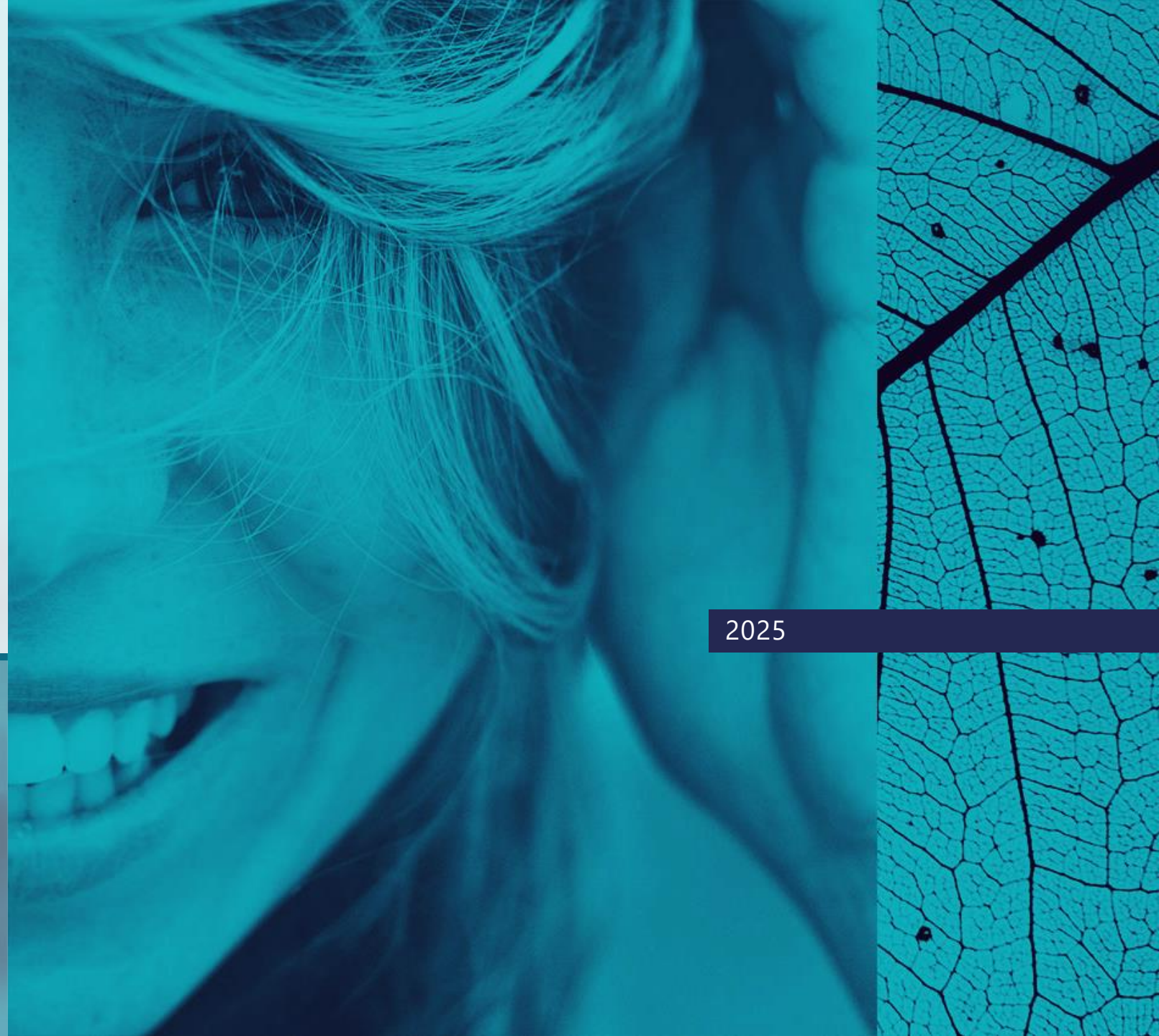
PLG
ProductLifeGroup
MEDTECH & CONSUMER HEALTHCARE

Services presentation BU Medtech & Consumer HealthCare



2025

Nutrition, Cosmetic, Medical devices

AGENDA

1. PLG at a glance
2. BU Medtech and Consumer HealthCare
3. PLG Network and Advocacy
4. Catalogue of services

Support patient access to safe and effective healthcare solutions by delivering worldwide consulting and outsourcing services through the entire product life.

PLG
ProductLifeGroup

Key Figures

150
COUNTRIES covered

2000
GLOBAL TEAM OF COLLABORATORS

60
NATIONALITIES

Dedicated **CSR Social Ambassadors**

55%
WOMEN AMONG OUR EMPLOYEES

1000
CLIENTS

Large & midsize BioPharma, and HealthTech* organizations

Inclusive Leadership with our **Shadow Board**

SILVER 2023 ecovadis Sustainability Rating

CERTIFIED ISO 9001:2015 COMPANY

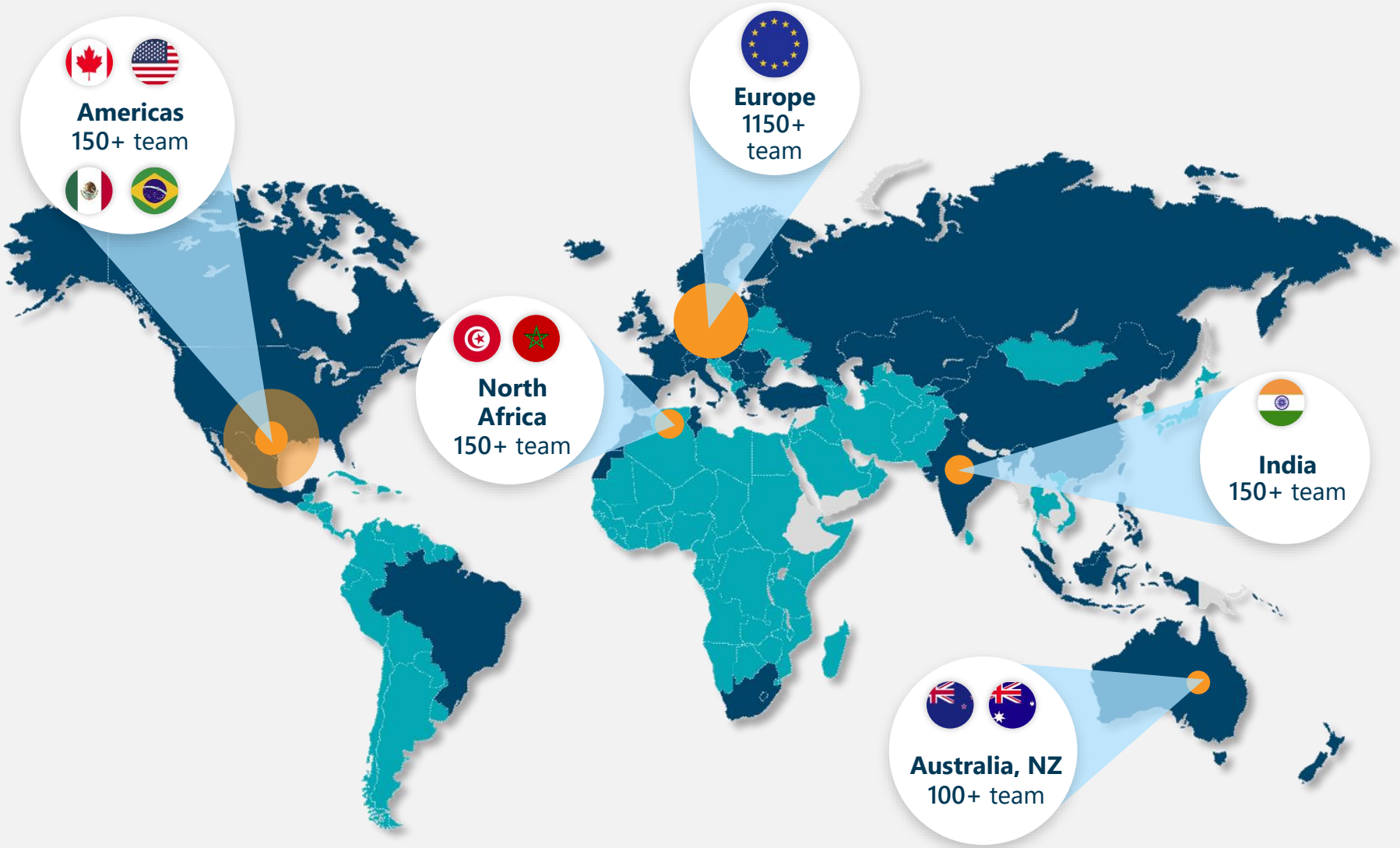
*Healthtech including MedTech, Biotech, e-Health startups

PLG AT A GLANCE

PLG Global Footprint

150+ countries

PLG own resources in **50+ countries**



PLG SERVICES & SOLUTIONS

One-stop-shop Platform delivering end-to-end solutions

Product Development

*All services related to **all phases of the development of healthcare innovations** until **market introduction**.*
*These include both **strategic and operational support for regulatory, scientific (CMC, clinical, non-clinical), and medico-economic activities.***

Life-cycle Management

*All services related to the **global roll-out and maintenance of established or innovative products portfolios.***
*These include **regulatory, vigilance and quality & manufacturing compliance activities at both central and local levels.***

Consulting & Digital

*All services that can help any company's **functions define their strategy and operate their business & digital transformation** as well as **M&A, market entry strategy and operational excellence.***

4 HEALTHCARE SECTORS

BIOPHARMACEUTICAL

- **Biotech and chemical medicines** *(innovative, established, generics, OTC/Rx)*
- **Advanced therapies** *(cell & gene therapies)*

MEDICAL

- **MedTech** *(medical devices, diagnostics)*
- **Medical procedures** *(diagnostic, therapeutic, aesthetic…)*

NUTRACEUTICAL

- **Food** *(common, enriched, novel)*
- **Food & dietary supplements**
- **FSMP** *(food for special medical purpose)*

COSMETIC

- **All types of cosmetics** *(with EU vs US specificities)*
- **Borderline products** *(regulatory pathway strategy across the 4 sectors)*

PLG VALUE PROPOSITION

Product Development

Bio Pharmaceutical

- **Regulatory science and global development strategy** (incl. consultations with agencies)
- **Full CMC development and related QA & QP services** (incl. interaction with CDMOs, EU batch certification and release)
- **Nonclinical development** strategy consulting & operational support
- **Clinical development** strategy consulting & operational support
- Assistance **to market access** at global and local level
- **Regulatory procedures and documents:** briefing packages, ERA, PDE, ODD, PIP, biowaivers CCDS / CCSI…
- **Medical writing & publishing:** IND / CTA, (A)NDA / BLA, all eCTD modules, study reports
- **Clinical trials applications** management
- **Marketing Authorization procedures** management (EU CP / DCP / MRP, US NDA / BLA)

Medical Device

- **Product classification and regulatory strategy**
- **Quality Management System (ISO 13485):** gap analysis and remediation support
- **MDR / IVDR compliance** (incl. files updating)
- Support with **technical documentation:** GSPR, risk management, usability, biological & clinical / performance evaluation
- **Clinical evaluation studies**
- **Notified Bodies:** scouting, selection, and coordination
- **Registration**: CE marking (EU), EUDAMED, 510K / PMA (US)
- **EU / UK authorized representative and PRRC** (Person Responsible for Compliance), **US FDA Agent**
- **Post marketing** surveillance **(PMS)** and clinical follow up **(PMCF)**

Consumer HealthCare

- **Regulatory strategy including borderline issues** (balance between innovation, regulatory status, claims and compliance)
- **Product development** (regulatory and scientific analysis at all stages)
- **Scientific, medical and toxicological expertise** (individual ingredients and finished product safety and performance)
- **Labels and promotional materials** review and compliance
- **Quality and post-marketing surveillance** (audits, complaints management and vigilance)
- **Marketing authorization / notification** (dossier preparation)
- **EU / UK responsible person**
- **Worldwide expertise** for regulatory requirements and assessment
- **M&A due diligences**

PLG VALUE PROPOSITION

Life Cycle

Regulatory Affairs & Operations

- **Worldwide interaction** with **Competent Authorities**
- **Global geographic roll-out** (submission strategy, dossier preparation, submission and follow-up)
- **MA lifecycle management** (incl. administrative, safety and CMC variations, renewals…)
- **Global E2E central and local outsourcing** (incl. geographic roll-out and lifecycle management)
- **Global regulatory intelligence and training**
- **Labelling and artwork** management (incl. readability testing)
- **Regulatory software** set-up, validation and management (EDMS, eCTD, RIMS…)
- **Regulatory information and document management** (IDMP, publishing, data entry, submission management, translations…)
- **Legal compliance**

Safety & Vigilances

- Full pre- and post-market **safety and vigilance consulting** (incl. PV systems set-up, validation and management)
- **Case management**
- **Qualified person** for PV (EU QPPV, Local QPPV, LSO)
- **Medical literature monitoring and screening** (local and global)
- **Global E2E central and local outsourcing** (incl. case management, literature monitoring, QPPV)
- **Clinical trials** safety support
- **Signal detection and risk management** (development and implementation of strategies and plans)
- **Quality and compliance:** assistance with audit/inspection preparation and training
- Full **Medical Information** services

Quality & Manufacturing Compliance

- Quality Management Systems (**QMS**) set-up, validation and management
- Quality risk management (**QRM**)
- Commissioning, Qualification and validation (**CQV**)
- Computer System validation (**CSV**)
- **EU and local Qualified Person (QP)** responsibility, Manufacturer's authorization
- **Interim / contract Quality Assurance**
- **Facilities engineering** (design, implementation, qualification)
- **Commercialization readiness (**incl. technological transfer, scale-up…)
- **Audits and Inspections readiness** (pre-and post-approval)
- **Remediation services (**CAPA plans, deviations, OOS…)

PLG VALUE PROPOSITION

Strategy & Digital

Strategies for Life Sciences

Along the product life cycle our strategies will help life sciences organizations achieve commercial sustainability:

- **Market and competitive analysis**
- **Market opportunity** assessment
- **Go to market** strategy
- **Pricing & reimbursement strategy**
- **Value proposition** development

We provide sound and comprehensive **support for go/no-go decisions** and beyond:

- **Due diligence** – commercial, access, regulatory
- **Target screening** for partnerships and licensing
- **Post merger Integration**
- **Fund raising** readiness for early-stage companies

Business Transformation

Building the organizations of tomorrow may involve big changes or small realignments:

- **Target operating model**
- **5-year road map**
- **Make or buy** trade-off
- **Process** mapping, process design

Creating an environment to ensure flawless execution optimizing resources and costs:

- **Industrial** excellence
- **Commercial** excellence
- **Manufacturing** footprint
- **Change management**

Digital & IT Services

Experts in **accelerating the digital transformation** of life sciences organizations to **build efficient business models**:

- Digital **vision**
- Digital **road map**
- **Process mapping**
- Solution identification & implementation
- **AI solutions** – from use case to implementation

Specialized consultancy in **pharma IT compliance and RA/PV/QA outsourcing/Staffing:**

- **Support and maintenance**: Infrastructure Services, Veeva, Ennov, TrachWise and DocuSign support services
- **Quality, Compliance and Security**
- **Pharma IT cloud:** EDMS+QMS, Argus safety and Halo PV, test automation
- **R&D**, laboratory, clinical, safety, product supply **IT solutions**

BU Medtech and Consumer Healthcare : presentation

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PLG DNA

Focus on Consumer Healthcare Products

Why Consumer HealthCare is important ?

Contribution to the patients' quality of life.

Contribution to the customer's health through wellness and beauty,

Regulatory compliance through different regulations related to nutrition products, cosmetic products, aesthetic technologies, medical devices, biocidal products, Apps…

PLG approach

The regulatory strategy should enable any company to evaluate regulatory risks and to take into consideration the scientific, medical and social context of their products.

Our regulatory, quality and scientific team advises you on the best strategy to apply:

- Choice of the most appropriate regulatory position to adopt, considering your constraints (composition, ingredients, claims, distribution networks & country)
- Understanding the requirements related to each regulatory framework together with the differences between product categories
- Strategy for the submission of registration dossiers in Europe and abroad
- Consolidation of the regulatory positioning of your products by scientific or toxicological research
- Communicate with authorities to advocate on behalf of manufacturers.
- Supervise development projects from start to finish
- Quality audits to ensure products are being manufactured with GMP methodologies at all stages of development
- Advocacy missions

Our work method is based on solid regulatory competencies together with interactions with authorities. This enables us to understand and determine how much room there is to maneuver and the possibilities for negotiation to support your efforts.

BU MEDTECH & CHC

VALUE PROPOSITION

BUSINESS DOMAIN

THOROUGH SERVICES

We provide support throughout the **entire product lifecycle,** covering everything from development to post-market monitoring. Whether you are a manufacturer or a distributor, we facilitate the development and market entry of innovations in CHC sectors like **nutrition products, cosmetic items, aesthetic technologies, medical devices, biocidal products, and applications...**

GLOBAL EXPERTISE & TAILORED SOLUTION

With decades of experience in **navigating complex regulatory landscapes** across global markets our experts ensure that your products & processes meet the stringent compliance standards required by EC, FDA, FSA & other global authorities.

Our team provides customized solutions that address your specific needs.

VALUE

Enhance the health and quality of life of customers by promoting wellness and beauty.

PROACTIVE RISK MANAGEMENT

We position ourself as a **strategic partner** rather than just a service provider. Our collaborative approach involves working alongside your internal teams, **sharing knowledge** & co-creating **proactive risk management** strategies that ensures that potential problems are identified and mitigated before they affect product launches and or business objectives.

HOLISTIC SOLUTION

We bring together **cross-functional regulatory, scientific, medical, toxicological and quality expertise** to drive business success from product development to post-market.

This approach ensures seamless alignment across all compliance functions, reducing complexity and enhancing efficiency & consistency.

BUSINESS ENABLER

Go To Market

Beyond compliance

Beyond regulatory and scientific assessments, we provide tailored strategies for market success complemented by essential services including Responsible Person (RP) designation and vigilance

In the loop

We conduct in-depth evaluations of your product(s), business objectives, and regulatory landscape to establish a foundation for success

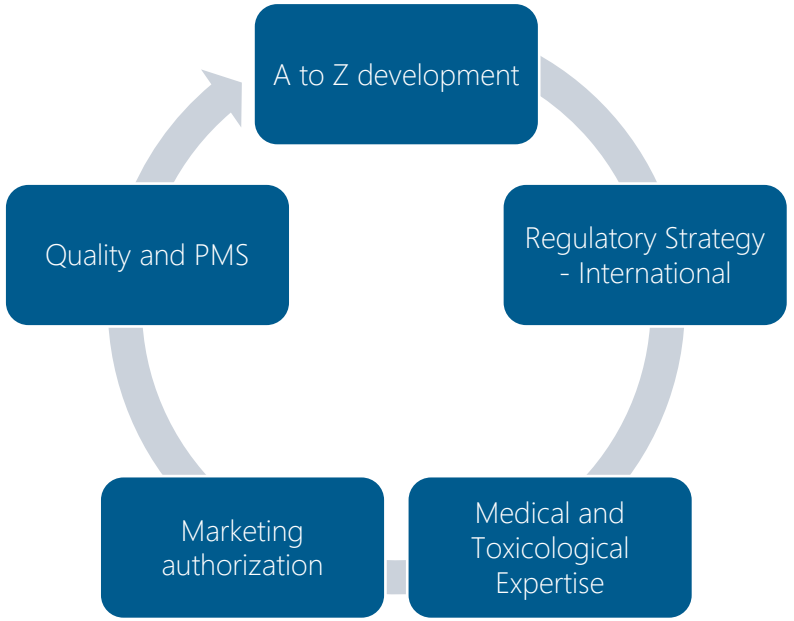
Analysis

Our dedicated team of regulatory affairs specialists, toxicologists, and scientific experts develop science-based strategies to navigate global compliance requirements

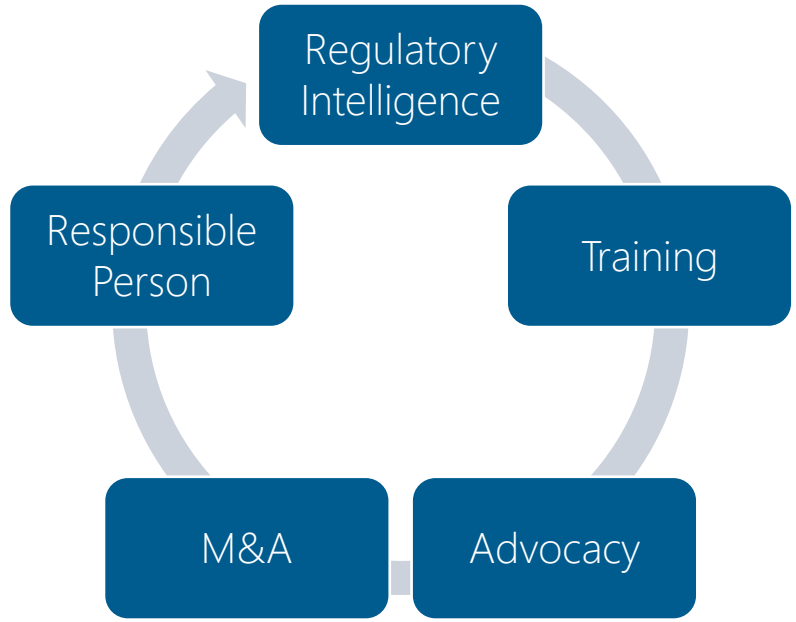
APPROACH

We developed a **tailored approach based on our client needs** and work closely to provide well-suited solutions :

for <u>their products</u>



for <u>their global strategy, knowledge, improvement and influence</u>



Our projects can be delivered :

- through consulting services with quotations, letter of missions or subscriptions.
- with insourcing services, mainly through remote referent/principal consultant

We cater to all the verticals mentioned here plus **borderline products**

Self-care Medical Devices	Nutraceuticals	Cosmetics	Borderline
			Biocidal /CLP/detergents Petfoods/feeds Drugs (THMPs) Goodies & Other self-care products

Regulatory, Quality Affairs
Science

Focus on Nutrition, Cosmetic, Medical device and beauty device services

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Wide breadth of service offerings in key industries

Regulatory Strategy / International Expertise

- Balance innovation with regulatory compliance
- Regulatory assessments worldwide

Product development

- Regulatory and scientific analysis to ensure compliance, safety and efficacy at all stages

Scientific, Medical & Toxicological expertise

- Validation of the safety and performance of your products

Label – Advertising

- Validation of promotional materials, labellings

Marketing authorizations

- Drafting of marketing authorization dossiers (ingredient, finish products)

Quality and PMS

- Quality audits (on site/products)
- Complaint management and vigilance

Due diligence for M&A

- Invest with confidence

Advocacy missions for our clients :

- Defending the company's interests with public decision-makers and regulatory authorities.
- Understanding and anticipating regulatory changes, mastering public decision-making processes, and implementing influence strategies.
- Engaging with various professional associations in Europe and on the international stage.

Food and nutritional product services : development, regulatory and claim supports

New Products: food – nutrition products – food supplements – medical foods – ingredients - additives

- Regulatory strategy: determination of the best regulatory pathways /status taking under consideration indications, distribution channel, formulation, active compounds, countries of marketing
- Theorical Development: composition and/or active ingredients (based on targeted claims, targeted diseases, medical recommendations, nutritional recommendations) *(Dietitian/Nutritionist/ Ph D Nutrition Team)*
- Investigation into the quality and conformance of raw ingredients including nutrients, chemical substances, botanicals and their extracts
- Determination of most suitable regulatory status for your finished products
- Analysis of potential borderline issues
- Compliance of formulation to applicable local or international regulations (worldwide)
- Determination of health and nutritional claims
- Auditing to ensure adherence to HACCP standards for manufacturing facilities

Labels and Promotional materials

- Creation of label and packaging content (required regulatory mentions)
- Validation of claims on packaging (nutritional and health claims)
- Validation of promotional content (for health practitioners and customers)

Innovation & Novel Food Project Management

- Organization and full project management of dossier writing and compilation
- Feasibility and risk assessment
- Access to RNI's database of resources containing 15 years worth of data
- Exclusive access to wide network of CROs and laboratories for novel food testing

Marketing Authorisation Requests and Post marketing Surveillance

- Reverse planning of ingredient/claims/ finished product registrations
- Drafting dossiers in conformance with applicable regulations
- Determination and management of safety and efficacy testings/trials
- Safety assessment report (*two RNI toxicologists – Eurotox and clinicians)*
- Follow-up and negotiations with authorities (national authorities; Europan Commission)
- Advocate on behalf of manufacturers
- Reimbursement request by NHS or private organization*

Food and nutritional product services : QC/QA and nutrivigilance supports

Quality Management System Implementation

- Implementation of ISO 22000, HACCP, 21CFR part 111 and international standards (Good Manufacturing practices), processus identification and standardization
- Qualification or Follow-up Audit of manufacturing facilities (CDMO, suppliers of active ingredients, additives

Quality Control Plan, Batch Release and Complaint Management

- HACCP : CCP determination, release criteria, specifications, OOS..
- Quality control : batch release (final products, raw materials)
- Quality Complaint Management (customer complaint)
- Labelling Quality Control (change control, first batch)

Nutri-vigilance

- Nutrivigilance case management : process for non serious and serious cases involving medical or scientific assessment/reviewer
- Assessment on file
- Assessment /Cases requiring oral and written follow-up
- Worlwide Management

Cosmetic product services : regulatory, claim and safety supports

Regulatory Affairs : Compliance of ingredients and formulation

- Regulatory strategy: determination of the best regulatory pathways /status taking under consideration indications, distribution channel, formulation, active compounds, countries of marketing
- Analysis of potential borderline issues related to ingredients or quality/quanti formulation
- Investigation into the quality and conformance of raw ingredients
- Safety assessments of compounds and finished formulations *(toxicologist)*
- Compliance of formulation (prohibited/restricted ingredients such as preservatives, colourants, UV filters etc.)
- Change control/back-up raw material assessment

Safety Assessment Toxicological Expertise

- Safety assessments of compounds and finished formulations
- Creation of the Product Information File (PIF) in accordance with EU Regulation 1223/2009
- Creation of “corporate” PIF dossier for worldwide launch)
- Authoring of the Cosmetic Product Safety Report (CPSR) parts A and B
- Change control/back-up raw material assessment, control of impurities
- Follow-up of raw material classification
- Other standards (annex 14 – CSAR in China)

Placing on the Market

- Product notification on the Cosmetic Products Notification Portal (CPNP) for the EU and UK
- EU and UK Responsible Person (RP) for cosmetic products
- Worlwide expertise

Label and Promotional materials

- Scientific validation and proof of cosmetic product claims
- Efficacy testings: coordination, testing protocol design with CRO
- Creation of label and packaging content (required regulatory mentions)
- Validation of promotional content (for health practitioners and customers)

Cosmetic product services : QC/QA, microbiology and vigilance supports

Quality Management System

- Implementation of ISO 22716 (Good Manufacturing practices), processus identification and standardization
- Declaration of Conformity ISO 22716
- Qualification or Follow-up Audit of manufacturing facilities (CDMO, suppliers of active ingredients based in Europe or outside
- PLG auditors certified
- Change control/back-up raw material assessment, packaging

Quality Control

- Batch release (raw materials or finished products)
- Stability review
- Quality Complaint Management

Product Development and Manufacturing process: from challenge tests to microbiological contamination control

PLG microbiologists with an in-depth experience in formulation, manufacturing facilities maintenance and qualification:

- Development of robust formulation against microbiological contamination
- Determination of characterization testings and challenge tests
- Stability study design
- Qualification of equipment's and water installation, follow-up and maintenance
- Making decision of packaging solution (compatibility with formulation, compounds, etc.)
- Technical support for formulation optimization and preservative system identification
- Expertise on presentive system (in-depth knowledge in preservatives and multifunctional preservatives)
- Engineering Support: design of a production workshop / analysis laboratory
- Drafting specifications for the purchase of equipment/ materials
- Microbiological analyzes (challenge test, cleaning verification, sterility test etc.)
- Identification of microorganisms / maintenance of bacterial strains

Cosmetovigilance

- Cosmetovigilance case management : process for non serious and serious cases involving medical or scientific assessment/reviewer
- Assessment on file
- Assessment /Cases requiring oral and written follow-up
- Worlwide Management

Medical Device - Topical and Aesthetic Solution supports

New Products, New Aesthetic Technologies, New Apps:

- Regulatory strategy: determination of the best regulatory pathways /status taking under consideration indications, distribution channel, formulation, active compounds, countries of marketing
- Analysis of potential borderline issues related to ingredients or quality/quanti formulation
- Investigation into the quality and conformance of raw ingredients
- Safety assessments of compounds and finished formulations (two RNI toxicologists)
- Biocompatibility strategy
- Clinical strategy (equivalence or clinical trial approach)

Label, IFU and Promotional materials

- Scientific of medical indications
- Usability testings
- Coordination of clinical trials and post marketing clinical surveillance
- Validation of label, IFU, promotional materials

Placing on the Market and EC certification

- Technical File writing (all parts)
- Notified body choice and management
- EC certification management
- PMS procedure and follow-up, change control procedure
- Local notification, European notification
- Complaint management & Materiovigilance

Quality, Auditing, Due Diligence

- Documentary Audit and Due Diligence of Legal Manufacturer and Medical devices (Owned Brand label)
- On-site or remote GMP audits in accordance to ISO 13485
- Qualification or follow up audits of suppliers, manufacturers and the supply chain
- Assist manufacturers to adopt the relevant quality standards
- Design / Conception parts

Selfcare Medical Devices - Topical and Aesthetic Solutions

Assisting you at all stages of the medical device product development and certification (class I, IIa, IIb and III)

PLG NETWORK

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ADVOCACY DEPARTMENT

PLG for the future

- Be active and recognized as experts in leading trade and scientific associations
- Defending positions and promoting ideas within the profession to be part of the change

Advocacy Missions

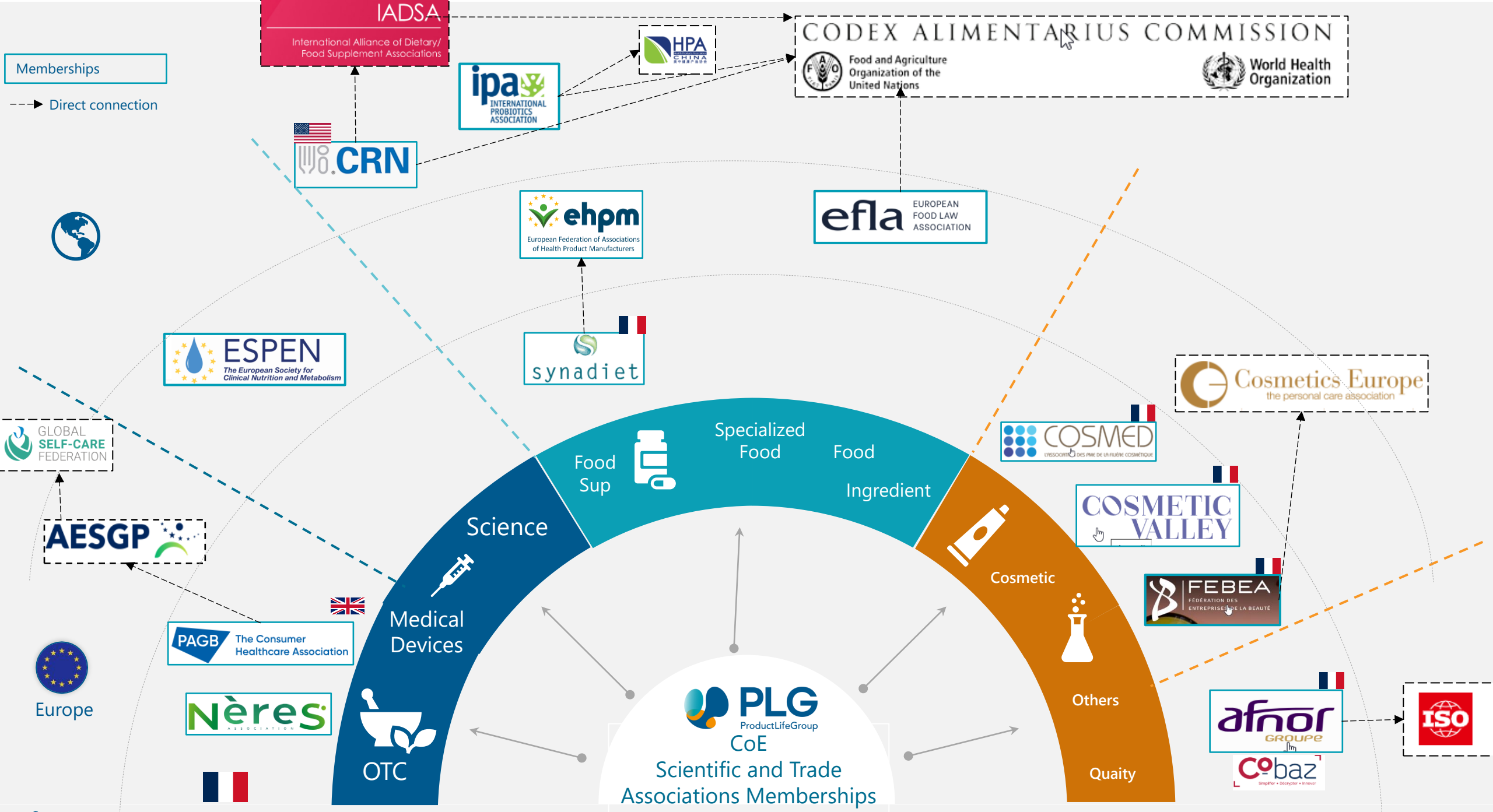
- Mastering public decision-making processes
- Representing and supporting client's and profession's interests with public decision-makers and regulatory authorities.
- Inform and influence specific audiences (general public, peers, policy-makers)

Technical and Regulatory Intelligence

- Having a clear picture of the sectors challenges
- Stay informed
- Understand, anticipate and train for regulatory changes

Thought Leadership

- Knowledge sharing as Key Opinion Leader (podiums, articles, webinars, events…)
- Raise awareness, defend a cause, promote a project


Memberships
Direct connection
IADSA
International Alliance of Dietary/ Food Supplement Associations
HPA CHINA
ipa INTERNATIONAL PROBIOTICS ASSOCIATION
CODEX ALIMENTARIUS COMMISSION
Food and Agriculture Organization of the United Nations
World Health Organization
CRN
ehpm
European Federation of Associations of Health Product Manufacturers
efla EUROPEAN FOOD LAW ASSOCIATION
ESPEN
The European Society for Clinical Nutrition and Metabolism
synadiet
Cosmetics Europe
the personal care association
GLOBAL SELF-CARE FEDERATION
COSMED
AESGP
COSMETIC VALLEY
FEBEA
PAGB The Consumer Healthcare Association
Europe
Nères
afnor GROUPE
Cobaz
ISO
Science
Medical Devices
OTC
Food Sup
Specialized Food
Food Ingredient
Cosmetic
Others
Quaity
PLG ProductLifeGroup
CoE
Scientific and Trade Associations Memberships

Catalogue of Services

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MEDTECH & CONSUMER HEALTHCARE

OFFERING NUTRITION

REGULATORY & SCIENTIFIC SERVICES

BEYOND COMPLIANCE

CORE REGULATORY / QUALITY / SCIENTIFIC PROCESS				
Ingredient Review	▪ Regulatory compliance	▪ Novel food review	▪ Scientific assessment	▪ Quality review
Formula Review	▪ Regulatory compliance	▪ Scientific Review	▪ Quality Review	▪ Batch Release
Label / Other material Review	▪ Regulatory compliance	▪ Review of voluntary mentions	▪ Mock-up/Design (Reg&Co)	▪ Review of Health Practitioners materials
Marketing authorization	▪ Drafting of dossier	▪ Submission	▪ Follow-ups with authorities	▪ Responsible Person EU/UK
Post-Marketing surveillance	▪ Review the implementation of quality processes, Complaints management, Nutrivigilance, ISO 9001/22000, FSSC 22000			

Portfolio Assessment	
Regulatory Strategy	▪ Determination of the best regulatory pathways taking under consideration indications, distribution channel, formulation, countries of marketing ▪ Advise on best status : Food, Enriched Foods, Foods for specific groups including Food for Special Medical Purposes, Food supplements
Theorical Development	▪ Composition and/or active ingredients (based on targeted claims, targeted diseases, medical recommendations, nutritional recommendations) with PLG Dietitian/Nutritionist/Ph D Nutrition Team ▪ Compliance of formulation to applicable local or international regulations (worldwide) ▪ Health and nutritional claims potential, Safety assessment reports ▪ Analysis of potential borderline issues and determination of most suitable regulatory status for your finished products ▪ Investigation into the quality and compliance of raw ingredients including nutrients, chemical substances, botanicals and their extracts & Auditing to ensure adherence to HACCP standards for manufacturing facilities (ISO 22000 / FSSC 22000)
Innovation & Novel food Project Management	▪ Organization and full project management of dossier writing, compilation and submission ▪ History of use assessment ▪ Feasibility and risk assessment ▪ Access to PLG's database of resources containing 15 years worth of data ▪ Access to wide network of CROs and laboratories for novel food testing
Labels and promotional materials	▪ Creation of label and packaging content (required regulatory mentions) ▪ Validation of claims on packaging (nutritional and health claims) ▪ Validation of promotional content (for health practitioners and customers)
Marketing authorizatons & PMS	▪ Reverse planning of ingredient/claims/ finished product registrations ▪ Drafting dossiers in conformance with applicable regulations ▪ Determination and management of safety and efficacy testings/trials ▪ Follow-up and negotiations with authorities, Advocate on behalf of manufacturers ▪ Reimbursement request by NHS or private organization ▪ Nutrivigilance – customer complaint management

Examples of projects

OFFERING Self-Care Medical Devices

REGULATORY & SCIENTIFIC SERVICES

BEYOND COMPLIANCE

CORE REGULATORY / QUALITY / SCIENTIFIC PROCESS

Feasibility	▪ Qualification as a medical device (EU & UK)	▪ Classification (I, IIa, IIb, III)	▪ Safety assessment (toxicology)	▪ Clinical assessment (intended purpose & claims)
Quality Management System	▪ ISO 13485 Implementation / auditing	▪ Process validation		
Technical Documentation	▪ Gap analysis	▪ Risk assessments	▪ Coordination of tests	▪ Full technical file writing
Market Authorization	▪ Notified body selection & submission	▪ Non-conformity audit resolution		
Post-Marketing	▪ Complaints management	▪ Advertising review	▪ PMS, PMCF, PSUR	

Portfolio Assessment

Theoretical Development	▪ Regulatory strategy and classification: Determine MDR class (I, IIa, IIb, III); justify borderline claims (e.g., drug vs. device). ▪ Substance-based device formulation and development. ▪ Mode of action analysis to confirm non-pharmacological, non-immunological, and non-metabolic effect. ▪ Biocompatibility strategy: ISO 10993 test matrix, toxicological risk assessment, exposure calculations, ADME per Rule 21. ▪ Clinical evidence planning: Develop clinical strategy (equivalence, WET), design ISO 14155-compliant clinical studies. ▪ CDMO qualification: Audit and onboard manufacturers for ISO 13485 conformity. ▪ Preclinical study planning: Absorption, toxicity, stability, usability, MoA justification.
Technical File	▪ Complete EU MDR and UK MDR Technical Documentation preparation. ▪ ISO 13485-compliant risk management files. ▪ Design and development documentation (design dossier, conception file). ▪ Expert reports: Biocompatibility assessment, clinical evaluation plans/reports (CEP/CER). ▪ PMS documentation: PMS Plan, PMCF Plan, PMS Report.
Market Authorisations	▪ Notified Body (NB) identification and qualification (with focus on oral and borderline formulations). ▪ Dossier compilation for NB submission: GSPR checklist, declarations, labelling, IFUs. ▪ Eudamed registration support.
Post Market Support	▪ Vigilance management: Complaint handling, field safety corrective actions (FSCA), batch release oversight. ▪ Post-market surveillance (PMS) activities: PMS reports, PMCF reports, PSURs.

Examples of projects

CENTER OF EXPERTISE SOLUTION

OFFERING Cosmetic

REGULATORY & SCIENTIFIC SERVICES

BEYOND COMPLIANCE

CORE REGULATORY / QUALITY / SCIENTIFIC PROCESS

Ingredient Review	▪ Regulatory compliance	▪ Toxicological Profiles	▪ Scientific assessment	▪ Quality review
Formula Review	▪ Regulatory compliance	▪ Scientific/Safety Review	▪ Quality Review	▪ Batch Release
Label / Other material Review	▪ Regulatory compliance	▪ Review of voluntary mentions	▪ Mock-up/Design (Reg&Co)	▪ Review of Health Practitioners materials
Marketing authorization	▪ Drafting of dossier : PIF	▪ Submission : CPNP	▪ Follow-ups with authorities	
Post-Marketing surveillance	▪ Review the implementation of quality processes, Complaints management, Cosmetovigilance, ISO 22716			

Portfolio Assessment

Regulatory Strategy	▪ Determination of the best regulatory pathways /status taking under consideration indications, distribution channel, formulation, active compounds, countries of marketing worldwide (**EU/USA/CHINA/etc.)** ▪ Analysis of potential borderline issues related to ingredients or quality/quanti formulation ▪ Investigation into the quality and conformance of raw ingredients / Change control/back-up raw material assessment ▪ Safety assessments of compounds and finished formulations ▪ Compliance of formulation (prohibited/restricted ingredients such as preservatives, colorants, UV filters etc.)
Theorical Development	▪ Toxicological expertise and dossiers : Safety assessments of compounds and finished formulations ▪ Creation of the Product Information File (PIF) in accordance with EU Reg 1223/2009 and Creation of “corporate” PIF dossier for worldwide launch ▪ Authoring of the Cosmetic Product Safety Report (CPSR) parts A and B ▪ Change control/back-up raw material assessment ▪ Scientific validation and proof of cosmetic product claims + Efficacy testings: coordination, testing protocol design with CRO
Labels and promotional materials	▪ Creation of label and packaging content (required regulatory mentions) ▪ Validation of claims on packaging (nutritional and health claims) and of promotional content (for health practitioners and customers)
QMS	▪ QMS / Implementation of ISO 22716 and declaration of conformity (Good Manufacturing practices), processus identification and standardization ▪ Qualification or Follow-up Audit of manufacturing facilities (CDMO, suppliers of active ingredients) ▪ PLG auditors certified ▪ Batch release / Stability review
PLG microbiologists with an in-depth experience in formulation, manufacturing facilities maintenance and qualification:	▪ PLG microbiologists with an in-depth experience in formulation, manufacturing facilities maintenance and qualification: ▪ Development of robust formulation against microbiological contamination ▪ Determination of characterization testings and challenge tests + Stability study design ▪ Qualification of equipment's and water installation, follow-up and maintenance ▪ Making decision of packaging solution (compatibility with formulation, compounds, etc.) ▪ Technical support for formulation optimization and preservative system identification ▪ Expertise on presentive system (in-depth knowledge in preservatives and multifunctional preservatives) ▪ Engineering Support: design of a production workshop / analysis laboratory ▪ Drafting specifications for the purchase of equipment/ materials ▪ Microbiological analyzes (challenge test, cleaning verification, sterility test etc.)

Examples of projects

Our team

Medical Devices and Consumer Healthcare

300+ customers

75+ experts

60% legal manufacturers

500+ projects/ year

FOR MORE INFORMATION

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