PLG
ProductLifeGroup

Product Development Consulting

Providing Drug Substance and Product Development Excellence through CMC, Regulatory, and Quality Consulting.

Elevate your biopharmaceutical product development projects with PLG's diverse industry expertise and experience. From your pre-clinical to late-stage clinical development, our seasoned team can guide your program.

We create development strategies in line with your budget and timing expectations.

Our experts ensure compliance with all GxP requirements and keep updated on dynamic regulatory guidelines and industry trends. In addition, we can provide a broad range of compliance services, including phase-appropriate QMS development, QA lot release, and QP services for your clinical trial needs.

You can trust our team to support your wide range of needs in drug substance and drug product development programs.

Our Services and your benefits with this solution:

We apply best practices and phase-appropriate development approaches using experienced consultants and deliver on the selected strategy.

1 Drug Substance Development: Early to Late Stage

Comprehensive early to late-stage drug substance development support, optimizing processes, ensuring quality, and expediting product development timeline.

5 Quality Assurance & QP Expertise: Ensuring Excellence

Elevate your product quality with our expert Quality Assurance and Qualified Person services, ensuring compliance, product integrity & efficient product launch.

2 Product Development & Optimization: Efficient Pharmaceutical Solutions

Streamline your drug product development and optimize processes with our expert services, paving the way for efficient, high-quality pharmaceutical solutions.

3 CMO/CDMO Search & Project Management: Seamless Solutions

Simplify your search for CMO/CDMO partner with our expert project management, ensuring seamless collaboration and successful outcomes in pharmaceutical development and manufacturing.

4 Regulatory Affairs: Product Development Compliance and Success

Navigate regulatory complexities with our Regulatory Affairs Services, guiding your product development through the most efficient regulatory pathway.

Innovation in Product Development

At PLG, our dedicated Research and Innovation (R&I) center is at the forefront of proposing cutting-edge solutions to tackle your new advanced therapies' regulatory and scientific challenges.

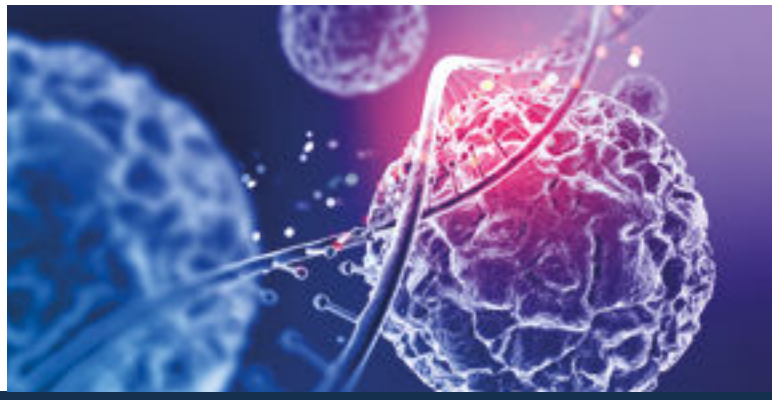
The ProductLife Group R&I team is made up of highly skilled and experienced scientists and engineers who have both a scientific background, in emerging fields ATMPs (advanced therapy medicinal products), RNA therapies, In Vitro Diagnostic Regulation (IVDR), combined therapies, and a global understanding of the innovative drugs regulatory journey.

One of our primary assets is our capacity to provide guidelines to fill the gaps in the regulations. For example, we can provide recommendations on the type and timeline for CMC assays for each product type, develop standardized protocols and guidance, and propose innovative & efficient approaches.

The team's work helps make these new therapies more accessible to patients and improves their safety and efficacy.

Our experience

- **We have a dedicated team of CMC and quality experts with an average experience of over 20 years in the biopharmaceutical industry.**
- **With over 500 completed projects in CMC and Quality, we have the expertise to navigate agencies' regulations and ensure compliance.**
- **We have an in-depth understanding of regulatory requirements for all the major regions and could cover a wide range of pharmaceutical forms across multiple therapeutic areas.**



Our tailored solutions include CMC HealthChek™ – Program Gap Analysis, designed to meet your needs and accelerate your time to market

BUSINESS CASE

Key Services Provided

1. **DP Expertise:** PLG's Senior Drug Product Consultant led the way, offering strategic guidance and overseeing CMO activities. This included technical direction, manufacturing, and the release of clinical batches.
2. **Analytical Excellence:** Our Head of Analytical Services and Senior Analytical Services Consultant ensured the robustness of stability protocols, specifications, and testing. Their expertise was instrumental in delivering reliable stability results.
3. **Regulatory Affairs (RA) Guidance:** PLG provided invaluable RA advice through experts with experience in combination products. This advisory support helped the client navigate complex regulatory requirements seamlessly.

Transforming Biopharmaceutical Manufacturing with End-to-End CMC Support

Client Profile

A global materials science company committed to advancing industries and enhancing lives through innovative products and technologies. The company embarked on a transformative journey into biopharmaceuticals and sought comprehensive support for their combination product development.

Challenges

1. Entering Biopharmaceuticals: As a newcomer to the biopharmaceutical industry, the client faced a steep learning curve, necessitating expert guidance in Drug Product (DP) development and regulatory compliance.
2. Stability Assurance: Ensuring the stability of their combination product was paramount, requiring analytical expertise and rigorous stability testing.
3. Regulatory Complexity: The unique nature of combination products demanded regulatory insight from experts with experience in this specialized field.

Results:

- **The client successfully initiated their venture into biopharmaceuticals, achieving milestones in drug product development.**
- **Robust stability testing protocols and analytical expertise guaranteed product stability, instilling confidence in regulatory submissions.**
- **Regulatory hurdles were expertly managed, setting the stage for compliance with combination product regulations.**

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BUSINESS CASE

Key Services Provided

1. **Regulatory Expertise:** Seasoned regulatory specialists collaborated closely with the client, devising a comprehensive strategy to maximize the potential of Breakthrough Therapy Designation and Rare Pediatric Disease Designation, ensuring alignment with the FDA's expectations.
2. **Strategic Support:** The team provided strategic guidance throughout the NDA preparation process, ensuring all elements of the submission were meticulously crafted, supported by robust clinical data and compelling justifications for expedited approval.
3. **Priority Review Preparation:** With an eye on expedited review, the team streamlined the submission, ensuring all documentation was concise, clear, and compelling, enhancing the chances of a successful Priority Review designation.
4. **Collaborative Approach:** Continuous collaboration with the client's internal teams ensured seamless integration of data and regulatory insights, facilitating a cohesive and compelling NDA submission.

Accelerated Regulatory Success with Breakthrough Therapy Designation and Rare Pediatric Disease Designation

Client Profile

A Phase 3 biotechnology company based in Boston, MA, pioneering a groundbreaking therapy for a rare pediatric disease. The company aimed for a successful New Drug Application (NDA) regulatory filing with Priority Review designation, coupled with Breakthrough Therapy Designation and Rare Pediatric Disease Designation, following FDA acceptance.

Challenges

1. Complex Disease Landscape: The rare pediatric disease presented unique challenges, requiring a deep understanding of both the disease and regulatory pathways.
2. Expedited Timeline: The client sought Priority Review to fast-track the approval process, demanding meticulous preparation and adherence to stringent timelines.
3. Regulatory Strategy: Crafting a robust regulatory strategy was imperative, incorporating both Breakthrough Therapy Designation and Rare Pediatric Disease Designation to enhance the application's chances of approval.

Results:

- **The NDA submission was accepted by the FDA, marking a significant milestone in the regulatory process.**
- **The application received both Breakthrough Therapy Designation and Rare Pediatric Disease Designation, underscoring the therapy's potential to address an unmet medical need.**
- **Priority Review designation was granted, accelerating the review process and significantly reducing the time to potential approval.**

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