



Regulatory Affairs and Quality Management System Consultancy

We offer the following to the Medical Device & Biotechnology sectors:-

Services

- Due diligence, gap analysis and document preparation for all classifications of medical devices, in-vitro diagnostics and advanced therapy medicinal products.
- Advice and generation of **regulatory** strategies including determination of classification for medical devices and regenerative products.
- Expertise in development of medical devices, advanced therapy medicinal products and other tissue engineering / regenerative medicine products.
- Guidance on **regulatory expectations** and **data requirements** throughout the full development cycle.
- Guidance in the use of technical standards relating to design control, risk management, biological safety and clinical evaluation of medical devices.
- Guidance and implementation of **quality management system** requirements for medical devices and in-vitro diagnostics. Auditing and gap analysis of quality management systems (**ISO 13485** and **21 CFR 820**).
- **Implementation** and **launch** in all critical and major markets.

Relevant Experience

- Our Co-founder and Regulatory lead has over 10 years working and leading **Regulatory** and **Quality** teams in University Spins outs, SMEs and large OEMs.
- ECT team members have completed a range of projects including
 - **EN ISO13485:2016** preparation and auditing
 - **MDR** remediation planning and execution
 - **21 CFR part 820** Technical File Creation for 510K and PMA Applications

Our Head of Regulatory Affairs:

- Has extensive experience working on **Advanced Wound Management, Electro-Mechanical, Orthopaedic and Cardiovascular products**
- Over 10 years experience leading Electro-Mechanical and Software Development teams to implement **Regulatory Strategy** for Class II and Class III Medical Devices.
- Offers friendly, practical and a fact based service.
- Combines extensive **Commercial, Product Development and Regulatory** understanding to provide a tailored approach to your company requirements.



Clients include;

- Multinationals
- SMEs
- University Spin-outs.

ECT Healthcare
Consultancy