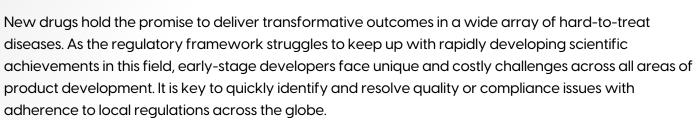
### propharma

# Accelerating Your Product Through Development





At ProPharma, we have extensive experience navigating the complexities of taking a product from the lab to a GMP facility through to clinical/commercial scale with a comprehensive suite of compliance and clinical drug safety services to effectively advance your product through clinical development. By partnering with your team to navigate and address complex regulations and compliance challenges, we ensure successful regulatory and commercialization outcomes. As your partner, we collaborate with you at every step to ensure success throughout the early concept stage of the product development lifecycle. development and increase your chances of commercial success.



#### **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.

### Delivering an Integrated Approach to Drug Development

ProPharma provides a complete outsourcing solution to drug developers to ensure stage-specific milestones are achieved, including:



### early-stage development

#### **IND/CTA Prearation**

- Animal/Toxicology studies
- Dosing strategy
- Strategic advice
- Manufacturing & control of materials
- Analytics & feasibility of specifications
- o Clinical & nonclinical study design
- Novel adaptive approaches

### **Manufacturing Technology**

- GMP, CQV, development of QMS, inspection readiness, selection of CMO
- Risk assessment of critical steps
- Analytical development
- $\circ$  Process development, validation,  $\delta$  mapping
- Technology transfer
- Preliminary/accelerated stability studies design

### Safety & Risk Assessment

- Risk-benefit evaluation
- RMP/REMS
- Key clinical documents: Investigator's Brochure (IB), protocols, etc.
- Environmental risk & containment for GMO licensing
- Safety data strategy for the BLA/MAA
- Labeling development

### **Development Planning**

- Overall regulatory strategy
- Orphan, pediatrics, & exclusivity
- o Planning for product evolution & portfolio
- o Process optimization, validation, & scalability
- Target product profile (TPP)
- Reimbursement strategies, enhancing the commercial potential of your future product

# 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 clients to tackle complex challenges. We help to ensure regulatory goals are met, business objectives are achieved, and patient health and safety is improved.

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

- www.propharmagroup.com
- info@propharmagroup.com



### clinical

### CMC & Manufacturing

- Global CMC strategy
- Quality by Design (QbD) & Quality Risk Management
- Process optimization
- QP & RP for EU release/distribution
- Supply chain audits

### Regulatory

- o Regulatory strategy (US & EU)
- Planning evidence strategy for reimbursement
- Agency advice and pre-submission meetings
- o RMP/REMS, PSMF
- Medical writing & publishing
- Submission & management of the BLA/MAA

### commercialization

#### **Product Launch**

- Process validation and continued process verification
- GDP QMS
- Compassionate use programs, postauthorization safety study (PASS)
- Product lifecycle management
- Reimbursement strategy
- Regulatory intelligence
- Review of promotional material (EU/US)
- Long term follow up analysis (LTFU)
- Long term stability design

### **Global Patient Safety**

- GVP QMS
- Medical information (MI) inquiries
- 24/7/365 MI contact center services in 30+ native languages
- AE/SAE intake, processing, & aggregate reporting
- EU Qualified Person for Pharmacovigilance (QPPV), Local Person for Pharmacovigilance (LPPV), EudraVigilance

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# Overcoming Regulatory, Technical, and Scientific Challenges Throughout the Product Lifecycle

ProPharma's Drug Development Team is a multidisciplinary team of scientists, engineers, nonclinical, clinical, and quality experts with the experience to guide your drug through development.

Our unique combination of expertise in US and EU Regulatory Affairs, CMC, and GMP allows us to connect scientific findings, product development, and quality to deliver solid regulatory solutions that bridge the knowledge gap and effectively place scientific development into the context of the regulatory framework.

With more than 25 years of hands-on experience advancing over 500 drug development projects from the lab to tech transfer, to clinic and through regulatory approval, our team of experts is capable of accelerating your product to market wherever you are in the development cycle.

- Biologics (peptide, proteins, vaccines)
- Cell and Gene Therapies
- Oligonucleotides
- Small Molecules
- Combination Products

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