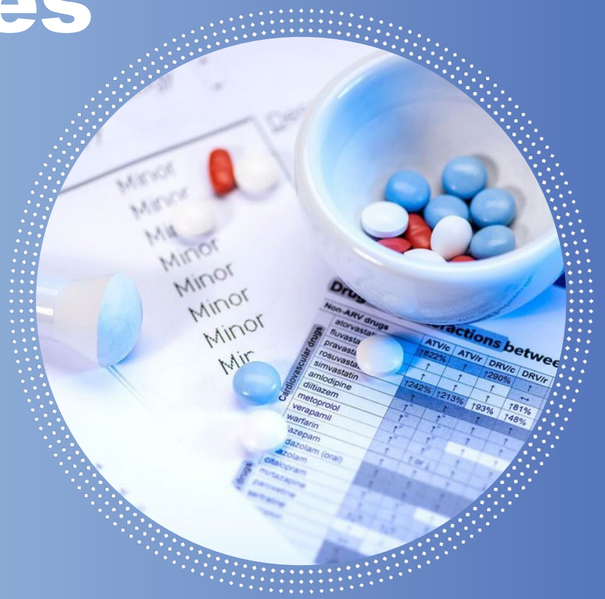
CALLISTO PHARMA GROUP

Technical Expertise from Development to Distribution

Consultancy Service Provider For Human and Veterinary, Pharmaceutical and Medical Device Industries



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ABOUT US

Callisto Pharma Group has grown from the formation, in 2003, of Callisto Regulatory Consulting Ltd, which provided regulatory and technical support to pharmaceutical manufacturers. Callisto has developed into a consultancy group that can provide a complete range of technical services across the whole supply chain within multiple regulated sectors including human, veterinary and herbal medicines, borderline products, biocides, medical devices and food supplements.

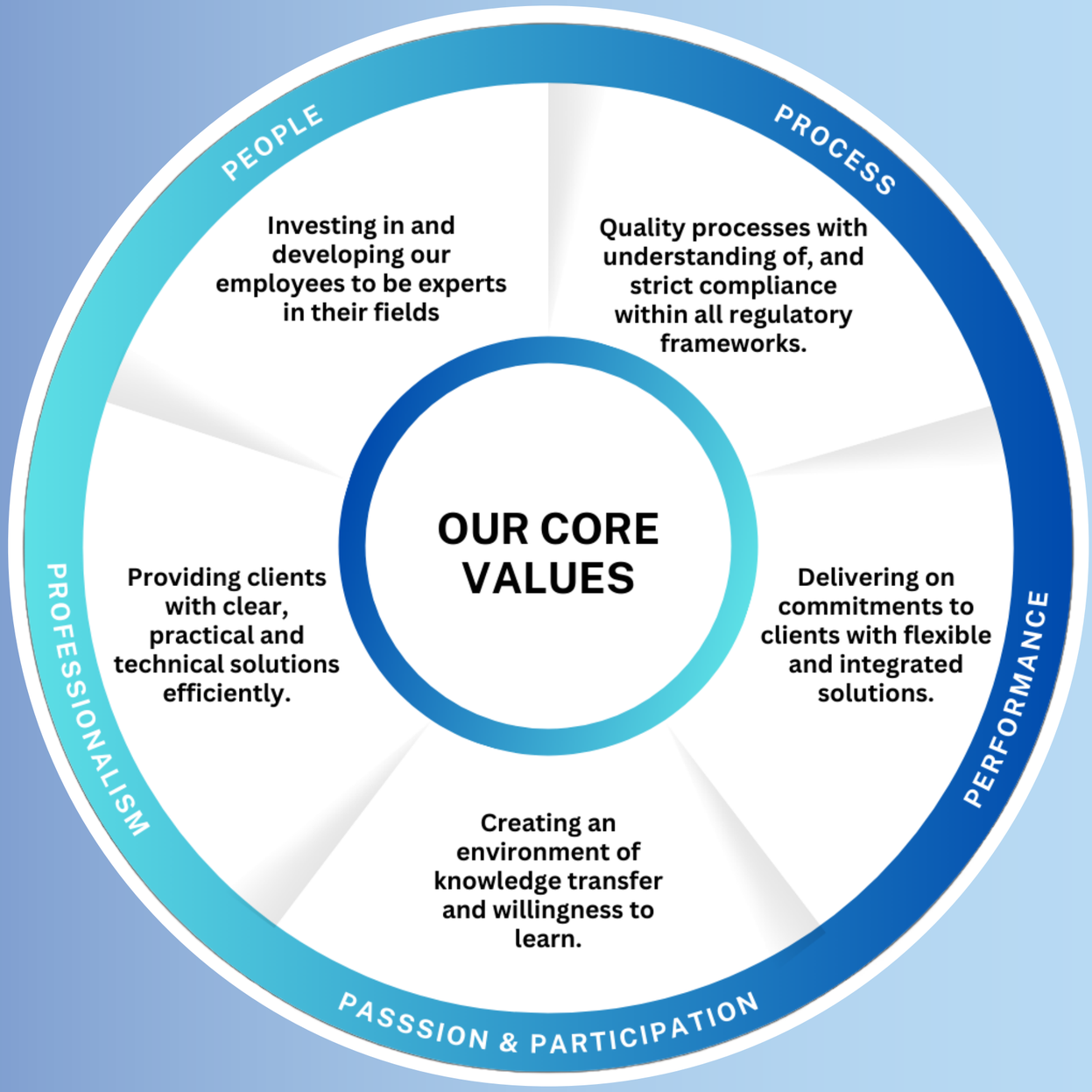
We work across the UK, Europe, and the rest of the world for clients operating in highly regulated sectors, ranging from global multi-nationals to single product licence holders.
Within the group we can provide product release and QP Technical support to manufacturers and licence holders. The group holds both an MIA and ManA granted by the MHRA to enable us to support clients wishing to import Licensed Human & Veterinary products into the UK.

An Irish group company was established 2018 in response to the UK's Brexit preparations to ensure continued services for many of our clients. We now also hold an MIA, VIA and WDA granted by the HPRA and, in conjunction with our UK licences, we maintain a European (EEA) footprint.

OUR VALUES

We invest in our people and infrastructure to enable us to be highly flexible, efficient and innovative.

We are proud of our heritage which is one of technical excellence and strong core values.



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COMPANY HISTORY & GROWTH

OUR HISTORY & GROWTH

Over 20 years of experience

2003

Having identified a potential gap in the market for consultancy services for MA holders outside of large pharma companies the company, then named Callisto Regulatory Consulting Limited, was incorporated.

2006

As its workforce continued to expand, the company established its first dedicated commercial office.

2012

In response to the demand for import and batch release services, Elara Pharmaservices Limited was founded, which held the necessary MIA & ManA to facilitate the delivery of these services.

2018

Elara Pharmaservices Europe Limited was founded and incorporated in Ireland, enabling the group to continue to provide services into Europe following the UK's departure from the European Union. The business held all relevant licenses supporting the delivery of all services to UK & overseas clients.

2019

To support its continued expansion, Callisto relocated its UK office to a larger site.

2022

The individual companies were rebranded to trade under the name Callisto Pharma Group. The change of trading name was the group's strategy to emphasise the strength of its offering across the complete supply chain.
A new office was also acquired in Ireland including an expansion of our EU workforce.

2023

Callisto continued growing rapidly, with its workforce growing to encompass 30 full time members of staff and its client base increasing to more than 100 organisations based across the globe.
Callisto also attended its first CPHI networking event in Barcelona.

2024

We continue to grow all our services and our client base. Moving into larger offices at the beginning of the year we are now 35+ employees. Callisto projects continued growth over the next 5 years throughout the range of services.

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SERVICES WE PROVIDE

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OVERVIEW OF SERVICES

REGULATORY AFFAIRS

Regulatory Services, MA Holding & User Testing

PHARMACOVIGILANCE

PV Services, QPPV & Clinical Support

BIOLOGICALS

ATMPs & Biologicals Regulatory, PV & GMDP Services

GMDP SERVICES

QP Services (GMP), GDP/RP/RPI, GxP, QMS, GxP Audit & Dev Tech

GENERAL QUALITY SERVICES

QC, QMS Support, Auditing & GMP Training

MEDICAL DEVICES

Technical Files, ISO 13485

VETERINARY

Regulatory, PV & GMDP Services

BIOCIDES & BORDERLINE

COPR & BPR AND IUCLID Dossiers

COSMETICS & FOOD SUPPLEMENTS

COPR & BPR and IUCLID Dossiers

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REGULATORY AFFAIRS

Obtaining, holding and maintaining a Marketing Authorisation requires expert Regulatory input to ensure compliance and the most effective and efficient route to market. As a Marketing Authorisation Holder, your licence is a valuable asset and we can help you obtain, protect and maintain that asset throughout the product lifecycle.

Our team is highly experienced with the UK and European regulatory bodies for human, veterinary and herbal medicines and can support all areas of the regulatory process;

- ✓ Completion of dossier due diligence and gap analysis reports.
- ✓ Preparation of regulatory dossiers for the UK, EU & other markets for a range of products including, NCE, Generic and Biological products.
- ✓ Research of available clinical data to support your chosen product and indications including generation of clinical bibliographies.
- ✓ Management of national, EU mutual recognition, decentralised and centralised procedures.
- ✓ Preparation of expert reports including Quality, Clinical and non-Clinical reports.
- ✓ Preparation of Risk Management Plans and Environmental Risk Assessments.
- ✓ Preparation of applications in vNeeS & eCTD format.
- ✓ Full range of Life Cycle management activities.
- ✓ Preparation of Product Information submissions including artwork generation.
- ✓ Reclassification applications.
- ✓ Applications for Certificates of Suitability via EDQM.
- ✓ Liaison with Regulatory Authorities including attendance at Scientific Advice Meetings.

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PHARMACOVIGILANCE

Callisto PV services and processes are scalable, meaning we can provide a full Pharmacovigilance service, that is flexible and tailored to meet your specific obligations as Marketing Authorisation Holder. Our bespoke TARA© database allows us to cater for clients with one product or hundreds of products in their portfolio. TARA© allows us to streamline our processes and efficiently manage and report your data.
We have our own in-house QPPVs and deputy QPPVs, situated both in the EU and the UK, who can develop and manage your quality systems and PV activities. We ensure you meet all compliance obligations and your patient's safety is effectively monitored and assured.

Our services include Post-marketing support and safety monitoring for all product types including human small molecules and biological products and veterinary products.

- ✓ Preparation and implementation of full quality management systems.
- ✓ Access to our bespoke Pharmacovigilance TARA© database, used for the collation, assessment and reporting of spontaneous adverse reactions.
- ✓ Electronic reporting via EVWeb and the MHRA Portal.
- ✓ Assessment of PVORs and ASPRs.
- ✓ Preparation of Periodic Safety Update Reports.
- ✓ Signal detection Safety Reports.
- ✓ Review of PVORs and ASPRs.
- ✓ Preparation of Periodic Safety Update Reports.
- ✓ Signal detection Safety Reports.
- ✓ Provison of 24-hour Qualified Person (EU & UK) and medic and medical information services.
- ✓ Production of Risk Management Plans & implementation of Risk Minimisation Measures.
- ✓ Auditing Pharmacovigilance systems and other PV related partners.
- ✓ Preparation for and assistance during Pharmacovigilance inspections.
- ✓ Provision of local contacts through our network of xxxxxx colleagues throughout EU.

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MEDICAL DEVICES

Considering the sometimes complex assessments of medical device products, we can review your products and advise as to the appropriate legislation to cover different devices in different markets, as we have extensive experience working with a range of device types and classifications.

We can support, advise and carry out the following;

- ✓ Guide and assist with data requirements, regulatory activities/applications and liaise with the appropriate regulatory bodies to ensure, where needed, that medical devices are approved by Notified Bodies.
- ✓ Advise on classification of your device and the most appropriate and efficient route to market.
- ✓ Preparation of applications for a change of classification due to a change in the product or the legislation
- ✓ We have experience in developing and implementing quality systems to support ISO 13485 and producing appropriate Technical Files and Clinical Evaluation Reports in support of CE or UKCA marking within all classification levels.
- ✓ Medical Device market surveillance, including Incident Reports and Field Safety Corrective Actions.

Current Medical Device requirements to move from MDD to MDR is something that we have built up a lot of experience with in the last number of years and are confident we can provide you with a quick and straightforward path for the transfer.

In the UK where UKCA marking came into force post Brexit, we can assist with approvals under the current and new UK MDR which is expected to be implemented in July 2025.

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VETERINARY SERVICES

- ✓ As with our human regulatory knowledge, our veterinary regulatory experts understand the best routes to market for your veterinary medicinal product.
- ✓ We can provide expert advise in regulatory strategy throughout the product development, considering your proposed target species and indications.
- ✓ Preparations of dossiers and due diligence reviews in line with the latest veterinary regulations in the UK and the EU.
- ✓ Our VIAs in the UK and EU, allow us to support you post grant of your marketing authorization with the provision of batch release services and a team of quality experts to assist with any issues that may arise.
- ✓ Our PV team can provide all the pharmacovigilance activities required such as provision of a QPPV (UK or EU), management of serious adverse events and electronic reporting to the authorities, amongst many other requirements.
- ✓ This ensures that Callisto can support you from development to distribution for your veterinary products. Callisto is set up to provide the same services with the veterinary medicinal industry as we are in human medicines.

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GMDP SERVICES

GMP Consultancy, Importation & Batch Release

Callisto Pharma Group have their own licences granted by the MHRA and HPRA enabling the importation of a wide range of human and veterinary medicinal products into both the UK and EEA. Our licences list several QC testing laboratories and storage & distribution sites, further facilitating the release and distribution of your products. Additional sites can be added as required to suit your specific supply chain. Callisto can also facilitate the importation of controlled drugs through our CD licence.
Our team of in-house QPs, supported by our QA team, provide the flexibility and responsiveness to cover any peaks or urgent supply chain demands you may have.

GDP Consultancy, RP & RPi Services

Our team of Responsible Persons (RPs) have extensive experience in Good Distribution Practice (GDP) and can provide distribution consultancy services in the UK and EEA. Through our numerous clients we have involvement in the import and export of both licenced and unlicenced medicines including controlled drugs in both territories.
We can supply from our in-house team both contract RPs and RPi's who are available to help you build your QMS and support not only your application for your WDA but provide ongoing expertise to manage your supply chain.

Additional QA Services

Callisto can also support the preparation and submission of client's MIA applications to facilitate their own importation activities.
We have a number of lead auditors in the team who can audit your API and manufacturing facilities to assure compliance with GMP requirements.

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GENERAL QUALITY SERVICES

QC Testing, Storage & Distribution

- ✓ Several QC testing laboratories and storage & distribution sites named on our licenses, further facilitating the release and distribution of human and veterinary medicinal products into the UK and EEA.
- ✓ Able to add additional sites to the licenses to accommodate particular client requirements.
- ✓ We can advise on and support the operation of your supply chain to make sure your transportation is in line with GDP.

QMS Support

- ✓ GAP analysis of existing QMS and Implementation of new QMS.
- ✓ Assistance in remediation programs.
- ✓ Initial supplier review & assessment and pre-inspection gap assessments.
- ✓ Ongoing vendor management of the entire supply chain.
- ✓ Preparation and management of Regulatory inspections and general RP services.

Auditing

- ✓ Audits of manufacturing sites, packaging sites, distributors, API, raw material suppliers and contract laboratories.
- ✓ ISO9001 and ISO13485 audits and general management of audit programs.

GMP Training

- ✓ Provide in-house training covering GMP and GDP activities

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COSMETICS & FOOD SUPPLEMENTS

Our regulatory experts can provide advise on regulations, claims and product labelling for your cosmetic and food supplement products including:

- ✓ Full review and support of manufacturing compliance.
- ✓ Review of the Formulation to confirm claims and relevant guidance and legislation.
- ✓ Review of proposed labelling to ensure compliance with the regulations and commercial requirements.
- ✓ Product Information File (PIF) compilation and maintenance for cosmetic products.
- ✓ Technical File complication and maintenance for food supplements.
- ✓ Submission of applications to the relevant authorities in the UK and EU and support through to approval.
- ✓ Ongoing life cycle management.
- ✓ Cosmetovigilance and post market surveillance.

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BIOCIDES & BORDERLINE

- ✓ Callisto can ensure that your biocidal products comply with the appropriate legislation. We can support your applications under COPR and the Biocidal Products Regulation (BPR).
- ✓ We can support with the preparation of IUCLID dossiers and provide life cycle management of the dossier.
- ✓ Our team can support with the submission and management of applications via R4BP3 and provide advice on inclusion of active ingredients under BPR and the associated regulatory obligations.
- ✓ Whilst most products clearly fall under specific legislation, some products are harder to distinguish from medicines. These products are referred to as borderline products until their status has been decided. It is the responsibility of the National Competent Authority (NCA) that determines whether a product falls within the definition of a medicine, or not. The types of products which may fall into the borderline category include Cosmetics, Food Products, Herbal Products, Biocides & some Medical Devices.
- ✓ At Callisto, we can review the available data and your product details and advise as to which legislation best fits your product and claims. We carry out this assessment with your intended commercial route in mind. We will liaise with the NCA to present your product and proposed claims and find the most efficient and cost-effective route to market for your product.

CONTACT US

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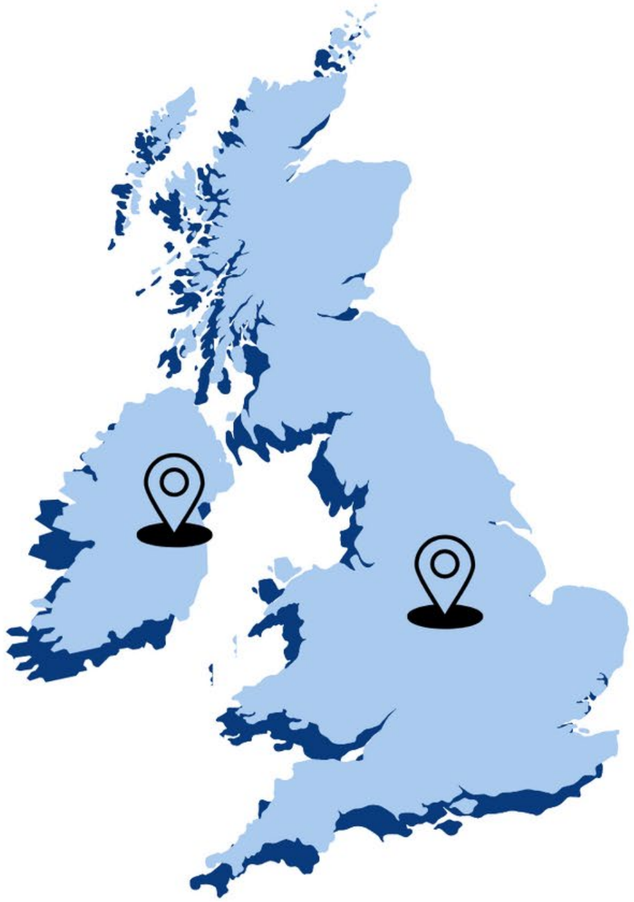

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