CORPORATE PRESENTATION

PRODUCTLIFE GROUP

September 01, 2021

PLG
ProductLifeGroup

AGENDA

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

A PARTNER WHEN AND WHERE YOU NEED ONE

A PARTNER WHEN AND WHERE YOU NEED ONE

PURPOSE / VISION / AMBITION

OUR PURPOSE

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

OUR BOOSTERS

- **Teamwork:** Diversity
- **Entrepreneurial mind-set:** Customer oriented
- **Learn to learn:** Continuous improvement

OUR VISION

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

OUR AMBITION FOR 2023

- Company size: Reach **1,000** head count
- Geographic coverage: Establish robust business in **North America**
- Customers: Build **key strategic accounts**

A PARTNER WHEN AND WHERE YOU NEED ONE

PRODUCTLIFE GROUP AT A GLANCE

7 out of the 10
TOP PHARMACEUTICAL COMPANIES are **our customers**

28 YEARS of experience

4 RIGHTSHORING SITES: Romania, Tunisia, India, and Mauritius

400 CUSTOMERS are

large, medium-sized, midsize, or small organizations or start-ups

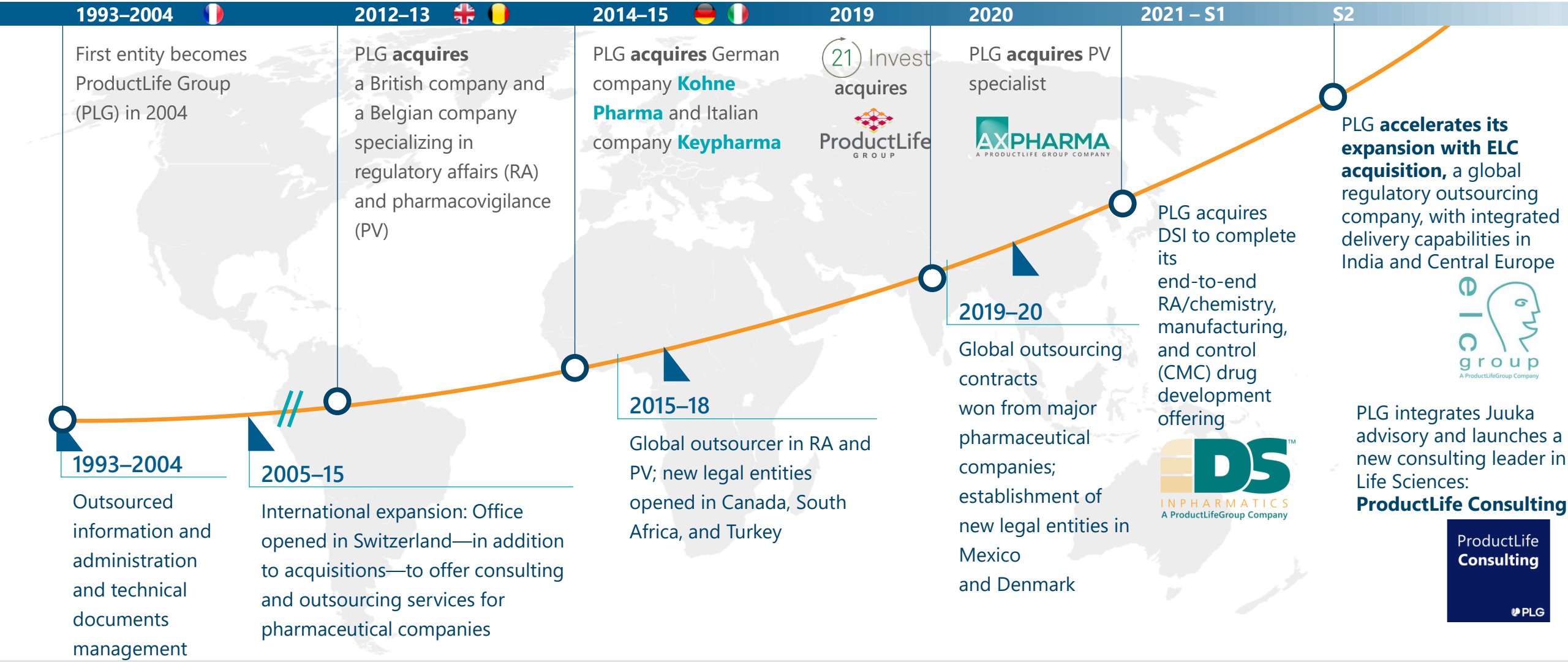
GLOBAL CAPACITY

900 EXPERTS worldwide

130 COUNTRIES covered

by our experts or partners on 5 CONTINENTS

YEAR AFTER YEAR—EXPANDING ITS SERVICES



A PARTNER WHEN AND WHERE YOU NEED ONE

PLG, YOUR WORLDWIDE PARTNER

PLG covers more than

40 countries

with its own resources

and more than

130 countries

with its global network

of qualified partners

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PLG ASSETS AT YOUR SERVICE

PLG ASSETS AT YOUR SERVICE

YOU CAN RELY ON

EXPERIENCE AND EXPERTISE

- Long-term partnership with major international life sciences players on large and complex programs such as UCB, Lundbeck, Johnson & Johnson, and Servier/Biogaran
- Listening to our customers and evolving to resolve their challenges and meet their requests
- Experts with broad and diverse experience gained over years in consulting

CONSULTING

- Strategy & Operations consulting in Life Sciences, Beauty industry & Ingredients
- ProductLife Consulting helps C-Level through a unique consulting model
- Strategy & Corporate Development, Market access, Go-to-Market, Due Diligence
- Operations: Distribution, Supply Chain, Manufacturing, R&I, Product Development
- Business Transformation and Change management

INNOVATION

- PLG is an associate partner of the EIT Health network, and it partners with innovative start-ups and IT companies to develop new digital approaches
- PLG has developed its own innovative tools such as a dual innovative solution to automate global and local literature searches in pharmacovigilance and another for automation of the monitoring of generic-products-information changes

COST EFFICIENCY

- Rightshoring: integrated delivery capability in India and nearshoring platforms in Romania, Tunisia and Mauritius
- Rightstaffing: The right level of skills at the right place at the right price
- Hybrid profiles (RA, PV,) in small countries
- Resource flexibility for your workload adjustment

GLOBAL PARTNERSHIP

- PLG has both a first-class staff and a qualified-partners network
- Single global governance
- PLG provides full support and global and local levels
- PLG has a clear understanding of relationships between corporate and local RA/PV functions

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 89/100 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 two days

3

OUR VALUE PROPOSITION FOR YOU

OUR VALUE PROPOSITION FOR YOU

OUR OFFERS AND VALUE PROPOSITION

CONSULTING (FROM STRATEGY TO BUSINESS TRANSFORMATION)

CMC and Quality

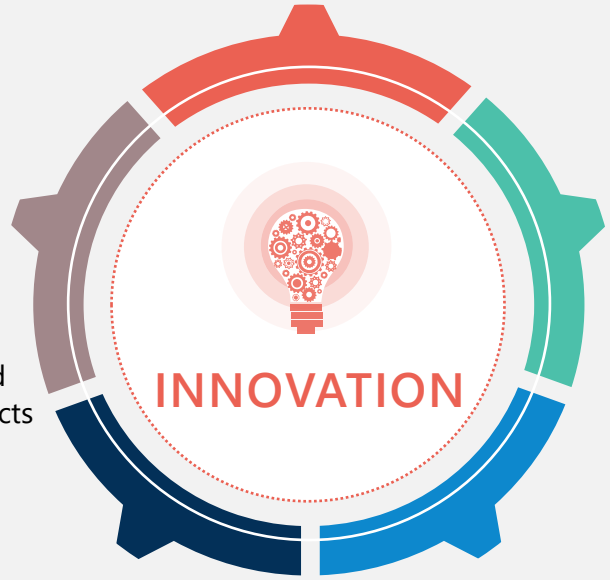
- RA CMC pre- and postapproval
- Integrated CMC development
- Quality systems consulting
- Operational quality assurance
- Audits and inspection readiness
- Management of compliance

Regulatory Operations

- Publishing
- Regulatory information management systems (RIMS) and Identification of Medicinal Products (IDMP)
- Product labelling management
- Readability testing
- Translations
- Data and document management
- Regulatory intelligence

Medical Devices

- Regulatory affairs
- Quality management
- Device vigilance
- Clinical evaluation



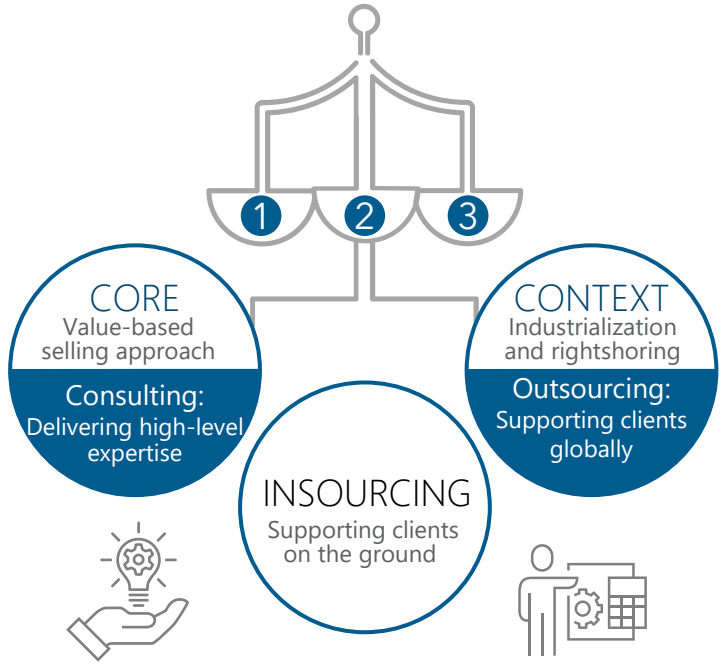
Vigilance and Medical Information

- Vigilance consulting
- Case management
- Qualified person for PV (QPPV), local qualified person for PV (LQPPV), local safety officer
- Medical information
- Literature watch
- Medical writing
- Cosmetovigilance

Regulatory Affairs

- Preapproval regulatory / development strategy and support
- Geographic rollout and life cycle management
- Interaction with regulatory agencies
- Health-care compliance
- Promotional material review

3 DELIVERY MODELS



OUR VALUE PROPOSITION FOR YOU

PLG TOP 5 CUSTOMERS BUSINESS CASES

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 and Switzerland ▪ Regulatory life cycle maintenance: Variations, approval management, artwork review, Certificate of Pharmaceutical Product, linguistic review, postapproval 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 and internationally ▪ Regulatory life cycle maintenance, initial filings of submissions, periodic safety update reports, and 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 and medical device company	▪ Regulatory and quality compliance (good manufacturing practice) outsourcing project ▪ Minor and major variations, including CMC variation, product quality review, technical files, and 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, and Africa ▪ Cosmetic and medical device products (RA, RM qualification, packaging, microbiology, analytical, formulation, and system administration	Since 2006, 50 FTEs (50 HC)
A US biopharma company	▪ Local PV activities in 37 countries, including an LQPPV and a local contact person for pharmacovigilance activities who have full product oversight and additional support, a deputy QPPV, and local literature surveillance	Since 2016, 5 FTEs (40 HC)

"The PLG network is very embedded—especially in Europe—and 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 and 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."

Source: Roland Berger interviews

OUR VALUE PROPOSITION FOR YOU: PLG'S LATEST ACQUISITION

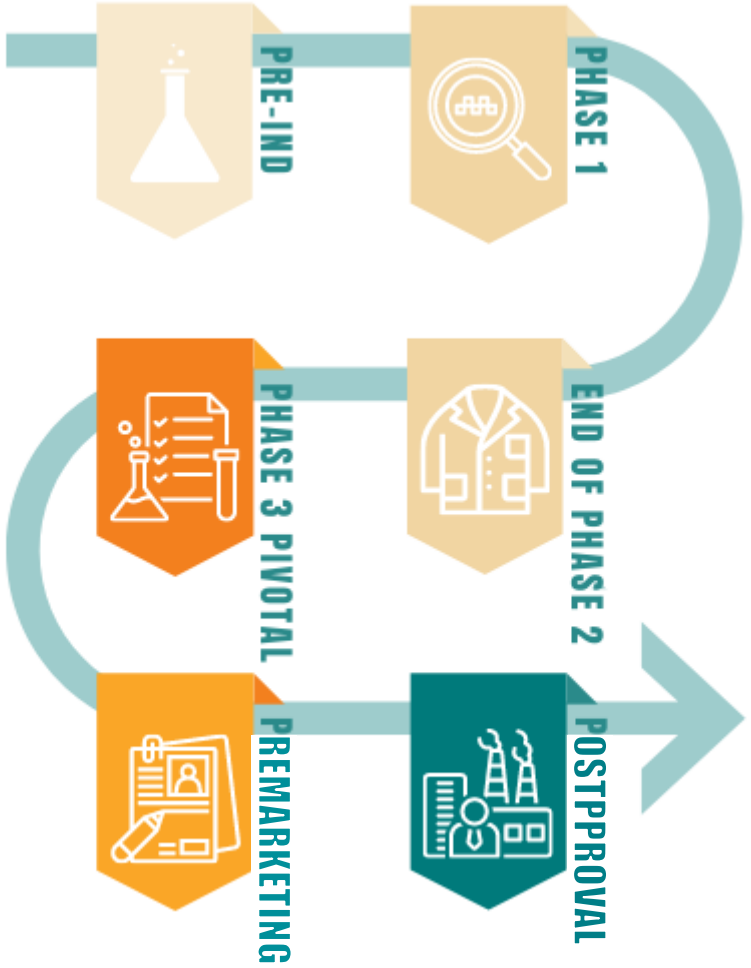
DSI'S EXPERTISE: EVERY STEP OF THE WAY

DSI BACKGROUND

Since 2007, DSI has offered pharmaceutical and biopharmaceutical companies one-stop, full-service regulatory and CMC consulting.

DSI uses multidisciplinary teams composed of manufacturing, quality assurance, and regulatory affairs experts.

DSI consultants bring decades of experience to every stage of the regulatory and product development processes.



DSI VALUE

- Hands-on, deliverable-oriented subject matter experts
- Practical regulatory, CMC, and quality assurance solutions
- Deeper CMC department when you need it

ACQUISITION VISION

PLG has taken the next step in its evolution as a global leader in end-to-end regulatory compliance services. Just six months after the group's acquisition of vigilance and medical information firm Axpharma, PLG announced the strategic acquisition of leading US regulatory drug development consultancy DSI. This latest acquisition will enable PLG to expand in North America and reinforce its expertise to support clients in the regulatory development of their innovative therapies.

OUR VALUE PROPOSITION FOR YOU: PLG'S LATEST ACQUISITION

DSI'S EXPERTISE: EVERY STEP OF THE WAY

DSI INPHARMATICS
A ProductLifeGroup Company

CHEMISTRY, MANUFACTURING, AND CONTROLS

- Integrated CMC development
- Materials characterization and formulation development
- Process development, optimization, and validation
- Analytical method development, optimization, and validation
- Stability program design and management
- Vendor/contractor identification and management
- Supply chain assessment and management

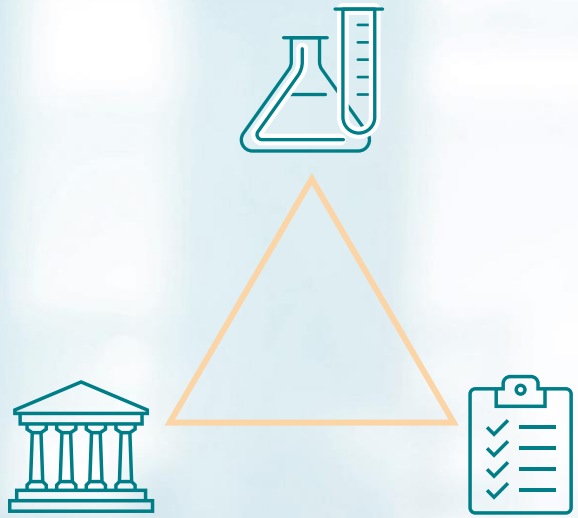
REGULATORY AFFAIRS

- Regulatory agency representation
- Regulatory strategy development
- Management and preparation of regulatory submissions
- Responses to regulatory challenges
- Expedited drug development
- Next-generation biotherapeutics
- FDA and EU agency experts

QUALITY ASSURANCE

- Design, implementation, and remediation of quality systems
- Management of CMC quality systems
- Compliance, vendor qualification, and mock preapproval audits
- Management of compliance situations

CMC



REGULATORY AFFAIRS

QUALITY ASSURANCE

CREDENTIALS

DSI TOP 5 CUSTOMERS BUSINESS CASES

Company	Scope of Activity	Key Figures
Small biotech company Boston, USA	DSI provided manufacturing, analytical, and regulatory for small and medium-sized enterprises by authoring and providing regulatory strategy for a new drug application (NDA) that included pharmaceutical manufacturing controls, control of excipients, container closure, stability, and 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 and accepted by the FDA. The FDA also granted the client's request for Priority Review. In addition, this engagement included the researching for and 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 and submitting successful NDAs. The gap assessment is a process that comprises many steps, and 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 and US marketing authorizations that include solid oral dosage and topical ointments. DSI provided the requirements and guidance for obtaining source documents from the active pharmaceutical ingredient (APIs), the excipient, and the manufacturing facilities. Using that information, DSI performed a comprehensive risk assessment for these products that met the client's needs and the regulatory requirements on schedule.	Up to 3 experts (150 hours a month)
Midsize pharma company Pennsylvania, USA	Experts in APIs support the identification and qualification of second-source vendors; validation; and registration batch manufacture. Complete quality assurance oversight of CMC operations. Regulatory strategic advice for upcoming NDA. Supply chain and logistics support for clinical operations.	Up to 5 experts (300–350 hours a month)

"I personally want to thank the DSI team for authoring an excellent CMC submission, answering numerous questions, and always being available to help. DSI did a great job with strategy and authoring, and 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."

Source: Roland Berger interviews