RED Medtech

Helping People Help People

redmedtech.co.uk

Our Expertise

Product Development

Technical and design documentation essential for assessment by your Notified Body and international regulators.

Project Leadership

Dedicated support for achieving your medical device development, quality and compliance project goals.

Quality Consulting

Helping you with ISO 13485 Quality Management System implementation, audit and certification.

Regulatory Compliance

Consulting and documentation demonstrating compliance for assessment by EU CE, UKCA and US FDA regulatory authorities.

To Book Your Free Project Consultation

Call : +44 (0)1267 243388
Email : hello@redmedtech.co.uk
Visit : www.redmedtech.co.uk

About Red Medtech

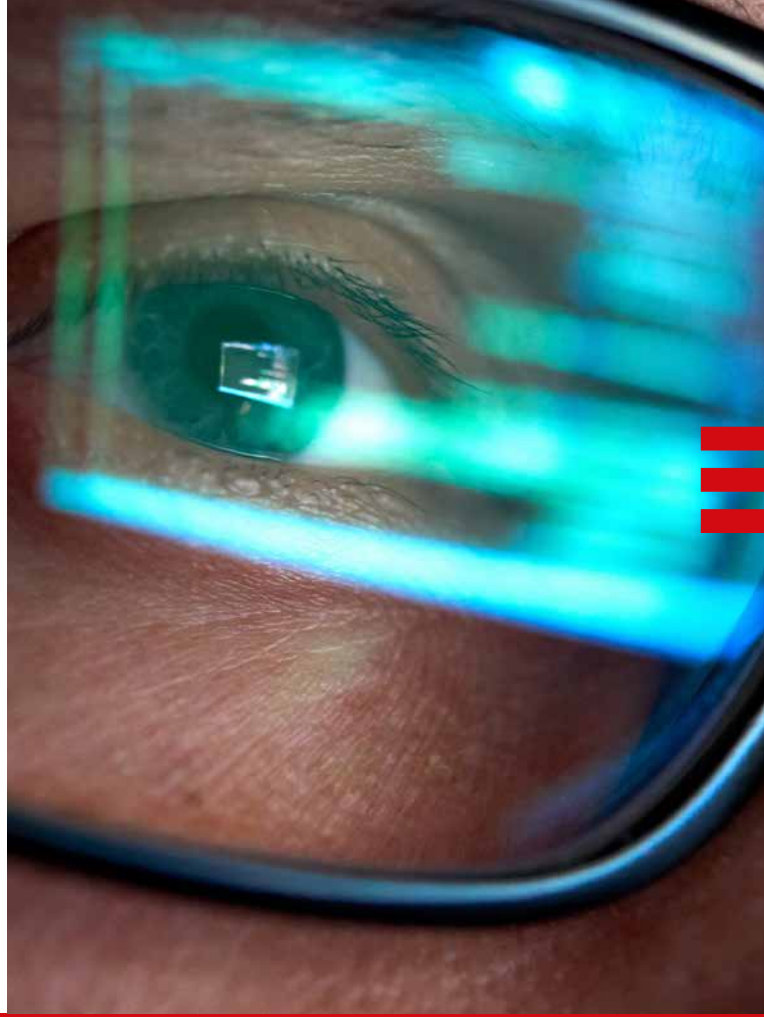
Management. Expertise. Flexibility

World class medical device project management providing tailored solutions to global clients.

We help medical device developers, designers and manufacturers deliver patient care solutions to market. Helping People Help People.

We are a boutique consultancy with specialism in product development, engineering and innovation. We love to work collaboratively with our clients to successfully navigate the product development journey from concept to market.

We bring our extensive professional expertise in healthcare technology, engineering and manufacturing to your projects. We've successfully delivered many medical technology projects across 10 different countries and counting!



Our aim is to positively impact as many patients and their healthcare providers as possible. That means getting safe and effective medical products to market and keeping them there; doing good and improving quality of life.

- Professor Laurie Rowe – Founder & Director, Medical Device Consultant.

About our founder

Professor Laurie Rowe

Inventor of several patents and recipient of the prestigious Kathbert Trophy awarded by the Institution of Engineering Designers (IED) for "Significant and developing contribution to design leading to a tangible advantage to commerce or society", Professor Laurie Rowe is passionate about using engineering for good.

With a career spanning over 20 years of both hands on industry experience and active consultancy, Laurie's background as an engineer specialising in the design and manufacture of medical devices means that she is that rare breed of industry expert. She spans both the product development life cycle AND regulatory compliance work.

This rich experience underpins **Red Medtech's unique offering** to successfully get your medical device from concept to market and beyond:

- A tried and tested process reflecting industry best practice and alignment with the ISO 13485 QMS standard,
- A best in class team of professional experts,
- And a network of trusted delivery partners.

Expertise

Product Development

Product Design History File creation and robust Technical Documentation.

- Applying engineering qualifications and experience to facilitate product development & innovation projects.
- Advising and supporting technical aspects, covering a wide range of device types and classifications.
- Engineering consulting support including (but not limited to) design, materials, manufacturing, processes, software life-cycle processes, testing, risk management, usability & human factors.
- Design History File (DHF) content creation and review. Technical Document compilation, audit and remediation.

Expertise

Project Guidance

Management for technical, quality and regulatory medical device projects.

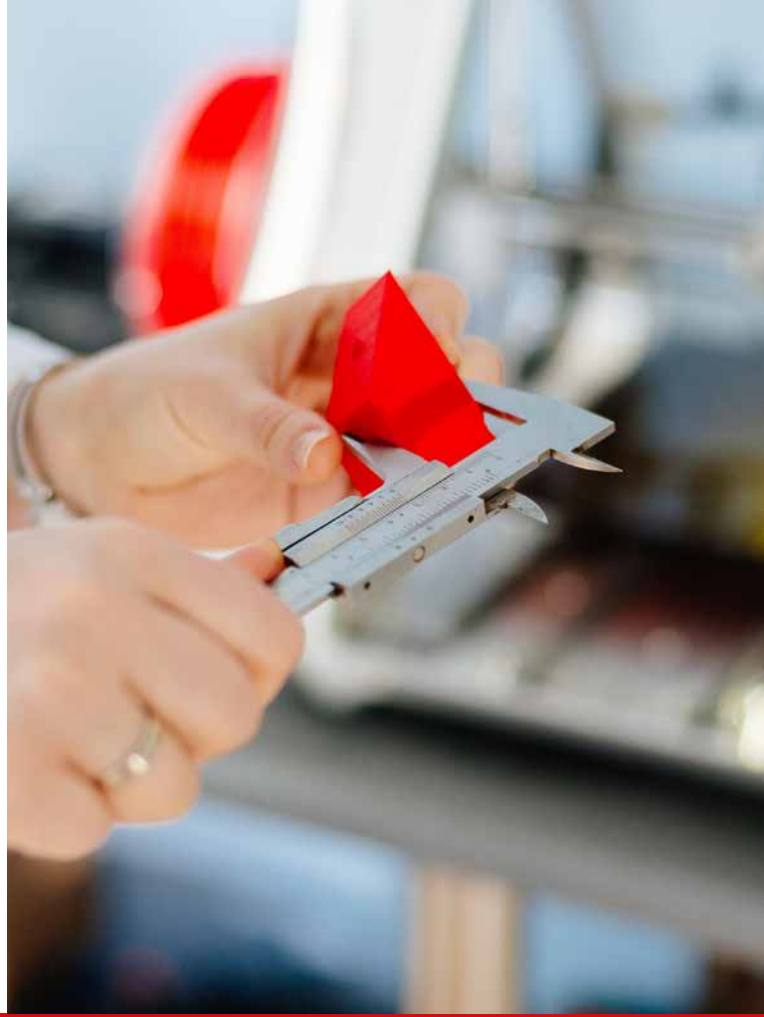
- Helping you with strategy, project planning, implementation, and post-completion activities.
- Consulting support from identifying resourcing needs and managing teams, to monitoring project performance, providing stakeholder updates and executive progress reporting.
- Supporting projects to improve quality, productivity, and compliance, scale-up and transfers.
- Assist in supplier and service partner identification, including testing and certification bodies.

Expertise

Quality Consulting

Quality Systems and product documents for achieving certification.

- Planning, implementation and maintenance of Quality Management Systems, including digital conversion projects from paper-based to electronic eQMS software solutions.
- Help with internal, external and supplier audits, identifying certification partners, preparing for Notified Body and Approved Body audits, managing post-audit activities and remediation work.
- Supporting your quality investigations and compliance projects including delivering QMS training.
- Consulting support for your ISO 13485 and MDSAP - Medical Device Single Audit certification projects.



Expertise

Regulatory Consulting

Compliance solutions and documented evidence for assessment by authorities.

- Provide information, advice and guidance so that you can understand the requirements, company obligations, and the processes involved in getting your medical devices developed, assessed, and certified/approved to legally place on their intended markets.
- Help to identify applicable regulations, directives, guidelines, horizontal and vertical standards.
- Support projects to maintain in market compliance including transitioning from EU Medical Device Directive to Medical Device Regulations, and FDA for USA.
- Provision of UK Responsible Person (UKRP) and EU Person Responsible for Regulatory Compliance (PRRC) for companies, including device registrations and consultation with applicable regulators, authorities and Notified/Approved Bodies on your behalf.

Delivery

“From concept to market success, we’re your trusted partner in medical device innovation. With expert guidance and dedicated support, Red Medtech helps you at every stage of product development. Together, let’s ensure your project’s success - to launch and beyond!”

Red Framework

Our Process

Our clients have access to the Red Medtech Framework - a tried & tested process in line with industry best practice, to achieve your product goal.

We work with our clients to design & develop products, navigate compliance pathways and sucessfully deliver medical devices to market.

The Red framework embeds a best-in-class approach for new product development into your business, to facilitate your future product pipeline.

1.

Initiation, opportunity and risk analysis.

Initial evaluation of possible development of commercial product.

2.

Formulation, concept and feasibility.

Definition of design inputs based on customer needs and technical requirements.

3.

Design and development, verification & validation.

Development of product design and of manufacturing process, test requirements and protocols.

4.

Final validation, design transfer, and launch preparation.

Final validation of manufacturing processes, preparation of product introduction.

5.

Product launch and post launch assessment.

Market introduction of product, continuous improvement, surveillance and vigilance.

Expertise

“Red Medtech, with Laurie Rowe, was an invaluable partner for Made for Movement (MFM) post-Brexit. They provided clarity on UKCA requirements, helping us navigate local regulations in the UK and Ireland. Their expertise also shed light on our Technical File’s compliance with the UK MDR. We highly recommend Red Medtech as your regulatory consultant!”

Red Allstars

Our People

A carefully selected team of subject matter experts, engineers & technical professionals.

Red Network

Our Partners

A network of trusted and approved suppliers, companies and organisations.

iED

IPEM
Institute of Physics and Engineering in Medicine

BHTA
British Healthcare Trades Association
Trade Affiliate

Global Medical Device Project Leadership

Expert support implementing European & British standards, directives and regulations for CE and UKCA.

Delivering domestic and worldwide design development and technical compliance projects internationally, including US FDA and MDSAP countries.

Free Project Consultation Call

Get started in 3 easy steps

1.

First Contact

- Basic company info
- Mutual NDA option
- Book your initial meeting

2.

FREE Initial Meeting

- Outline project goals
- Your current situation
- Agree consulting service

3.

Your Customised Proposal

- Review deliverables
- Accept your proposal
- Book project start date

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