

The logo consists of a large white circle containing the text "DLRC" in a dark blue, sans-serif font. This central circle is partially overlapped by two smaller, solid blue circles, one positioned above and to the left, and the other below and to the right.

DLRC

Advancing global patient healthcare through regulatory excellence

DLRC — award-winning regulatory affairs consultancy



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

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 and HTA landscape efficiently and effectively.

Unlocking the benefits of regulatory and HTA clarity

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



Ambitious startups

Overcome regulatory and HTA hurdles efficiently to reach milestones quickly.



Expanding biotechs

Access broad regulatory and HTA 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

250 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 and HTA 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

HTA strategy and evidence planning

Operations

Procedural management: Global regulatory agencies

Clinical trial applications

Marketing authorisation

Medical and scientific writing

Regulatory operations and publishing

Regulatory lifecycle management

EU HTAR / Joint Clinical Assessment readiness

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.



Meet the leadership team



Dianne Lee

Chief Executive Officer

Champions DLRC's unwavering dedication to regulatory excellence.



Wafa Bouaziz

Chief Regulatory Officer

Leads Global Regulatory Strategy and Excellence



Sebastian Payne

Chief Business Officer

Drives DLRC's commercial strategy to transform regulatory challenges into client success.



James Biddlecombe

Chief Operating Officer

Leads Global Regulatory and Consulting Operations



Annette Delling

Director of Quality

Ensures DLRC aligns to all relevant quality and compliance standards.



Chris Middleton

Chief Finance Officer

Upholds DLRC's strategic financial leadership and commitment to fiscal integrity.

A proven track record of client success

Our work speaks
through the lasting
impact of our
partnerships.

DLRC has
supported over

250

Clients supported in
the past 5 years

63

Scientific Advice
procedures managed

Over

60

Orphan Drug
Designations obtained

75

Marketing authorisation
applications
(MAA/BLA/NDA) in the
past 5 years

1

First Joint Scientific
Consultation
conducted in the
past 12 months

Over

80

EU and FDA
meetings supported
in the past 5 years

Over

250

Clinical studies
submissions approved in
the past 5 years

31

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 regulation and HTA with confidence?



Contact us today to propel
your project to success.

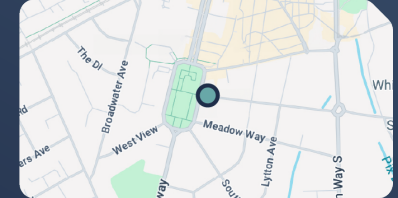
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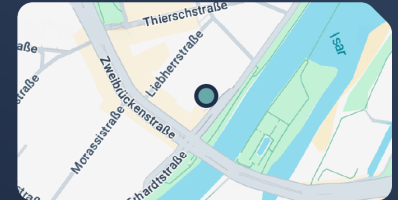
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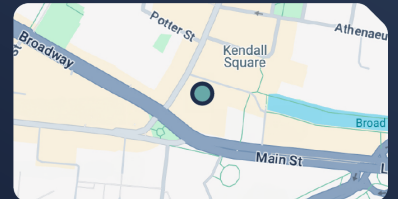
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