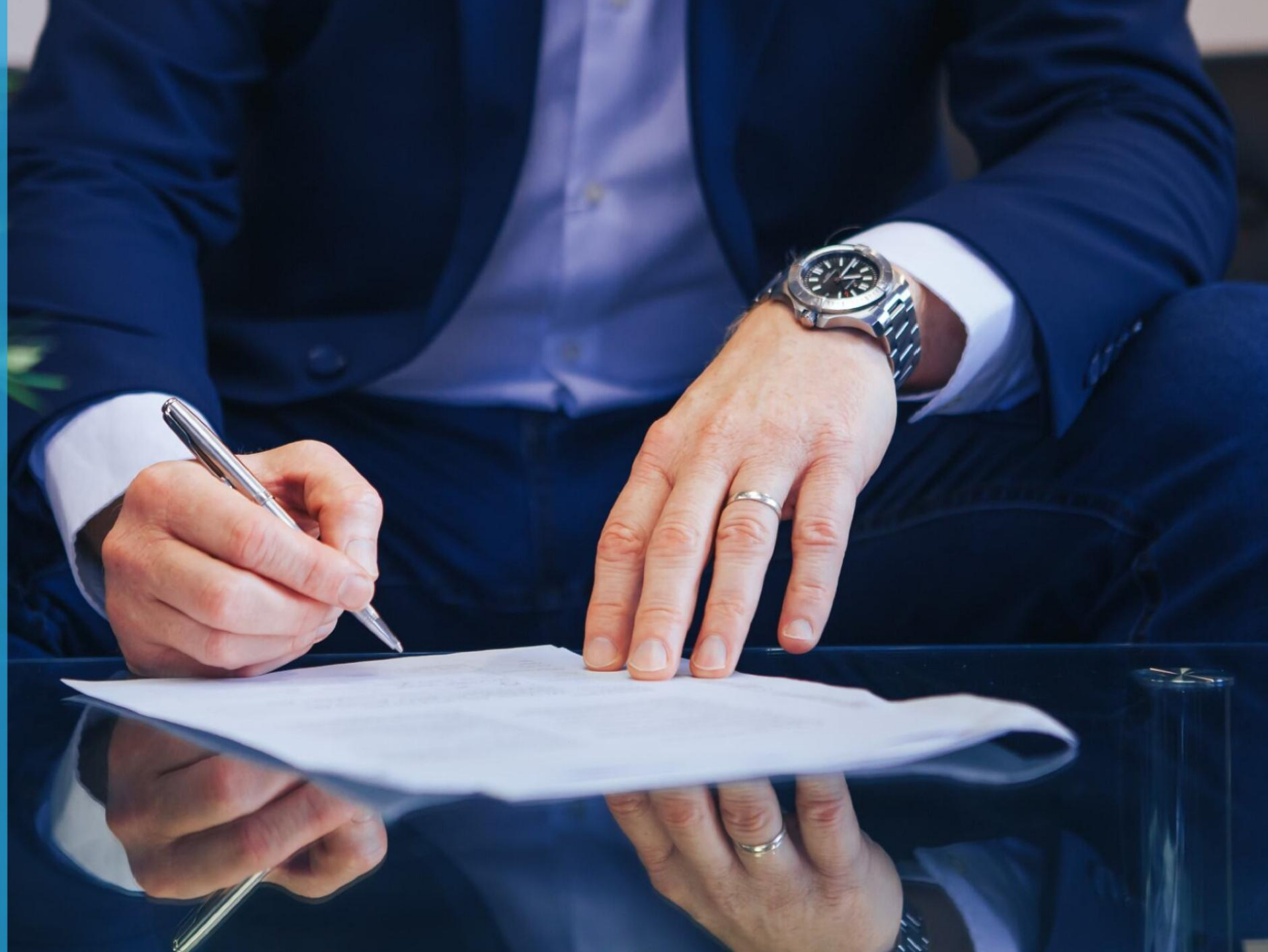
GreyRigge
Associates

Experts

Transformative

Agile



Who we are

Originally founded by Dr. Lee Smith in 2010, a merger of like-minds grew the business in 2023, creating two Managing Partners, Lee and Samantha Dowse, both based in the UK.

Success brought further expansion into APAC in 2024 to include Dr. Andrew M Thomson as Managing Partner based in the Japan office, forming GreyRigge Associates as it is known today.

Where we work

Our global network of offices in the Americas (Cambridge, USA), EMEA (nr London, UK) and APAC (Kobe, Japan) provide a 24/7 capability often needed by our clients.

Many clients work in a follow-the-sun environment and they expect that same level of professionalism from their suppliers. In addition, our remote-working and onsite capabilities ensure that clients are supported in the time zones that they specify.

Broad and deep services

GreyRigge Associates

The Biotech Consultancy

Accelerating Biotech Success – From Innovation to Launch

We partner with biopharmaceutical companies to navigate the complexities of drug development, from early innovation to commercial launch. Our extensive expertise combined with our client-centric approach, transforms & accelerates medicines to market while improving quality & safety.

Preclinical

- Translating science into development-ready strategies
- Developing proof of concept to support filings
- Considering regulatory and CMC up-front

Phase I

- Establishing regulatory strategies, quality systems, and CMC processes
- Evaluating & managing CDMO(s) for clinical manufacturing & analytics
- Ensuring smooth clinical supply for first-in-human (FIH) trials

Phase II

- Scaling, optimising & characterising processes & assays using QbD
- Working with international agencies globally to build regulatory strategies
- Ensuring clinical materials are considered comparable between trials

Phase III

- Ensuring CMC and quality systems are ready for full-scale production
- Planning and executing PPQs & assay validation
- Enabling pivotal late-stage clinical trials and inventory generation

Commercial

- Developing supply chain strategies while ensuring regulatory compliance
- Strategising and facilitating product launch, market launch analysis and post approval lifecycle management
- Navigating global regulatory authority approvals

Our Associates

We choose only the most experienced and authoritative to join GreyRigge. We look for a blend of committed industry experts and seasoned consultants. Whilst over two-thirds of the team bring a PhD, we value their 1,000+ years of industry experience just as highly.

GreyRigge Associates is a global biotech partner delivering consultancy, management expertise and training across the entire product development journey. Our extensive biopharmaceutical industry experience and pragmatic, agile approach enables transformational success by accelerating our clients' medicines to market.

Contact Us

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