
ASPHALION
Knowledge from experience
Regulatory, Scientific & Safety
Consulting in Life Sciences

MISSION

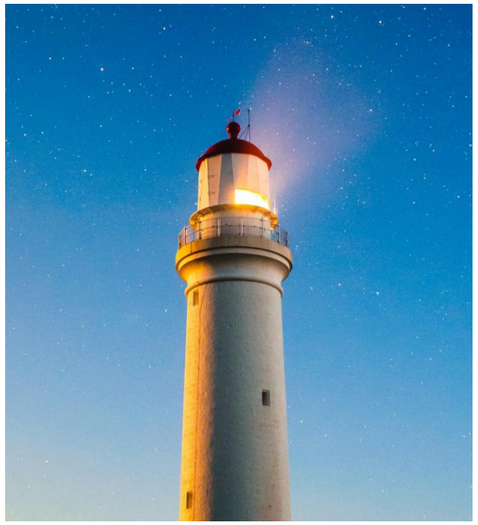
Build innovative and impactful solutions

Driven by commitment and enthusiasm, we join forces with our clients to build innovative and impactful solutions that improve people's health.

VISION

Leading consultancy

As specialized consultants, our vision is to lead innovation in the healthcare sector by integrating regulatory expertise, operational excellence, and digital technologies to deliver real value for our clients.



VALUES

Commitment

At Asphalion, commitment is the foundation upon which we build our collective success. We strengthen our internal and external connections by fostering an environment of trust, loyalty, and collaboration.

Quality

Our commitment to quality means ensuring excellence, reliability, and compliance, so that every project meets or exceeds the highest standards and client expectations, while fostering a culture of continuous improvement.

Teamwork

Teamwork at Asphalion is based on collaboration and mutual respect. We value individual contributions and foster an environment where the exchange of knowledge and skills allows us to overcome any challenge together and reach new goals.

Adaptability

We have the capacity to respond promptly and effectively to environmental changes and ever-evolving business needs, turning challenges into opportunities, fostering collaboration to develop agile solutions, and continuously innovating with each project, each client, and each challenge.

Innovation

At Asphalion, innovation is a shared mindset: thinking differently, continuously learning, and transforming how we work to create real value for our clients, our company, and society.

Purpose-Led

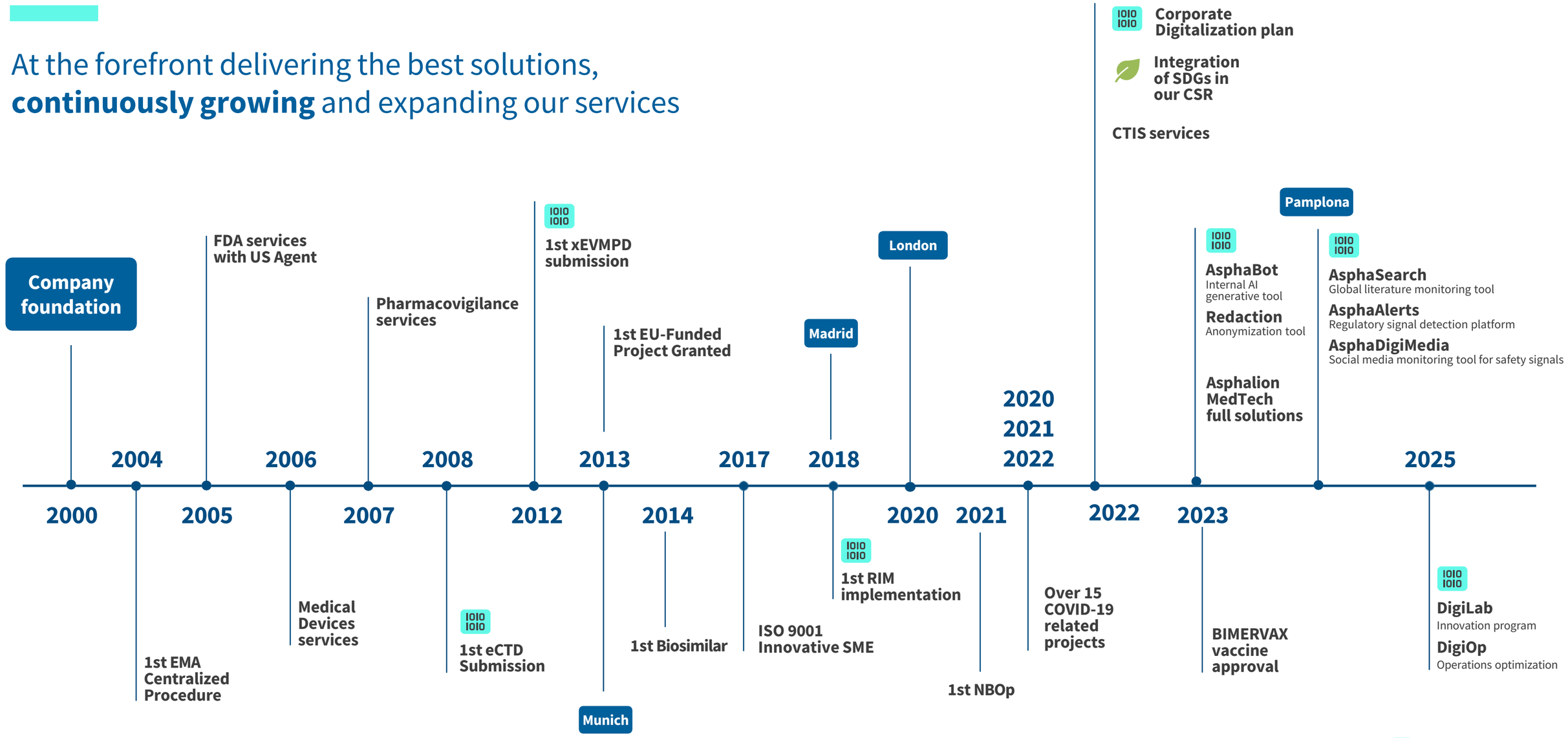
Guided by a deep sense of purpose, we approach every challenge with intention and passion. Our work is more than what we do — it's a calling to create a lasting, positive impact on health and well-being.

We are a leading consultancy and solutions provider of **Regulatory, Scientific & Safety services** with presence in Barcelona, Madrid, Munich, London, Lisbon and Milan.

25+	190+	2,500+	10,000+
Years	Team	Clients	Projects

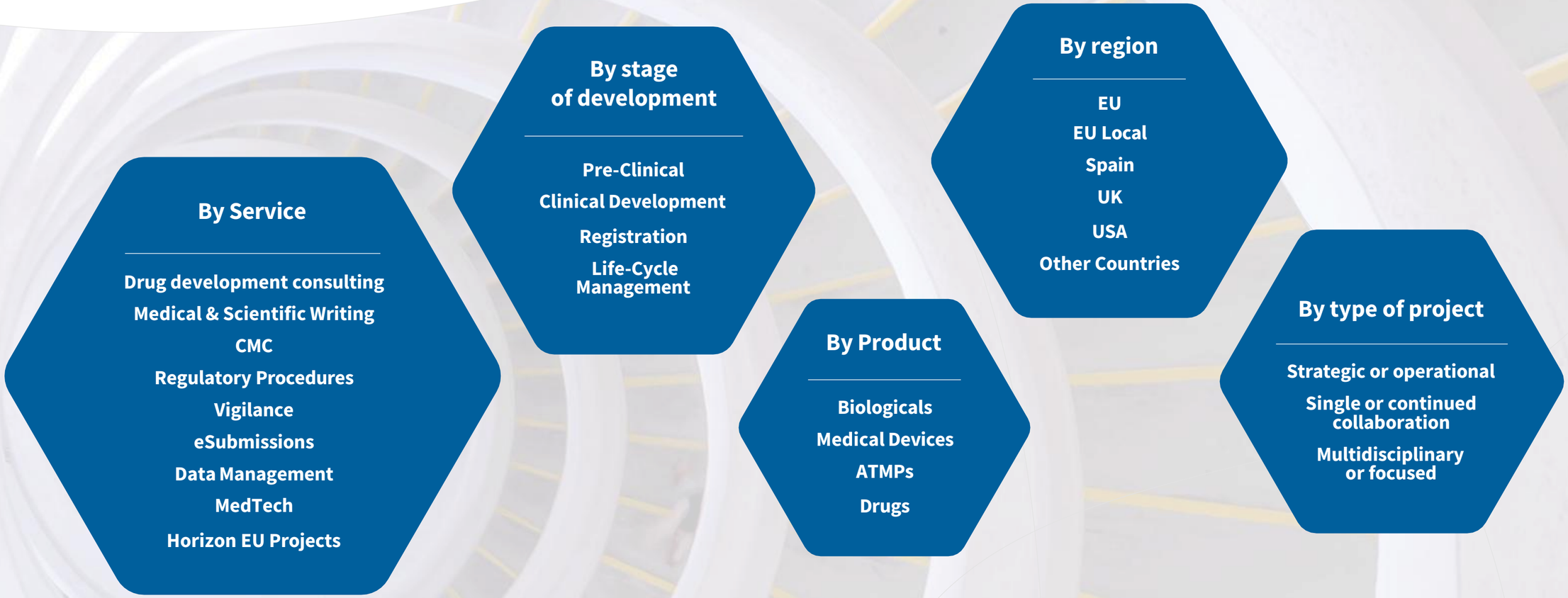
Our journey

At the forefront delivering the best solutions,
continuously growing and expanding our services



Our Solutions

Thanks to our wide scope of services we can offer you **tailored solutions** for all your regulatory and safety needs



Asphalion End-to-End support during product life-cycle

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Drug discovery → **Non-Clinical** → **Clinical** → **Dossier preparation** → **Market Authorization** → **Post-Authorization**

- Regulatory Roadmap
- Regulatory strategy
- Feasibility assessments
- Gap analysis

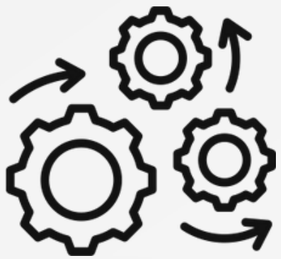
- Support in Scientific Advice meeting (EMA, FDA, NCA)
- SME & Orphan Drug designation process
- Clinical Trial Application & CTIS
- IMPD + IB
- IND, PIPs/iPSPs, GMOs
- Scientific, Medical and Regulatory writing

- Pre-submission meeting
- Medical writing for preclinical and clinical section (M2-5)
- CMC writing (M3 & M2.3)
- eCTD publishing
- Data disclosure

- EU (CP, DCP, MRP, RUP and NP); MHRA (IRP, NP); US (ANDA, BLA, NDA); ACCESS Consortium and RoW procedure management
- Translations management
- Life-Cycle management
- Variations management

CMC Gap Analysis | Feasibility Assessments | Strategic Consulting | CMC writing during development | CMC writing for registration and life-cycle

Experience



Continuous Improvement

Vision

Pharmacovigilance Drug Safety for Clinical Trials | EU-QPPV, PSMF, RMP and PV agreements | Case management, safety reports

Regulatory Operations

xEVMPD:
- New MAs
- Variations
- Investigational products (IMP)

SPOR:
- SMS
- OMS Registrations
- QC Eudravigilance registrations

ISO IDMP compliance:
- Consulting and Strategy
- Data management
- IDMP readiness
- Regulatory intelligence

Implementation of:
- CTMS, RIMS, DMS, eCTD tools, etc.
- Overall Data Management: Preparation, Migration , Validation
- Active Regulatory Review

eSubmission:
- eCTD Publishing & eSubmission
- Document & Compilation
- Software Implementation & Audits
- Regulatory Intelligence
- Trainings

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Asphalion Subject Matter Experts Overview

Our experts are also our technical project team

30+ Regulatory experts

30+ Pharmacovigilance experts

20+ Clinical & Pre-clinical writers

5+ Artificial Intelligence experts

Lidia Cánovas
Telematics Working group in **Medicines for Europe**

Laura Casals
SME for Regulatory Procedure/ eAF Management - **EMA**
Advertising of medicinal products - **AEFI**

Daniel Langa
SME for eCTD 4.0 implementation - **EMA**
RDDS WG - **MFE**
ROG - **HMA**

Pablo Núñez
ICH M4Q(R2) - **Medicines for Europe**

Ricard Andreu
Coordinator of the Drug Device Combination Working Group - **AEFI**
CMC expert

Ana Viñas
Former senior professional at the Spanish Agency for Medicines and Medical Devices (**AEMPS**)

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20+ Clinical & Pre-clinical writers

5+ Artificial Intelligence experts

Núria Romero
AI SME**- AEFI**

Diego Sanoja
New Technologies & AI Working Group - **ASEBIO**

Fran Rodríguez
Drug Device Combination Working Group - **AEFI**
Medical Devices expert

Sonia López
Pharmacovigilance Working Group - **AEFI**

Ivette Camarasa
Variations Working Group - **AEFI**

Nuria García Pazos
Appointed by **EMA** as Industry SME for Clinical Trial Information System (CTIS)

Vicente Tur
Coordinator of the Spanish Association of Pharmaceutical Industry (**AEFI**) electronic Submissions Working Group

Drug Development Consulting

Our Regulatory and Strategic Consulting team offers comprehensive support throughout the drug development process, from initial stages to market launch.

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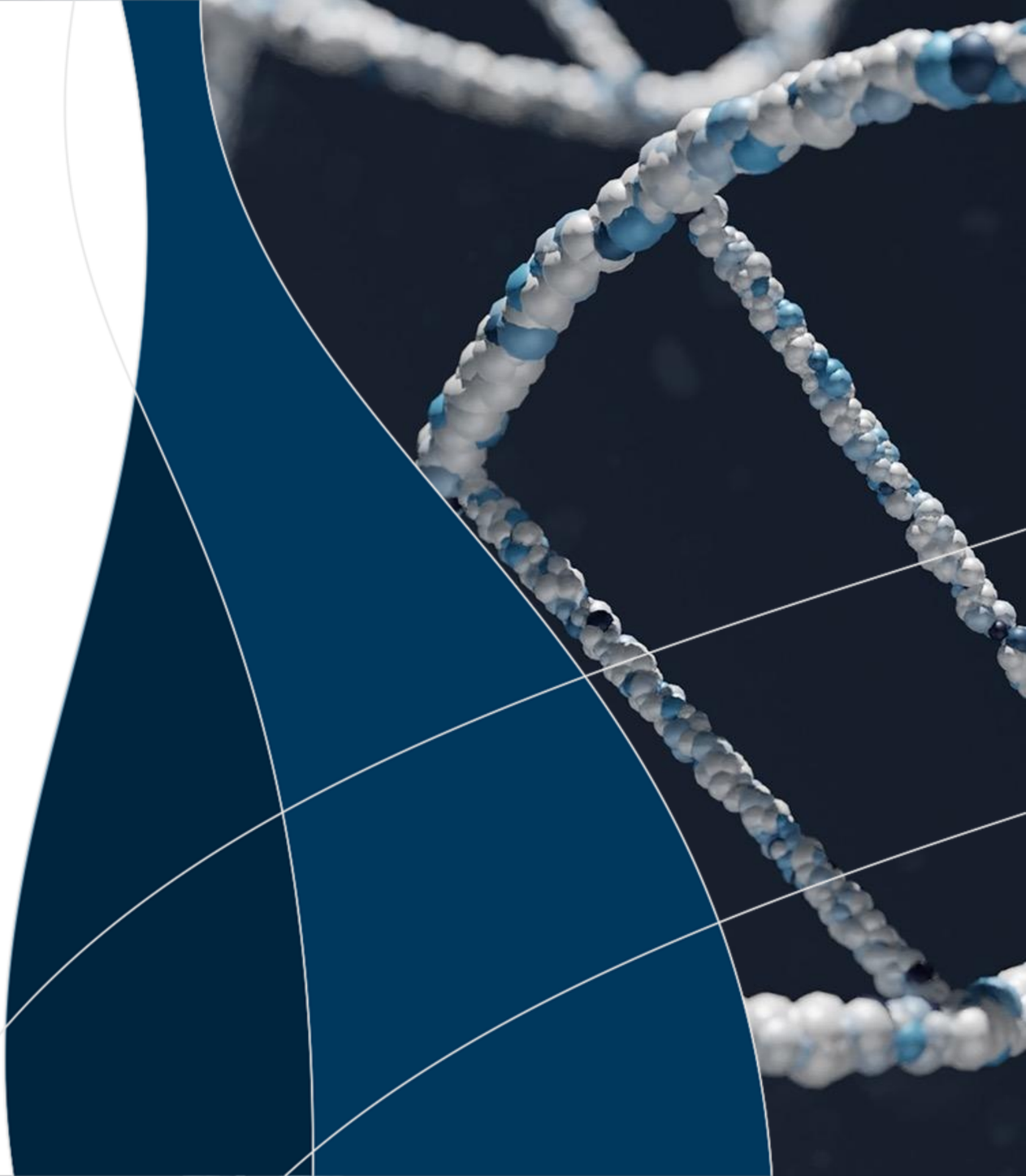
Our Drug Development Consulting solutions

We provide expert guidance and solutions in all the required areas, ensuring a seamless journey towards successful product:

- Ad hoc regulatory advice and strategic consultancy during product development
- Regulatory Roadmaps and preparation of preclinical and clinical development plans
- Feasibility assessment, including overview of timelines development and costs
- Scientific Advice meetings preparation with regulatory agencies (EMA, FDA, MHRA and NCA)
- Support in Clinical Trial Application (preparation and submission) in EU (IMPD via CTIS) and US (IND)
- Assistance in the preparation of Orphan Drugs Designation (ODD) and Pediatric Investigational Plans (PIPs) in EU and US
- Fast track Regulatory Tools (PRIME, Conditional Approval, ILAP, Breakthrough program, etc)
- Experts in EU and FDA procedures and strong expertise with ATMPS, Biologicals and Biosimilars

Medical and Scientific Writing

Our Medical and Scientific Writing team provides you with support to build the foundations of strong non-clinical and clinical developments



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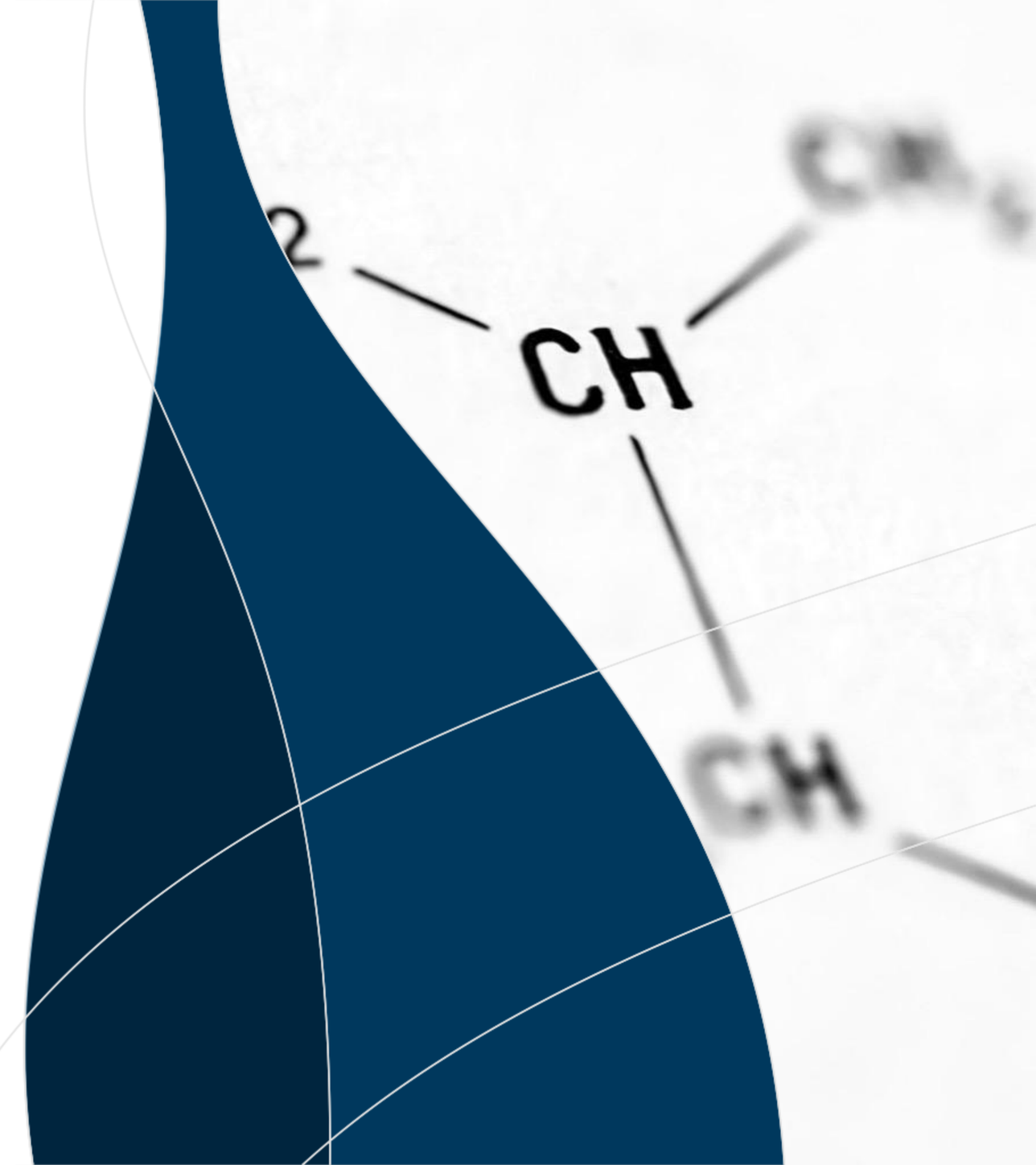
Our Medical & Scientific Writing solutions

We provide specialized expertise in key areas, ensuring a smooth and efficient path to product approval and commercial success:

- Complete Module elaboration of non Clinical and Clinical sections according to legal basis: Modules 2; 4; and 5.
- Non Clinical and Clinical Expert signatures of dossiers.
- ACOs/ANCOs
- Preparation of RMPs, PSURs and DSURs.
- Study protocol drafting and Review.
- IMPD/IND and Investigators Brochure (IB) writing
- Applications for line extensions to new indications.
- Responses to agencies and justification of questions
- Bibliographic searches and compilations to support dossiers and responses to agencies.

CMC

Complete CMC services with broad expertise for strengthening compliance and shortening deadlines



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Our CMC solutions

We can offer support during drug development, registration and Life-Cycle Management, including:

- Strategic development CMC consulting and Roadmaps Integrated with Non-clinical & Clinical development
- Gap analysis at every stage of drug development and Due-diligence of in-licensed dossiers
- Implementing and managing Quality by Design
- EU IMPD & US IND(A) – writing, review and/or updates
- Expert Reports
- Expert support on responses to Deficiency Letters
- Ad-hoc and CMC regulatory strategy
- CTD Module 3 & 2.3 writing, review and/or updates for the EU and US, including:
  - EU ASMF and US/ROW DMF
  - Certificate of Suitability to the monographs of the European Pharmacopoeia (CEP)
  - EU MAA (CP, DCP, MRP, NP)
  - US ANDA and NDA (505(b)(1) and 505(b)(2))
- Variations, renewals and notifications - strategy, writing, review and/or update of dossier
- Complete portfolio maintenance for EU, USA, Canada and ROW

Regulatory Procedures

Systematic management of regulatory procedures for optimized time to market

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Our Regulatory Procedures solutions

- Assessment of regional requirements (Module 1 for new MAA and registration procedures)
- Support and management of new Marketing Authorization Application submissions to comply with critical timelines
- Centralized Procedures (CP) in EMA
- Decentralized Procedures (DCP) and MRPs (Mutual Recognition Procedures) with all European Agencies, including support for National Phases for product information translations, mock-up review, follow-up with advisors until authorization
- National Procedures, including Fast-Track procedure
- FDA procedures (IND, NDA, BLA, ANDA)
- Global roll-out in emerging markets
- Reliable coordination of local partners for global registration procedures (ROW)
- Management of labelling
- Promotional material review
- Translations

eSubmissions

Highest efficiency in electronic regulatory publishing and submissions by using the latest tools and applying sophisticated project management

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Our eSubmissions solutions

- Conversion from paper submissions to eCTD format
- Comprehensive eCTD services (defining eCTD granularity, submission readiness assessment including quality check, eCTD readiness review and gap analysis, etc..)
- Document Formatting
- Preparing eCTD submission-ready Clinical Study Reports
- eCTD compilation and publishing
- Validation and quality control of the eCTD sequence.
- Submission of eCTD using Agencies' gateways and portals
- Project management and timeline for the publishing process
- Full life-cycle support for Europe, USA, Canada, Switzerland, Saudi Arabia, GCC, and more
- Software installation, training, validation and support
- Translation Management for Centralised Procedures
- e-regulatory specialists' implant

Data Management

Achieve efficiency by using the
latest Data Governance and E-Tools

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Our Data Management solutions

ISO-IDMP Services

- Consultancy on ISO-IDMP requirements
- Trainings to support your ISO IDMP knowledge
- Strategic input to support you succeed in your project
- Pharma data management: data collection and/or extraction, data verification, mapping and cleaning
- Finding different solutions if a RIM system is not a possibility
- Tool and process adaptation for ISO-IDMP compliance
- Data mapping with SPOR master data
- GAP analysis of IDMP readiness
- ISO-IDMP enrichment

RIM Services

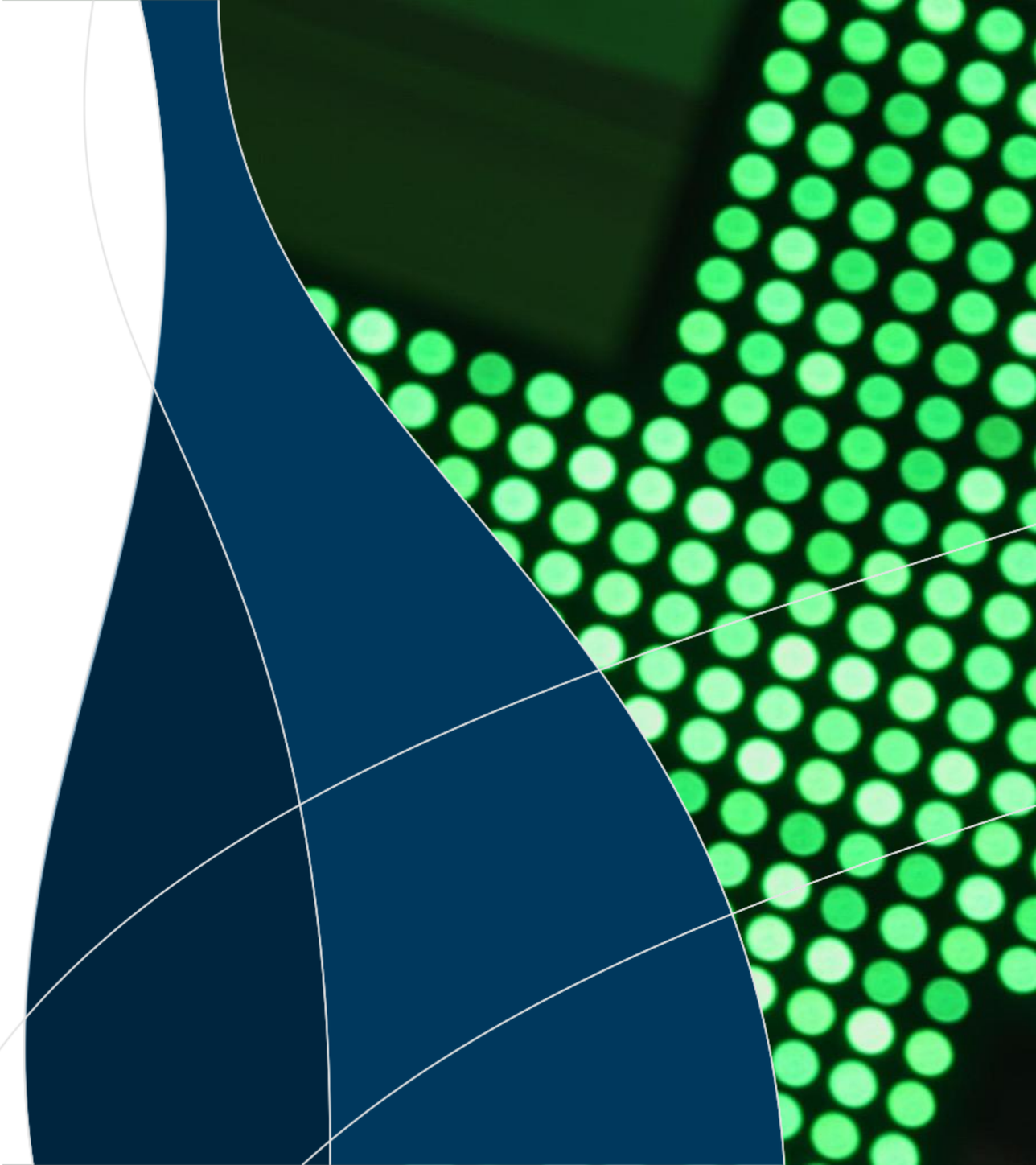
- Selection of RIM
- Migration
- Validation
- Active Regulatory Review

Project Management

- Training and training materials related to the system

Vigilance

Put your Vigilance activities in safe hands with Asphalion



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Our Vigilance solutions

Human & Veterinary Pharmacovigilance

- EU-QPPV and Deputy
- Local PV support covering all EU and RoW countries
- Global & Local Scientific Literature searches
- PSMF and PV agreements
- Aggregate Safety Reports: RMP, DSUR, PSUR/PBRER and ACO
- Management of ICSRs
- Drug Safety for Clinical Trials
- Quality system, SOPs and Audits
- Medical advisor support and medical information management
- EudraVigilance support and xEVMPD
- PV Training
- Case management using Asphalion’s validated Safety database
- Signal management
- Regulatory intelligence

Post-marketing Surveillance (PMS) for Medical Devices

- Gap analysis/audit of PMS System
- PMS SOPs definition and PMS plan
- PMS system set-up
- Scientific Literature search
- Safety alerts screening from Competent Authorities websites
- Incidents & complaints management
- Field safety corrective actions management
- Annual PMS report & PSURs & SSCP & PMSR
- Trend analysis
- Surveys
- PMCF analysis and report

QxP Audits

Compliance meets excellence

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Comprehensive GxP Audit Services

Focus

Internal / External Audits:

- Comprehensive assessments to ensure that the QMS complies with regulatory standards
- Management of customized programs, including individual audit reports and general summaries
- Follow-up: Optional review of action plans to address audit findings

Supplier / Vendor Audits:

- Qualification and monitoring of suppliers to ensure compliance and reliability
- Supplier management/Qualification program
- Follow-up: Optional evaluation of strategies to resolve audit findings
- Mock Inspections

Post-marketing Surveillance (PMS) for Medical Devices

- GxP audits and mock-inspections, including CAPA management
- GxP consulting, gap analysis, remediation activities, training and operative support
- Manufacturing/distribution licenses including Health Authorities (EU or FDA) inspections management
- Quality Management System (QMS) consultancy since designing (e.g. preparing SMF, QOS), implementing and/or just optimization
- Support in obtaining different certifications (e.g., ISO 9001, among others)

Asphalion MedTech

Our team of Medical Device consultants, will keep you ahead of market challenges and will help you meet all regulatory and quality requirements

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MedTech

Our MedTech solutions

Support in Development:

- Customized regulatory roadmaps under MDR/IVDR requirements
- Feasibility assessments and qualification & classification analyses
- Critical review of clinical and preclinical development strategies
- Regulatory product plans and reports (including design & development, risk management, verification and validation, clinical evaluation and performance evaluation, software Life-Cycle Management, biocompatibility assessment and usability).
- Support for the selection of adequate Notified Body
- Expert advice in EU-funded projects

Support for CE certification & CE maintenance:

- Gap analysis of Technical Documentation under MDR/IVDR requirements
- Compilation or update of Technical Documentation under MDR/IVDR requirements
- Writing of specific modules, including General Safety and Performance Requirements (GSPRs) Checklist, IFUs and labelling, etc.
- Writing and update of Clinical Evaluation Plans and Reports under MDR requirements
- Writing and update Performance Evaluation Plans and Reports under IVDR requirements

Support in definition or gap analysis of PMS system under MDR/IVDR requirements

- PMS implementation, including SDEA elaboration, events and complaints management, safety alerts screening, etc.
- Elaboration of PMS reports and PSURs
- Definition and implementation of action plan in regards to non-conformities from Notified Bodies

Support in definition and implementation of QMS according to ISO 13485, 21CFR820 and MDR/IVDR:

- Strategic advice for QMS definition (scope, policy, list of procedures, etc.)
- Elaboration and review of Standard Operating Procedures and other quality documentation according to Client's needs
- QMS trainings
- Management review meetings
- Online and onsite Internal Audits
- Online and onsite third-parties Audits (suppliers, manufacturers, distributors, etc.)
- Support during Notified Body Audits
- Definition and implementation of action plan in regards to CAPA

Horizon Europe

Expert regulatory partner to ensure compliance with regulatory requirements, consortium objectives, maximizing requested benefit and impact

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Horizon Europe Projects

Support in proposal preparation as regulatory expert partner:

- Advice on the alignment of project idea with call text
- Regulatory activities definition according to the scope of the project and TRL
- Regulatory work package (WP) writing including Tasks and deliverables
- Support to the coordinator through the proposal writing process

Regulatory activities during project execution:

- Regulatory roadmap and pathway definition for innovative medicinal products and medical devices for Health applications
- Early regulatory engagement with regulatory authorities for correct product development, pre- clinical and CMC data validation, and definition of best clinical strategy for future product commercialization:
  - Scientific Advice (SA) with EMA and Innovation Task Force (ITF)
  - National Competent Authorities (NCA) meetings
  - Meeting with Medical Device EC expert panel
- Continued assessment on the applicable technical standards, regulatory guidelines and ethical issues during project execution.
- Elaboration of the regulatory documentation for the preparation of a Clinical Trial application
- Preparation of regulatory workshops
- Support in the regulatory requirements for medical devices development for future CE marking

Horizon Europe Projects

Therapeutic vaccine (RIA/FP7)
Therapeutic TriMIx/mRNA-based Vaccine in Chronic HIV-1 Infected Patients on Antiretroviral Therapy.

Spiomet
This Polycystic Ovary Syndrome (PCOS) In Adolescent Girls and Young Women: Toward A Treatment Guided By Pathophysiology.

In2sight
Our aim is to act on the biocompatibility tests (ISO10993 EU norm) which are unsustainable for small-medium industries and for the society.

Tumor LN
Tumour–lymph node-on-chip platform for personalized cancer treatment.

ATMPs (H2020)
The project aims to help standardize and accelerate development of ATMPs, allowing potentially transformative treatments to reach patients sooner.

4D biomaterials for MRONJ bone regeneration
The GreenNanoBone project develops bioactive, antimicrobial 4D materials for bone regeneration to prevent and treat MRONJ, combining AI-driven design with sustainable materials to improve patient outcomes and support green industrial innovation.

Therapeutic vaccine (RIA/H2020)
Development of a Combination of Therapeutic Vaccine, Broadly Neutralizing Antibodies and Viral Reservoir Activators to Modify Latent Reservoirs in Chronic HIV-1 Infected.

Biomaterials (RIA/H2020)
Tailored elastin-like recombinamers as advanced systems for cell therapies in diabetes mellitus

Covid-19 vaccine
RBDCOV, towards a new COVID-19 vaccine for children, adolescents and immunocompromised people using a recombinant protein.

UROPRINT
Urinary bladder bioprinting for fully autologous transplantation.

Biomaterials (RIA/H2020)
Smart Bone Regeneration to improve treatment options for patients with large bone defects.

Sustainable hydrogels for fracture healing
The HYDROHEAL project develops sustainable, cost-effective hydrogels from renewable biomaterials for targeted drug delivery in fracture therapy, enabling local, stimuli-responsive drug release to improve healing, prevent infections, and support EU circular economy goals.

Microbiome & Therapeutic vaccine (RIA/H2020)
Microbiome-based stratification of individuals at risk of HIV-1 acquisition, chronic clinical complications, antimicrobial drug resistance, and unresponsiveness to therapeutic HIV-1 vaccination.

Multimodal nanoparticles
Development of a safe and highly sensitive multimodal nanoimaging agent enabling noninvasive, quantitative and longitudinal stem cell tracking and whole body biodistribution.

Gene therapy (RIA/H2020)
Development of an innovative gene therapy platform to cure rare hereditary muscle disorders.

Gene therapy (RIA/H2020)
Development of Next Generation Gene Therapies for Cardiovascular Disease.

Covid-19 monitoring
The project aims to develop a portable, non-invasive and real-time health monitoring platform for the evaluation of microvascular health in COVID-19 patients that are in intensive care units.

Targeting cancer stem cells in CRC and PDAC
The MEDICS project develops IGN116, a therapy targeting cancer stem cell bioenergetics in colorectal and pancreatic cancers, alongside scalable GMP manufacturing and GLP-ready studies to support commercialization and improve future cancer care in Europe.

Biomaterial
The FORCE REPAIR concept is based on a unique 3D printable hyaluronic acid-based self-healing hydrogel (HA-Ag-DH) with antibacterial and bioadhesive properties for chronic wound treatment.

In Vitro Diagnostic IVD
ECHiLIBRIST aims to develop and clinically validate a quantitative test for the measurement of biomarkers to improve risk stratification of fever syndromes and thus, enhance child survival.

In Vitro Diagnostic
The METHYLOMIC project will build on multiple previous cohort studies that confirmed epigenetic biomarkers as the most stringent predictor of response to biological therapy, zooming in on CD.

PV and CTIS for CT with Cell Therapy
The PragmaTIL trial aims to optimize treatment of cancer patients with Tumour-Infiltrating Lymphocytes Adoptive Cell Therapy (TIL-ACT) and substantially expand and improve the clinical implementation of this treatment modality in academic hospitals.

Establishing safe and sustainable pharmaceutical life cycles
Research and innovation contributing to sustainable future access to medicines through full life cycle approaches covering pharmaceutical design, manufacture, use, and disposal.

Cell Therapy ATMP
IMMUTOL will leverage the power of tolerogenic VitD3DC-based immunotherapy to develop a more potent and durable treatment for MS and, in turn other autoimmune inflammatory diseases with an unmet medical need.

A cost-effective combined advanced therapy
The proposed SINPAIN therapy will combine RNA technology, nanocarriers and an improved hyaluronic acid-based knee viscosupplement (IA-HA).

Biomaterial for wound healing
The NABIHEAL project will develop multifunctional biomaterials to improve wound management. The resulting biomaterials will enable affordable treatment of wound infections or prevention.

4D bioprinting for corneal repair
The KeratOPrinter project develops a 4D bioprinting platform to produce a functional, biocompatible human cornea, combining advanced bioinks, high-precision cell printing, GMP-compliant manufacturing, and early regulatory engagement.

In vivo immune cell imaging for cancer care
The VIVID project validates non-invasive imaging of immune cell dynamics in cancer patients using BEACON labelling agents and multimodal ^{19}F MRI, supporting personalized cancer therapies and clinical translation.

Why work with us

As a close, committed and **high added-value partner**, we contribute decisively to the success of your project

- Global reach
- One-stop shop, end to end services
- Tailored made solutions
- High satisfaction rate from our clients
- Solutions for high complex challenges
- We are an extension of your team
- Digital Mindset
- Solid partners network
- Expertise
- Flexibility
- Quality
- Commitment

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Testimonials

What clients say about us...

I appreciate the fact of receiving **multidisciplinary** support in the regulatory and scientific field.

Regulatory Affairs Manager
European pharmaceutical company

Thank you very much for helping us complete the submission on time, taking into account that we always send you the documents at the last minute.

Your **flexibility and dedication** are always of great help in these critical moments.

Head of Regulatory Affairs
European biopharmaceutical company

It has been my privilege and pleasure to work with many executives and my experience with you has always been **excellent**.

Couldn't ask for more!

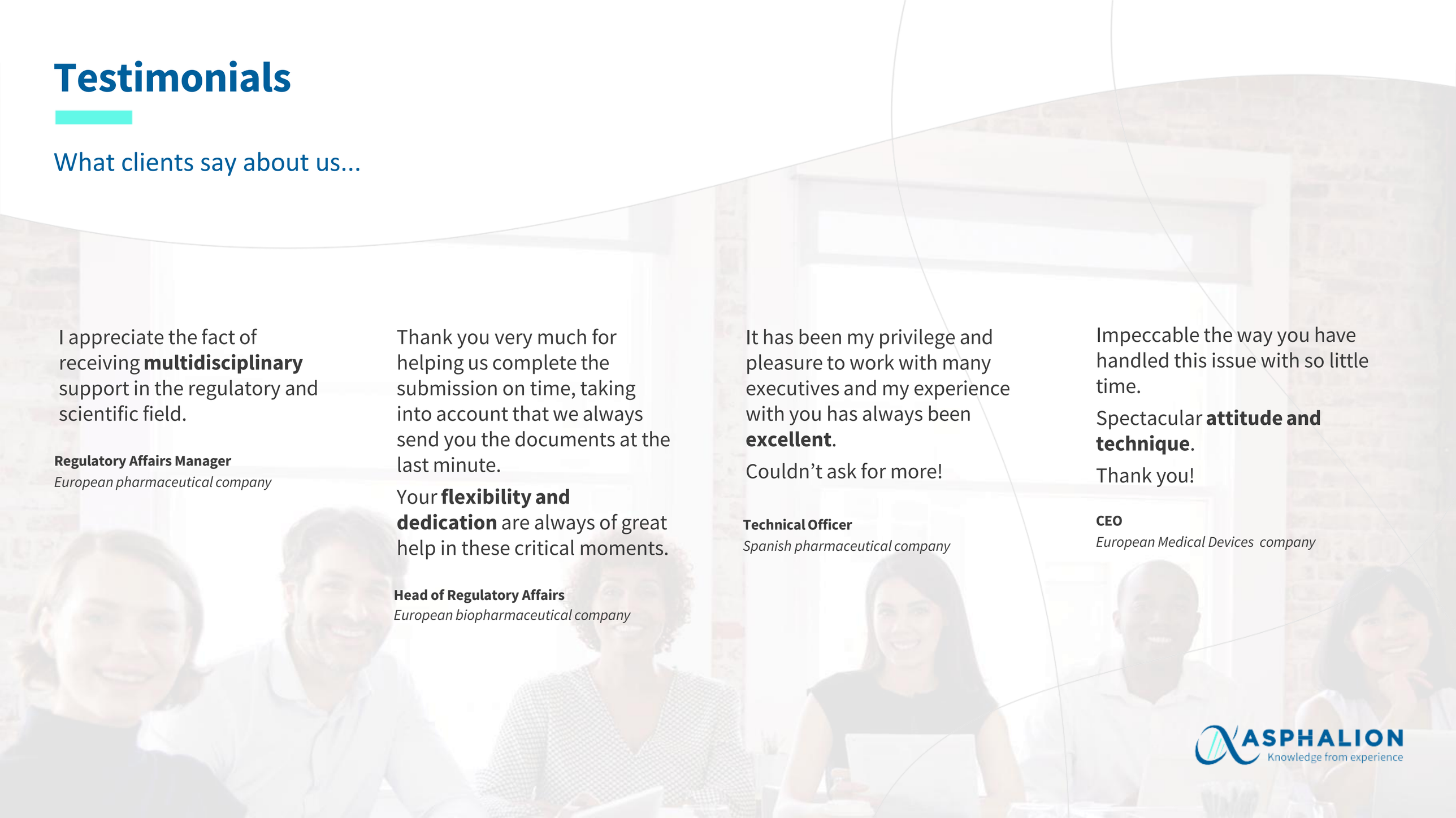
Technical Officer
Spanish pharmaceutical company

Impeccable the way you have handled this issue with so little time.

Spectacular **attitude and technique**.

Thank you!

CEO
European Medical Devices company



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Contact

In case you are interested in our services,
please contact us for more information!

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Certificates

ISO 9001:2015
ISO 13485:2016
ISO 27100:2022

INNOVATIVE SME
Valid until Dec 5th 2027

As a company committed to sustainability, we follow the UN's 2030 Agenda and its Sustainable Development Goals.

BRONZE | Top 35%
ecovadis
Sustainability Rating
DEC 2024

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