all data and documentation during the submissions process
- Inhouse expertise in all major eCTD databases that include Lorenz® DocuBridge, Extedo's eCTDmanager®
- Cloud access on Lorenz's DocuBridge®
- Efficient procedures for Data security and disaster management along with in-house developed e-processes and secure FTP servers.

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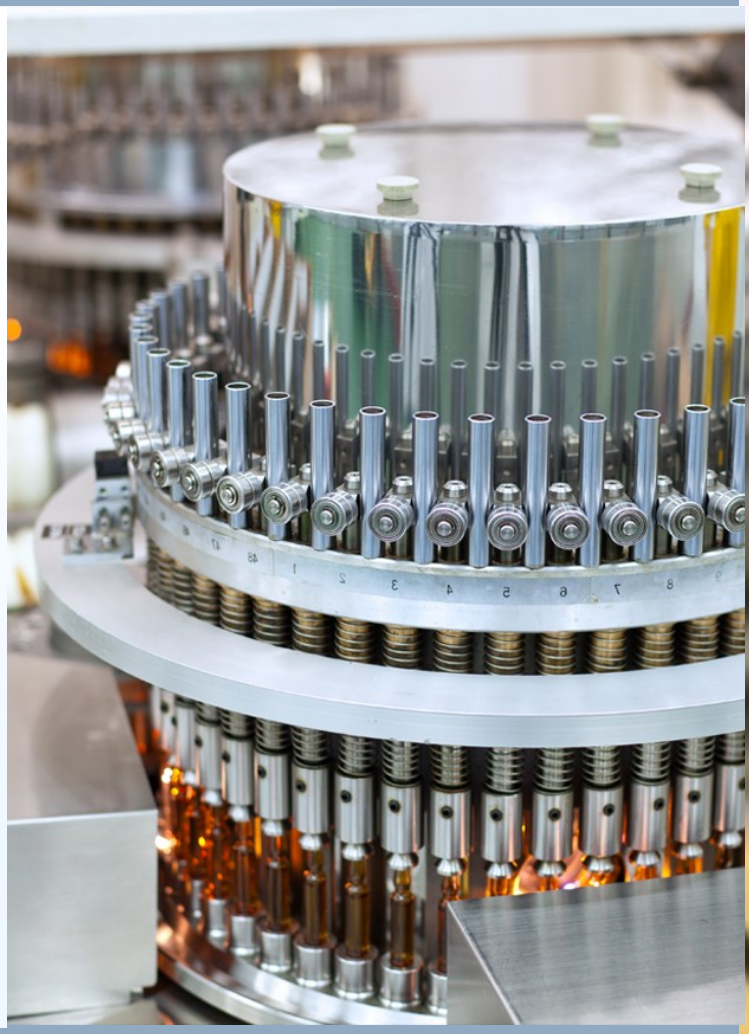
Quality Driven by Passion @DDReg

We stand committed to high QUALITY of services for global markets in cost efficient manner. By QUALITY we mean more than just services meeting our own specifications. It means meeting customers' requirements and ensuring QUALITY at all levels of dealing with our customers.



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