Claire Murphy

Personal Information		
	▪ Date of birth :	18 / March / 1970
	▪ Place of birth :	Cork, Ireland
	▪ Nationality:	Irish
	▪ Id. # :	X-1427750-W

Academic grade	
	▪ Electronic Engineer - B.E. (Elect.), University College Cork (National University of Ireland) Cork (1991) Final project: "Design of an instrument to measure motor position and velocity a resolver"
	▪ Biomedical Auditor, American Society for Quality . Certificate number 249,date 10/22/2005

Professional Career:

Dates	Company	Position
2.000-…	**Tecno-med Ingenieros, S.L.** Barcelona - Spain	Associate Consultant ▪ Medical Devices Consultant
1995-1999	**Tecno-med Ingenieros S.L.** Barcelona – Spain	Consultant ▪ Electromedicine manufacturer
1991-1994	**Electromedicina y Afines, S.A.** Barcelona – Spain	Quality Assurance ▪ Software Programmer for Audiometry

PROFESSIONAL MERITS:

- Biomedical Auditor, American Society for Quality. Certificate number 249,date 10/22/2005
- Member of the Spanish standardization subcommittee SC209 (electromedical products) from AENOR
- Author of several divulgation articles about quality and regulatory for medical devices and the contribution to the "Fundamentals of EU Regulatory Affairs 2004" with the chapters "4. Medical Device Premarket Requirements", "5. Medical Devices Conformity Assessment Procedures and Notified Bodies" and "6. Medical Device Compliance: Postmarket Requirements" ISBN 0-9673115-6-X . RAPS Regulatory Affairs Professionals Society.
- Professor of the courses "Quality Systems in Medical Devices manufacturing", "Clinical Equipment Maintenance Management" and "Medical Technologies Evaluation" of the Biomedical Engineering Master of the Catalonia Polytechnic University and Barcelona University 2007 -2010
- Professor of the course "Medical Devices Regulatory requirements and CE marking" of the Bio nanotechnology Master of the Autonomous University of Barcelona - 2008

PROFESSIONAL EXPERIENCE:

Present position – Associate consultant (Tecno-med Ingenieros)

A. General Experience

- Consultancy for the application of the requirements of the Medical Devices Directive 93/42/EEC and the In Vitro Diagnostic Medical Devices Directive 98/79/EEC for manufacturers of these devices established within Spanish territory. Hands-on tasks include:
  - Classification of medical devices
  - Format and preparation of Technical Documentation for conformity assessment. (MEDDEV & STED)
  - Determination of standards applicable to particular medical devices and establishment of test protocols in accordance with these standards.
  - Clinical evaluation of medical devices including research of appropriate bibliography and comparison of similar devices available on the market acc EN ISO 14155-1 & 2, MEDDEV 2.7.1 and annex X
  - Risk management plans and periodic reports for particular medical devices previously in accordance with standard EN ISO 14971.
- Consultancy for the establishment and implementation of Quality Management Systems for subsequent certification to standards EN ISO 9001; EN ISO 13485 and QSR GMP (21CFR820). Hands-on tasks include:
  - Development of quality policies, manuals and objectives.
  - Development of process maps, diagrams and indicators.
  - Development of procedures, work instructions and test methods.
  - Follow-up monitoring of system implementation through internal audits.
- Consultancy for the validation of special and/or automated processes used in the manufacture of medical devices. Hands-on tasks include:
  - Establishment of process specifications including URS for software-controlled processes.
  - Development of validation plans and protocols.
  - Assessment of test methods used to implement validation protocols and review of the results obtained.
- Consultancy for the application of national Spanish requirements for the commercialization of medical devices in accordance with Royal Decree 1591/2009 (MD), Royal Decree 1616/2009 (AIMD) and Royal Decree 1662/2000 (IVD). Tasks performed include:
  - Preparation, presentation and follow-up of applications for manufacturing / importing licenses.
  - Communication / register of medical devices and IVDs to be placed on the market in Spain.
  - Publicity authorizations.
  - Clinical trials authorizations.
- Professor of training seminars on topics specific to medical devices:
  - Sterilization processes of medical devices. Validation and routine control - TMI
  - EN ISO 14971:2007 Risk Management - TMI
  - EN ISO 13485:2003 – TMI
  - IEC 60601-1 3rd edition - TMI
  - Validation of Computerized Systems, 21CFR11 - TMI
  - CE Marking Requirements – TMI
  - ISO 13485 Quality Systems applied to Hospitals – SEEIC
  - CE marking – CIDEM
  - New Royal Decree 1591/2009 – TMI
  - Audit acc ISO 13485 - AENOR
- Auditor expert in medical technology in CE Certification audits in Spain for Notified Bodies 0434 Det Norske Veritas and 0843 UL.
- Presence and assistance during quality system audits performed by Notified Bodies for medical device CE marking.

B. Product Experience

Consultancy tasks included the review of device and test specifications, intervention in risk analysis and clinical evaluation of the following product lines:

- Active implantable medical devices: cardiac pacemakers, urinary stimulator for disabled people
- Anesthetic and respiratory devices: oxygen masks, nebulizers, flowmeters, anesthesia breathing circuit,
- Assistive products for persons with disability: assistive walking devices, foot orthosis and prosthesis
- Biologically derived devices: no experience in this category
- Complementary therapy devices: arm mud bath,
- Dental devices: dental implant systems (CE mark and FDA 510k submission), burs, abutments, filling materials, cements, amalgam mixers, dental motors and turbines, dental aspirator
- Diagnostic and therapeutic radiation devices: RX tables, RX generators, RX detectors
- Electro medical mechanical devices: dental chairs and accessories, hearing aids, electrical suction pumps EN 10079-ff, physiotherapy stimulation devices, TENS, non-invasive sphygmomanometers EN 1060, devices and software for neuro navigation, laser therapy devices, haemodialysis equipment, aphaeresis equipment, electrical patient chair and stretcher, PACS, ultrasonic echograph, mammography equipment.
- Healthcare facility products: medical gas pipeline systems, barcode id readers, sterilizers (steam and ETO)
- Hospital hardware: Ambulance stretcher, instrument tables,
- In vitro diagnostic devices: specimen containers, reagents for detection of herpes, LIMS for blood glucose monitoring,
- Laboratory equipment: special centrifuges (platelet separation), blood refrigerators
- Non active implants: intravascular implants, otologic implants, neurosurgery implants, ophthalmic implants, dental implants
- Ophtalmic and optics devices: ophthalmic frames and lenses, sunglasses with corrective lenses, contact lenses, intraocular lenses, PPE optical spectacles with corrective lenses
- Reusable devices: surgical instruments, protective cover,
- Single-use devices: surgeons gloves EN 455-1, gauze dressings, bandages, blood lines, fistulae needles, suction catheters, nasogastric enteral feeding tubes, haemodialysis devices, vacuum suction sets, intravascular catheters EN ISO 10555-1 (sterilization methods: ETO, moist heat, plasma, irradiation gamma and electron beam)

C. Technology Experience

Consultancy tasks included the review of process specifications and process validation for the following technologies:

- sterilization processes (application of EN 550, EN 552 and EN 554 for the validation and routine monitoring of ethylene oxide, irradiation and moist heat sterilization processes).
- packaging processes for terminally sterilized medical devices (application of ISO 11607)
- clean room conditions (application of EN ISO 14644 and particular requirements for microbiological conditions)
- automated assembly processes for non-active medical devices (application of IQ, OQ, PQ methods and relevant guidance documents for software validation)

D. Auditing and Technical File review

ISO 13485 internal audits (including TF review, risk evaluation, clinical data, IFU) participating as leader auditor for:

- Active implantable medical devices (AIMD0101)*
- Anaesthetic and respiratory devices (MD0101)*
- Dental devices (MD0401, MD0303, MD0403, MD1106)*

- Electro mechanical medical devices (MD1101, MD1103, MD1104, MD1106, MD1108, MD1109, MD1202, MD1301, MD1111)*
- Hospital hardware (MD1107)*
- In vitro diagnostic devices (IVD0401, IVD0406, IVD0404)*
- Non active implantable devices (MD0202, MD0203, MD0204)*
- Ophthalmic and optical devices (MD0105, MDS7005, MDS7001)*
- Reusable instruments (MD0106)*
- Single-use devices (MD0301, MD0302, MD0303, MD0102, MD0104, MD0106, MD0107, MD0108, MD0109)*

  sterilization methods: ETO, moist heat, plasma, irradiation gamma and electron beam (MDS7006)*
- Technical aids for disabled persons (MD0103)*
- Diagnostic and therapeutic radiation devices (MD1201)*
- Assistive products for persons with disability (MD0103)*
- Complementary therapy devices (MD0106)*
- Healthcare facility products (MD0108)*
- Laboratory equipment (IVD, Blood bank)

*Codes of competence according NBOG BPG 2009-03

Evaluation of conformity MD CE marking audits as product expert for:

- Ophtalmic intraocular lenses, class IIb
- Dental units, class IIa
- Neonatal incubators, class IIb

FDA inspections participating as consultant of the auditee for:

- Sterile, single-use medical devices, class II
- Surgical gloves, class II
- Amalgam dental capsules, class II
- Dental implants systems, class II

Previous positions: - Responsible for Quality Assurance / Software Programming Development (Electromedicina y Afines, S.A.)

A. General Experience

- Quality control study for the production of audiometers, inspection and testing for product approval / rejection and final product testing.
- Establishment of processes for ISO 9002 and FDA cGMPs.
- Elaboration of the company's quality manual
- Implementation of the company's quality system.
- Responsible for software in the CDTI project "Development of a clinical audiometer" (Ref:910058)
- Responsible for software in the CDTI project "Development of a clinical impedance-meter" (Ref: IT92/80)
- Responsible for software in the CIRIT project "Development of a high frequency audiometer" (Ref: IT93)
- Responsible for software in the CIRIT project "Development of a speech audiometer" (Ref: IT94)
- Set-up and configuration of the development system for INTEL micro-controllers.
- Development of software for audiometry.
- Installation of audiometers in various locations in Spain.
- Development of and automatic tonal audiometer for diagnosis.

B. Product Experience

Design, development, transfer to production and production monitoring of the following electromedical devices:

- Audiometers (screening, diagnostic and clinical models)

- Equipment for collective audiometry
- Impedance-meters (diagnostic and clinical models)
- Software for controlling all company developed models.
- Software for patient data management.

C. Technology Experience

Technologies used in the development and small-scale production of the above-mentioned devices, including hand-on experience of:

- Printed circuit board design, debugging and implementation.
- Electronic assembly, debugging and implementation.
- Use of appropriate instrumentation for electrical safety testing.
- Microcontroller programming using adapted C programming language and associated emulators.
- DOS-based programming using C programming language and standard data bases such as FoxPro and Clipper.
- Windows-based programming using C++, Visual Basic and OTS data bases such as Access

D. Intellectual Property

Elaboration of the documentation and registering of the products:

- Intellectual Property Register – "AudiLAB" Program, May 1995
- Intellectual Property Register – "InmiTRON" Program, May 1995

OTHER PROFESSIONAL SKILLS:	
Software	Current every-day use: - Microsoft Office (Word, Excel, Access, Outlook, Powerpoint) - Project - Visio - Microsoft Internet Explorer, Front-Page Publisher Previous experience - Borland C++ and associated developer framework - Visual Basic - AccessBasic - C, Pascal,
Languages	Fluent English, Spanish and Catalan Understand / read German and French

Professional Membership	▪ Member of the Spanish Quality Association (AEC) ▪ Member of the Regulatory Affairs Professional Society (RAPS) ▪ Senior member of the ASQ society

Training courses	▪ New Royal Decree 1591/2009. AEFI Barcelona January 2010. ▪ New Spanish Medical Devices Royal Decree. AEMPS Madrid December 2009 ▪ Quality Systems applied to medical devices. AEFI – FENIN 21 to 23 july 2009 ▪ Spanish licenses for manufactures and importers of medical Devices AEMPS (Madrid, September 2008) ▪ Test according UNE EN 60601-1:2008. USA and Canada Deviations SGS Spain (Madrid, September 2008) ▪ Spanish Vigilance System and new MEDDEV 2.12.1 rev5 2007 guideline. AEFI Carmen Valls Spanish Health Authorities Vigilance Responsible. (Barcelona, April 2008)

- Update of the changes in the Royal Decree 414/1996 (Spanish transposition of the directive 93/42/EEC). AEFI. Cristina Batlle Ministerio Sanidad y Consumo. (Barcelona, Mars 2008)
- New standard EN IEC 60601-1:2006. Lab. Intertek (Dusseldorf, Nov 2007)
- Validation of Computerized Systems used in manufacturing. AEFI (May 2007 – Madrid)
- Medical Devices Biocompatibility. Laboratory BIOLAB Sept 2007 – Barcelona)
- Adverse incidents communication and investigation. SEEIC (June 2006 – Santiago)
- Course ISO 13485:2003. Meddevnet. (Feb 2006 – Barcelona)
- Work-shop safety in medical systems. SEEIC. (Sep 2005 – Zaragoza)
- Work-shop control of sterilization. SEEIC (June 2005 – Canarias)
- Work-shop sterilization. CEDEST (Spanish Sterilization Society). (May 2005 – Merida)
- Course ISO 14971, Meddevnet (May 2005 – Barcelona) (May 2005 – Barcelona)
- Course ISO 13485:2003. Medical Forum Expo. (May 2005 – Barcelona)
- Quality in Healthcare Organizations DNV Spain, (Nov 2004 – Barcelona)
- Course specialization electromedicine and clinical engineering SEEIC (Spanish society of electromedicine and clinical engineering), (Sep 2004 – Cordoba)
- Training course NB 0843 (UL UK), (May 2004 – London)
- ISO 13485:2003 (Yasushi Murayama, TÜV Product Service Japan, Düsseldorf, November 2003)
- Revised Japanese Regulation Outlines (Yasushi Murayama, TÜV Product Service Japan, Düsseldorf, November 2003)
- Quality Management in the Clinical Laboratory – ISO 15189 (TQM Services Inc., Düsseldorf, November 2003)
- Professional workshop on Aesthetic Medicine (Barcelona College of Medicine, Barcelona, October 2003).
- Computerized System Validation. 21 CFR Part 11 - Electronic Records and Signatures (Management Forum, London, July 2003)
- Speaker at the course on CE-Marking of In Vitro Diagnostic Medical Devices (Underwriters Laboratories, Barcelona, May 2003)
- Statistics – Medical Device Clinical Trials (Management Forum, London, December 2002)
- Medical Devices Risk Management and Risk Analysis (Underwriters Laboratories, November 2002)
- Electromedicine Convention / Jornadas de electromedicina (SEEIC, Cuenca, Mayo 2002)
- FDA 510(k) Approval for the USA (Underwriters Laboratories, November 2001)
- IVD Directive (Underwriters Laboratories, November 2001)
- Electromedicine Convention / Jornadas de electromedicina (SEEIC, Seville, Mayo 2001)
- RAPS Convention, Madrid, May 2001.
- Presentation of the White Book on the Medical Device Industry - Presentación del Libro Blanco del Sector de Productos Sanitarios (FENIN, Madrid, Abril 2001)
- Master in European Registration of Medicinal Substances – Module 9: Medical Devices - Master en Registro Europeo de Medicamentos – Módulo 9: Productos Sanitarios (U.A.B., Barcelona, Marzo de 2001).
- ISO 9001:2000 (Det Norske Veritas, Barcelona, Febrero 2001).
- Informative workshop on legislation aplicable to In Vitro Diagnostic Medical Devices - Jornadas Informativas sobre Legislación de Aplicación a los productos sanitarios para el Diagnóstico In Vitro (FENIN, Barcelona, Mayo 2001)
- Workshop on Royal Decree 1662/2000 concerning In Vitro Diagnostic Medical Devices - Jornada Real Decreto 1662/2000 relativo a productos sanitarios para diagnóstico in vitro. (FENIN, Madrid, Noviembre 2000)
- Electromedicine Convention - Jornadas de Electromedicina. (SEEIC, Zaragoza, Junio 2000)
- Quality and Hospital Management - Calidad en la Gestión Hospitalaria (LRS, Madrid, Junio 2000)
- Workshop on New Legislation concerning Packaging and Packaging Waste -

Seminario Nueva Legislación de Envases y Residuos de Envases. (Barcelona Activa, Barcelona, julio 1999)

- ISO 9001, versión 2000. (Barcelona Activa, Barcelona, junio 1999)
- GMP – Quality in the pharmaceutical, cosmetic and medical device industries - Curso Normas GMP. Calidad en la industria farmacéutica, cosmética y material sanitario. (Barcelona Activa, Barcelona, abril 1999).
- Bioengineering Network Workshop Jornadas de la Xarxa Temática de Bioenginyería (Barcelona, junio 1997)
- Course on the impact of legal requirements concerning the environment - Curso Impacto de las exigencias del medio ambiente (Barcelona, junio 1997)
- Workshop "Design – factor for competitiveness" - Jornadas "Diseño – factor de competitividad" (Barcelona, octubre 1996)
- Workshop on Royal Decree 414/1996 concerning Medical Devices - Seminario Real Decreto 414/1996 que regula los productos sanitarios (FENIN, octubre 1996)

Congresses and Exhibitions

- Regular attendance at commercial exhibitions and congresses specific to the medical device industry:
  - Medica – Dusseldorf, Germany
  - ExpoOptica – Madrid Spain
  - ExpoDental – Madrid Spain
  - IDS – Cologne – Germany
  - FDM – Barcelona – Spain
  - COSMOBELLEZA – Barcelona Spain
  - SEEIC – Elecrtomedicine and clinical engineering
  - CEDEST – Sterilization society congress
  - SEIB – Biomedical engineering congress
  - SEGCI – Spanish Society of Research Quality (Pharma)

Technical Publications

"Fundamentals of EU Regulatory Affairs 2004" with the chapters "4. Medical Device Premarket Requirements", "5. Medical Devices Conformity Assessment Procedures and Notified Bodies" and "6. Medical Device Compliance: Postmarket Requirements" ISBN 0-9673115-6-X . RAPS Regulatory Affairs Professionals Society.

ISO 13485:2003 Quality Management Systems for Medical Devices" - "ISO 13485 Sistemas de Calidad Productos Sanitarios", Medical Devices Net, Barcelona, November 2003 / February 2004.

"Electronic Records and Signatures – Safety and Confidentiality" - "Registros y Firmas Electrónicos – Seguridad y Confidencialidad", Medical Devices Net, Barcelona, Abril 2003.

"UNE EN ISO 13485:2001 Standard – Quality Systems for Medical Devices" - "Normativa UNE EN ISO 13485:2001 – Sistemas de Calidad Productos Sanitarios", Medical Devices Net, Barcelona, Octubre 2002.

"Validation of Manufacturing Proceses – Medical Technology" - "Validación de Procesos de Fabricación – Sector Tecnologías Sanitarias", Medical Devices Net, Barcelona, Octubre 2002.

"Vigilance System Procedures for Manufacturers, Importers and Distributors of Medical Devices" - "Procedimientos Sistema de Vigilancia Fabricantes, Importadores y Distribuidores Tecnología Sanitaria", Medical Devices Net, Barcelona, Septiembre 2002.

"Medical Device Classification" - "Clasificación de productos sanitarios", Medical Devices Net, Barcelona, Agosto 2002.

""Directive 98/79/EC: CE-Marking of In Vitro Diagnostic Medical Devices" - "Directiva 98/79/CE: Marcado CE de Productos Sanitarios para Diagnóstico In Vitro." Canals X., Murphy C. Puntex Todo Hospital, núm 157, Junio 1999

"ISO 9000 Quality System Standards" - "Normes de Qualitat ISO 9000." Canals X., Murphy C., Revista Associació Catalana de Enginyers de Telecomunicació ACET, Enero 1997.

"CE-Marking of Medical Devices" - "Marcado CE de Productos Sanitario." Canals X, Murphy C., Riu P., Silva F., Mundo Electrónico 1997.

"Directive 93/42/EEC: CE-Marking of Medical Devices" - "Directiva 93/42/CEE: Marcado CE de Productos Sanitarios." Canals X., Murphy C., Riu P., Silva F., Puntex Todo Hospital, núm 134, 1997.

"Measurement of Hearing Loss using Collective Audiometry" - "Medida de Pérdidas Auditivas mediante Audiometría Colectiva." Canals X., Murphy C., Actas XIII Congreso Anual de Sociedad Española de Ingeniería Biomédica, pp5-6, 1995

Barcelona, 10 mars 2010