propharma

improve the health and safety of patients.

From early concept development through each clinical phase, product launch, and commercialization, we partner with pharmaceutical, biotechnology, and medical device and diagnostic clients to tackle complex challenges. We help to ensure regulatory expectations are met, business goals are achieved, and patient health and safety is improved.

Our highly trained, experienced team of 2500+ professionals provides the highest quality of services on a global scale to solve the unique and complex regulatory challenges life science companies face at any stage of the product development lifecycle.

Development

Tomorrow's therapeutic promise begins with your discovery and a solid regulatory and commercialization strategy today.

Clinical

We become an extension of your team to deliver thorough study methodology, implementation, and reporting.

Commercial

Compliance and surveillance complexities demand continuous and sharp focus from pre-product launch through to postmarketing.

Contact us to learn how our experienced team can help ensure successful outcomes throughout the product lifecycle.

https://www.propharmagroup.com/

info@propharmagroup.com

REGULATORY SCIENCES

- Regulatory Strategy and Gap Analysis
- Nonclinical, Clinical, PK/PD, and CMC Expertise
- Regulatory Writing
- Scientific Advice and Health Authority Liaison
- Dossier Compilation and Publishing
- FDA/EMA Submission Development and Management
- Product Lifecycle Management and Maintenance
- Extensive Cell and Gene Therapy Experience

LIFE SCIENCE CONSULTING

- Compliance
- QMS Development and Management
- Product and Process Lifecycle Management
- Commissioning, Qualification, and Validation
- Engineering and Project Management
- Clinical Services, GCP, and Medical Monitoring
- Specialized Services: Cell and Gene Therapy; Data Integrity

R&D TECHNOLOGY

- Scientific and Clinical Business Analysis
- Project and Portfolio Management
- Technology Assessments and IT Road Mapping
- Bioinformatics and Data Science
- Clinical Systems Implementation (GCP/GLP)
- Computer Systems Validation
- Workflow Process/Design
- AI/ML Engineering

CLINICAL RESEARCH SOLUTIONS

- Clinical Data Management
- Regulatory Operations and Publishing
- Statistical Programming and Biostatistics
- Decentralized Clinical Trials
- Clinical Operations and Development
- Medical Writing
- Clinical Program and Project Management
- Medical Affairs

PHARMACOVIGILANCE

- Safety Management Plan Development
- Clinical and Postmarketing PV Auditing
- ICSR Processing, Submission, and Reporting
- QPPV and LPPV Services
- Global and Local Literature Screening
- Signal Management
- PSMF Development and Maintenance
- RMP Development and Maintenance

MEDICAL INFORMATION

- Bilingual Native-Speaking Specialists
- Global 24/7/365 Contact Center Support
- Adverse Event (AE) Intake and Follow-up
- Product Complaint Intake and Follow-up
- Medical Writing
- Content Management
- Promotional Review
- Clinical Trial Emergency Unblinding Services
- Congress/Booth Support

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