Advancing global patient healthcare through regulatory excellence

DLRC — award-winning regulatory affairs consultancy

DLRC Group are proven specialists in global product development and regulatory affairs

We partner with everyone from top 5 pharma to innovative startups, providing expert guidance, tailored strategies, and dedicated support to advance medicinal products and medical devices throughout their lifecycle.

Thriving in a dynamic industry

The life science sector presents transformative opportunities but comes with challenges:

Compliance demands

Evolving regulations require experienced, nuanced handling.

Intense competition

Agility and innovation are key to progressing where others fail.

Fiscal pressure

In a complex environment, creating value fast is essential.

The key to success?

Partnering with an experienced, reliable, and proactive advisor to navigate the regulatory landscape efficiently and effectively.

Unlocking the benefits of regulatory clarity

No matter your size or goal, a well-managed regulatory strategy brings valuable rewards:

Ambitious startups

Overcome regulatory hurdles efficiently to reach milestones quickly.

Expanding biotechs

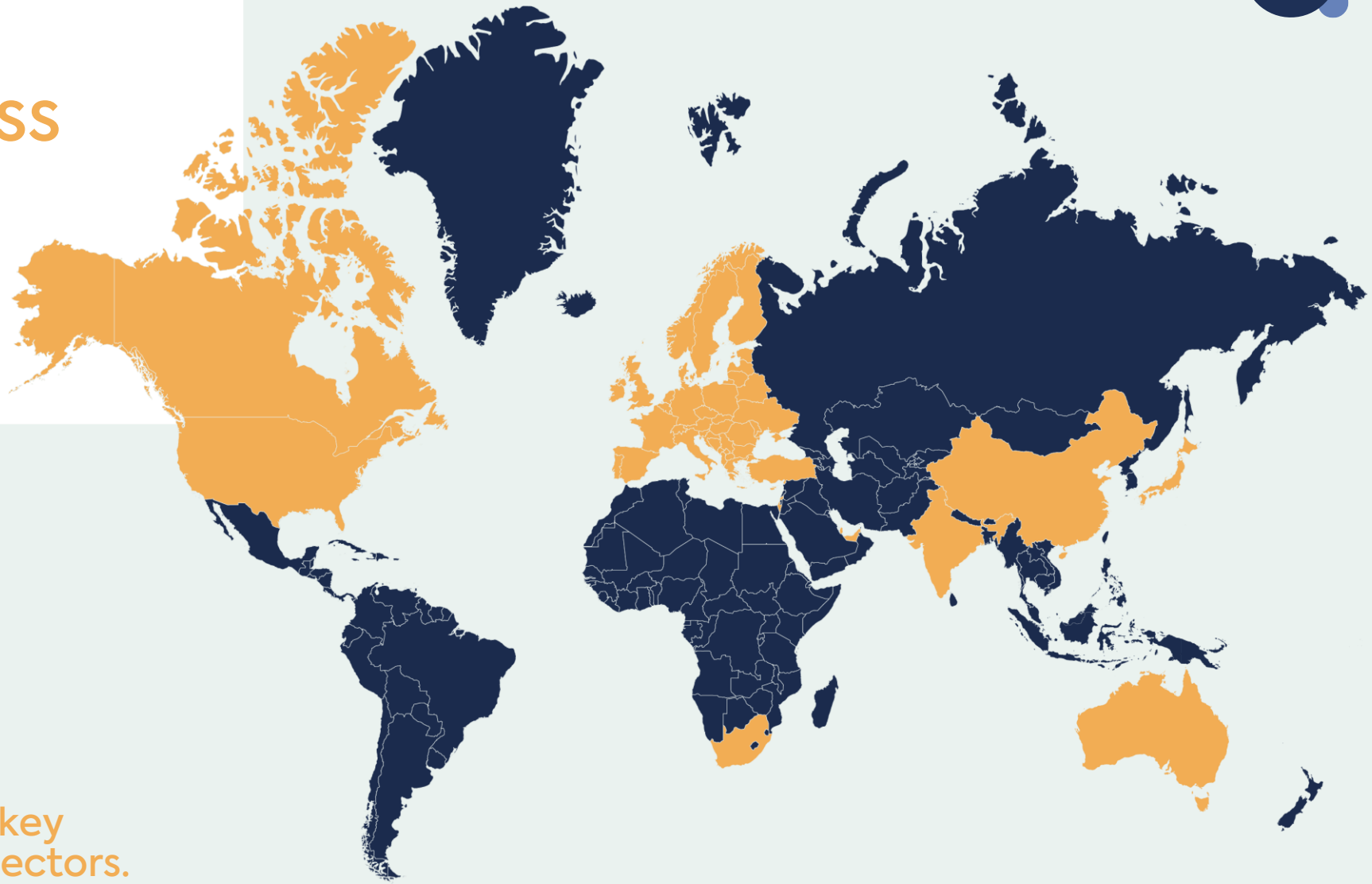
Access broad regulatory expertise to expand into new markets.

Established enterprises

Outsource for efficiency and scalability to enhance operations.

Mapping your path to success

With expertise in **50+ therapeutic fields and tailored services**, we are uniquely positioned to deliver outstanding outcomes globally.



Trusted by over

130 clients across key markets and sectors.

Bespoke delivery models to meet your needs

At DLRC, we know that a flexible approach is key to effective partnerships. Whatever your objective, challenge, or situation, we can help:

Ad hoc support

Get expert regulatory advice and insights as needed.

Project-based

Opt for full outsourcing or flexible, integrated support for maximum efficiency.

Team augmentation

Quickly integrate skilled professionals into your team for key roles.

Virtual regulatory department

Benefit from end-to-end outsourcing backed by stringent quality standards.

Global expertise with the personalised approach

We are committed to bringing you an exceptional client experience

Single point of contact

Enjoy streamlined communication with a dedicated expert managing your needs.

Shared knowledge

Leverage insights from a large team of professionals with deep industry understanding.

All-in-one solutions

Benefit from our complete suite of in-house capabilities, services, and resources.

International reach

Access support and perspectives from our strategically located global offices.

Our full range of services

Strategy	Global strategic advice	Regulatory route to clinic / market	Gap analysis & due diligence	EU CTR: Implementation & transition planning	Health authority engagement & negotiations	Expedited pathways	Paediatric development
Operations	Procedural management: Global regulatory agencies	Clinical trial applications	Marketing authorisation	Medical and scientific writing	Regulatory operations and publishing	Regulatory lifecycle management	
Representation	US agent	Authorised representative medical devices	Legal representative under EU CTR	SME / ODD / MAH holder			

Driving your success with industry connections

Our extensive network brings unparalleled benefits

Access to insights & best practices

Use our broad client insights to understand regulators' stance on complex products.

Commitment to innovation

Implement cutting-edge strategies for navigating nuanced regulations.

Regulatory intelligence visibility

Benefit from between-the-guidelines advice.

A voice for your interests

Have your needs represented and prioritised in the industry.

Navigating EU Regulatory Filings:

Strategic and Technical Support for Cell Therapy Medicinal Product

The situation

DLRC collaborated with a US biotechnology company in the mid-development phase of a Cell Therapy Medicinal Product (CTMP). The client required DLRC's expertise in EU regulatory requirements and CMC to advance their product to marketing authorisation (MA) filing, leveraging the EU's fast-to-market regulatory pathways for products addressing unmet medical needs in an oncology indication.

Our solution

DLRC successfully guided and assisted the client from their mid-clinical development phase up to the MA filing, including supporting the conditional MA and EU Accelerated Approval strategy, Agency meetings, PIP compliance check and publishing of the MAA.

The outcome

DLRC helped the client achieve a key corporate milestone for their innovative product, expanding product development and access to the EU region.

We thank you and the entire DLRC team in helping us achieve this milestone!

Meet the team

Dianne Lee

CEO

Champions DLRC's unwavering dedication to regulatory excellence.

Kevin Judges

Head of Regulatory Solutions

Aligns regulatory and business objectives for a seamless client experience.

Alisdair Falconer

Director of Regulatory Consulting

Leads DLRC's consulting group with emphasis on strategic regulatory delivery.

Greg Dombal

President, DLRC Inc

Drives DLRC's US strategy with 25+ years' experience engaging with regulators.

Annette Delling

Director of Quality

Ensures DLRC aligns to all relevant quality and compliance standards.

Wafa Bouaziz

Managing Director & Head of Regulatory Affairs, Orphix

Steers DLRC's EU operations through strategic regulatory leadership.

A proven track record of client success

Our work speaks through the lasting impact of our partnerships.

60
Scientific Advice procedures managed

Over
30
Orphan Drug Designations obtained

250
Clinical studies submissions approved in the past 3 years

Over
250
Clients supported in the past 5 years

30
INDs submitted and cleared in the past 3 years

How we can work together

1

Introductory meeting

Contact us to discuss your needs with our consultants.

2

Receive our proposal

Tailored to your needs and the scope of engagement.

3

Formalise partnership

We sign agreements and plan a kick-off meeting.

4

Kick off the project

Our teams integrate for success.

5

Seamless engagement

Collaboration that adapts to your way of working.

Trust built on excellence and integrity

Our innovative, industry-leading solutions are underpinned by our commitment to:

Community engagement
Outreach through charity and school partnerships

Environmental sustainability
Minimising impact and achieving net zero

Professional development
Unrivalled training and development opportunities

Diversity, inclusion, and equality
Fostering a fair and inclusive culture

Employee well-being
Prioritising satisfaction and holistic support

Anti-bribery and corruption policy
Zero tolerance for bribery and corruption

Your trusted regulatory partner

Ready to navigate global regulations with confidence?

DLRC

Contact us today to propel your project to success.

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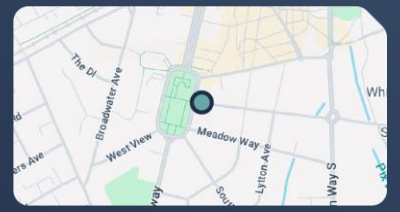

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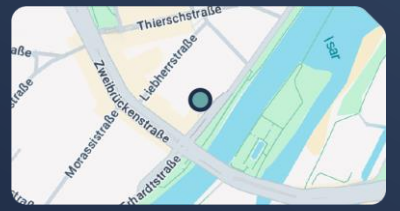

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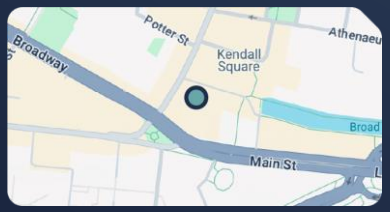

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