



Product Development, Commercial and Project Management Consultancy

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

Services

- **Programme and Project management** from initial concept, through product development and design transfer to launch and commercialisation.
- Due diligence, gap analysis and document preparation for all classifications of medical devices.
- Advice and generation of **commercial and regulatory strategies** including determination of classification for medical devices and regenerative products.
- Strategic Commercial advice and guidance on all critical markets, including route to all major markets. **Technical Marketing and Sales and marketing.**
- Detailed **Technical File Creation** including **Software and Hardware Verification and Validation** for all major markets
- **Design Transfer and Manufacturing Scale up** including completion of critical validation and verification steps such as **IQ, OQ and PQ.**
- Technical RCA and Problem Solving
- **Market Analysis and Competitive Set Analysis** as well as Product Positioning and critical marketing
- Due Diligence and **M&A support**
- Generation and Implementation of **Quality Management System** documents (SOPs)

Relevant Experience

- Our Co-founder and **Product Development and Commercial** Project lead has **over 20 years experience** working and **leading product development and commercial teams** in University Spins outs, SME's and large OEMs.
- The team is also trained in **Prince 2 Project management** and has a history of delivering product development and commercial projects on time and on budget.

Our Commercial and Product Development Team:

- Have extensive experience working on **Advanced Wound Management, Electro-Mechanical, Orthopaedic and Cardiovascular products**
- Over **20 years experience** leading **Electro-mechanical and Software Development teams** to development and launch 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