PLG ProductLifeGroup

CALLISTO PHARMA GROUP
Technical Expertise from Development to Distribution
A ProductLife Group Company

QP, RP, and EU/UK MIA licenced services

PLG's Strategic Outsourcing Solutions for GMP & GDP Quality and Compliance

Integrating with your supply chain and GMP/GDP environments

The challenges of the UK & EU regulatory landscapes require reliable qualified expertise.

Through our Callisto affiliate, PLG provides high-level outsourcing services that integrate with your supply chain and Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP) environments.

Our EU & UK Manufacturer's/Importer's Authorisation licences cover both Human and Veterinary Medicines, and with our EU MIA(IMP) licence we can support customers with the importation of Investigation Medicinal products from around the world into Europe.

Together with our robust Pharmaceutical Quality System, we can guide you through EU & UK importation and certification processes, ensuring your regulatory compliance expectations are met.

Our experienced team bridges the gap between regulatory expectation and operational reality, for uninterrupted market access while maintaining patient safety.

This quality expertise, together with our commercial and market knowledge, allows us to fully support your business needs for complete peace of mind.

Qualified Person (QP) & GMP Services

The manufacture and importation of medicines from across the globe requires a thorough awareness of the latest regulatory requirements and often requires the collaboration of several partners to ensure products are manufactured, tested and transported in accordance with their marketing authorisations and GMP requirements.

Qualified Persons must validate products certified for use in the UK and EU are compliant with Annex 16 requirements. The process involves building relationships and rigorous technical oversight to ensure requirements can be both met and demonstrated.

For many clients, maintaining their own MIA to enable importation and operating a fully functioning **Pharmaceutical Quality system (PQS)** is both cost prohibitive and a significant administrative burden.

PLG's QP services offer scalable support for batch certification and release, while negotiating the complexities of third-party manufacturing oversight, quality control testing and vendor assurance across the entire supply chain.

By providing objective, expert assessment of batch records and manufacturing data, we resolve compliance bottlenecks and ensure that only products meeting the stringent safety, quality and efficacy standards expected reach the patient.

We also offer a **contract QP service** to provide short term or longer-term support for your business to ensure your regulatory compliance and patient safety.

Through an independent review of your current processes, we can help you create a compliant, inspection-ready, **PQS,** without adding any unnecessary complexity to your operations.

Responsible Person (RP/RPi) & GDP Services

Maintaining a **Wholesale Distribution Authorisation (WDA)** demands constant oversight, robust systems and an experienced RP/RPi. Yet many companies struggle to secure the expertise required to consistently meet GDP expectations while keeping operations agile.

PLG provides **highly experienced RP/RPi's across the UK and EU,** who take full legal responsibility for your quality system. We ensure your medicinal products are stored, transported, and handled in full compliance with GDP requirements, keeping you inspection ready.

From **self-inspection and vendor qualification to deviation management and ongoing compliance support,** we manage the complexity, allowing you to focus on growing your business with confidence.

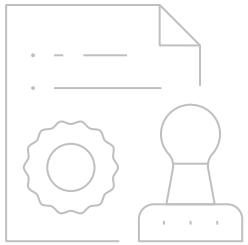
Integrated Importation Solutions

By integrating PLG's Human, Veterinary, and Investigation Medicinal products (IMP) importation licences, we provide a unified regulatory gateway that simplifies complex, multi-sector supply chains. Our infrastructure allows partners to manage diverse product portfolios through a single point of contact, significantly reducing the administrative burden of coordinating multiple third-party providers.

This synergy ensures that whether a product is a commercial human medicine, a specialised veterinary treatment, or an investigational medicinal product (IMP), it benefits from the same high standards of QP and RP oversight.

Our cross-sector expertise enables us to identify efficiencies in cross-border logistics, particularly when navigating the diverging requirements of the UK and EEA. By aligning these services, we provide a robust, scalable solution that protects your technical compliance while accelerating market access for your entire product range.

PLG's licences:



- **MIA (EU):** Human Medicinal Products into the EU
- **UK MIA:** Human Medicinal Products into the UK
- **VIA (EU):** Veterinary Medicinal Products into the EU
- **ManA (UK):** Veterinary Medicinal Products into the UK
- **MIA (IMP) (EU):** Specialist Importation and Certification of Investigational Medicinal Products into the EU

Human Medicinal Products

PLG holds both EU and UK Manufacturer's/Importer's Authorisations (MIAs), which allows us to offer a consolidated pathway for batch certification and importation that maintains full compliance across both jurisdictions.

Our dual MIA and UK MIA status enables the legal importation of human medicinal products for both markets, acting as a pre-verified regulatory bridge that significantly expedites the transfer of stock.

Within this framework, our Qualified Persons (QPs) perform mandatory batch certification under Annex16 to ensure all products align with their respective Marketing Authorisations and GMP standards.

We can also offer a contract Responsible Person (RP) and Responsible Person for Import (RPi) service to provide the necessary oversight of Good Distribution Practice, maintaining product integrity throughout the supply chain.

This integrated approach reduces the need for multiple third-party contractors and provides a direct, efficient route for cross-border pharmaceutical logistics.

Veterinary Medicinal Products

The regulatory requirements for veterinary medicines have diverged under the EU Veterinary Medicines Regulation and the UK Veterinary Medicines Directorate (VMD).

Our VIA (EU) and ManA (UK) licenses provide the technical framework required to manage these distinct systems, providing animal health companies with an efficient route to market.

VIA (EU) and ManA (UK) licenses allow the importation and assembly of veterinary medicinal products in their respective territories. These licenses serve as an established gateway, shortening times when moving veterinary stock between the UK and the EU by addressing both regulatory environments through a single partner.

Our QPs verify technical compliance and provide the final certification required for legal release, and we can also offer a contract Responsible Person (RP) service to manage the technical requirements of distribution, including cold-chain and controlled drug security.

Utilising our dual-territory presence allows for a streamlined supply chain that effectively addresses the diverging regulatory standards of both markets.

EU Investigational Medicinal Products Importation

Efficient clinical trial supply depends on reliable, compliant importation and rigorous Qualified Person (QP) oversight. By holding an MIA(IMP), PLG provides the essential regulatory framework for the importation and batch certification of Investigational Medicinal Products across the EU.

This license acts as a vital gateway, ensuring every batch meets the specific technical requirements of the Clinical Trial Regulation (CTR) to enable seamless release to trial sites.

Our experienced QPs manage the mandatory certification and documentation process, maintaining strict supply chain governance through close coordination with sponsors, CMOs, and distribution partners. By removing the operational and regulatory complexity of IMP logistics, we help mitigate the risk of trial delays and ensure your studies remain compliant and on schedule.

This integrated approach provides a direct, high-speed route for clinical materials entering the EEA, providing the necessary technical leadership to support the entire trial lifecycle from importation to site delivery.

GMP and GDP Auditing services

Maintaining compliance across complex supply chains requires more than periodic checks, it demands structured oversight and experienced judgement.

PLG delivers comprehensive GMP and GDP audit programs to assess manufacturers, distributors, and service providers against EU and UK regulatory expectations.

Our auditors combine technical expertise with practical insight, identifying risks early, strengthening quality systems, and supporting continuous improvement.

From routine qualification to for-cause and mock inspections, we help ensure your business always remains inspection-ready.

With a presence in 150+ countries, own resources in 50+ countries, and a team of over 2,000 professionals, **PLG** acts as a one-stop-shop partner for the pharmaceutical, biotechnology, medical device, nutrition, and cosmetics sectors. Our mission is to support clients in accelerating innovation, ensuring compliance, and ultimately improving human health.

From Product Development to Market & Patient Access, from Regulatory Affairs and Safety & Vigilance to Consulting & Digital, our global experts join forces to shape the future of PLG's client offering across multiple domains, including Biopharma industries, Consumer Healthcare, and Medical Devices.

With a goal of continuously improving the value delivered to people and customers, PLG is committed to long-term partnership, innovation, flexibility, and cost efficiency.

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