propharma

Cell and Gene Therapy Center of Excellence: Accelerating Your Product Through Development

Reducing Risk, Ensuring Compliance, and Accelerating Access for Patients

Cell and gene therapy products, or advanced therapy medicinal products (ATMPs), 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.

At ProPharma, we understand that "the product is the process," and we have extensive experience navigating the complexities of taking a product from the lab to a GMP facility through to clinical/commercial scale. By partnering with your team to identify and address potential risks early in the process, we can help accelerate your product development and increase your chances of commercial success.

Development

Tomorrow's therapeutic promise begins with your discovery & a solid regulatory & 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 post-marketing.

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

https://www.propharmagroup.com/
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Delivering and Integrated Approach to Cell and Gene Therapy Development

ProPharma provides a complete outsourcing solution to cell and gene therapy developers to ensure stage-specific milestones are achieved, including:

Early-Stage Development

IND/CTA Preparation
- Animal/Toxicology studies
- Dosing strategy
- Long term follow up analysis (LTFU)
- 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, and mapping
- Technology transfer

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, and exclusivity
- Planning for product evolution and portfolio
- Process optimization, validation, and scalability
- Target product profile (TPP)
- Reimbursement strategies, enhancing the commercial potential of your future product

Clinical

CMC & Manufacturing
- Global CMC strategy
- Quality be Design (QbD) and Quality Risk Management
- Process optimization
- QP and 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 and management of the BLA/MAA

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Commercialization

Product Launch
- Process validation and continued process verification
- GDP QMS
- Compassionate use programs, post authorization safety studies (PASS)
- Product lifecycle management
- Reimbursement strategy
- Regulatory intelligence
- Review of promotional materials (EU/US)

Global Patient Safety
- GVP QMS
- Medical Information (MI) inquiries
- 24/7/365 MI contact center services in 30+ native languages
- AE/SAE intake, processing and 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's Cell and Gene Therapy Center of Excellence is a multidisciplinary team of scientists, engineers, nonclinical, clinical, and quality experts with the experience to guide your cell and gene therapy 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 100 cell and gene therapy projects from the lab to tech transfer; to clinic and through regulatory approval, our team of experts can accelerate your product to market wherever you are in the development cycle.
- Gene therapy medicinal products (GTMPs)
- Somatic cell therapy medicinal products (sCTMPs)
- Tissue engineered products (TEPs)
- Combination products (in both EU and US regulatory environments)

Improving Patient Health and Safety

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.

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