CORPORATE PRESENTATION

PRODUCTLIFE GROUP

January 16, 2023

PLG
ProductLifeGroup

AGENDA

1. A partner when and where you need one
2. PLG assets at your service
3. Our value proposition for you

Q & A section

A PARTNER WHEN AND WHERE YOU NEED ONE

PURPOSE / VISION / AMBITION

OUR...

PURPOSE

Improve human health by delivering regulatory compliance services for the **safe & effective use of medical solutions.**

VISION

Continuously improve the value delivered to our people & our partners so that we become the **leading global** life sciences **strategic partner** for **regulatory compliance**.

AMBITION FOR 2025

€ 200M revenue within the **Regulatory & Compliance Market.**
30% of our people located in **Global Operational Platforms.**
10 Strategic Accounts.
A Global Brand (Europe, N. America, APAC).

BOOSTERS

Teamwork: Diversity

Entrepreneurial mind-set: Customer oriented

Learn to learn: Continuous improvement

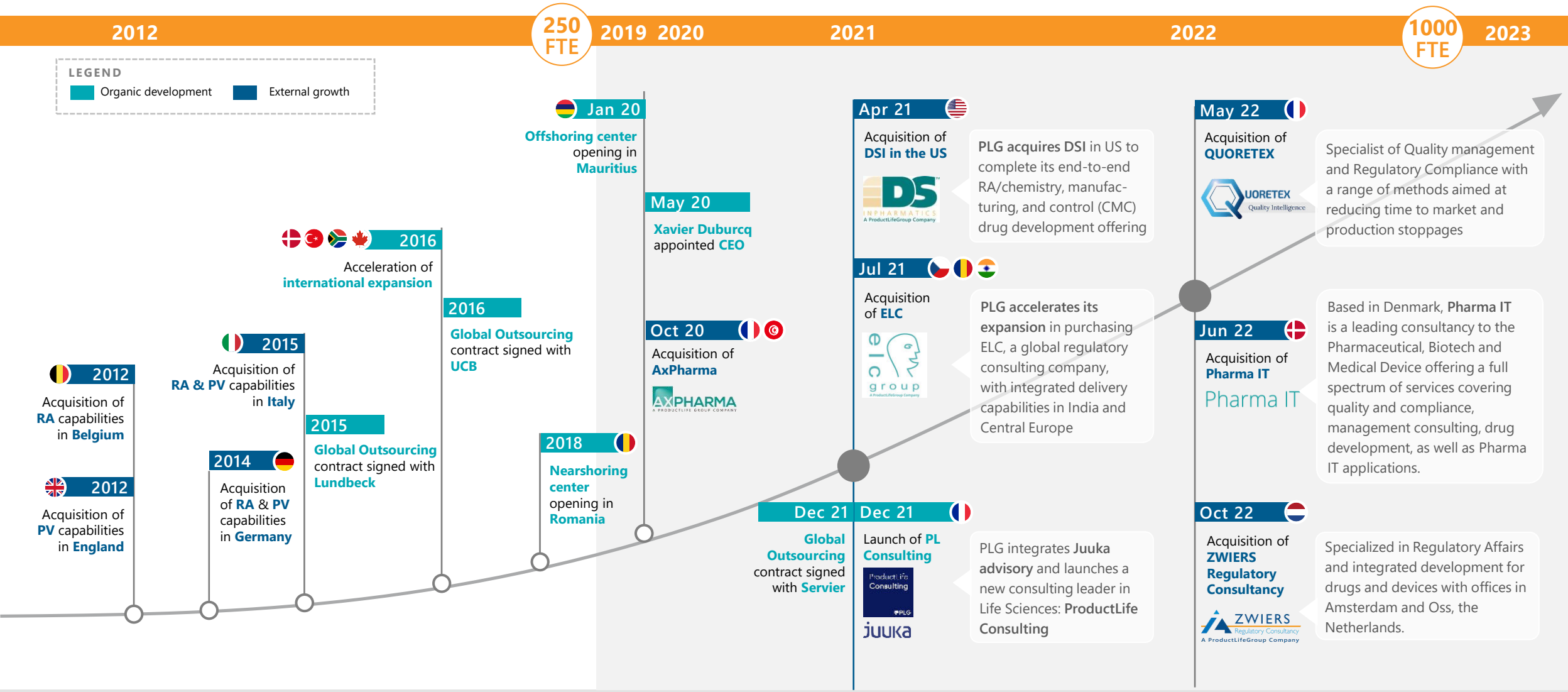
A PARTNER WHEN AND WHERE YOU NEED ONE

PRODUCTLIFE GROUP AT A GLANCE

by our experts or partners
on 5 CONTINENTS

LONG TRACK RECORD OF ORGANIC & EXTERNAL GROWTH, WITH A STRONG ACCELERATION SINCE 2020

UPDATE ON PLG



A PARTNER WHEN AND WHERE YOU NEED ONE

PLG, YOUR WORLDWIDE PARTNER

PLG covers more than

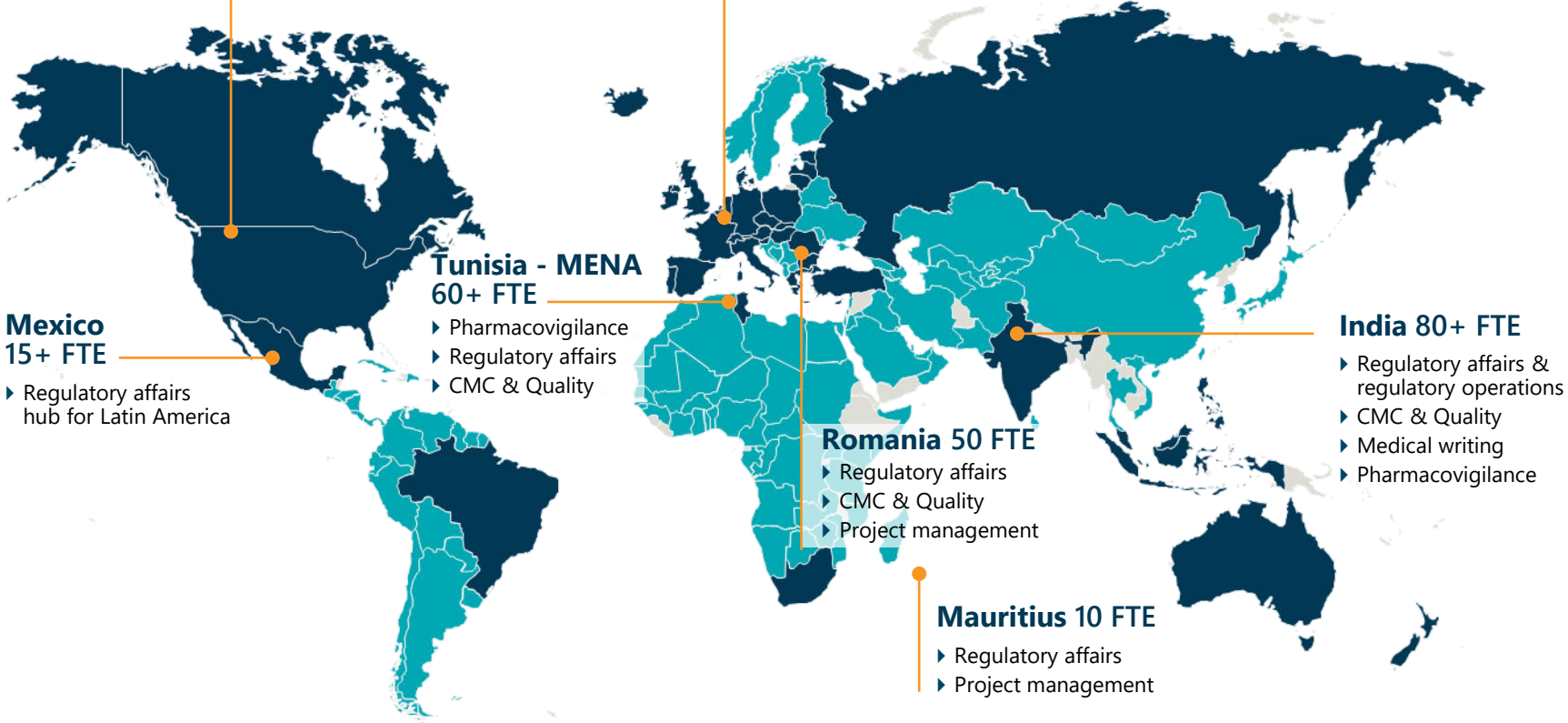
50 countries with its own resources, and more than

150 countries

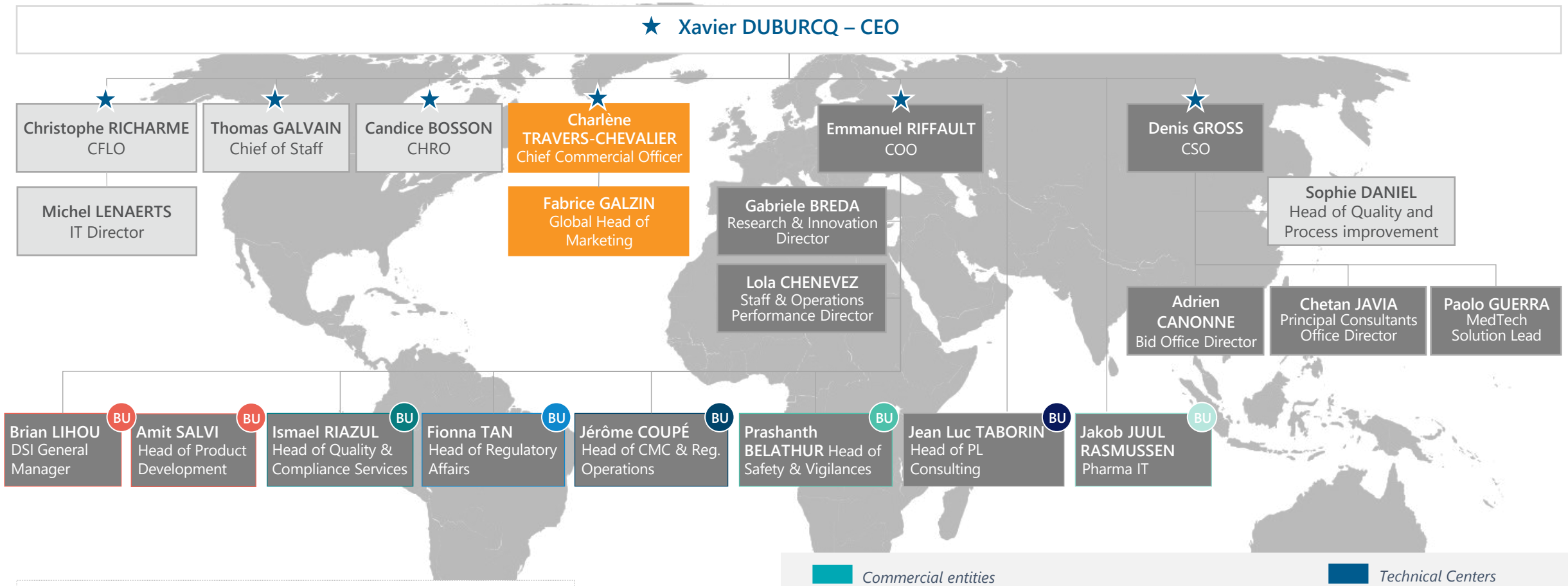
with its global network of qualified partners

5 right shoring sites

Romania, Tunisia, India, Mexico, Mauritius



ORGANIZATION ALIGNED WITH OUR AMBITION



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PLG ASSETS AT YOUR SERVICE

PLG ASSETS AT YOUR SERVICE

A SINGLE PARTNER FOR ALL ACTIVITIES

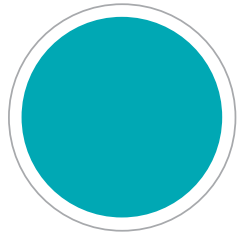
Flexible options align with client goals and needs

On-site staffing

Dedicated ProductLife Group **team or individuals**, working on-site at **client facilities** within client environment (system-process & management).

Hybrid Approach

Progressive shift from On-site staffing to full outsourcing solution, with **shared responsibilities**. This approach is **tailored to client needs and maturity**



Full Regulatory Outsourcing

Outsourcing of full regulatory activities and process established for **long-term oversight**, secured by **robust governance.**

Management of regulatory activities for filing and maintaining defined **product portfolios within defined geographies.**

PLG ASSETS AT YOUR SERVICE

ANTICIPATE AND ADAPT TO ECOSYSTEM'S EVOLUTIONS

R&I AXES

A.I. & digital transformation of regulatory and compliance

A.I., NLP, automation, optimization, advanced regulatory intelligence, master data management, IDMP…

Advanced methods for (new) product development and assessment

Quality by design, simulations, real word evidence/performance, patient centricity, health technology assessment…

Ecosystem shared value of regulatory & compliance activities

Start-ups growth, new business models, open innovation, impact of regulatory science…

NEW SERVICES

B2M "Biotech to Market"

E2E Regulatory, CMC, Compliance, Market Access, Supply Chain services to support EU market entry

Med-Tech new services

IVD: EU / UK and US

SaMD: RA & QA support during LCM

Start-ups support

Cost-efficient services to strengthen deck and strategy (regulatory/clinical gap analyses, market access, …)

PARTNERSHIPS

eit Health

Co-funded by the European Union

EIT Health is the core entity to support R&I in Life Sciences in Europe. EIT Health's Venture Centre of Excellence is exclusively recommending PLG to help expedite the navigation of regulatory barriers. PLG is also part of 2 awarded innovative projects in Med Tech.

Strategic global partnership to assist manufacturers in Biocompatibility testing (IVD & MedTech)

Tentamus Labs for Life

france biotech
biotech | medtech | e-santé | IA
LES ENTREPRENEURS DE LA HEALTHTECH

EUROPHARMSMC
CONNECTING & SUPPORTING PHARMA ACROSS EUROPE

TECHNICAL UNIVERSITY OF CLUJ-NAPOCA ROMANIA

PLG ASSETS AT YOUR SERVICE

OUR GLOBAL SOCIAL RESPONSIBILITY

We take care of our people, and our people take care of your projects

- We have built a strong and engaging environment to attract people with entrepreneurial mind-sets
- We implement and follow individual development plans, and we invest in talents in the forms of people review, trainings, and so on

OUR VALUES

We promote gender parity, and we ranked 95/100 on the Gender Equality Index

New times, improved corporate social responsibility, direct benefits for customers

- We always carefully monitored home office work even before the COVID-19 pandemic, operating at 50% remote work
- Since the pandemic this past year, our processes have matured, and we have onboarded in home offices most new employees on any project—nearly everywhere in the world—in only 2 days

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OUR VALUE PROPOSITION FOR YOU

SERVICES

OUR OFFERS AND VALUE

CONSULTING (FROM STRATEGY TO BUSINESS TRANSFORMATION)

ProductLife Consulting

PLG

- CMC dossier creation and maintenance
- Quality systems consulting and IT management
- Audits & inspections readiness
- Operational QA & QC, remediation plans
- Deviations/CAPAs/OOS
- Commissioning Qualification Validation (CQV)
- Computer Systems Validation (CSV)
- IT security and data integrity
- Medical device consulting

- Integrated CMC/RA-Q development
- Regulatory, nonclinical & clinical development strategy & operations support
- Medical writing: IND/CTA, NDA/ANDA, BLA, eCTD modules 2.4 – 2.7, 4 & 5, clinical study reports
- Regulatory documents: biowaivers, briefing packages, ERA, PDE, ODD, PIP, CCDS/CCSI,

- Global regulatory intelligence & strategy
- Dossier preparation for multiple geographies
- Global geographic rollout & lifecycle management
- Local regulatory support & local agent
- Interaction with regulatory agencies worldwide
- Healthcare compliance
- Artwork management

- IND/CTA, eCTD publishing
- RIMS with RA & PV integration (IDMP, XEVMPD, DADI, LCM etc.)
- Pharma IT organization & applications set-up, support and maintenance
- IT cloud for dedicated EDMS/PV systems
- Product labelling management
- Readability testing
- Translations

- Vigilance consulting
- Case management
- Qualified person for PV (QPPV, LQPPV, LSO)
- Medical information
- Literature monitoring (local & global)
- PV medical writing: periodic reports, clinical overviews, PSMF
- SDEA between client & partners
- Materiovigilance
- Cosmetovigilance

OUR VALUE PROPOSITION FOR YOU

PLG TOP 5 PHARMA/BIOTECH REGULATORY BUSINESS CASES

"The PLG network is very embedded—especially in Europe—& the group's experts know the different markets very well. That is why we started to work together."

"The people I work with are both experienced & experts in their fields. We prefer a single contact who can deal with all of the countries we operate in rather than have a multitude of local players."

Company	Scope of Activity	Key Figures
A BELGIAN PHARMA COMPANY	| A central–local outsourcing operating model for RA in the European Union (EU) for 32 countries in the EU plus Ukraine & Switzerland | Regulatory life cycle maintenance: Variations, approval management, artwork review, Certificate of Pharmaceutical Product, linguistic review, post approval management	Since 2018: 30 full-time equivalents (FTEs) (60 head count [HC]), 35 countries
A NORDIC PHARMA COMPANY	| A central–local outsourcing operating model for RA in the EU & internationally | Regulatory life cycle maintenance, initial filings of submissions, periodic safety update reports, & renewals | Regulatory consulting with operational rollout of new biotech product worldwide	Since 2015: equivalent to an average 30 FTEs (75 HC), 90 countries
A FRENCH GENERIC DRUG & MEDICAL DEVICE COMPANY	| Regulatory & quality compliance (good manufacturing practice) outsourcing project | Minor & major variations, including CMC variation, product quality review, technical files, & regulatory intelligence	Full portfolio (>500 APIs), 12 FTEs (16 HC)
A US PHARMA COMPANY	| End-to-End R&D support in Europe, the Middle East, & Africa | Cosmetic & medical device products (RA, RM qualification, packaging, microbiology, analytical, formulation, & system administration	Since 2006, 50 FTEs (50 HC)
A TOP 25 INDIAN GENERIC PHARMA COMPANY	| Initially started with multiple EU registrations, mostly DCP's since 2011 | Inclusive of Medical Writing, eCTD Publishing & Submission Management | Regulatory life cycle maintenance: Variations, approval management, artwork review, Certificate of Pharmaceutical Product, linguistic review, post approval management	Since 2011: Up to 5 experts, Average billing of 150 hours per month.

Source: Roland Berger interviews

CREDENTIALS

PLG/DSI TOP 5 DEVELOPMENT & CMC BUSINESS CASES

"I personally want to thank the DSI team for authoring an excellent CMC submission, answering numerous questions, & always being available to help. DSI did a great job with strategy & authoring, & the project never would have come together without DSI's project manager's leadership to completion. I will call on DSI again for the next one. Thank you, all!"

"When we speak about DSI experts, we speak of them like they are our own team members. We truly love working with DSI."

Company	Scope of Activity	Key Figures
SMALL BIOTECH COMPANY BOSTON, USA	DSI provided manufacturing, analytical, & regulatory for small & medium-sized enterprises by authoring & providing regulatory strategy for a new drug application (NDA) that included pharmaceutical manufacturing controls, control of excipients, container closure, stability, & analytical validation. The drug product was approved before the FDA's Prescription Drug User Fee Act deadline.	Up to 6 experts (150 hours a month)
VIRTUAL BIOTECH COMPANY NEW JERSEY, USA	DSI authored a Biologics License Application (BLA) for an anti-CD3 monoclonal antibody that is being developed for the delay or prevention of type 1 diabetes. The BLA was filed & accepted by the FDA. The FDA also granted the client's request for Priority Review. In addition, this engagement included the researching for & authoring of an overarching process development report.	Up to 7 experts (150 hours a month)
SMALL PHARMA COMPANY, ISRAEL	For this project, DSI supplied our client with a team of individual subject matter experts experienced in authoring & submitting successful NDAs. The gap assessment is a process that comprises many steps, & the entire process typically takes four to six weeks.	Up to 5 experts (4-week turnaround)
MIDSIZE PHARMA COMPANY NORTH CAROLINA, USA	DSI has authored multiple nitrosamine risk assessments for a client with views to both European & US marketing authorizations that include solid oral dosage & topical ointments. DSI provided the requirements & guidance for obtaining source documents from the active pharmaceutical ingredient (APIs), the excipient, & the manufacturing facilities. Using that information, DSI performed a comprehensive risk assessment for these products that met the client's needs & the regulatory requirements on schedule.	Up to 3 experts (150 hours a month)
MIDSIZE PHARMA COMPANY PENNSYLVANIA, USA	Experts in APIs support the identification & qualification of second-source vendors; validation; & registration batch manufacture. Complete quality assurance oversight of CMC operations. Regulatory strategic advice for upcoming NDA. Supply chain & logistics support for clinical operations.	Up to 5 experts (300–350 hours a month)

Source: Rol& Berger interviews

OUR VALUE PROPOSITION FOR YOU

PLG TOP 5 PHARMA/BIOTECH VIGILANCE BUSINESS CASES

"The PLG team really understood our major concerns from the beginning. The provision of relevant information regarding the ever-changing regulatory landscape allowed us to make prudent business decisions. Their communication coupled with their professionalism made for a successful project."

"PLG's flexibility & creativity to accommodate our most stringent & complex require-ments was truly appreciated."

Company	Scope of Activity	Key Figures
AN ITALIAN RESEARCH & DEVELOPMENT COMPANY	| Pre-Clinical & Feasibility studies for New Chemical Entity (NCE). | Managing their first In Human study & starting a 6-month repeated toxicology study. | Assisting the client in the Scientific Advice Meeting, Phase 2 & 3 clinical study management, Supporting ALL the activities leading to the product registration.	Since 2017: Up to 6 experts, Average billing of 250 hours per month.
A TOP 20 CHINESE BIOTECH COMPANY	| Due Diligence & Feasibility Advice for New Biological Entity (NBE) | Drafted Pre-Clinical & Clinical strategy for client's data in confirmation of the development plan for Scientific Advice Meeting (SAM) with EU Agency.	Since 2017: Up to 5 experts, Average billing of 100 hours per month.
A US BIOPHARMA COMPANY	| Local PV activities in 37 countries, including an LQPPV & a local contact person for pharmacovigilance activities who have full product oversight & additional support, a deputy QPPV, & local literature surveillance	Since 2016: 5 FTEs (40 HC)
A GLOBAL TOP 100 US/INDIAN based GENERIC pharma company	| Market Authorization Transfer of over 800 MA's in the EU. | Life Cycle Maintenance of total product portfolio. | Pivoted into providing full Pharmacovigilance support for complete generic portfolio. | Main consultancy for the provision of ongoing regulatory advice within the EU.	Since 2013: Up to 8 experts, Average billing of 300 hours per month.
A CHINESE TOP 5 PHARMA COMPANY	| First Full EU Registration, further entrusted with All New European Registrations. | Dossier preparation & provide complete Pharmacovigilance portfolio support. | FLMP: Full Life Cycle Maintenance Program.	Since 2015: Up to 6 experts, Average billing of 180 hours per month.

FOR MORE INFORMATION

CONTACT US

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