ProductLife
research
&innovation

PLG

Pave the route **to success** for **your Innovative Products** with PLG

Recognising the dynamic shifts in the Biotech, Pharma and MedTech industries, ProductLife Group has created a dedicated Research and Innovation offering tailored to support the dynamic needs of start-ups and established companies.

PLG
ProductLifeGroup

We have assembled a network of **domain-related experts in regulatory, market access, IP,** PhD's in biology, chemistry, clinical scientists and software engineers. They have been gathered to **design and implement comprehensive global strategies.**

Further building on our resources, PLG has connected with several associations across Europe, including academic hubs, and has a partnership with EIT Health, allowing us access to k**ey resources and methodologies** to support more robust validations and seek investor funding on behalf of our clients.

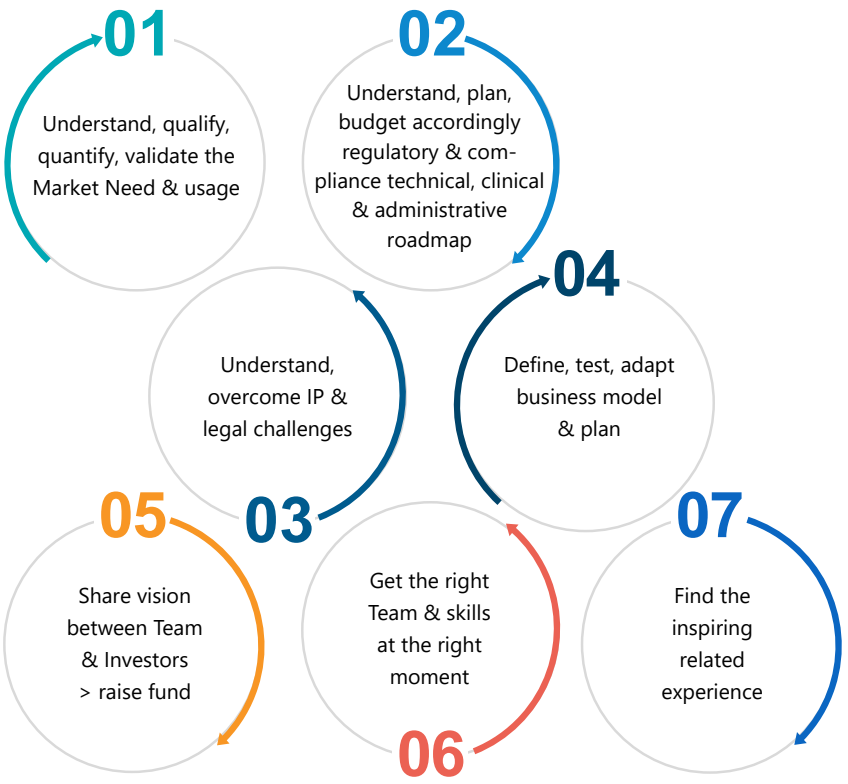
PLG has also enhanced our h**uman and scientific networks with technological resources.** We have an arsenal of software and AI tools supporting clients with data management and assisting in more complex analytical projects.

Regulatory Affairs | **IPLandscape** | **Market Intelligence**

A NUMBER OF CHALLENGES TO OVERCOME

At PLG, we understand that there can be many challenges ahead as a start-up or small business.

Based on our experience, we have identified some of them and there are a few you may not have considered.



OUR TAILORED SERVICES

	Biotech & Pharma	MedTech
Global Strategy	▪ Regulatory intelligence ▪ Regulatory Go-To-Market Strategy ▪ Due diligence of existing modules ▪ Target Product Profile	▪ Regulatory: Device qualification & device classification analysis ▪ Regulatory Go-To-Market Strategy ▪ Due Diligence of Technical File
Product Compliance	▪ CMC Healthchek (TM), CMC writing (ASMF, DMF, CEP, M2.3 & M3) ▪ Manufacturing & Distribution: GMP Support, CDMO selection & Manufacturing Strategy including TPP	▪ ISO 13485 Compliance ▪ ISO 14791 Risk Management ▪ ISO 62304 SAMD ▪ Cybersecurity ▪ AI as a medical device (AIaMD), Ethics for AI
Product Development	▪ Scientific Advice Meetings: Management of SAM with targeted regulatory agency ▪ Pre-Clinical & Clinical Services: Study design, CRO selection, study management, clinical trial application, quality & safety for clinical trials	▪ Scientific Advice Meetings: Management of SAM with targeted regulatory agency ▪ Pre-Clinical & Clinical Services: Study design, Lab & CRO selection, Study Management & Clinical Evaluation (MDR) / Performance Evaluation (IVDR)
Regulatory Affairs & Operations	▪ Dossier compilation, eCTD publishing & submission ▪ Submission Management ▪ Artwork management, Readability Testing & translations	▪ Notified Body Support: First Conformity Assessment & periodic vigilance support ▪ Device Registration: MDR/IVDR compliant CE marking ▪ 510(k) / De Novo / PMA compliant FDA approval

IT Solutions

- Start-up cloud solutions: ENNOV EDMS, RIMS and ARGUS with HALO PV
- IT quality and compliance: Cloud QMS

Market Access

- Price & reimbursement analysis and strategy
- Medico-economics studies
- Marketing and commercial: Product promotion

WHY CHOOSING PLG?

EXPERTISE

PLG has both deep technical domain and transverse expertise to cover CMC, Quality, Pre-Clinical, Clinical, Regulatory, Market Access and eventually Pharmacovigilance & Safety.
Our experts keep abreast of the ever-evolving regulatory landscape and have years of experience in successfully bringing products to the market.

GEOGRAPHY

PLG's global coverage can support start-up companies in their market(s)'s analysis and selection consistently with their fundraising strategy. With our local experts, we can collect supplementary data for market analysis, pre-clinical and clinical testing, consolidating.

NETWORK

Similar to global coverage, PLG's partner network allows us to leverage on many different services, skills sets & professionals. All with the ability to help accelerate your projects: Investor and VC companies, Corporates, KOLs, CROs, CDMOs, Notified Bodies, Health Authorities as well as High-Level experts for niche products.

PROJECT MANAGEMENT

PLG is a combination of technical & managerial expertise. Our project managers have a high degree of technical knowledge. They can coordinate and handle multidisciplinary projects that require regulatory, clinical, business to work together for example. They also have multilingual skills of communication.

R&I APPROACH

We have launched a dedicated R&I department to anticipate regulatory and societal evolutions be at the forefront of technology and regulatory science innovation. We can also work together in collaborative public funded projects.

GROWTH

Our clients are usually start-up companies. These companies will grow and as they do, PLG is there to guide this growth. We encourage structural growth with the upgrading of the company's resources to cloud-based solutions. Inherent growth, where PLG can train the company's staff to grow and develop their competencies.

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