Trevor S. Lewis - Training Record

Address: 7 Pinewood Drive, Ashley Heath, Market Drayton, Shropshire TF9 4PA, UK.

Tel: +44 (0)1630 67 37 37 Mobile: +44 (0)7739 73 31 77

Skype: trevorlewis2

Email: trevorlewis2@medicaldeviceconsultancy.co.uk

Course/Seminar, Organisation, Duration: 2012 – 2013

Medical Device Compliance Seminar (TRaC Global, Cambridge, ½ day, 2013) Introduction by Mark Heaven, CEO of TRaC Global followed by these presentations:

- Medical Device Directive overview / update. Martin Penver, Operations & Technical Manager, LRQA.
- Essential Performance, Functional Safety & Risk Management, Chris Rouse, Safety Director, TRac Global.
- Wireless Technology in Medical Devices, Dr. Simon Hindle, Principle Radio Engineer, TRaC Global.
- A Case Study: Bringing your Medical Device to Market, John Chewins, BioxyQuell Product Manager, Bioquell.

Institute of Ergonomics & Human Factors – Clinical Human Factors Group Open Seminar: Ergnomic in Healthcare – Expert Design (Buxton, Health and Safety Laboratory, ¾ day, 2013) presentations:

- Human Factors, Healthcare and Design, Darren Whitehouse, HSL Buxton.
- The impact of poor design; a clinician's perspective, Chris Frerk, NHS Doctor.
- Understanding the breadth of design (Emma Boakes, CHFG).
- Considerations when choosing and introducing devices to patients, Jennifer Martin, Nottingham University.
- Considerations for manufacturers, Ann Blandford, UCL Interaction Centre.
- Using simulation in the development process, Richard Featherstone.
- Other aspects of design – applications, Lauren Morgan.

CE2012 EU Medical Device Regulatory Revision Conference (Birmingham, 1 day, 2012)
Organised speakers, agenda and worked with UK HealthGateway and Conventus to deliver:

- The Regulation of Medical Devices – Global Trends. How we arrived, where we are and what the future may hold – tomorrow's global medical device regulation. Alan Kent, former Chief Executive of the MDA and former member of the Global Harmonisation Task Force (GHTF).
- The Recast/Revision of the Medical Device Directives – problems and solutions? Trevor Lewis, Medical Device Consultancy.
- Clinical Evaluation – what it is and how it should be done. Dr. Pete Wall, Isca Healthcare Research.
- Can Europe grow it's medtech industry and lead the world on medical device regulations? John Wilkinson OBE, Former Chief Executive of Eucomed and Head of Devices MHRA.
- The In Vitro view, what the Recast means for diagnostics and why IVDs are key to the future of healthcare. Doris-Ann Williams MBE, Chief Executive, BIVDA.
- Working with the Recast/Revision for IVDs, Dr. Kirk Buller, Regulatory Affairs Manager, The Binding Site.
- Working with the Recast/Revision for General and Active Implantable Medical Devices, Phil Brown, Chairman of ABHI Technical Policy Group.
- NICE – what is expected from devices that get recommended for use in the NHS and what you need to do. Mark Campbell, NICE Programme Director for Devices and Diagnostics.
- Independent Health Technology Assessment, Michael Stewart, European Director, ECRI Institute.
- Revision next steps for medical device manufacturers in the EU, Neil Adams, Director Operations and Delivery, BSI Healthcare.

Course/Seminar, Organisation, Duration: 2011

Putting Ideas into Production, Applied Eventology Masterclass (MedilinkWM, Birmingham, 1 day)
- Attended presentations: An Overview of the Medical & Healthcare Sector, Richard Stone, MedilinkWM; The Research & Development Process, Daniel Steenstra, Innovations; IP Considerations for Medical Devices, Mike Dowler, Marks & Clerk; The Clinical Trials Process, Dr Pete Wall, ISCA Healthcare Research; and The Manufacturing Process, Daniel Steenstra, Innovations Factory.

The Medical Device Directive and the Future Recast (Informa Life Sciences 2 day conference, Brussels)
- Overcoming Obstacles with Practical Solutions-Industry Experience, Laura Locati.
- Implementation of the MDD for a Combination Product – A Product Designers Perspective, Dr. Sean Willis.
- Definition and Classification of Medical Devices, Mika Reinikainen.
- Clinical Data Concerns and Solutions, Dr. Torsten Kayser.
- Impact of the MDD on Clinical Data – A Notified Panel Discussion:
  - Dr. John O'Dwyer, Medical Director, NSAI, Ireland.
  - Dr. Gert Bos, Head of Regulatory and Clinical Affairs, BSi, UK.
  - Ronald Nash, Technical Manager (Medical), AMTAC, UK.
  - Chris Jepson, Global Manager-Medical Device Certification, SGS, UK.
- National Perspectives in regards to Clinical Data Evaluation – A Member State Panel Discussion:
  - Ann O'Connor, Director of Human Products Authorisation and Registration, Irish Medicines Board, Ireland.
  - Sabina Hoekstra-van den Bosch Pharm.D, Senior Advisor, Ministry of Health, The Netherlands.
  - Maria Judite Neves, Health Products Director, National Authority of Medicines & Health Products, Portugal.
  - Dr. Isabel Scuntaro, Swissmedic, Switzerland.
- How To Do A Literature Review, Dr. Nazarena Mazzaro, Head of Corporate Clinical Research, Ambu.
- What Has Changed for Post Market Surveillance Since The Directive Has Been Implemented? Dr. Philippe Auclair, Senior Director, Regulatory Strategy and Advocacy, Abbott Quality & Regulatory EMEA, Abbott Vascular International, Belgium.
- Post Market Surveillance – Notified Body Opinion, Dr. Gert Bos, BSi, UK.
- Post Market Clinical Follow Up, Dr. Anna Heile, Senior Clinical Research and technical Specialist, Codman & Shurtleff, a J&J Company, USA.
- Key Audit Requirements, Charles Bright, Plasmed Consultants, UK.
- Keynote: The Recast Clarified by the EU Commission, Jacqueline Minor, Director of Consumer Affairs, European Commission, Health and Consumers Directorate-General, Belgium.
- How Do We Reach A Safe, Smart And Sustainable Legal Framework, John Brennan, Director Technical and Regulatory Affairs, Eucomed, Belgium.
- The Recast – Viewpoint from A Notified Body, Dr. Gert Bos, BSi, UK.
- Practical Guidance On Related Directives RoHS, REACH, and WEEE, Ruxandra Cana, Partner, Field Fisher Waterhouse LLP, Belgium.
- Making Health IT Safe, Martin Ellis, Chair, Intellect Clinical Safety Forum & Patient Director, BT Health, UK.
- Medical Device Software to Meet 2007/47/EC Life Cycle Requirements Post-Conference Workshop (1 day).
  - Software Regulations, Classification, Design and Development to Meet the State-of-the-Art, Trevor Lewis.
  - Medical Software Development from Concept to Market, Alan Johnson, Director of Technology, Tactiq.
  - Legal Challenges Concerning Telemedicine, Stefaan Callens, Kim Cierkens, Callens Law Firm, Belgium.

Course/Seminar, Organisation, Duration: 2011

Going Global: Partnering and Investing in International Life Sciences (Elsevier webinar 1.5 hours)
- This webinar discussed the need to understand your potential partner's innovation record; how to measure Success in the market; understand geographic considerations; how to identify and mitigate risk; and the use of a check list.

BioWales 2011 (Welsh Assembly Government, South Wales, total 1.5 days)
- Attended presentations: Opening Address by Prof. Paul Smith, Cardiff University and MediWales Director; The Role of the Chief Scientific Adviser for Wales, Prof. John Harries, Chief Scientific Adviser, Welsh Assembly Government; GE Healthcare Diagnostics, Dr. Klaus Hochleitner, Global Product Technical Specialist, Diagnostic Devices, GE Healthcare; Diagnostic Techniques: What's on the Horizon? Dr. Molly Price-Jones, Senior Director, Gen-Probe; Future Technologies for Diagnostic Devices, Huw Summers, Prof. of Nanotechnology for Health, Swansea University; Supporting Innovation in Welsh eHealth Industries, David Ford, Director, eHealth Industries Innovation Centre, Health Informatics Laboratories, Swansea University; eHealth for the Community, Richard Pugh, Community Development Manager, Tenovus; Location, Location, Location – where next for smart pills & capsules, Martin McHugh, Business and Technology Development Manager, Zarlink Semiconductor; Issues, Challenges & Opportunities for Life Sciences & Health Technologies, Tony Davis, Chairman, Medilink UK; Single Evaluation Pathways for Medical Devices, Mirella Marlow, Programme Director, Devices & Diagnostics Systems, Centre for Health Technology Evaluation NICE; Investment Landscape – Early Stage Medtech and Healthcare Companies, Dr. Mark Payton, Fund Principal, Mercia Technology Seed Fund; Venture Capital, Brenig Preest, Investment Director, Excalibur Fund Managers. Clinical Access, Sue Bale, Assistant Nurse Director, Aneurin Health Board.

Welsh Wound Network Meeting (Wales, ¾ day)
- Supported by the Welsh Government to promote the world class capability of the Welsh wound care sector.
- Attended presentations on Wound healing health economics, Prof. Ceri Phillips; Welsh Wound Innovation Centre, Prof. Michael Clark; Surgical Materials Testing Laboratory, Dr. Pete Phillips & Dr. Gavin Hughes.

Difficult People Made Easy - Nancy Slessenger (RSA Interims, RAC Club, London, 45 minutes)

Centenary of the nuclear atom: The life & work of Lord Rutherford – Dr. Peter Ford MBE, University of Bath (Staffordshire University, 1 hour). This provided useful insights about the development of modern physics.

Course/Seminar, Organisation, Duration: 2010

In Vitro Diagnostics (SMi Conference, 2 days, London 2010)
Presentations included:
- Analysing Key IVD Market Driver, David Huckle, Adam Business Associates.
- Emerging Trends in Immuno and Molecular Diagnostics, eddie Blair, Integrated Medicines Ltd.
- Delivering on the Promise of Personalized Healthcare, Ansar Jawaid, AstraZeneca.
- Understanding the Role and Impact of New Technologies in Point of Care Testing, Anthony James, NHS Institute for Innovation and Improvement.
- Point-2-Point Genomics Presentation, Ray Harrison, Point-2-Point Genomics Ltd.
- Pricing and Reimbursement Strategy for In Vitro Diagnostics, Gerald Schnell, Simon-Kucher & Partners.
- Drivers of Supply & demand for Diagnostics, Devaki Nair, Royal Free Hospital.
- Clinically Useful Point-of-Care Diagnostics for Infectious Diseases, Penny Wilson, Technology Strategy Board.
- IVD Industry Guidelines, Study Design & Analysis Considerations, Vicki Petrides, Abbott Laboratories.
- The Process of Market Surveillance and Auditing, Elaine Mooney, Irish Medicines Board.
- Future of Diagnostic Test in Clinical Practice for Personalised Medicine, Anil Modak, Cambridge Isotope Labs.
- How Do Pharma/Biotech Companies Acquire Personalized Medicine Technologies, Adrian Dawkes, Pharma Ventures.
- Applying Microfluidics to Enable Point-of-Care Immunodiagnostics, Holger Bartos, Boehringer Ingelheim Microparts.
- The Introduction of Diagnostics for Personalized Medicine in the UK National Health Service, Rob Elles, National Genetics Reference Lab, Manchester.
- Opportunities for New Biochip Technology in Laboratory & Point of Care Testing, Till Bachmann, University of Edinburgh.
- Improving Molecular Diagnostics through Biochips and Nanotechnology, Moncef Benkhalifa, Unilabs, France.
- From Early Development to Proof of Concept: Key Aspects of the POC Study, Michael-Friedrich Boettcher, Bayer.
- Emergence of Non Traditonal Stakeholders in the IVD Industry, Harry Glorikian, Scientia Advisors.

Development of IVD SMEs: What Are The Business Models and Are They Viable? (SMi Post-Conference Workshop, ½ day, London 2010)
Discussions led by David Wilson, VP Commercial Operations Europe Molecular Detection Inc. Presentations included:
- Key industry challenges;
- Innovation, drivers of adoption, and barriers to entry; and
- Funding and time to market.

Regulatory Landscape, MEDTEC UK April 2010 (Canon Communications, 1 day conference)
- MDD in Europe Now and Future, Steve Owen, Head of Policy, European and Regulatory Affairs, MHRA.
- Clinical Evaluation and Investigation, Dr. Ir. Gert Bos, Head of Regulatory and Clinical Affairs BSi Healthcare.
- Reprocessing of Single Use Devices (SUDs), Pete Schroeer, Director Europe Quality Systems and Regulatory Affairs, Johnson & Johnson.
- A Successful Implementation of Requirements Revised by Directive 2007/47/EC, A Case Study and Industry Perspective, Dr. Stefan Menzl, Director Regulatory Affairs, Compliance Europe, Africa Middle East, Abbott Medical Optics, AMO Germany.
- E-Labelling of Medical Devices – Latest News, Joachim Wilke, Director Affairs & Policy Europe, Medtronic.
- Post Market Surveillance and Vigilance: Discussing The Practicalities and Highlighting The Challenges Facing Companies Who Have To Report Into Multiple Countries, Sandy Geddes, Reg. Dir., Boston Scientific.
- Medical Devices Recast – Where Do We Stand? Perspectives. Philippe Auclair, Director, Regulatory Compliance, Quality Systems and Government Affairs, Abbott Vascular International BVBA.
- The Regulation of Software as a Medical Device, Mika Reinikainen, Managing Director, AbNovo.

FDA - Update on the Regulation of In Vitro Diagnostic Devices, Alberto Gutierrez, Director of Office of In Vitro Diagnostic Device Evaluation and Safety, IVD Technology magazine Virtual Conference (1 hour).

Course/Seminar, Organisation, Duration: 2010

Panel Discussions on Immunassays; Lab Automation and Instrumentation; and Molecular Diagnostics, IVD Technology magazine Virtual Conference (3 hours).

- Panelists included Ian Wright, Head of Global Assay Development, Siemens Healthcare Diagnostics; David Fraser, Technology Transfer Leader, BBInternational; Vincent Tummuinello, Senior Marketing Manager, bioMerieux; Robin Felder, Professor of Pathology and Associate Director of Clinical Chemistry, University of Virginia, USA; Charles Hawker, Scientific Director for Automation and Special Projects, ARUP; Damon Getman, Senior Staff Scientist, Gen-Probe; Larry Mimms, VP R&D, Quidel; Chad Gerber, Director of Contract (IVD) Oligonucleotide Manufacturing, Biosearch Technologies; and Jason Erickson, Director of Quality, Biosearch Technologies.

Examining the Past, Present and Future of the IVD Industry, webcast by IVD Technology magazine (1 hour)

- Technology, Products and Research & Development, Larry Mimms, Quidel Corp.
- Regulations, Standards, Government and Legal Affairs, Jonathan Kahan, Hogan Lovells.
- Business and Marketplace Issues, Scott Garrett, Beckman Coulter.

Business Landscape, MEDTEC UK April 2010 (Canon Communications, 1 day conference)

- Surviving the Squeeze: Trends from the Medical Technology Industry, Chad Whitehead, Partner, Global Life Sciences Ernst & Young.
- The Changing NHS Research Environment for Medtech Clinical Trials, Dr. Mark Lewis, Health Management and Clinical Research Consultant.
- Evaluation of Medtech Products by NICE, Mirella Marlow, Programme Director – Devices and Diagnostic Systems, National Institute for Health and Clinical Excellence (NICE).
- Procurement Landscape – How To Make Yourself Attractive To The NHS, Colin Callow, Lead Associate, NHS Institute for Innovation and Improvement & Senior Programme Manager, NHS Technology Adoption Centre.
- Discussion: The Future of Medical Device Development For An Ageing Population; The Anticipated Budget Cuts; How Will Regulations Be Applied? Cost Effectiveness and Reimbursement Mechanisms.

Future Paths for MedTech Regulation (ABHI Legal & Regulatory Conference, 1 day, London 2010)
Presentations included:

- Status of EU Commission Work, Dr. Peter Bischoff-Everding, Legal Officer Cosmetics and Medical Devices.
- Industry Proposals, John Brennan, Director of Regulatory Affairs, Eucomed.
- UK Regulator's Position, Steve Owen, Head of European and Regulatory Affairs (Devices) MHRA.
- Introduction of New Device Technology, Malcolm Carlisle, Chairman ABHI Technical Policy Group.
- What needs to be addressed in the Recast of the Devices Directive: A Clinical Perspective, Dr. Susanne Ludgate, Medical Director MHRA.
- UDI/AIDC an update on Commission Proposals, Jim Willmott, Global Labelling Manager, Smiths Medical.
- MHRA Medical Device Technology Forums, Dr. Chris Brittain, Senior Medical Officer Clinical Devices.
- Design Management – the Key to Safety and Performance in Med. Dev. Tech., Richard Snell, Altrika Ltd.
- The work of the Committee on the Safety of Devices, Dr. John Perrins, Chair of MHRA Committee.

Mobile Healthcare: Is there an App for that? (MediLinkWM, 1 day, Coventry, 2010)
Attended presentations including Understanding the opportunities for mobile applications in medicine and healthcare, Chris Dyke MedilinkWM; The impact of mobile applications in improving healthcare in the UK, George MacGinnis, PA Consulting; Looking to the future, what's on the apps horizon? Nick Hunn, Mobile Data Association; A clinical perspective, Prof. Ian Wells, Royal Surrey County Hospital; JSJS Design Case Study: Developing a successful application; John Shermer; EMIS Case Study: Developing a successful application, Paula Turnock & Nathan Zardin; Symptometrics Case Study: Developing a successful application, Mark Croft.

Combating Infectious Diseases: A Partnership Approach, an Infectious Diseases Control Network (IDCN) Conference (MediLinkWM, ¾ day, Coventry, 2010)

- Attended presentations given by Richard James, Prof. of Microbiology, Director of the Centre for Healthcare Associated Infections, School of Molecular Medical Sciences, Faculty of Medicine & Health Sciences, University of Nottingham on Public Health Challenges & Opportunities in Infectious Diseases; Peter Lambert, Professor of Microbiology, School of Life and Health Sciences, Aston University on Technology to Combat Infectious Disease; Dr. Rupert Osborn, CEO, IP Pragmatics on Public Sector Laboratories – Infectious Diseases Capabilities & Opportunities for Industry; Duncan Kerr, Midven on Funding Opportunities for SMEs and workshop discussions on overcoming barriers to collaboration.

Course/Seminar, Organisation, Duration: 2009

Horizons in Healthcare (MediWales seminar, ½ day held at Heath Park Campus, Cardiff, 2009)
- Attended presentations given by Prof. Perumal Nithiarsu, on the Role of computational modelling in healthcare and Prof. Christopher Butler, School of Medicine, Cardiff University on the Point of care testing in primary care; the need for joined up thinking.

The New MDD for Medical Device Manufacturers, webinar by Intertek Notified Body 2009 (1 hour)
- Review of detailed requirements arising from the Medical Device Directive Revision 2007/47/EC, Ron Nash.

BioWales 2009 (Welsh Assembly Government, South Wales, total 1.0 day)
- Attended presentations: Opening Address by Rt Hon Rhodri Morgan, First Minister for Wales; The ongoing story of Dafydd & Goliath, Stephen Britton, Managing Director, Siemens Healthcare Diagnostics; Next generation sensors and diagnostics: the impact of nanotechnology, Prof. Steve Wilks, Co-Director, Centre for NanoHealth Swansea University; The Shakerscope, Dr. David Williams, Director, Shakerscope; A new respiratory aid, Prof. Bill Johns, Director, Haemair; It's Deja Vu all over again, Prof. Jeremy Stone, Deputy Chairman, Excalibur Group; Starting a company from the very start, David Baynes, CEO, Fusion Group and Current investment trends in Wales, Peter Wright, Investment Director, Finance Wales.

New Technologies in Healthcare 2009 (Welsh Assembly Government, South Wales, total 0.5 day)
- Attended presentations concerning The AIDC Centre for Wales – Facilitating the Application of RFID Technology, Hywel Williams, Manager, National AIDC Centre for Wales; RFID – Existing Standards and Current Developments in Healthcare, Dr. Christoph Thuemmler, Director, Institute for Applied eHealth; Informing Healthcare – New Technology and Improving Patient Safety; Nick Elcock, Organisational Readiness Manager, Informing Healthcare; The Health Technology Market, Gwyn Tudor, Forum Manager, MediWales; Doing Business with the NHS, Nick Cowley, Deputy Director, Welsh Health Supplies; and Winning Business in The NHS, Jon Wilks, Director, UK Healthgateway.

Advancing Clinical Development of Molecular and Other Diagnostic Test for Respiratory Tract Infections (United States (US) Food and Drug Administration's (FDA's) and the Infectious Diseases Society of America (IDSA) Public Workshop, 2 days, Washington DC, USA 2009). This workshop provided insights from some of the world's leading clinical specialists in respiratory tract infections, regulators and industry based specialists.

This comprehensive workshop covered the following topics with world class, leading experts in their respective fields:

Clinical Background and Perspective
Where we stand: the clinical perspective. Review of current diagnostic methods for common respiratory tract infections. Pathogens we can and cannot rapidly detect in patients with:

- ***Acute otitis media and acute rhinosinusitis***. Ellen Wald, M.D. Alfred Dorrance Daniels Professor on Diseases of Children and Chair, Dept. of Pediatrics, University of Wisconsin School of Medicine and Public Health, Pediatrician-in-Chief, American Family Children's Hospital.
- ***Lower respiratory tract infection***. Andrew T. Pavia M.D., FAAP, FIDSA George and Esther Gross Presidential Professor, Chief, Division of Pediatric Infectious Diseases, University of Utah.
- ***Acute exacerbations of chronic bronchitis***. Sanjay Sethi M.D., FACP Professor of Medicine Division Chief, Pulmonary/Critical Care/Sleep Medicine University at Buffalo, State University of New York Section Chief, Pulmonary/Critical Care/Sleep Medicine VA WNY Healthcare System
- ***Community-acquired bacterial pneumonia***. John G. Bartlett, M.D. Professor of Medicine The Johns Hopkins University School of Medicine.

Regulatory Background
FDA regulatory structure and paradigm for in vitro diagnostic tests.

- ***General regulatory framework for in vitro diagnostic devices***. Sally Hojvat, Ph.D. Director, Division of Microbiology Devices, Office of In Vitro Diagnostic Device Evaluation and Safety, Center for Devices and Radiological Health, Food and Drug Administration.
- ***Regulatory approach to the development of tests for respiratory tract infections***. Kathleen Whitaker, Ph.D. Scientific Reviewer, Division of Microbiology Devices, Office of In Vitro Diagnostic Device Evaluation and Safety, Center for Devices and Radiological Health, Food and Drug Administration.
- ***Required performance data and statistical evaluations***. Estelle Russek-Cohen, Ph.D. Team Leader Mathematical Statistician, Division of Biostatistics, Office of Surveillance and Biometrics, Center for Devices and Radiological Health, Food and Drug Administration.

Technical Background and Laboratory Perspective
Perspective of the laboratory diagnostician. Clinical performance of cleared FDA diagnostic microbial tests.

- ***Strengths/weaknesses of diagnostic devices for viral/bacterial pathogens and unmet needs***. Christine Ginocchio, Ph.D. Senior Director, Division of Microbiology, Virology and Molecular Diagnostics, Department of Pathology and Laboratory Medicine, North Shore LIJ Health System Laboratories Research Associate Professor, Department of Genetics and Molecular Microbiology, SUNY Stony Brook, NY.
- ***Multiplex RT-PCR and emerging technologies for the detection of respiratory pathogens***. Angela M Caliendo, MD, PhD Professor and Vice Chair, Pathology and Laboratory Medicine Emory University School of Medicine.
- ***Interpretation of assays for S. pneumoniae***. Bernard Beall, Ph.D. Chief, Streptococcus Laboratory, Respiratory Diseases Branch Centers for Disease Control and Prevention.

Industry Perspective
Industry Perspective on the development of molecular tests for respiratory infections.

- ***Challenges in the development of molecular methods for the diagnosis of respiratory viruses***. Richard Janeczko, Ph.D. Vice President, Emerging Markets and Technology, Luminex Molecular Diagnostics.
- ***Challenges in the development of molecular methods for the diagnosis of bacterial pathogens in respiratory infections***. Fred C. Tenover, Ph.D. D(ABMM) Senior Director, Scientific Affairs, Cepheid. Consulting Professor of Pathology, Stanford University Adjunct Professor of Epidemiology, Rollins School of Public Health, Emory University.

Biomarker Development
Review of biomarkers in the diagnosis, triage, and management of respiratory tract infections.

- ***Existing biomarkers for respiratory infections and strengths/weaknesses of available data***. David Gilbert, M.D. Chief of Infectious Diseases and Director of Earle A. Chiles Research Institute, Providence Portland Medical Center and Professor of Medicine Oregon Health and Science University.
- ***Study design and statistical issues in biomarker clinical trials***. Sumithra J. Mandrekar, Ph.D. Senior Associate Consultant, Division of Biomedical Statistics and Informatics, Associate Professor of Biostatistics Mayo Clinic College of Medicine.
- ***Case study: Perspective on the development and validation of procalcitonin for triage of respiratory infections***. Cynthia Fowler, M.D. Senior Medical Director, Global Medical Affairs, bioMerieux.

Panel Discussion: Use of current biomarkers and the design of clinical trials to evaluate biomarkers in patients with respiratory tract infection.
- Acute tracheobronchitis
- Acute exacerbation of chronic bronchitis
- Community-acquired pneumonia
- Acute otitis media/rhinosinusitis

Influence of rapid molecular diagnostics
Influences of rapid molecular diagnostics on:

- **Appropriate antibiotic use and emergence of antibiotic resistance**. Louis B. Rice, M.D. Chief, Medical Service, Louis Stokes Cleveland VAMC Professor of Medicine, Case Western Reserve University School of Medicine.
- ***Detection of MDR – M. Tb***, Susan E. Dorman, M.D. Associate Professor of Medicine Center for Tuberculosis Research, Johns Hopkins University School of Medicine.
- ***Detection of anthrax and other biothreat agents***, Michael G Kurilla, M.D., Ph.D. Director, Office of BioDefense, Research Affairs Associate Director for BioDefense Product Development DMID, NIAID, NIH, DHH.

Design of clinical trials of new molecular diagnostic devices alone or in combination with an experiment drug in patients with respiratory tract infections.
Design of clinical trials of molecular diagnostic devices and drugs in patients with respiratory tract infections:

- ***Evaluating only a diagnostic device.*** Robert Becker, M.D. Chief Medical Officer, Office of In Vitro Diagnostic Device Evaluation and Safety, Center for Devices and Radiological Health, Food and Drug Administration.

- ***Evaluating both the diagnostic device and a new drug or new drug regimen***. Kristen Meier, Ph.D. Mathematical Statistician, Division of Biostatistics, Office of Surveillance and Biometrics, Center for Devices and Radiological Health, Food and Drug Administration.

Industry perspective on clinical trials and other facets of the development and approval of new diagnostics for respiratory tract infections. Thomas Grewing, Ph.D. Senior Director R&D QIAGEN Hamburg GmbH, Research & Development.

Use of molecular diagnostics to detect pathogen resistance

- ***Detection of both MSSA and MRSA***. Lance Peterson, M.D. Director, Microbiology and Infectious Disease Research, Healthcare Epidemiologist North Shore University Health System Clinical Professor, University of Chicago Pritzker School of Medicine.
- ***Detection of multi-drug resistant gram-negative respiratory bacteria in at risk patients***. Robert A. Bonomo, M.D. Director, VISN 10 GRECC, Professor of Medicine, Pharmacology, and Molecular Biology and Microbiology, Case Western Reserve University School of Medicine.

There were also Group Discussions where each group member was asked to discuss the topics from the perspective of development, evaluation and clinical integration of diagnostic tests for respiratory tract infection. These included the unmet diagnostic needs in the care of patients with respiratory tract infections; understanding the use and performance of existing FDA approved/cleared devices; what characteristics would make future diagnostic products most useful for use with respiratory infections; the clinical perspective about the inclusion of low-prevalence analytes and/or newly discovered 'possible pathogens' in respiratory panels; and other general issues of concern.

Course/Seminar, Organisation, Duration: 2008

UK Competent Authority, MHRA, Medical Device Vigilance Conference (NEC Birmingham, 2 days):
- Launch of MHRA vigilance guidance, Kent Woods.
- MHRA expectations of manufacturer's EU post market surveillance and vigilance systems, Clive Bray.
- The MDD Revision, what does it mean for manufacturers, John Wilkinson (ABHI).
- Overview of the new Vigilance MEDDEV Rev 5 - major areas of change, Tony Sant.
- MHRA best practice guidance for reporting and investigating adverse incidents, Roy Saunders.
- Field Safety Corrective Actions and Field Safety Notices, Hazel Randell.
- Clinical Investigations and Adverse Incidents, Susanne Ludgate.
- Workshop exercises were undertaken on the morning of the second day.
- MORE II Tutorial.
- Working with the media, Simon Gregor.
- Question & Answer session with Clive Bray & Susanne Ludgate.

Managing the Revisions to the Medical Device Directive (Informa Life Sciences 2 day conference)
- Overview of the major revision to the Medical Device Directive, Dario Pirovano.
- Deciphering the changes to conformity assessment procedures, Jeff Vest.
- Examining the reclassification of products, Chris Jepson.
- Reprocessing of Single Use Devices (SUDs), Pete Schroeer.
- Reprocessing of single-use medical devices – An opportunity for quality improvement and saving potentials, Nikou Ghassemieh.
- Updating the clinical data requirements, and implications of updates to clinical requirements, Anna van der Hoek.
- Enhancing the vigilance guidelines in the MDD, Laura Locati.
- Implications of updates to Vigilance and Post Market Surveillance, Peter Schroeer.
- Discover the enhanced labelling requirements – alternative labelling, Joachim Wilke.
- Hazardous material use: di(2-ethylhexyl) phthalate (DEHP), David Cadogan.
- Case examples of the impact of the revisions to the MDD on Cordis, Europe, Tom van der Schatte Olivier.
- Advanced Therapy Medicinal Products (ATMP), Sabine Kloth.

Navigating the FDA Regulatory Framework (Informa Life Sciences 1 day symposium)
- Developing an investigational device exemption (IDE), Brian Kunst.
- 510(k) Pre-market notifications, regulations and definitions, Brian Kunst.
- System 510(k) requirements and strategy, Kristin Zielinski.
- Post-market requirements for 510(k), Kristin Zielinski.
- Understanding the FDA approach to pre-market approval (PMA), Judith O'Grady.
- Post-approval requirements for a PMA, Judith O'Grady.
- FDA regulations for combination products, Karen Long.
- What are the quality requirements for the approval process?, Kaiser Aziz.
- Risk management and the application of ISO 14971 within the quality system, Charles Sidebottom.
- The FDA process of appeals, Kristin Zielinski.

BioWales 2008 (Welsh Assembly Government, South Wales, total 0.5 day)
- Attended presentations concerning Innovation: Nanotechnology & Medicine by Professor Ruth Duncan; Focussing Science on Improving Patient Care by Dr. Jerry Hutchinson; A Magnet for Global Innovation by Ron Petersen of the Boots Innovation Centre and Innovation in Medical Devices by Professor Peter Wells.

Course/Seminar, Organisation, Duration: 2008

Medical Device Technology 2008 Conference, (NEC Birmingham, 1 day)
- Total Quality Matters, David Purnell.
- Current issues, with clinical evaluations: changes to the requirements for clinical evaluation in the European Medical Device Directive, Jeremy Tinkler.
- Current state and future evolution of European regulatory requirements, Mika Reinikainen.
- Revision of the Medical Devices Directive, an industry perspective, Dario Pirovano.
- Revision of the New Approach and consequent effect on medical devices, Jos Putzeys.
- Revised sterilization standards, what a notified body expects to see for validation reports, Henry Sibun.
- Environmental compliance for medical devices, Professor George Howarth.

Market Access for Point-of-Care Diagnostics (Informa Life Sciences 2 day conference, Amsterdam)
- Point-of-care testing: What is the current strategy? Meinhard F. Schmidt, Head Decentralized Solutions, Roche Diagnostics.
- POCT expediting the patient pathway: Improving outcomes, Christopher P. Price, Visiting Professor in Clinical Biochemistry, University of Oxford.
- Integrating point-of-care testing into the clinic, Johannes Kedzierski, CEO, Alkmaar Medical Centre.
- Building a Quality system into your processes, Dr. Ian Watson, Consultant Biochemist, University Hospital Aintree.
- Point-of-care coagulation testing Accuracy equivalence and quality, Dr. Piet Meijer, Director, ECAT.
- Establishing the clinical utility of Point of Care Testing (POCT), Dr. Joan Pearson, Clinical Lead for POCT, Leeds Teaching Hospitals.
- Reimbursement for Point-of-care diagnostics-opportunities and barriers, Dr. Mark Charny, Managing Director, Translucency UK.
- Future trends in the POCT market: platform technologies for point of care testing, Dr. Gert Blankenstein, Head of Product Development, Industrial Customer Business, Boehringer Ingelheim microParts GmbH.
- Fully automated molecular diagnostics for decentralised clinical testing, Dr. Ian George, Business Development Manager, Enigma Diagnostics.
- Innovation in POC diagnostics: Perspectives form a startup, Will Colón, Commercial Director, Oxford BioSensors.
- Smart integrated biodiagnostic systems for healthcare: The SmartHEALTH Integrated Project, Professor Calum McNeil, Professor of Biological Sensor Systems and SmartHEALTH Coordinator, Newcastle University.
- The role of home healthcare in managing chronic disease, Malcolm Luker, CEO & General Manager, Home Diagnostics, Philips Healthcare Incubator.
- High street pharmacy management of long-term conditions, Roger Kirkbride, Independent Pharmacy Consultant.
- Direct to consumer laboratory testing, Dr. Gillian Hart, Scientific Director, YorkTest Laboratories.
- Providing integrated connectivity solutions, Christina Rode-Schubert, Secretary General, CIC Europe and Thomas Norgall, Fraunhofer Institute for Integrated Circuits – BMT.

How to Implement the New European Vigilance Procedures (Medical Device Technology, 1 hour webcast).
- Webinar given by Roger Gray.

Developing Biochemicals and Chemical Reagents for Next-Generation Immunoassays (Medical Device Technology, 1 hour webcast)
- Overview of Biochemicals and Reagents Used in Assays, George Parsons.
- Applying Biochemicals and Reagents to Assays, Craig Hixson.
- The Future of Biochemicals and Reagents in Assays, Sulatha Dwarakanath.

How to Engage with a Prime Contractor: An Overview of the Thales Group's Purchasing Strategy
40 minute presentation by Steve Davies, Purchasing Director at Intellect UK, London.

Cell, Sell, Sell (MediWales seminar, attended for ½ day, Cardiff)
- Attended presentations Andrew Davidson, Managing Director of DTR Medical; Mark Casey, Procurement NHS Lothian; and Larry Petterson, Head of Procurement & Commercial Development, Cardiff and Vale NHS Trust. This provided useful insights on selling to the NHS.

Course/Seminar, Organisation, Duration: 2007

Next-Generation Amplification Methods for Molecular Diagnostics:
Webcast run by IVD Technology magazine (1 hour)
- Essential Principles of Amplification Technologies, Professor Andrea Ferreira-Gonzalez.
- Applying Amplification Methods in Molecular IVDs, Dr. Damon Getman.
- The Future of Amplification Technologies, Dr. Gregory Tsongalis.

UK Competent Authority, MHRA, Current Regulations and Medical Device Directives:
An Update from the Regulator (London, 1 day)
- Update and Progress Report on the Revision of the Medical Devices Directives, Richard Gutowski.
- Notified Bodies: Latest Developments, Rob Higgins.
- Device Vigilance Update: Common Trends, Pitfalls and Problems, Tony Sant.
- Update on Tissue Engineering, Jeremy Tinkler.
- NICE Workshop: involving device manufacturers in producing NICE guidance, Mirella Marlow and Seren Phillips of NICE.

Electro-Medical Devices: Regulations and Standards (Informa Life Sciences 3 day conference)
- Overview of the Medical Devices Directive, Ian Cutler.
- Defining the EN 60601 family of standards, Dr. Didier Bozec.
- Achieving Electromagnetic Compatibility (EMC) for medical device safety, Keith Armstrong.
- Performance testing, Chris Marshman.
- Identifying the Global Harmonisation Task Force (GHTF), Alan Kent.
- Understand the impact of environmental regulations, Aidan Turnbull.
- Overview of design principles, Matt Wherry.
- EMC measurement and testing, Dr. Martin Robinson.
- Producing the technical file, Dave Imeson.
- Defining risk management for electro-medical equipment, Richard Young.
- Conformity assessment procedures, John Webster.
- Product liability, Julian Acratopulo.
- Describing software standards for medical devices, Chris Pickles.

Environmental Legislation for Medical Devices Workshop (1 day):
- Implications for the WEEE Directive, Professor George Howarth.
- Detailing the impact worldwide of RoHS regulations on the medical device industry, Dr. Freimut Schröder.
- Directive 2005/32/EC on the eco-design of Energy-using Products (EuP), Aidan Turnbull.
- Practical approach to REACH, Professor James Clark.
- Description of the Battery and Accumulators Directive (2006/66/EC), Steve Norgrove/Aidan Turnbull.

Creating Collaboration in Medicine – Opportunities & Challenges
(Cardiff University Innovation Network, 2 hours) Attended presentations given by:
- David Powell, Cardiff & Vale NHS Trust.
- Sir Christopher O'Donnell, co-chair Health Industry Task Force (HITF).

Photonics Cluster (UK) LED Safety Course presented by Dr. Neil Haigh (Birmingham, 1 day)
- This course covered light, radiometry and photometry;
- Hazard classifications and rationale for LEDs, lamps and lasers; and
- Practical laboratory experiments to reinforce lessons learnt.

UK Disease Management & Remote Patient Monitoring Services (Birmingham, ½ day)
- Frost & Sullivan interactive workshop organised via Medilink West Midlands.

Course/Seminar, Organisation, Duration: 2007

The Waste Electrical and Electronic Equipment (WEEE) Regulations
A DTI seminar on compliance (Cardiff, 1 day)
- WEEE Regulations, Jeanne Grey.
- The WEEE Regulations and the Environment Agency, Bob Mead.
- Producer Compliance Schemes – Services for Producers, John McKie.
- The Distributor Take Back Scheme – Services for Distributors, James Skidmore.

Medical Device Technology 2007 Conference, NEC Birmingham (1 day)
Attended the following seminars:
- The Centre for Evidence-based Purchasing Sue Norris, Head of NHS Purchasing and Supply Agency Centre.
- Implementation & update on the revision to the Medical Devices Directive, Mika Reinikainen.
- The proposed EC regulation for Advanced Therapy Medicinal Products: current situation and borderline with medical devices, Alison Wilson.
- Effects of the Medical Device Directive revision on clinical trials, Dr. Susanne Ludgate, MHRA.
- New US/FDA Postmarket Surveillance and Inspections Initiatives, Tim Ulatowski, Director, Office of Compliance, Center for Devices and Radiological Health, US Food and Drug Administration.
- Integrating risk management (ISO 14971) into your quality management system and other developments in risk management: are you ready? Bert Degens.
- MSOG – A tool to promote the cooperation and uniform enforcement of market surveillance of medical devices, Maria Judite Neves, Head of Medical Devices Department, INFARMED, Competent Authority for Medicines and Medical Devices, Portugal.
- The Global Harmonization Task Force – Regulatory Model for Medical Devices, Dr. Carl Wallroth.
- Vigilance reporting: harmonizing your systems for global compliance, Mika Reinikainen.

Inaugural Meeting of the Welsh Wound Special Interest Group (Wales, ¾ day)
- Supported by the Welsh Assembly Government (WAG) and MediWales to promote the world class capability of the Welsh wound care sector.
- This brought together all leading institutions and interested parties based in Wales including the world leading Wound Healing Research Unit (WHRU).

Body Language a MindSkills Workout (Leadership Dynamix Forum, IoD London)
- Interactive discussion facilitated by David Norman (½ day).

Raising Finance (MediWales seminar, ¾ day Cardiff)
- Presentations given by EPSRC, Technology Strategy Board, Deloitte, Longbow Finance, Wales Fund Managers, Finance Wales and Boots Centre for Innovation.

Course/Seminar, Organisation, Duration: 2006

Software for Medical Devices (IET, London 1 day)
- Placing UK Health in Perspective, Surgeon Commodore Lionel Jarvis, Ministry of Defence.
- ISO 14971 – Risk Management and Software Standards, Mejdi Majed, Intertek.
- ISO 62304 – Process Standards for the Development of Medical Software, Peter Jordan.
- Medical Device Security in Hospital Networks – New ISO/IEC Work Proposal, Dr. Nick Mankovich, Director of Product Security, Philips Medical Systems.
- Threat of Breaches of Cyber Security to Medial Devices, Dennis Lindsey, NHS Account Manger, McAfee.
- Medical Software Standards & the NHS, Geoffrey Cusick, Head of Medical Physics, UCL Hospitals, London.
- Standards, regulations and hospital developers, Justin McCarthy, Cardiff and Vale NHS Trust.

Medical Innovation Forum 2006 Conference, (Olympia, London, 1 day)
Attended presentations and discussions concerning:
- Patent Office services to assist in Patent enforcement, Jason Bellia, Patent Examiner.
- The Design Process – A high level overview of techniques used for medical product design, Ken Hall, Technical Director, Triteq.
- Case Studies of successful Electronic Device History Records (eDHR) Implementations, Sean O'Sullivan, Managing Director, Camstar Europe.
- Translating clinical evidence into evidence based medical practice – the medtech challenge, George Samson, CEO, APA Parafricta.
- Minimally Invasive Surgical Devices, Dr. Gareth Thomson, University of Dundee.

Wound Management, through partnership (Medilink Yorkshire & Humber, ½ day)
- Speakers included Professor Keith Harding, Departmental Head, Wound Healing Research Unit; Professor of Rehabilitation (Wound Healing), Cardiff University; Clinical Director of Wound Healing, Cardiff & Vale NHS Trust.
- Professor Peter Vowden, Departmental Head of Vascular Surgery, Bradford Royal Infirmary and visiting Professor in Wound Healing Research, University of Bradford.
- Chris Roberts, Head of Market Development, Antibacterials, Smith & Nephew Woundcare Management.
- Breda Cullen, Research Fellow, Johnson & Johnson Advanced Woundcare.
- Andrea Nelson, Reader, University of Leeds
- Simon Barrett, Tissue Viability Nurse Lead, East Yorkshire and Yorkshire Wolds and Coast PCTs.

Medical Device Technology 2006 Conference, (NEC Birmingham, ½ day)
- Participated in a Risk Management Workshop led by Mark Boult, Principal, DNV Consulting.
- This covered various techniques and approaches with interactive practical exercises.

MidTECH Innovation Conference, (National Motor Cycle Museum Birmingham, 1 day)
- Presentations provided different perspectives from generating innovations from within the UK's National Health Service (NHS) and how to exploit the technology for the benefit of all stakeholders.

BioWales 2006 (Welsh Development Agency, Cardiff, total 1.0 day)
- Attended presentations concerning laboratory on a chip, venture capital, maggot therapy, telehealth technologies, portable insulin pump, molecular probe technology, artificial hearts, imaging of brain function and the keynote address "How Diagnostics are Transforming the Healthcare Market Place" by Sir William Castell, President & CEO GE Healthcare.

Plastics in Medical Devices, Plastics and Rubber Weekly, (EMAP Comm.s Brussels, 2.0 days)
- Attended presentations concerning the latest legislation, design for manufacture, China, drug eluting stents, DEHP, new materials, testing, shielding for EMC, biocompatibility, use as a scaffold on which to grow cells, coatings and barrier films.

Course/Seminar, Organisation, Duration: 2006

UK Optical Biochips Open Day, (Cardiff University, 1 day)
- This seminar included presentations on technology and applications of innovations from around the UK and internationally; including keynote speaker Professor James Leary, Purdue University, USA, on Nanophotonic Devices for Nanomedicine.

Clusters, Economic Development and Innovation: Empirical Evidence and Policy Implications in the UK Biotechnology Sector, (part of ESRC Social Science Week06, Cardiff University, ½ day)
- This national seminar was organised in conjunction with the Advanced Institute of Management Research and included presentations on cluster development, methods of gaining evidence and policy implications. Speakers included Professors Phil Cooke & Rick Delbridge and Dr. Calvin Jones.

Problems? What Problems? (International Business Wales, ½ day)
- Interactive creative seminar on various problem solving and creative thinking techniques.

International Marketing Communications – Made Simple (International Business Wales, ½ day)
- This seminar included presentations by Peter Gaunt and Simon Preston of Strategem that covered key topics concerning international marketing and communications.

Getting the Best from Overseas Visits (International Business Wales, ½ day)
- This seminar included presentations by Peter Gaunt and John Sharp of Strategem that covered key topics on international business development.

Course/Seminar, Organisation, Duration: 2005

The Role of Marketing in the New Product Development Process (CIM, Cardiff 2 hours)
- Route-to-Market presentations given by Gwyn Tudor, Director of Contact Innovation; and Jarred Evans, Commercial Manager, National Centre for Product Design and Development Research.

Negotiating Risk Capital Transactions (Finance Wales, Cardiff 0.5 day)
- Valuing Businesses and Case Studies.
- Deal Structures and Case Studies.
- Due Diligence and Deal Completion.
- Exit Strategies and Routes.

Medial Device Standards & Regulations – All Change (IEE, London 1 day)
- Overview of medical device standards, Dr. Hans Sethi, Elekta.
- Product standards – IEC 60601-1 Third Edition Philosophy and Changes, Richard Mellish, MHRA.
- Risk management standards and IEC 60601-1, Brian Bibb, Elekta.
- Usability – IEC 60601-1-6, David Embrey, Human Reliability Associates.
- Views from the Test House, Steve McRoberts, UL Testing.
- Medical Device Software Standards, Peter Jordan, Sensible Standards.
- Standards, regulations and hospital developers, Justin McCarthy, Cardiff and Vale NHS Trust.

EMC for Functional Safety and Reliability (IEE, Bristol 1 day)
- Introduction to EMC for functional safety, Keith Armstrong, Cherry Clough Consultants.
- Legal requirements and liability issues, Simon Brown, Health & Safety Executive.
- Some real-life safety problems caused by inadequate EMC, Keith Armstrong, Cherry Clough Consultants.
- Principles of functional safety, Simon Brown, Health Safety Executive.
- How EMC-related functional safety problems can occur, Keith Armstrong, Cherry Clough Consultants.
- Safety integrity levels (SILs) and all that…, Simon Brown, Health & Safety Executive.
- EMC techniques for mitigation and risk-reduction, Keith Armstrong, Cherry Clough Consultants.
- Verification of the EMC design, Keith Armstrong, Cherry Clough Consultants.

Selling to the NHS (MediWales Seminar , ½ day held at ECM^2, Port Talbot)
Attended the following presentations and related discussions:
- Walter Williams, NHS Purchasing and Supply Agency (PASA).
- Mark Chataway, Hyderus Cyf a Welsh based international pharmaceutical consultancy.

Science & Innovation Symposium (Cardiff 1 day) Welsh Assembly Government;
Joint Professional Forum Health and Well-Being Group in collaboration with MediWales.
Speakers included:
- Mr. Rhodri Morgan, First Minster National Assembly for Wales.
- Mrs Ann Lloyd, Director NHS Wales.
- Sir Roger Jones OBE, Chair Welsh Development Agency.
- Dr. Nick Thomas, Principal Scientist, GE Healthcare.
- Professor Stephen Tomlinson, Provost and Deputy Vice-Chancellor, Cardiff University.
- Mr. Paul Button, Ortho-Clinical Diagnostics, a Johnson & Johnson Company.
- Mr. V'Iain Fenton-May, Specialist Principal Pharmacist.
- Mr. Allan Jones, Assistant Director of Social Services, Ceredigion County Council.
- Mr. Gwyn Tudor, MediWales; and Dr. Claudia Bazzoni, Wales Office of Research & Development.

BioWales 2005 (Welsh Development Agency, Cardiff total 1.0 day)
Attended all the following presentations:
- What's new in embryonic stem cell research, Professor Martin Evans, Cardiff University.
- Larger company perspectives on doing business in Wales: James Christie, Protherics; Dr. Philip Gould, Provalis and Dr. Ian Watkins, Merck Chemicals.
- Future of Healthcare: Dr. Ruth Hall, Chief Medical Officer, NHS Wales and Dr. Michael Clark, Wound Healing Research Unit.
- Report on the Healthcare Industries Task Force, Richard Carter, Head of Industry Sponsorship, Department of Health.
- Turning ground-breaking research into successful business ventures in Wales, Dr. Nick Bourne, Cardiff University.

Course/Seminar, Organisation, Duration: 2005

Negotiating with International Companies (WalesTrade International (WTI), ½ day)
- This seminar included presentations by Peter Gaunt and John Sharp of Strategem that covered key topics that are vital to international success and indeed all negotiations.

Building the Dragon, How to accelerate the evolution of smart innovative businesses in Wales (Cardiff University Innovation Network, 1 hour) Attended presentations given by:
- Henry Kenyon, PricewaterhouseCoopers concerning findings from a recent survey.
- Chris Ready, Economy Power a case study of rapid and innovative growth.

Influencing and Persuading Mindskills Workshop (Leadership Dynamix Forum, IoD London)
- 90 minute workshop on powerful language patterns and interactive discussion facilitated by David Norman; and
- Presentation "A Joined-Up Approach to Leadership Development" by Mike Alsop and Mike Clark of Group4Securicor (½ day).

Power, Politics and Influence in Leadership Mastery (Leadership Dynamix Forum, IoD London)
- Interactive discussion facilitated by David Norman; and
- Valuing Corporate Leadership, Gareth Jones, Head of Organisational Development at M&G Investment part of Prudential plc (½ day).

Significant selected books studied:
- Information Security, A Director's Guide published by the Institute of Directors.
- Directors' Remuneration, A practical guide to setting the pay and benefits of senior executives, A Director's Guide published by the Institute of Directors.
- Never Eat Alone and other secrets to success, one relationship at a time, Keith Ferrazzi with Tahl Raz.
- Who moved my cheese? Dr. Spencer Johnson.
- Rich Dad, Poor Dad, Robert Kiyosaki, with Sharon Lechter.
- Rich Dad, Poor Dad 2, The Cashflow Quadrant, Robert Kiyosaki, with Sharon Lechter.
- Rich Dad, Poor Dad Guide to Investing, Robert Kiyosaki, with Sharon Lechter.
- Rich Dad's, Retire Young Retire Rich, Robert Kiyosaki, with Sharon Lechter.

Course/Seminar, Organisation, Duration: 2004

FDA Seminar (UK Trade & Investment, London, 2 days)
- Chaired by Fred Bassnett UK Trade & Investment presentations provided by FDA senior officials: Heather Rosecrans, Director of Premarket Notification 510(k) Program and Christine Nelson, Director, International Affairs Staff for the Center for Devices and Radiological Health (CDRH).
- Topics covered included: Overview of the FDA; Import Requirements; Investigational Device Exemptions (IDEs); 510(k) Premarket Notification; Pre-Market Approval (PMA); Design Controls; FDA Inspections; Post Market Surveillance / Vigilance; 21 CFR Part 11 Electronic Records and Electronic Signatures. Plus a presentation by Marguerite Meyer on Doing Business in the USA.

Are your improvements really improving your business?....
(Joint IEE & SWIMM manufacturing best practice seminar, South Wales, 1 hour)
- James La Trobe-Bateman, reModel and Andrew Lowe, Ortho Clinical Diagnostics presented the use of the reModel tools for modelling business processes and how they are used to optimise performance.

Financing Growth '04 (WDA Finance Wales conference, 1 day)
- Chaired by Peter Sissons; presentations by 3i; Xenos; Interregnum; Justin Urquhart Stewart; and Sahar Hasemi of the Coffee Rublic Plc.

Successfully Exporting to the French Healthcare Sector
(WalesTrade International (WTI) Healthcare Cluster Event, ½ day)
- This seminar included presentations by Caroline West, WTI; Ian Morrison, International Healthcare Consultant; Jeanne Dench, former French Trade Commissioner in London; Andrew Stevenson, Export Manager - Mangar International; and Steve Rawlings, WTI.

Telehealth Wales "Master Class" (1 day)
Conference Sponsored by the Welsh Assembly Government & Welsh Development Agency
- Presentations given by: Prof. Heinz Wolff: The multi-faceted support needed for "independence" in the home. Problems and solutions; Bernard Wignall, Huntleigh Healthcare: Service modelling and service reengineering; Ben Stanberry, Avienda: Legal, Ethical and Risk management issues; Angela Single, Nestor: Supporting People at Home using Technology; Dr. Kevin Doughty, Tunstall/CUHTec: Towards an integrated approach to healthcare; Peter Range, CareCymru: The Building Blocks for a Converged Health & Social Care Model; Phil Toms, Newport Housing Trust: Future Proofing Lifetime Homes to prolong independent living.

Acessing Clinical/Academic Expertise (MediWales seminar, ½ day held at Miskin Manor)
- Presentations given by local universities and medical schools.

Showcasing Commercial Expertise (MediWales seminar, ½ day held at ECM^2, Port Talbot)
- Presentations given by Biotrace; First Numerics; GE Healthcare and Polymer Health Technology.

Master Class – Fundamentals of Finding Finance (Medilink East seminar, ½ day)
- Presentation given by Alan Barrell who is 'Entrepreneur in Residence' at the University of Cambridge.

Conducting a risk analysis in accordance with EN 60601-1-2: 2001 (Webinar 1 hour)
- Organised by Intertek ETL Semko that covered a risk management approach to EMC testing of medical devices.

Course/Seminar, Organisation, Duration: 2004

Medical Device Regulation (ABHI Annual Conference, 1 day, London)
Presentations included:
- Health Industry Task Force (HITF) Overview by Lord Warner, Parliamentary Under Secretary of State for Health in the Lords.
- MHRA Organisation by Professor Kent Woods, Chief Executive MHRA.
- European Update – Government Viewpoint by Steve Owen, Director of European and Regulatory Affairs (Devices) MHRA.
- Latest Developments – Industry Viewpoint by Malcolm Carlisle, Eschmann Holdings Limited.
- Public Perception and Transparency by Dr. David Jeffreys, Department of Health.
- European Regulations on Human Tissue Engineered Products by Shayesteh Fuerst-Ladani, Manager International Regulatory Affairs, Hoffman-La Roche.
- Reclassification by Dr. Ing. Dario Pirovano, Director Regulatory Affairs Eucomed, Belgium.
- Reclassification by Steve Owen, Director of European and Regulatory Affairs (Devices) MHRA.
- Current Trends in Standardisation – Directions for the Future written by Richard Moore, Eucomed.
- Update on Global Harmonisation (GHTF) and Global Nomenclature (GMDN) by Maurice Freeman, Chair SG1 GHTF and Chair MAPG of GMDN.
- EU Enlargement by Roland Gerard, Director of Government Affairs and Regulatory Compliance, St. Jude Medical (EMEA).
- European Clinical Evaluation Task Force by Dr. Susanne Ludgate, Medical Director MHRA.

Regulatory Update for Electro-Medical Device & Equipment Manufacturers
(Management Forum seminar, 1day, London) Presentations included:
- Medical Directives Directive by Ian Cutler.
- IEC/EN 60601-1-2 the EMC Standard for Electro-Medical Devices and Equipment by Dr. Didier Bozec.
- IEC/EN 60601-1 the Electrical Safety for Electro-Medical Devices and Equipment by Ian Gillham.
- The New Electromagnetic Compatibility (EMC) Directive by Chris Marshman.
- Interference Risks in the Healthcare Environment by Chris Marshman.
- WEEE, RoHS and EuP Directives by Vic Clements.

UK Government's Consultation on the EU Services Directive (DTI, Cardiff 2 hours)
- Heinz Kesel, DTI Lead Negotiator, Liberalisation of Services explained the aims and implications of the directive. Robert Howe, DTI Project Manager, Liberalisation of Services in the EU explained the public consultation process.

Quality & Regulatory Requirements for Medical Device Markets
(Medilink West Midlands Seminar held at Advantage West Midlands, Birmingham, ½ day)
- CE Marking, Technical Files & Risk Analysis, John Adcock; Labelling Considerations, Tim Cockrill; Validation Issues, Fursey Duggan and FDA Overview & ISO 13485, James Love.

Finding Solutions for the NHS through new Business Opportunities
(UHCW NHS Hospital Walsgrave, Coventry, ½ day) Presentations included:
- New Hospital: Opportunities Looking for Industry Solutions by Liz Thiebe, Director, New Hospital Service Design and Carl Holland, Operations Manager, Pathology/Oncology; NHS – New Procurement Policies, Jonathan Wedgebury, CEO NHS Healthcare Procurement Consortium; Introduction – Medical Technologies Cluster, Chris Ramsden, Advantage West Midlands, Medical Technologies Cluster Manager; Regional Dimensions and Support Networks, Tony Davies, CEO Medilink West Midlands; Industry Testimonial, Warren Gray, Sales Director, MCS Medical and Business Support for Innovation and Diversification, Alan Lord, Diversification Manager Business Link.

Opportunities for Healthcare Companies in the EU Accession Markets
(WalesTrade International Healthcare Cluster Event, ½ day)
- This seminar included presentations by David Hawkins, UK Trade & Investment; Crispin Kirkman, Emerging Technologies Network Agency Limited; Jon Love, Espicom; Dr. Rick Greville, ABPI Wales and Brian Meredith, European Information Centre, Cardiff.

Course/Seminar, Organisation, Duration: 2004

Medical Device Technology 2004 Conference, NEC Birmingham (1 day)
Attended the following seminars:
- Introduction to the Medical Device (MD) and In Vitro Diagnostic (IVD) Directives, Sue Spencer, Cascade Consulting Ltd; MHRA Perspective on Recent Developments, David Jefferys, Head of Medical Devices Sector, Medicines and Healthcare products Regulatory Agency; ISO 13485: 2003 The Transition, Chris Jepson, Product Certification Manager, SGS UK & President of the European Notified Body Group; ISO 14971: 200X Still the choice for risk management? Dr. Harvey Rudolph, Global Programme Manager Medical Devices, Underwriters Laboratories Inc.; Market Surveillance Operations Group (MSOG) as an essential tool for the enforcement of the Medical Devices Directives, Dr. Heitor Manuel Ribeiro Costa, Director of Medicines & Healthcare Products, Infarmed and Chairman MSOG; Notified Body Operations Group: A progress report, Steve Owen, Head of European and Regulatory Affairs, MHRA and Chairman NBOG; FDA: Global Markets – Global Standards and An Update on Key Initiatives, Tim Ulatowski, Director, Office of Compliance, Center for Devices and Radiological Health, US Food and Drug Administration; The MDD review: The Eucomed Perspective, Dario Pirovano, Director of Regulatory Affairs, Eucomed; Update from the Clinical Evaluation Task Force, Jean-Claude Ghislan, Directorm Evaluation of Medical Devices, AFSSAPS and Practical Application of Risk Management, Paul Lafferty, Principal Consultant, Quintiles Consulting.

Industry Briefing on Current Regulatory Issues in the Medical Device Sector
(MediWales Seminar , ½ day held at ECM^2, Port Talbot)
Attended the following presentations and related discussions:
- Anne Jury, Medical Devices Regulatory and Quality Management Consultant. Provided an overview on current regulatory issues in the medical device sector and examined current issues in CE marking.
- David Bentley, Group Regulatory Affairs Manager, Huntleigh Healthcare. Provided insights into how a large company manages regulatory issues; overview of his role and case studies into dealing with more distant markets such as China.

BioWales 2004 Exploring current issues and emerging trends (Welsh Development Agency)
This was a major two day conference sponsored by the Welsh Assembly Government. Attended all the presentations that were all highly professional and informative:

- Keynote lecture day 1: Growing a Bioscience Business, Dr. Richard Palmer, CEI, Alizyme PLC.
- Therapeutics Research and Development: Hadyn Parry, Molecular Nature Ltd; Dr. Andrew Williams, Marix Drug Development Ltd; and Prof. Ruth Duncan, School of Pharmacy, Cardiff.
- Medical Devices, Concept and Commercialisation: Greg Baily, Huntleigh Diagnostics Ltd; Robin Lewis, The Magstim Co. Ltd, and Jon Moore, Gyrus Group PLC.

- Keynote lecture day 2: A Vision for UK Bioscience, Graham Branton, Bioscience Unit, DTI.
- Academic Strengths in Wales: Prof. David Wynford Thomas, Dept. of Pathology, University of Wales College of Medicine (UWCM); Prof. Paul Smith, Dept.of Pathology, UWCM; Dr. Tony Fentem, Institute of Grassland and Environmental Research; and Prof. Tim Maughan, Wales Cancer Trials Network, Cardiff.
- Finance and Support for Growing Companies: Gary Partridge, Finance Wales; Jeremy Curnock Cook, Bioscience Managers Ltd; and Gretel Leeb & Sarah Williams, Welsh Development Agency.
- Customers, the Driving Force for Business: Patrick Purcell, Patent Office; Dr. John Anson, Amersham PLC; Dr. Allan Syms, Welsh Development Agency.

The Power of Networking: Ingredients of Successful Networking
(Cardiff University Innovation Network, 1½ hours) Attended presentations given by:
- Guy Griffiths, Executive Director – BNI Devon, Cornwall ad South Wales.
- James La Trobe-Bateman, reModel Consultants International.
- Polly Nelson, Research Director, Fire Without Smoke Software Ltd.

Significant selected books studied:
- Shut Up and Listen, Theo Theobald and Cary Cooper.
- Foundations for Growth, key questions for the ambitious board; A Director's Pocket Book published by the Institute of Directors and KPMG.
- Next-Generation Pulse Oximetry; ECRI Health Devices, Special Issue February 2003, Volume 32, Number 2.
- Corporate Governance, A Director's Guide published by the Institute of Directors.

Course/Seminar, Organisation, Duration: 2003

Winning and Retaining Medical Business, Plastics and Rubber Weekly, EMAP Communications
Presentations each lasting 30 minutes on the following (total 1 day):
- Impact of medical device regulations; Securing your business against liability in the US medical device market; Analysing the changing role of the contract manufacturer in the medical market; Evaluating the business prospects for utilising plastics in tubing in the medical device industry; Evaluating the scope for plastics growth in the telemedicine market; Fighting against the reuse of single use devices; Utilising cyclic olefins as a clear alternative plastic for pharmaceutical and medical applications; and Exploring the business opportunities arising from using anti-infective materials for medical applications.

Responding to Clinical Needs (MediWales Seminar, ½ day held at ECM^2, Port Talbot)
Presentations were given on the following:
- Dr. Michael Clark, Wound Healing Research Unit, Cardiff; David St. George, Celtic Dimensions concerning innovation and general issues in the National Health Service; Robert Wallis and Dr. Jeanette De Diemar of the Welsh Development Agency; John Maisey, University Hospital of Wales Clinical Engineering; and Rodney Palmer, Performance Health Products on Welsh issues from the viewpoint of an SME.

The New Global Era: ISO 13485: 2003 The International Quality System for Medical Devices (the Institute of Quality Assurance [IQA] Medical Quality Group in conjunction with the Biomedical Division of the American Society for Quality [ASQ] 1 day)
- Speakers included: Ed Kimmelman, Chair of the ISO TC 210 Working Group 1; Dr. Eamonn Hoxey, Senior Director, Europe/Middle East/Africa Quality and Compliance Services, Johnson & Johnson; Glen Emelock, Senior Partner, The CRO Group; Susan Jacobs, President QMS Consulting & Chair of ASQ Biomedical Division and Paul Brooks, Head of Notified Body, BSi, Inc. This seminar provided useful insights from some of those who wrote the standard, audit to it and use it. The relationship with European CE marking and US FDA Quality System Regulation was explained.

FDA and EU Inspections of Medical Device Manufacturing Facilities (Henry Stewart, London)
- Presentations were given by the Medical Devices Agency (now part of MHRA – Medicines and Healthcare products Regulatory Agency), a Conformity Assessment Body and industry professionals.
- Provided practical insights on successful approaches to manufacturing inspections including the Quality Systems Inspection Technique (2 days).

The Key to Business Success – is Six-Sigma the Answer? Professor Hefin Rowlands (IEE - Manufacturing and Management Section and University of Wales College Newport)
- Presentation on principles, scope and structure of Six-Sigma and discussion (2 hours).

Medical Device Technology 2003 Conference, NEC Birmingham
- United States Food and Drug Administration presentations by Kimberley Trautman on Today's most important issues involving FDA's medical device quality system regulation and Jan Welch on Current IVD Issues from an FDA Perspective.
- Other topics attended Dealing with the FDA – an industry perspective ISO 13485 and its implications; Micromoulding; The true meaning of partnership between a moulder and an end user; Near-Net-Shape manufacturing of medical devices by powder metallurgy; Applying advanced design technology and modern practices in medical product development; Getting medical device innovation to the consumer: The role of health technology assessment; Best practice in materials selection and design; Membranes for biosensing and medical device applications; and Novel bioactive silicones for medical devices (2 days).

The Medical Devices Faraday Partnership combined seminar of MediWales and The Materials Technology Forum In Wales (Held at ECM^2, Port Talbot, ½ day)
- Presentations covered an introduction from Dr. Norman Waterman, Quo-Tec; Sue Dunkerton, Director of the Medical Devices Faraday Partnership; Dave Revitt, National Co-ordinator, Medilink; and Professor Roger Feneley, Bristol Urological Institute.

Course/Seminar, Organisation, Duration: 2002

Financing Growth Conference, sponsored by Finance Wales, Welsh Assembly Government, British Venture Capital Association (BVCA) & the London Stock Exchange
- Major conference and seminar on financing options from a Welsh perspective (1 day).

Understanding the NHS Market for eHealth (Silicon Bridge Research)
- Seminar to review, update and explore critical issues (1 day).

Winning & Retaining Medical Business [plastics focus], EMAP Communications
- Conference organised by Plastics & Rubber Weekly and European Plastics News.
- Topics covered included: supplier selection criteria, critical success factors, the changing role of the injection moulder, case studies, European regulatory framework and related issues (1 day).

WalesTrade International Export Services (Healthcare / Biotech Cluster)
- Seminar on EU Clinical Trials Directive (½ day).

WalesTrade International Export Services (Healthcare / Biotech Cluster)
- Seminar on services provided to exporters (½ day).

Joint Export Training Standards (JETS) Assessor Training (British Chambers of Commerce and Institute of Export - external tutors)
- Introduction to JETS course and trainer assessment procedures and methodology.
- Practical exercises and assessments undertaken to ensure process and techniques established.
- Feedback and discussion with trainers, steering group and other assessors part of course.
- Able to undertake both course and assessor assignments (2 days).

Going Global (British In Vitro Diagnostic Association - BIVDA)
- Provided insights US, Canadian and Japanese IVD regulations.
- Provided insights on mutual recognition agreements (MRAs) and the work of the global harmonization task force (GHTF).
- Provided insights on design controls, performance evaluation and international trials.
- Participated in workshops on labelling, vigilance and new product planning (2 days).

Future Competitiveness of Wales Innovation, Entrepreneurship and Technological Change (University of Glamorgan and University of Glamorgan Business School)
- Presentations by Dr. Emyr Roberts, Head of Economic Policy, Welsh Assembly;
- Professor Michael Quayle, Director University of Glamorgan Business School; and
- Keynote address Professor Michael Porter from Harvard University by satellite.
- Provided insights on Welsh economic policy and the power of clusters. (1 day).

Lean Enterprise for SMEs (IEE – Manufacturing and Management Section)
- Provided insights on what lean enterprise is, how to implement it and sustain the benefits derived from implementation (2 hours).

Integrated Strategic Quality Systems (IEE – Manufacturing and Management Section)
- Provided insights and discussion on current thinking concerning the use of TQM, Kaizen, Six Sigma, Taguchi, use of neural networks and Intelligent Quality Systems (2 hours).

World Class Benchmarking for SME's (IEE – Manufacturing and Management Section)
- Provided insights on the importance of benchmarking in the improvement process using The European Foundation for Quality Management Business Excellence Model (2 hours).

Success through Excellent Design, interactive seminar organised by South Wales Branch, The Chartered Institute of Marketing in conjunction with Design Wales.
- Covered the practical why and how of design that can result in competitive advantage. Examples of local support and case studies were provided (2 hours).

Significant selected books studied:
- The Essays of Warren Buffett, Lessons for Investors and Fund Managers, Lawerence A. Cunningham.
- The Warren Buffett Way, Investment Strategies of the World's Greatest Investor, Robert G. Hagstrom, Jr.
- Sven-Göran Eriksson on Football with Willi Railo and Håkan Matson.

Course/Seminar, Organisation, Duration: 2001

The Canadian Medical Devices Market, seminar organised by Canadian High Commission
- Practical review of the market dynamics, opportunities, regulatory requirements and related issues, including the use of Canada as a launch pad to the American market (½ day).

GCP for Medical Devices with Danielle Giroud (1 day Management Forum workshop)
Good Clinical Practice (GCP) scope included:
- Regulatory environment for clinical trials in Europe and the United States.
- Clinical development plans.
- Vigilance requirements during clinical investigations.
- Integrating the clinical research activity with the company quality system.

Electronic Records and Electronic Signatures - 21 CFR 11 US Regulations
(Dr. Bob McDowall organised by Henry Stewart Conference Studies, London)
- One-day workshop on key issues, problems, solutions and case studies including IT Departments (1 day).

Medical Devices Agency (UK Competent Authority) Management Forum symposium entitled:
An Update from the MDA on Recent Developments in the Devices Sector (1 day).
Presentations included:
- The Next Five Years for MDA – The Corporate Plan (Dr. David Jefferys).
- Update on European Issues – The Review of MDD 93/42 and The Developing Role of Notified Body Oversight Group (Steve Owen).
- Update on the Regulation of Healthcare Products of Human Origins and Tissue Banking (Mike Cox).
- Vigilance and Adverse Incident Reporting: How to Learn the Lessons (Clive Bray).
- The Control of Clinical Investigations of Medical Devices - How to work successfully with MDA (Dr. Suzanne Ludgate).
- Medical Devices in Primary Care (Dr. Suzanne Ludgate and Dr. Helen Glenister).
- Managing Patients' Expectations with Devices (Dr. Helen Glenister).
- Short presentations and discussion on the Global Harmonisation Task Force; Single Use Devices & Decontamination; Implementation of the IVD Directive; The MDA Devices Evaluation Service; Classification Borderline Issues; Committee on the Safety of Devices and Mutual Recognition Agreements.

Welsh Medical Technology Forum, Meeting the Regulatory Challenge, Cardiff
- Seminar covering European and US requirements for medical devices and IVDs, ISO 9000: 2000, Quality Function Deployment and Six-Sigma initiatives (½ day).
- Repeated training later in the year at St. Asaph, North Wales (½ day).

How to get your share of the USA marketplace (Naidex/Medtrade Seminar)
- Presentation by Sheldon Prial based on his lifetime of experience in the homecare business (1 hour).

Internet Strategy & Practical Actions, WalesTrade International
Healthcare and Medical Sector Cluster seminar arranged as part of the Internalisation of SMEs (½ day).
- Covered marketing strategies, tools, techniques and legal issues.

Microsoft Access – Basic, and PowerPoint – Intermediate, Acorn Training
- Word, Excel and PowerPoint already used in all business functions and training undertaken to gain more from use of existing computer and software systems (2 days).

The Development of an IT Strategy to Improve Quality
(IEE - Joint meeting Manufacturing and Management Section & Knowledge Services)
- Discussion meeting with presentations by Dr. Hefin Rowlands and Mr. John Williams of the University of Wales College Newport, including case studies (2 hours).

Materials from a Motorsport Perspective, The Materials Technology Forum In Wales
- Including presentations from the Bluebird Project and Williams Grand Prix Engineering (½ day).

Course/Seminar, Organisation, Duration: 2000

Medical Device Technology European Conference, Paris
- Topics attended covered health technology assessment; US FDA up-date from FDA covering risk management, least burdensome provisions and overview by Dr. Feigal Director of CDRH; electronic records and signatures; ISO 9000: 2000; post-market surveillance; reuse of single use devices; third party reimbursement in Europe and a strategic view from the Chief Executive of the UK Medical Device Agency Dr. Jefferys (2 days).

Millennium Diagnostic Conference 2000, Whatman Healthcare
- Topics attended covered the future of diagnostics; extraction of nucleic acids using filter based technology; quantitative immunochromatographic assays using magnetic assay reader; current issues in rapid tests; identification of food-borne pathogens; the place of gold (and silver) in rapid tests; optimisation of conjugate release materials in lateral flow immunoassays; artificial receptors; design and manufacture of diagnostic tests; when a line is not a line; trouble shooting nitrocellulose membranes; pressure sensitive adhesives in diagnostic tests; near patient test for direct direction of helicobacter pylori antigens in stool; impact of new IVD regulations and validation of production equipment (2 days).

Financing Overseas Trade, part of Winning Overseas Management Briefings and Welsh Development Agency's Internationalisation of SMEs Programme (½ day).
- Seminar on managing the financial risks in export markets, including getting paid.

Finance Wales, (Welsh Medical Technology Forum, Penllergaer)
- Seminar on financing options in Wales for healthcare companies (½ day).

Clinical Trials in Canada, seminar organised by Canadian High Commission
Practical review of the clinical trials sector and regulatory submissions in Canada (½ day).

Medical Device Regulation - understanding the European marketplace (ABHI/IBC, UK)
- Eighth annual Association of British Healthcare Industries conference (2 days) on aspects of implementing the medical devices and in vitro diagnostics Directives; effect of NICE; technology assessment; environmental issues; human and animal tissues. Included a brief up-date on the US regulatory scene.

Exporting and the Internet, part of Winning Overseas Management Briefings and Welsh Development Agency's Internationalisation of SMEs Programme (½ day).

Patent Office
- General talk on services provided to assist with intellectual property. Part of Welsh Development Agency's Internationalisation of SMEs Programme for the Medical Device Cluster (½ day).

National Institute for Clinical Excellence (NICE): implications for the medical device industry
Medical Device Technology Conference, UK, Professor Peter Littlejohns, NICE (30 minutes).

Quality Function Deployment (QFD) and its applications
(IEE - Joint meeting Quality Management & Manufacturing and Management Section)
- QFD overview, applications and Mitel Telecommunications case study (2 hours).

Significant selected books studied:
- The future of communications for business, understanding and exploiting changes in voice and data technology. Institute of Directors.
- Effective Business Meetings. Institute of Directors.
- Managing knowledge in the digital age. Institute of Directors.

Course/Seminar, Organisation, Duration: 1999

The Impact of New Procedural Rules on Intellectual Property Litigation in the UK (Simmons & Simmons) (½ day).
- Practical guide to pre-litigation strategy, settlement, dispute resolution, case management and costs.

Sustaining Innovation (Welsh Design Advisory Service, Cardiff)
- Design and innovation in Wales, Gavin Cawood, WDAS (20 minutes).
- Removing barriers to innovation, Professor James Woudhuysen, Seymour Powell (1 hour).

Seminar (Centre for Innovation in Healthcare Technology, Glasgow Caledonian University)
- EN Standards and CE Marking - NHS wheelchair service view (40 minute lecture).
- Regulatory Concerns - Global Trends in Harmonisation (45 minute lecture).
- Medical Device Directive (MDD) Inspections (40 minute lecture).

The New Alchemists, Professor Charles Handy lecture (Cardiff, IoD & Association of MBAs)
- Evening lecture and discussion centring on Handy's book of the same title (2 hours).

Medtrade Europe, (Luxembourg)
- Attended seminars on Homecare Operations: new strategies for marketing your business;
- How to out-promote and out-advertise everyone you are competing with, no matter how big they are;
- Exporting - the right way;
- Understanding the UK homecare market and how to get your fair share (total 4 hours).

Quality in Design and the Integration of Quality Management Systems (IEE - Joint meeting Quality Management & Manufacturing and Management Section)
- Quality in design, quality function deployment, Taguchi methods and their integration. (2 hours).

Welsh Medical Technology Forum ½ day seminars attended:
- Telemedicine (BT Telemedicine Centre, Cardiff) demonstrating:
  - BT Intranet and Continued Professional Development.
  - First Virtual wide band teleconferencing.
  - E-commerce.
  - Teleradiology.
  - TDS Dermatology store and forward teledermatology.
- Exploiting New Product Opportunities (QED Centre, Treforest) covering four case studies involving industry, the NHS and academia.
- NHS - a vision for the future (NHS Hensol Castle, Pontyclun) involving NHS Trusts, Welsh Office and Office of R&D for Health & Social Care.

Significant selected books studied:
- Losing My Virginity, the autobiography, Richard Branson.
- Spiral Dynamics - mastering values, leadership, and change D. E. Beck and C. C. Cowan.
- Financing Growth, produced by Grant Thornton for the Institute of Directors.
- The Independent Director, produced by Ernst & Young for the Institute of Directors.
- Putting a price on your business, produced by Deutsche Morgan Grenfell for the Institute of Directors.
- Management buy-outs, produced by Phildrew Ventures for the Institute of Directors.
- The New Alchemists, Charles Handy.

Course/Seminar, Organisation, Duration: 1998

Exporting Medical Devices to the USA (IEE - Medical Technologies Industry Group)
- Practical guide to US Food and Drug Administration (FDA) regulations with case studies. (1 day).

Managing Your EC Business to Facilitate US Market Entry (ABHI / Simmons & Simmons)
- Practical guide to US Food and Drug Administration (FDA) regulations with case studies (½ day).

Medical Decision Making (British Association, Cardiff)
- Three papers on making decisions and methods used: The use of decision support systems in diabetes management, Mr. S. Carey; Diagnosis - a matter of chance, Dr. F. Dunstan; and Drawing blood and drawing conclusions, Dr. B. Nix (½ day).

Intelligent Decision Support in Clinical Practice (IEE - Medical Technologies Industry Group)
- Papers on trends in therapeutic decision support for general practice, engineering software tools, neural network based imaging, clinical trials, EEG/ECG analysis and expert systems. (1 day).

Medilink Live (York, UK)
- Attended seminar on Product Development by Professor Heinz Wolff (1 hour).

How to Re-cycle Packaging, The Material Technology Forum in Wales (Abercynon)
- Seminar on regulations with The Institute of Materials and the Environment Agency (½ day).

Telemedicine: Bringing Services to the People (Welsh Office & NHS Wales)
- Workshops on developments in the UK: memory aids, monitoring, finance and legal issues (1 day).

Medtrade Europe, (Luxembourg)
- Attended seminars on European reimbursement; How to break into the USA Market; Understanding the UK Homecare Market; Special Support for the Elderly on the Internet; Customer Service: Strategies for Combating Competition; Capitalising on Home Healthcare Opportunities in the Pacific Rim; and Home Healthcare - An American Perspective (8 hours).

Wales Regional Technology Plan (RTP) Conference (Welsh Development Agency, Swansea)
- Learnt of progress with this important plan and discussed possible initiatives within several sectors, including the medical device sector. (1 day).

SMART Wales (Welsh Office, South Wales)
- Seminar on grant options, such as SMART and SPUR for small and medium size enterprises (½ day).

Industry-Academic Links (Welsh Medical Technology Forum, WDA Offices, Swansea)
- Seminar involving Medical Research Council, Imperial College, Teaching Company Directorate, industry and local universities (½ day).

Regulation and Marketing for Self Diagnostic & Home Monitoring Products (SMi, London)
- Two days seminar on key issues regarding regulation and marketing of self diagnostic and home monitoring products (2 days).

Electrical Impedance Tomography, Dr. H. Griffiths, Department of Medical Physics and Bioengineering, University Hospital of Wales (Institute of Physics, 5th February, Swansea)
- Review of electrical impedance tomography and related spectroscopy (1 hour).

The NHS Market for Medical Systems and Devices, (ABHI/IBC Conference, Solihull)
- Review and practical suggestions about approaching "The New NHS" in association with the Association British Health-Care Industries (ABHI, 1 day).

"Setting the Agenda 1998" (Chartered Institute of Marketing)
- Healthcare Industry Group, Second Annual Conference held at the Royal Society of Medicine. Speakers included Roy Lilley, Dr. Harry Burns, Nigel Edwards, Carolyn Regan, Sandra Meadows and Lord Hunt all concerning "The New NHS" White Paper of December 1997 (1 day).

Course/Seminar, Organisation, Duration: 1997

Biotechnology, The Job Creation Industry of the 21st Century (Institute of Welsh Affairs)
- Seminar with a presentation by Professor Campbell, Department of Medical Biochemistry, University of Wales College Cardiff. Discussed issues concerning Pembrokeshire. (1 day).

Diagnostics of the Future (British In Vitro Diagnostics Association, London)
- Industry leaders provided insights and views on the major developments, drivers and influences in this expanding market sector. (1 day).

Awareness Seminar (IEE - Medical Technologies Industry Group)
- Presentations given by David Rosin, Consultant General Surgeon on The Operating Room in the Next Century and Alan Kent, Chief Executive MDA on Insight into the Medical Industry (½ day).

Market Research, the what, the why and the how. (Chartered Institute of Marketing)
- Healthcare Industry Group meeting held at Anglia and Oxford NHS Executive Office. (1 day).

Preparing for EMU - The Business Perspective (Financial Times, Cardiff Breakfast Meeting)
- Led by FT Foreign Editor, Quentin Peel insights were gained from industry observers, including Michael Gardiner of Ernst & Young, about how monetary union will affect all businesses. (2 hours).

Selling Diagnostics & Home Monitoring Products to the Consumer (SMi, London)
- Following an overview, topics covered included lobbying for the right to promote and sell, working with patient and pressure groups, media techniques and consumer marketing. (1 day).

Regulation & Marketing for Self Diagnostic & Home Monitoring Products (SMi, London)
- Covered in-vitro diagnostics, medical and consumer products from new product development, through to marketing and regulatory issues with numerous case studies. (2 days).

Medical Devices Directive (IEE - Medical Technologies Industry Group, co-sponsored by the Institute of Physics and the ABHI)
- General introduction and detailed consideration of conformity routes especially Annex II & III. (1 day).

Medical Device Regulation in the USA and Canada (IBC UK Conference) (2 days).
- Included in-depth reviews on validation process, software validation, design controls, purchasing and vendor quality, management responsibility and EU/Harmonisation Issues.
- The FDA & Worldwide Quality System Requirements Guidebook for Medical Devices, Kimberly Trautman. Book studied in conjunction with 4 hours of FDA produced video tape featuring Kimberley Trautman.

Medical Devices Regulation: Implementation Developments (Association of British Health-Care Industries, supported by the Medical Devices Agency) (1 day).
- Used post-meeting notes for private study.

The Impact of Environmental Issues on the Medical Device Industry (Association of British Health-Care Industries, supported by the Medical Devices Agency) (1 day).
- Used post-meeting notes for private study.

Technology Transfer in Medical Physics (Institute of Physics, Congress 97)
- Subjects covered in the morning included Intellectual Property, NHS and University Based Schemes.
- In the afternoon topics included CE Marking, In-House Standards, MedLINK and County Durham Development Company medical device sector activities. (1 day).

From the Electron to the Top Quark: a Century of Particle Physics (Institute of Physics, Professor Frank Close, Rutherford Appleton Laboratory)
- Discussed discovery of electron, structure of atoms and quarks 100 years after electrons discovery. (1 hour).

Course/Seminar, Organisation, Duration: 1997

Wales Regional Technology Plan (RTP) Conference (Welsh Development Agency, Cardiff)
- Involved in various issues with medical device sector. Objective of the RTP, an EU programme is "To develop a consensus on a strategy to improve the innovation and technology performance of the Welsh economy". (1 day).

Medical Devices Directive - A Survival Guide for Small Businesses (Association of British Health-Care Industries, supported by the Medical Devices Agency) (1 day).
- Covered Essential Requirements; Device Classification & Conformity Assessment Routes; role of Notified Bodies; exporting to the USA; new product introductions and related issues.

Rapid Prototyping (Dr. Dimov, University of Wales College of Cardiff for IEE)
- Review of all current methods, including advantages and disadvantages. (1 hour lecture).

dna Management Performance and Self-Mastery Programme (David Norman)
- SelfSkills, including techniques based on Myers-Briggs, Herrmann, Belbin, Covey and others. (1 day).
- LifeSkills, including how to create the future you want. Learnt how to have it all. (1 day).
- Accelerated Learning, building the learning organisation, included speed reading techniques. (1 day).
- MindSkills, including techniques on how to develop whole-brain use, improve IQ and intuition. (1 day).
- PowerSkills, including how to neurologically programme yourself for success. (1 day).
- Creative Problem-Solving, using the powerful Kancept™ Brainstorm methods. (1 day).
- Communicating for Results, influence, integrity & persuasion using Neuro Linguistic Programming. (1 day).

Femtosecond Lasers; Opening up the way for new X-ray to T-ray Sources (Prof. Sibbett, University of St. Andrews, Institute of Physics, at University of Wales, Cardiff) (1 hour seminar).
- Covered self mode locking lasers (Kerr-lens), overview of femtosecond lasers and use as optical drivers that has led to the development of all solid-state, tuneable femtosecond lasers.

Health and Safety, The Professional Engineer's Contribution (Mr. Windsor Coles, HM Health and Safety Executive in association with the IEE, Manufacturing Section) (2 hour seminar).
- Examined the requirements of existing and proposed legislation and the contribution that must be made by professional engineers for proper identification, assessment, control and management of risk.

Course/Seminar, Organisation, Duration: 1997

Welsh Medical Technology Forum ½ day seminars attended:

- Academia and Industry: University of Wales College of Medicine and Partners:
  - Included overview of UWCM research; A flash is better than a glow - Prof. Campbell; overview of the Therapeutics and Toxicology Centre - Prof. Routledge; Medical Devices - Which? Dr. Spendley and Dr. Williams of Cardiff Bioanalytical Services Ltd.
- Lasers in Medicine. Joint meeting with Welsh Optoelectronic Forum:
  - Included background on laser diodes and their applications, dermatology applications, radiation and tissue effects and the use of the Argon laser in dentistry.
- Countdown to CE - A Year Minus 11 Days:
  - Review of progress with MDD, Technology Transfer & CE Marking, implementation issues and forces shaping a "Europe First" policy by US based firms.

Significant selected books/audio cassettes studied during 1997:

Book-Talk, Management Book Summaries on Tape, four per month, including:

- Beyond Certainty, Charles Handy.
- Conflicts of Leadership, Bengt Karloff.
- Negotiating Tactics, Wyvern Crest Publications.
- Fabled Service, Betsy Sanders.
- The 80/20 Principle, Richard Koch.
- Dealing with Difficult Colleagues, Peter Wylie and Mardi Grothe.
- The Courageous Messenger, Daniel Oestreich and George Orr.
- Winning Ways Through Corporate Governance, Neville Bain and David Band.
- Who Knows Wins, Ketan J. Patel.
- Get Innovative or Get Dead, Matthew J. Kiernan.
- Managing by Values, Ken Blanchard and Michael O'Connor.
- The Hungry Spirit, Charles Handy.
- Stairway to Success, Nido Quebain.
- Maverick, Ricardo Semlar.
- The Absolutes of Leadership, Philip Crosby.

Simon & Schuster Audioworks:

- The Psychology of Achievement, Brian Tracy.
- Awaken the Giant Within, Anthony Robbins.
- NLP, The New Technology of Achievement, Faulkner, McDonald, Hallbom & Smith.
- How to Get Your Point Across in 30 seconds or less, Milo Frank.

Other Useful Books:

- The PhotoReading Whole Mind System, Paul Scheele. Learning Strategies Corporation.
- Introducing Neuro-Linguistic Programming, O'Connnor and Seymour. Aquarian/Thorsons.
- The Conscious Universe, Kafatos and Nadeau. Springer.
- Rubicon - the fifth dimension of biology, Anthony Campbell. Duckworth.
- Accelerated Learning Techniques in Action, Rose, Nicholl & Nicholl. Nightingale Conant (Video).
- Sun Tzu, The Art of War for Executives, Donald G. Krause. Nicholas Brealey Publishing.

Course/Seminar, Organisation, Duration: 2006

Managed Care, Discover the latest global developments in (SMi)
- Contents included review of economic and social pressures, recent America, European and Asian developments, the role of information technology and the device market. (2 day seminar, 1996).

Telemedicine in Wales: Progress and Potential (Welsh Office & NHS Wales)
- An international conference with video links to Norway and the USA, covering the TEAM Project in Wales, an overview of other UK projects especially in Scotland, technology developments, medico-legal aspects of telemedicine and a review of the services provided by WorldCare. (1 day course, 1996).

Managed Care, New Opportunities and Future Trends in Europe for (SMi)
- Contents included review of American history and current trends, UK position and perspectives, major drivers, emerging implementation and current situation in The Netherlands, Sweden, Italy, Germany, Switzerland and France. (2 day seminar, 1996).

Medical Design & Manufacturing East 1996
- Establishing Successful Medical Device Operations in Europe: Product Development, Manufacturing and Distribution I, II & III (3x ½ day seminars)
- Current Issues in Product Clearances: IDEs, 510(k)s, and PMAs. (½ day seminars)
- Software Development Methodologies for Medical Devices (1.5 hours seminar)

Association for the Advancement of Medical Instrumentation (AAMI) Annual Meeting (1996):
- Consolidation and Downsizing: A New Paradigm for Clinical Engineering (1.5 hrs plenary)
- Vendor/Health Care Enterprise Relationships (½ day seminar)
- Migration of Technology from Health Care Institutions to Homecare Settings (½ day seminar)
- Monitoring Systems: New Applications and Interfaces (½ day seminar)
- Medical Device Litigation: Deposition Vignettes (1.5 hours seminar)

US Food and Drug Administration (FDA) Medical Device Update:
Design Controls, GMP Requirements and Marketing Clearance (3 day course held in Paris, 1996)

Collaborate to Compete Seminar (Industry/Academic - Welsh Development Agency, 1 day, 1996)

Royal Society of Arts: Environmental Design of Medical Products (RSA, 1 day workshop, 1996).

Ultrasound in Medicine (Evening seminar by Professor Wells, Institute of Physics, 1996)

Significant selected books/audio cassettes studied during 1996:
- Accelerated Learning Techniques, Tracy & Rose, Nightingale-Conant Audio.
- The Second Curve, Ian Morrison, President of the Institute for the Future, Random-House Audiobooks
- How to Develop a Positive Attitude, Elwood Chapman, Kogan Page Motivation Cassettes.
- How to Motivate People, Twyla Dell, Kogan Page Motivation Cassettes.

Book-Talk, Management Book Summaries on Tape, four per month, including:
- Not Just for CEOs, John H. Zenger.
- The Death of Competition, James Moore.
- Cross Cultural Communication, Gregory Barnard.
- Database Marketing, Ian Linton.
- Transforming the Bottom Line, Tony & Jeremy Hope.
- The Road Ahead, Bill Gates.
- Corporate Excellence in the Year 2000, L. King Taylor.
- Creating Top Flight Teams, Hilarie Owen.
- How to Transform your Company and Enjoy It, Ken Lewis & Stephen Lytton.
- Making TQM Work, Kit Sadgrove.

Course/Seminar, Organisation, Duration: 1994 - 1995

Welsh Medical Technology Forum Seminars attended during 1995:
- Clinical Trials, with various groups from NHS Wales (½ day).
- Funding for Biomedicine and Health R&D, with Wales' Relay Centre (½ day).
- Multimedia Conference, with Welsh Development Agency (2 days).

Marketing for Success (Welsh Development Agency, 1 day seminar, 1995)

Significant selected books/audio cassettes studied during 1995:
- Management Guide to Managing, Kate Keenan, Ravette Publishing Ltd.
- The Empty Raincoat, Charles Handy, including Random House Audio Books.
- Goals, Zig Ziglar, Simon & Schuster Audioworks.
- The Seven Habits of Highly Effective People, Stephen Covey, Simon & Schuster Audioworks.
- The End of the Nation State, Kenichi Ohmae's, Book-Talk, Management Book Summaries on Tape.

Welsh Medical Technology Forum Seminars attended during 1994:
- Medical Design and Materials, with The Design Council (½ day).
- Successful Product Development, with The Design Council (½ day).
- Biotechnology and Sensors, with Cranfield Biotechnology Centre (½ day).
- Medical Device Directorate with Medical Device Agency (MDA, UK, 1 day).
- Diagnostics for Cardiovascular Disease, with UK Diagnostics Club (1 day).
- Partnerships and Alliances in the Medical Industry, with Welsh Development Agency (1 day).
- Strategic Alliance Seminar for European Transtech Conference (2 days).

Significant selected books/audio cassettes studied during 1994:
- Accelerate Your Learning, Rose & Goll, including completion of 200 page workbook.
- The Business of Assertiveness, Fritchie, BBC/Business Matters Management Guides.
- The One Minute Manager, Dr.s Blanchard & Johnson, Nightingale-Conant Audio.
- The One Minute Manager Builds High Performing Teams, Dr. Blanchard, Carew and Parisi-Carew, Harper Collins Audio Books.
- Success Secrets, Mark McCormack, Harper Collins Audio Books.
- Yes or No, The Guide to Better Decisions, Dr. Spencer Johnson, Harper Collins Audio Books.

Course/Seminar, Organisation, Duration: 1991 - 1993

Intellectual Property & Licensing (Lion Worldwide, 2 day course, 1993)

Medical Devices Directives, Their Impact on Your Business (ABHI, 1 day course, 1993).

Round table discussion/response of leading UK medical suppliers to the Lilley Report on Improving The NHS Supplies Service commissioned by the NHS Trust Federation Standing Committee on Supplies and Purchasing. (1 day meeting, 1992)

Welsh Medical Technology Forum Seminars attended during 1993:
- Industry/Academic Links (½ day).
- Funding Medical Technology (½ day).
- Quality & Regulatory Affairs (½ day).

Significant selected books/audio cassettes studied during 1993:
- In Search of Excellence, Peters and Waterman, Hamlyn Books on Tape.
- The Joy of Stress, Dr. Hanson, Hamlyn Books on Tape.
- Marketing Warfare, Ries and Trout, Hamlyn Books on Tape.

French (Stage 1&2, South Glamorgan County Council, night school classes, 1992 - 1993)

German (Stage 1, South Glamorgan County Council, night school classes, 1992 - 1993).

Accelerated Innovation Training (Mentra/Innovation Wales, 8 day course, 1992 - 1993).

Health Technology 2010, The Future for Wales? (seminar given by Director of NHS Wales)
(1 day inaugural Welsh Medical Technology Forum seminar, 1992)

Technology in the Third Millennium: Health. (The Royal Society, 2 day seminar, 1992)

The Role of European Community Research and Technology Development Programmes
(European Union/Welsh Development Agency seminar in North Wales, 1 day, 1992)

New Developments Following Thrombolysis (Management Forum, 1 day course, 1992)

The Conduct of Wound Care Trials (Management Forum, 1 day course, 1992)

Project Management Course (University of Lancaster in-house, 8 day course based on MSc, 1991)
- Project Planning and Control.
- Quality Assurance and Management including:
- ISO9000 (BS5750), Audits, and Statistical Process Control.
- Failure Mode & Effects Analysis.
- Design Reviews.
- Teams and Leaders.
- Time Management and Stress.

New Products and Services, Winning Strategies (Strategic Planning Society, 1 day course, 1991)

Course/Seminar, Organisation, Duration: 1969 - 1990

Surface Mount Technology Assembly & Repair Processes (Pace Technology, USA, 1 day course, 1990)

New Product Strategy (Strategic Planning Society, 1 day course, 1990)

"Yes" Sales Seminar (Advanced Training, 1 day course, 1990)

Strategic Planning and New Product Development (1985 - 1990)
- Regularly attended relevant evening seminars both in London and Cardiff.

Sales and Marketing Management (1985 - 1990)
- Monthly management meetings, sales & marketing meetings attended in several companies.
- Attendance at various British neonatal medicine based conferences local, national and international.
- Attendance at Association for the Advancement of Medical Instrumentation (AAMI), Society of Paediatric Research (SPR), American College of Obstetricians & Gynaecologists (ACOG), Medical Design & Manufacturing (MD&M), Arab Health, Medica and American Heart Association (AHA) annual conferences.

University of Reading (1979 - 1982)

BSc (Hons) Physics and Electronics with subsidiary Mathematics 2(ii).

3 months, during 1980, spent as Quality Assurance Engineer, Digital Electronics Ltd., (part of the Kontron Group) Watford, England. Undertook inspection and test duties on a wide range of medical vital signs monitors for ECG, arrhythmia, temperature and blood pressure.

Royal Air Force (RAF) Service (1974 - 1979)

Officer training and initial jet pilot training (1978 - 1979)

RAF Odiham, technician servicing helicopter avionics (1977 – 1978).

RAF Cosford, Apprentice Technician Air Communications and Air Radar (1974 - 1977).

At RAF Cosford placed first in technical subjects with a distinguished pass and winner of the Royal Aeronautical Book Prize.

Distinctions obtained for both ONC in Electrical and Electronic Engineering and City & Guilds in Telecommunications.

The Cavendish School, Hemel Hempstead, Hert.s (1969 - 1974)

Five "O" Levels: English Language, Mathematics, Physics, Chemistry and Geography.

Two CSEs: French and English (language and literature).

Notified Bodies Under the Proposed New EU Medical Device Rules co-author with Paul Ranson, a Partner at Fasken Martineau, article for The Bureau of National Affairs, Inc. (January 2013). To be provided to Bloomberg.

The Recast/Revision of the Medical Device Directives – problems and solutions? (30 minutes, September 2012) as part of the CE2012 EU Medical Device Regulatory Revision Conference (1 day, Birmingham, UK).

TheraEDGE and RAPP-ID

Provided from 2007 to 2012 regulatory and exploitation advice to TheraEDGE, a major European FP7 theranostics project that developed molecular diagnostic platform technology for lower respiratory tract infections in the community. The aim is achieve better use of antibiotics. This included regulatory training in Spain during 2010.

Have provided since 2011 regulatory and exploitation advice to RAPP-ID, a major Innovative Medicines Initiative (IMI) developing molecular diagnostic platform technology for respiratory tract infections, sepsis and tuberculosis in the hospital and ultimately in the community. The aim is provide better detection methods to assist in antibiotic stewardship and effective treatments, assist drug discovery and improve the efficacy of clinical trials. Provided regulatory training and made a major contribution to the consortium's Regulatory White Paper (2012).

The Future of Healthcare? Kill the bugs save the world! Invited webinar for IDA Consultants (May 2012).

The Future of Healthcare? Kill the bugs save the world! Invited two part article published online by pharmaphorum™ (April 2012).

Diagnostics & Pharmaceuticals; The Future of Healthcare? Invited key note speaker to the Ethical Medicines Industry Group (EMIG), Business Development Group (March 2012).

IP breast implant affair – it hasn't all been said. (February 2012) Brief commentary on the Poly Implant Prosthese (PIP) situation and lessons to be learned published in Script Regulatory Affairs.

The PIP breast implant affair – it hasn't all been said. (February 2012) Brief commentary on the Poly Implant Prosthese (PIP) situation and lessons to be learned published in Script Regulatory Affairs.

The growing role of diagnostics-based models in combating antimicrobial resistance, Clinica, article written with Ashley Yeo (January 2012)

The Future of Healthcare is Going to be More Personalized and More Regulated. Published by UBM Canon in Consultants Corner Newsletter (November 2011).

Not mentioned in *Dispatches*, response to Channel 4 television programme about medical device regulation, discussion of important points not raised and implications of the medical device industry. Medtech Business (Issue19, June 2011, p8&9).

Medical Device Classification, part of Applied Eventology Masterclass Medical Devices: Putting Ideas into Production (MediLinkWM, 1 hour, Birmingham, 2011). Presented and participated in April and September.

What Europe could lose: a regulatory system in the spotlight – Interview (2 March 2011) with Ashley Yeo for Regulatory Affairs Medtech and later Clinica Medtech Intelligence discussing the Recast of the medical device directives and related issues (May 2011).

Testing times ahead for Medtech software and manufacturers – Interview with Ashley Yeo for Clinica discussing the challenges of medical device software for manufacturers and regulators (March 2011).

The Medical Device Directive and the Future Recast (Informa Life Sciences 2 day conference, Brussels, 2011), Chaired the second day and then led a workshop concerning Medical Device Software to Meet 2007/47/EC Life Cycle Requirements (1 day, Brussels, 2011). Following this an article was written by Amanda Maxwell of Clinica (published on 2nd February 2011): Why medtech industry must remain creative, not strangled by bureaucracy.

The impact of regulations on mobile healthcare applications, Mobile Healthcare: Is there an App for that? (MediLinkWM, ½ hour, Coventry, 2010).

Review and comments provided for an article by MedilinkWM submitted to the MedTech Business Review for the May 2010 issue: The Recast Medical Devices Directive – Force for Good or Threat to the Medtech Industry?

EU Regulatory Requirements for Medical Devices, New Technologies in Healthcare 2009 (Welsh Assembly Government, South Wales, 15 minutes, May 2009).

An Introduction to the United States Food and Drug Administration for Medical Devices.
Presented a workshop/seminar for Informa Life Sciences (London, 1 day, May 2009).

Companies need pre-emptive approach in matters of device regulation, interview at BioWales 2009 with Ashley Yeo, Editor of Clinica World Medical Technology News (South Wales, April 2009).

Regulatory Trends in Europe (MediWales seminar, Cardiff 30 minutes, June 2008).

An Introduction to the United States Food and Drug Administration for Medical Devices.
Presented a workshop/seminar for Informa Life Sciences (London, 1 day, May 2008).

Software: all important, but all too easily overlooked. Clinica, World Medical Technology News (Issue 1303, 2008).

Book review of Save Smart, Earn More: The new rules for retirement investing by Dennis Blitz for *On Target* the magazine for healthcare sales & marketing professionals. (Issue HSP23 p22, June 2008).

The First Customer. Short article for *On Target* the magazine for healthcare sales & marketing professionals. (Issue HSP20 pp12-13, March 2008).

European Medical Device Requirements for Electronic Contractors ...or all the boring things you need to know That help you make money and keep it! Intellect UK industry trade association (London, 45 minutes, 2008).

The challenge of FDA expectations for foreign manufacturers. Navigating the FDA Regulatory Framework Symposium, Informa Life Sciences, 1 day conference. (Amsterdam, 40 minutes, 2008).

Examining the software regulations for medical devices, co-author with Fursey Duggan.
Managing the Revisions to the Medical Device Directive, Informa Life Sciences, 2 day conference (Amsterdam, 40 minutes, 2008).

Entrepreneurial people and entrepreneurial companies, specially invited speaker at Medilink West Midlands Annual Awards Event (Birmingham, 15 minutes, 2007).

IEC 60601 collateral standards and other guidance for real world benefit.
Presented at Informa Life Sciences Electro-Medical Devices: Regulations and Standards Conference (London, 40 minutes, 2007).

The Medical Devices Directive Revision, including the Active Implantable Medical Devices.
Presented at Medilink West Midlands (Birmingham, 1 day, 2007) to cover the most recent developments.

An Introduction to the United States Food and Drug Administration for Medical Devices.
Presented a workshop/seminar for Informa Life Sciences (London, 1 day, 2007).

An Introduction to the United States Food and Drug Administration for In Vitro Diagnostics.
Presented a seminar for The British In Vitro Diagnostics Association (BIVDA, Belfast, 1 hour, 2007).

Invited to participate in Plastics & Rubber Weekly roundtable Medical Devices Forum.
One of nine specially invited people from design, manufacturing, compliance and business development to discuss medical device market growth, opportunities, compliance issues, materials and supply chain management. (London, ½ day, 2007).

The Revision of the Medical Devices Directive and the changes that will affect your business and Other New Approach and Related Directives to Consider when CE Marking, BioBusiness Northern Ireland (Belfast, ½ day, 2006).

Overview of Global Demand and Challenges for Plastic in Medical Devices, Plastics and Rubber Weekly, EMAP Communications - opening presentation (Brussels, 30 minutes, 2006).

Series of Compliance Online Webinars covering the revision of the Medical Devices Directive, other New Approach Directives to consider when CE marking medical devices and European clinical data requirements for the Medical Devices Directive. (Via the web, 3 hours in total, 2006).

Electrical and Electronic Safety in Medical Devices - Human Factors, Software and Electromagnetic Compatibility (Touch Briefings, Medical Device Manufacturing and Technology 2006). Paper written with co-author Mr. Keith Armstrong, Cherry Clough Consultants.

Four Day European Medical Device Directives, Seminars on Old, New and Global Approaches in Turkey as part of a European Union sponsored programme. Seminars held in June 2005, January and March 2006 (Izmir, Ankara & Istanbul a total of 12 days).
- Presented all seminars working with a local translator.

From Concept to Profit, Making It Happen in Global Markets, BioMed Central 2006 (Belfast, 1 day)
- Keynote speaker, provided opening address on global business development in the medical device, diagnostic, biotechnology and closely related industries.
- This presentation covered key cluster development, regulatory, business development and challenges including visions of the future.

Medical Technologies Cluster Forum (Walsall, West Midlands, ½ day, 2006)
- Presented the findings of the Medical Technologies Cluster Research Project, a major research project into the NHS, private healthcare providers and medical technology industry in the West Midlands undertaken by Medical Device Consultancy during 2005.

The Revision of the Medical Device Directive and Related Issues (MediWales seminar, Cardiff ½ day, 2006)
- Presented on Medical Device Directives, and other New Approach Directives to consider when CE marking medical devices.

Introduction to the Medical Device Directive and Recent Revision and Implementing an Appropriate Quality System (Learning Skills Council and Medilink West Midlands Seminar held at Staffordshire University, Stoke-on-Trent, 1 day, 2005)
- Chairman of the seminar and presented on Medical Device Directives.

Medical Devices Directive Revision – Real World Implications for You (2005)
(Medilink West Midlands Seminar held at Warwick University, ½ day)
- Provided in depth review of the revision to the European Medical Devices Directive and other related Directives.

Existing products: how far should firms go in evaluating new risks? and Clinical trials or literature reviews? Get real or face stricter rules. Regulatory Affairs Bulletin.
(Spring 2005, Issue No. 5 published by Medical Devices Faraday Partnership)
- Two articles based on a series originally written for Clinica, World Medical Device and Diagnostic News.

Why software design tools make excellent business sense. Joint article with Dr. Dave Jennings and Mr. Fursey Duggan for Clinica, World Medical Technology News (Issue 1163, 2005).

Chapter 8 Quality Systems of Medical Devices Manual (Published by Euromed Communications Ltd, 2005)

Medical Device System Design Compliance, with a focus on software solutions (2004)
(Medilink West Midlands Seminar held at Advantage West Midlands, Birmingham, 1 day)
- Chairman and principle organiser of the seminar and presented: Chairman's Introduction: the importance of getting it right.

Software in the real world: how many bugs do you have? Short article for Clinica, (2004)
World Medical Device & Diagnostic News (Issue 1128).

Clinical trials or literature reviews: get real or face stricter rules. Short article for Clinica, (2004)
World Medical Device & Diagnostic News (Issue 1124).

Existing products: how far should firms go to evaluate new risks? Short article on EMC for Clinica, (2004)
World Medical Device & Diagnostic News (Issue 1122) discussing state of the art and product liability issues.

All Change but Are You in Demonstrable Control? Regulatory Affairs Bulletin
(Spring 2004, Issue No. 3 published by Medical Devices Faraday Partnership)
- This short article provided a perspective on recent changes in quality systems and related standards, including use of the United States Food and Drug Administration's Quality Systems Inspection Technique (QSIT).

Quality & Regulatory Requirements for Medical Device Markets (2004)
(Medilink West Midlands Seminar held at Advantage West Midlands, Birmingham, ½ day)
- Chairman of the seminar and presented on FDA Inspection (30 minutes).

BioWales 2004 Exploring current issues and emerging trends (Welsh Development Agency)
This was a major two day conference sponsored by the Welsh Assembly Government.
Chair for the following session on Medical Devices, Concept and Commercialisation (1 hour).

Winning and Retaining Medical Business, Plastics and Rubber Weekly, EMAP Communications (2003)
- Presented 'Understanding the market dynamics of plastics in the medical sector (30 minutes).

How Do Successful UK Medical Device Companies Sell to the USA Healthcare Market? (2003)
Medilink North West in conjunction with Trade Partners UK.
- To present: Regulatory Issues (50 minutes).

FDA and EU Inspections of Medical Device Manufacturing Facilities (Henry Stewart, London, 2003)
- Chairman of two-day seminar that provided practical insights into all aspects of medical device facility inspections both by the FDA and by Notified Bodies (2 days).
- Provided final presentation 'Other Issues That Affect Your Facilities Compliance' that covered important but often forgotten aspects of maintaining compliance and avoid adverse outcomes (1 hour).

Review of the Report on the Functioning of the Medical Devices Directive, Southern Medical Alliance
- Presentation on report findings and related seminar discussion (2002, 2 hours).

Medilink (North West) Update on the Medical Devices Directive, (2002, 1 day)
- To present 'Global Harmonization and the Future of Medical Device Regulation' written by Alan Kent, former Chief Executive of the Medical Devices Agency and active member of the Global Harmonization Task Force (1 hour).

Winning and Retaining Medical Business, Plastics and Rubber Weekly, EMAP Communications (2002, 1 day)
- Presentation 'Exploring the market dynamics of plastics in the medical sector' (1 hour).
- Related article in Plastics and Rubber Weekly.

Southern Medical Alliance, Making Profits and Maintaining Regulatory Compliance, (2002, 1 day)
- Co-Chairman of meeting, covering European and US current and tricky regulatory requirements for medical devices including 21 CFR Part 11, human and animal tissue considerations, Human Blood Directive, IVDs, ISO 9000: 2000 and human factors in design.
- Speakers included Fursey Duggan, David Jones and Trevor Lewis.

MediWales/WMTF, Health Technology Assessment (HTA) and Related Issues, (2002, 1 day)
- Co-Chairman of meeting, covering clinical, regulatory, entrepreneurial and practical aspects of HTA.
- To provide a short presentation on the National Institute for Clinical Excellence (NICE) and encourage debate from the floor.

Southern Medical Alliance, Making Profits and Maintaining Regulatory Compliance, (2002, 1 day)
- Co-Chairman of meeting and main presenter, covering European and US requirements for medical devices and IVDs, ISO 9000: 2000, Auditing and Quality Systems Inspection Technique (QSIT).
- Auditing presented by David Jones, all other topics by Trevor Lewis.

Regulatory Trends and the Global Village, World Markets Series Business Briefing, for World Markets (2002) Research Centre (WMRC). Co-author with Mr. Alan Kent, former Chief Executive UK's Medical Devices Agency (MDA). Article covers key global regulatory issues and the impact of modern information and telecommunications technology on the regulatory control of medical devices.

Going Global (British In Vitro Diagnostic Association – BIVDA, 2002)
- Presented a 45 minute 'Introduction to FDA' (Food and Drug Administration) focused on IVDs.

Up-Date on the European MDD and Hot FDA Issues, (2001) One-day seminar for BIA Scotland.
- Co-presented with Fursey Duggan covering the Human Blood Directive, Review of the MDD, Notified Body Oversight Group, ISO 9000: 2000 Human and Animal Tissues, Clinical Trials, Design for Validation, 21 CFR Part 11, Human Factors, Design and QSIT.

Making Money from Concepts, Medilink Live, Doncaster (2001)
- 1 hour presentation covering all key aspects of business development in the medical device, diagnostic, biotechnology and closely related industries.

From Concept to Profit, special presentation for BIA Scotland in conjunction with Scottish Biomolecule (2001) Club and Scottish Enterprise Biotechnology and held at Scottish Enterprise Lanarkshire.
- 1.5 hour presentation covering all key aspects of business development in the medical device, diagnostic, biotechnology and closely related industries.

Welsh Medical Technology Forum, Meeting the Regulatory Challenge, Cardiff (2001)
- Co-Chairman of meeting, covering European and US requirements for medical devices and IVDs, ISO 9000: 2000, Quality Function Deployment and Six-Sigma initiatives (½ day).
- Presented 'Meeting the Regulatory Challenge: Benefits from Regulation, Introduction to the European Medical Devices Directive and US Food and Drug Administration' (1 hour).
- Repeated in St. Asaph, North Wales for the Welsh Medical Technology Forum during November.

Welsh Medical Technology Forum, Funding – The Way Forward, All Nations Centre, Cardiff
- Chairman of meeting, SMART, SPUR, RIN, TICP and other programmes presented (2000, ½ day).

Good Manufacturing Practice - implications and impact for the Medical Device Industry (2000) Scottish Bionetwork Association, including lectures on regulatory challenges and factory inspections (2 day course co-presented with Dr. David Jones).

Chair of question and answer session with an associated surgery during the conference (2000, 1 hour) Medical Device Technology European Conference, Paris.

Intellectual Property Rights Do's and Don'ts. Part of Welsh Development Agency's Internationalisation of SMEs Programme for the Medical Device Cluster (2000, 45 minutes).

Welcome and introduction to fostering the best business climate in Europe (2000, 20 minutes) Medical Device Technology Conference 2000 in Birmingham, UK on behalf of The New Valleys Partnership and Welsh Development Agency. Part of the 'Financing case studies and round table'.

CE Marking and FDA Approval: How to access 90% of the world's market for medical devices Medical Device Technology Conference 2000 in Birmingham, UK on behalf of The New Valleys Partnership and Welsh Development Agency (1 hour).

Meeting the Regulatory Challenge. Part of Welsh Development Agency's Internationalisation of SMEs Programme for the Medical Device Cluster (2000).
- Covered US FDA, EU Directives and other major issues for global marketing (½ day).

Total value management. Medical Device Technology magazine
January/February 2000, Volume 11, Number 1, pages 46-50.

Centre for Innovation in Healthcare Technology, Glasgow Caledonian University (1999)
- European Medical Devices Directive (40 minute paper).
- Practical Steps to Implementing the Directive (50 minute paper).

FDA Approval / CE Marking, Medilink Live, Newcastle, UK (1999, 1 hour).

European Medical Device Directives - a guide to beneficial implementation, Financial Times (1999)
- 80,000 word management report covering all aspects of European medical device directives, related regulation, quality systems, standards and methods.

Self diagnostics and home marketing, strategies for success. Medtrade Europe (1999, 1 hour).

Surgery on regulatory problems, or opportunities for progress! Medtrade Europe (1999, 1 hour).

Medical Devices and Diagnostics in Wales - a well kept secret (20 minute paper) presented at a breakfast meeting at the Medical Device Technology Trade Show 1999 on behalf of The New Valleys Partnership and Welsh Development Agency.

Self diagnostics and home monitoring: exploring new business opportunities
Medical Device Technology magazine. March 1999, Volume 10, Number 2, pages 18-22.

Market drivers: preparing for the future, Medical Device Technology magazine
January/February 1999, Volume 10, Number 1, pages 17-21.

Self Diagnostics and Home Monitoring Products - Strategies for Success, Financial Times (1998)
- 80,000 word management report covering all aspects of product development from market drivers, management systems, regulatory affairs, marketing, distribution, influence of managed care, use of evidence, key market segments, return on investment calculations and a review of emerging technologies.

Regulatory considerations for home monitoring and self-diagnostic products (1998)
The Regulatory Affairs Journal (Devices) November 1998, Volume 6, Number 4, pages 263-272.

Medical Devices in Wales - a missed opportunity or hidden success? (1998)
- presentation to New Valleys Partnership, Bridgend Wales (30 minutes).

FDA Approval / CE Marking, Medilink Live, York, UK (1998, 1 hour).

Trends towards the home for self monitoring and diagnostics. Medtrade Europe (1998, 1 hour).

European Managed Care for Medical Devices - myth or momentous? Medtrade Europe. (1998, 1 hour).

Managed Care: Has the Revolution Arrived? Medical Device Technology magazine
March 1998, Volume 9, Number 2, pages 42-48.

Progress in '97? FDA - Friend or Foe? Medical Device Technology magazine
January/February 1998, Volume 9, Number 1, page 40.

Merger mania in 1997? Medical Device Technology magazine
January/February 1998, Volume 9, Number 1, page 41.

Diagnostics of the Future, supported by the British In Vitro Diagnostics Association (1997)
- Chairman of Conference. Industry leaders to share insights and views on the major developments, drivers and influences in this expanding market sector. (1 day).

New Product Development - What Makes Winners. Regulation & Marketing for Self Diagnostic & Home Monitoring Products. SMi Conference, London. (1997, ½ hour & chair ½ day).

Looking towards America. Managed Care Europe, an SMi Publication
April 1997, Volume 1, Issue 2, pages 18/19, 23.

Chairman of proceedings at CellPath PLC launch of an agreement with Second Opinion Solutions A/S to market Telepathology products. Gave talk on Telemedicine & Telepathology (1997, 5 minutes & chair ½ day).

Medical Devices and European Managed Care Systems - Learning from the US Model and Setting Priorities (Or *What they didn't teach you at HMO School*) SMi Conference, London. (1996, ½ hour).

Managed Care - The Next Revolution or Evolution? Medical Device Technology magazine
December 1996, Volume 7, Number 10, pages 24-26.

FDA - Friend or Foe? Medical Device Technology magazine
November 1996, Volume 7, Number 9, pages 24-30.

FDA Import Bans, The Regulatory Affairs Journal (Devices)
November 1996, Volume 4, Number 4, pages 278-284.

Medical and Business Lectures, Papers, and Presentations: 1987 - 1995

Marketing For Success, Seminar for Source Wales, Welsh Development Agency (WDA) lecture on Creating Customers For Life (1995, ½ hour).

Welsh Medical Technology Forum Seminars (1994)
- Chairman of Meeting: Biotechnology and Sensors, with Cranfield Biotechnology Centre (½ day).
- Chairman of Meeting: Partnerships and Alliances in the Medical Industry, with WDA (1 day).

Invited speaker to Kancept™ Master Workshop, a novel method of accelerated management thinking developed by Mr David Norman, Kancept International (1993, 1 day seminar).

First IEE Innovation Conference on Technology Exploitation and Investment, paper on Technology Exploitation and Extracting Return on Investment (1993).

Successful Product Development Seminar with The Design Council and Welsh Medical Technology Forum. Case study paper on Huntleigh Healthcare (Cardiff) Ltd (1993).

Welsh Office Innovation Review: short case study on use and application of Accelerated Innovation within Huntleigh Healthcare (Cardiff) Ltd (1993, ¼ hour).

Swansea, University of Wales: Business Development, Myth, Magic or Management? (1993)
- included techniques and case study to final year students on BSc Innovation/Business courses (1 hour).

Mold, Wales: Chairman on workshop for Medical/Biomedical EC Programmes at Innovation in the Regions, EC Conference on Research & Technology Development (1992).

Jersey: Business Strategy and Nature to the world-wide Huntleigh Healthcare distributors and key staff (1992).

London: New Product & Business Development to Strategic Planning Society (1992).

Singapore: Use of Ultrasonic Pocket Dopplers to Far East distributors (1990).

Houston, Texas Children's Hospital, USA: Phototherapy (1989).

Boston, Harvard Medical School, USA: Phototherapy (1988).

Singapore: Neonatal Medicine, week long training for Far East distributors (1988).

Jamaica: Thermal Regulation of Neonates to Air-Shields Vickers sales staff (1987).

Dubai: Thermal Regulation of Neonates to Gulf Health Ministers (1987).