

Trevor Lewis

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

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***Medical Device Consultant of proven ability,
with an international reputation in regulatory affairs and
exceptional skills in healthcare technology business development.***

Medical Device Consultancy, 6/95 – Present. Founder and Principal Consultant.

- Specialist international consultancy providing business development assistance for governments, universities, medical device, diagnostic, biotechnology and pharmaceutical companies.
- Has provided training of national regulatory authorities and senior officials in European Union (EU) medical device directives, especially in China, Egypt and Turkey but also all MEDA countries.
- Has provided review, guidance and advice on medical regulation implementation to Canada, the Republic of Moldova, Hong Kong and China. This has included working with the European Commission and Chinese Government via BSI on the comparison of clinical evaluation in both jurisdictions to inform the European Commission (EC) and Chinese Food and Drug Administration (CFDA) for use in future discussion about clinical evaluation.
- Provides medical device and in vitro diagnostic companies with a diverse range of services from strategic research, business planning, regulatory affairs (EU & US), quality systems through to all kinds of business development issues and related training.
- Supports and mentors senior management with their strategic planning, marketing, product management, quality systems and regulatory compliance issues in the US, Europe and beyond.
- Sets up and leads focused experienced teams with expertise to deliver cost effective results.
- Former Partner for Exploitation and Regulatory Affairs in TheraEDGE an €8 million EU Framework (FP7) Project and consultant to RAPP-ID a €14.7 million Innovative Medicines Initiative (IMI) project both in molecular diagnostics. Have provided regulatory and exploitation advice to another multi-million European Commission Horizon 2020 application for a novel molecular diagnostic project in cancer detection.
- Has provided expert research, advice and support to Regional Development Agencies (RDAs and their equivalents) such as the 'Medical Technologies Cluster Research Project' for Advantage West Midlands (AWM) and 'Medical Device Sectoral Support Project' for the Welsh Development Agency (WDA).
- Has provided assistance in the planning and development of numerous national and international medical device conferences, including presenting at and chairing major meetings.
- Writes on varied medical device business topics, especially regulatory affairs and is often approached for his opinion by the trade media, or asked to write articles on specific topics.
- Several previous clients, initially engaged with at the start-up stage, have grown and developed into successful businesses that have been sold and provided substantial returns for their founders and investors.
- Works with both the smallest and largest entities to achieve demanding requirements. This often involves advising and persuading the top management, as an outsider, to implement change and motivate them to carry it through whilst achieving all their many conflicting objectives at typically stressful times in the business cycle.

General Manager Experience, Ferraris Group plc, 7/94 - 6/95

General Manager of Ferraris Development & Engineering Company, trading as Ferraris Medical.

Led a team of more than 40 people, including senior managers for sales, finance, manufacturing, engineering and new product development. Chaired monthly management meetings. Resolved long standing trade mark and regulatory compliance issues. Led the planning of a new office and manufacturing facility. Achieved profitability despite adverse circumstances.

Director Innovation Wales (SEWBIC Ltd), 1/93 - 4/96

Director of a Business Innovation Centre, dedicated to the profitable creation and improvement of small and medium sized companies in Wales. Undertook business reviews and assisted company start-ups, including business planning. Provided the board and other stakeholders with advice on strategic marketing policies and the design of new innovation courses. I assisted, as part of a team, in the transformation of this mainly public sector funded body into a commercially based consultancy.

Senior Manager, Huntleigh Technology plc, 3/89 - 10/93 (USA & UK)

Divisional board member of Huntleigh Healthcare. As Sales and Marketing Manager led an innovative medical device development that tripled sales and assisted in the division's profitability turnaround. Virtually eliminated post-launch change costs directly as a result of implementing suggested predictive engineering product development strategies, and overcame numerous issues that ultimately led to winning a Queen's Award for Export (1992) and Technology (1993). Promoted to Director, Corporate and New Business Development at Huntleigh Healthcare. Previously Business Development Manager (1989 in USA, 1990-92 in UK) and holder of several posts simultaneously, including General Manager of Huntleigh Weighing Systems.

Undertook research, evaluated options and made recommendations concerning strategy, products and all business opportunities, including their financial appraisal and potential return on investment.

Initially employed in the USA office (six months 3/89 to 9/89) to determine the potential of the business, recommend key restructuring and assist local management to implement required changes.

Marketing Manager, Air-Shields, Vickers plc, 3/85 - 2/89 (USA & UK)

Rapidly promoted from Design Engineer to Product Manager (UK); then to Marketing Manager, Infant Care for Air-Shields Vickers (USA) with global responsibilities to maximise gross profit. Initiated \$7 million three year development plan for innovative new product range. Created a new marketing platform that became the industry standard – the Quiet Time (QT) neonatal incubator. This led to improvements in the way neonates were cared for globally.

Financial Analyst, Grieson, Grant & Co., 3/84 - 2/85

High Technology Securities Analyst (North American) for stockbrokers based in the City of London working closely with a partner. Evaluated the financial condition of corporations, their products, markets, management and suitability as investment vehicles.

Research and Development Engineer, Smiths Industries plc, 7/82 - 2/84

Completed the design of complex engine simulation equipment for use in production of the Harrier 'Jump Jet' digital engine controller. Managed a small team of apprentices, workshop personnel and junior engineers.

University of Reading, BSc(Hons) Physics & Electronics with Mathematics, 1979 - 1982

Quality Assurance Engineer at Digital Electronics, 7/80 - 9/80

Tested and set up patient monitoring equipment prior to release to customers.

Royal Air Force, Avionics Apprentice and Flying Officer, 1974 - 1979

Apprentice Technician in Air Communications and Air Radar, placed first in technical subjects and received a book prize from the Royal Aeronautical Society. Served on helicopters at RAF Odiham and in Northern Ireland before becoming a student jet pilot and Flying Officer.

Previous Career Summary, 1974 - 1995

- *Trevor Lewis has previous experience of, as part of a team, growing two publicly quoted companies from around £10 million to £100 million in sales within a five year planning period. Responsibilities have included technical, sales, marketing and general management roles. He has led a subsidiary of another quoted company successfully and profitably through an exceptionally challenging period of change and achieved significant results despite adverse conditions.*
- *Previously Trevor has been General Manager of Ferraris Medical; Director of Corporate and New Business Development of Huntleigh Healthcare; 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.*
- *Early career (1974 - 1979) in the Royal Air Force, including service as a Air Communications and Air Radar Technician and student jet pilot reaching the rank of Flying Officer.*

Sample of Invited Public Speaking Engagements

- *Invited to write a two part article for pharmaphorum™ *The Future of Healthcare? Kill the bugs save the world!* (April 2012).*
- *Invited key note speaker at the Ethical Medicines Industry Group (EMIG) *Diagnostics & Pharmaceuticals – The Future of Healthcare* (March 2012).*
- *The impact of regulations on mobile healthcare applications for Medilink West Midlands (2010).*
- *Entrepreneurial people and entrepreneurial companies, Medilink West Midlands, Annual Awards Event, Birmingham (2007).*
- *From Concept to Profit, Making It Happen in Global Markets, BioMed Central all Ireland initiative, Belfast (2006). Keynote address centred on global business development in the medical device, diagnostic, biotechnology and closely related industries. Included comments on the challenges of key cluster development, regulatory compliance and raising finance.*
- *Neonatal Phototherapy, Harvard Medical School, USA (1988) invited lecture.*
- *Thermal Regulation of Neonates to Gulf Health Ministers in Dubai (1987).*

Affiliations

- Member of Medilink West Midlands: 2010 - Present
- Member of The Institute of Directors: 1993 - Present
- Member of The Chartered Institute of Marketing: 1993 - Present
- Member of The Welsh Medical Technology Forum, now MediWales (co-founder): 1992 - 2011
- Member, The Strategic Planning Society: 1990 - 1994
- Member, Association for Advancement of Medical Instrumentation: 1989 - 1993
- Member, Institute of Electrical Engineers and Chartered Engineer: 1987 - Present
- Member, Institute of Physics and Chartered Physicist: 1986 - Present

As part of previous committee and community work Trevor Lewis has undertaken the following:

- Member of the Advantage West Midlands Cluster Opportunity Group (COG).
- Member of the Steering Group for Welsh Medical Products Development Centre.
- Member of the National Steering Committee for the Development of NVQs.
- Participated in the Review of National Curriculum for Technology in Wales.
- Llandough - South Wales, Dyspraxia Awareness Group - founder member.
- Been an adviser to the Engineering Training Authority (Entra) on Competence Standards for the Marketing and Selling Function, National Vocational Qualifications Level V.

General Interests

- All aspects of science, financial investment and bird watching.
- Clay pigeon shooting – in all its forms.
- Playing various musical instruments, including the didgeridoo.