PROPHARMA GROUP®

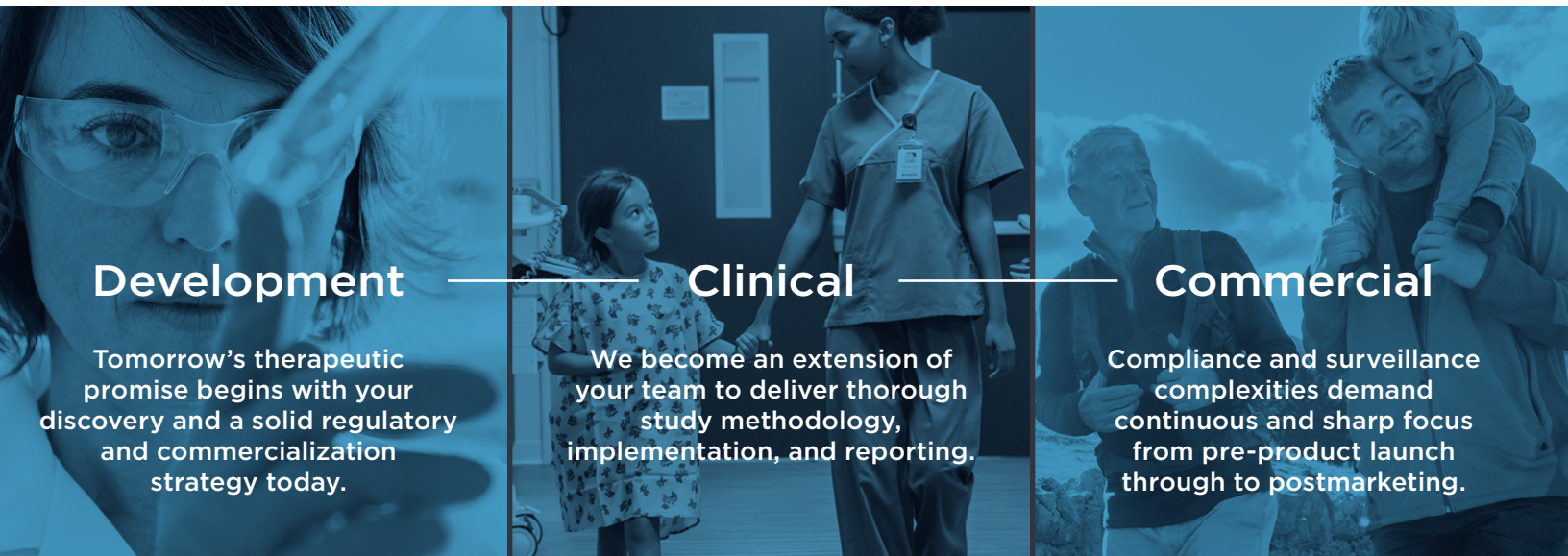
Improving Patient Health and Safety

Accelerating Your Product Through Development

Reducing Risk, Ensuring Compliance, and Accelerating Access for Patients

New drugs hold the promise to deliver transformative outcomes in a wide array of hard-to-treat diseases. As the regulatory framework struggles to keep up with rapidly developing scientific achievements in this field, early-stage developers face unique and costly challenges across all areas of product development. It is key to quickly identify and resolve quality or compliance issues with adherence to local regulations across the globe.

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

EARLY-STAGE DEVELOPMENT

IND/CTA PREPARATION

- Animal/Toxicology studies
- Dosing strategy
- Strategic advice
- Manufacturing & control of materials
- Analytics & feasibility of specifications
- 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
- Process development, validation, & 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
- Planning for product evolution & portfolio
- Process optimization, validation, & scalability
- Target product profile (TPP)
- Reimbursement strategies, enhancing the commercial potential of your future product

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

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

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

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COMMERCIALIZATION

PRODUCT LAUNCH

- Process validation and continued process verification
- GDP QMS
- Compassionate use programs, post-authorization 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

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

ProPharma Group'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

Improving Patient Health and Safety. At Every Step.

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 expectations are met, business goals 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.

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