GLOBAL CONSULTING COMPANY

Services

Regulatory Affairs

Regulatory Strategy:

- Regulatory Pathways Analysis
- Regulatory Pathway Write-up
- Industry Guidance and Trainings

Regulatory Information Management:

- Support with Regulatory Data (Pre-market, Market Access, and Post-market) according to FDA and EU MDR requirements
- Support with Regulatory Project Management, Data Trending, and Tracking

Regulatory Submissions and Registrations:

- FDA Pre-Submission (Q-sub)
- 510(k)s
- Post Market Approval (PMAs)
- New Drug Applications (NDAs)
- Investigational New Drug (IND) Application
- EU MDR and UCKA Technical Document Write-up and Submission
- EU and UK Authorized Representation
- Market Registration and Submission Support (India, EMEA, UK, Canada, LATAM, APAC)

Talent Recruitment

Global Talent Sourcing and Recruitment:

- Talent Screening and Selection
- Interview and Onboarding Support
- Talent Placement (Temp to Hire)

Clinical Trials

Clinical Trial Oversight:

- Remote Clinical Trial Monitoring and Oversight
- Trial Initiation and Closure Support
- Clinical Data Management

Clinical Trial Documentation:

- Development of Study Documents (including Protocols, Renewals, and Study Amendments)
- Clinical Trial Applications
- Investigator Brochures
- Support with Informed Consent Documentation
- Support with IEC / IRB submissions

Clinical Trial Management:

- Support with Marketing Recruitment Materials
- Enrollment Strategy development
- Support with Advertising Materials
- Telephone Screenings
- Customized Recruitment Monitoring and Reporting

Project Management

Project Management and Tools:

- Development of Project Documentation (Charters, Project Plans, and other)
- Lean Processes Implementation and Training
- Project Team management (Resources Analysis, Leadership Communications and Presentations)
- Project Tracking Activity and Reporting
- Process Validation and Implementation
- Customized Project Tools

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