MDC

Medical Device Consultancy

## Specialist advice and assistance for medical device companies

Medical Device Consultancy provides specialist business development and regulatory affairs consultancy to medical device, in-vitro diagnostic and related companies, including partner search and selection projects.

Medical Device Consultancy works with specialist associate consultants both in Europe and North America to provide in-depth assistance with:

- Strategic business reviews & planning, marketing, research and product management from concept to market.
- Preparation for FDA inspections or Notified Body audits, including mock audits and internal auditor training.
- Regulatory documentation to comply with European Union Directives or FDA requirements.
- European Authorised Representative services and US Agent capability.
- Pragmatic quality system development for starts-up through to multinationals that meet the international requirements of ISO 9001: 2000; US FDA Good Manufacturing Practices GMP); and ISO 13485: 2003 Medical devices – Quality management systems – Requirements for regulatory purposes.
- Validation procedures for processes, products and software.
- Marketing communications advice, including full multi-media services.
- Legal services for start-ups through to multinationals.

Trevor Lewis BSc(Hons), CEng, CPhys, MIET, MInstP, MCIM, MInstD

Principal Consultant

Trevor Lewis has more than 25 years varied experience in all aspects of medical device business development including strategic market research, marketing, business planning and strategy, product management, total quality management and regulatory affairs, especially in Europe and the United States.

Trevor has previously been General Manager of Ferraris Medical; Director, Corporate and New Business Development of Huntleigh Healthcare, the core business of Huntleigh Technology plc; Marketing Manager, Infant Care for Air-Shields Vickers; High Technology Securities Analyst (North American) for stockbrokers Grieveson & Grant and a Development Engineer at Smiths Industries. He spent his early career in the Royal Air Force as an apprentice and flying officer.

Trevor is an active speaker and writer, including two major Financial Times Management Reports:

**European Medical Devices Directives – a guide to beneficial implementation**

This report covers all aspects of the European medical devices directives, related regulation, quality systems, standards and methods. It also provides insights in how to integrate this with United States (US) Food and Drug Administration (FDA) requirements.

**Self Diagnostics and Home Monitoring Products – strategies for success**

This report covers all aspects of product development including a review of technologies, from market drivers, market analysis, regulatory affairs, marketing, distribution, through to use of evidence and return on investment calculations.

Contact
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