

Franck Martin

Country Manager & Senior Consultant

Franck Martin joined the Emergo team in 2009, spearheading the opening of Emergo's new office in Paris and adding further depth to Emergo's team in Europe. Franck brings to Emergo a comprehensive understanding of international quality system, regulatory and product compliance issues during six years he spent with French Notified Body LNE/G-MED. In addition, he has worked for respected device manufacturers including Alcon Labs and Bernas Medical, experience that gives him a uniquely holistic perspective on regulatory compliance.

EXPERIENCE:

Country Manager & Senior Consultant, Emergo France - April 2009 to current

Perform regulatory analysis for devices and combination drug devices. Compile Technical Files, Design Dossiers, and Clinical Evaluation Reports. Perform clinical assessments after reviewing databases and evaluating scientific literature. Assist manufacturers and suppliers in developing, implementing and maintaining quality system compliance programs and procedures in accordance with ISO 13485; FDA cGMP; and CMDCAS. Perform quality system assessments for compliance with FDA regulations, ISO, European Union Directives and Health Canada requirements. Represent the array of consulting services available to our clients and help customize consulting solutions to clients' specific needs.

Unit Manager, LNE/G-MED – 2006 to 2009

- Management of G-MED's Implantable and Invasive Medical Devices Unit, as well as management and support of the project leader and of client satisfaction. Responsible for G&O's definition and financial follow up of the unit.
- Management of major accounts including, customer follow up: certification process and Technical File assessments; certification management: certification planning and regulatory strategy; development: new certification (ISO 15378) and opportunities for regulatory evolution.
- Contribution to accreditation programs PMAP FDA (USA), PAL (Japan), TGA (Australia).
- Management of regulatory and voluntary audits following 90/385/EEC, 93/42/EEC, 2003/32/EC, 2005/50/EC, ISO 9001 and ISO 13485 – Lead Auditor LNE/G-MED /ICA (Afnor)/IRCA (BVC).
- Technical File assessor (Annex III and II.4: 90/385/EEC, 93/42/EEC), as well as regulatory & standards surveillance regarding: medical lasers; active implants; filler; radiology/echography/MR; medical software; ophthalmology; cardiovascular surgery; aesthetic surgery and; diagnostic imaging.
- LNE Pedagogic Manager and Trainer: ISO 13485:2003, ISO 14971:2007, 90/385/EEC, 93/42/EEC, Canadian, Australian, and Taiwanese regulations.

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Project Leader/Auditor/Assessor, LNE/G-MED - 2003 to 2006

- Regulatory and voluntary certification management of client portfolios: 90/385/EEC, 93/42/EEC, ISO 9001, ISO 13485.
- Lead Auditor and Technical File assessor (Annex III and II.4: 90/385/EEC, 93/42/EEC), as well as regulatory and standards surveillance regarding: medical lasers, active implants, radiology/echography/MR and; medical software.
- Organization and completion of QMS and Regulatory Audits (Europe, USA, other global markets). Implementation and follow up for quality system improvement. Follow up with the accreditation and inspection audits (Cofrac, SCC, Afssaps, and Health Canada).

Senior Technical Support (Worldwide), NetTest – PHOTONETICS – 2000 to 2003

- Technical support of measure and test systems for WDM networks, laser systems and optical fiber: tunable laser, modular system, PMD and optical analyzer.
- Management of customer satisfaction team and acted as the internal auditor.

Technical Support Laser Specialist EURMEA, Laboratories ALCON – 1996 to 2000

- Technical support, Laser specialist, in Europe. Field intervention in the event of a crisis.
- Responsible for competency and training follow up of 42 Field Engineers and management of field support.
- Management of the refurbishing lab and acted as the European Trainer as well as the Internal Auditor, Europe (ICA/Afnor)

LASER Field Engineer, BERNAS MEDICAL – 1989 to 1996

- Field engineer in France and the Middle East for medical lasers in surgery and ophthalmology (Gynecology, ENT, Neurosurgery, Cardiology, Urology, Dermatology): MBB-Dornier (YAG), Sharplan CO₂, YAG), HGM (Argon, Krypton), Surgilas (CO₂, YAG, LBO), Cynosure (DYE, Alexandrite), Summit (Excimer).

Sergeant, Military Service – 1988 to 1999

- 57th Transmission Army, (Franco-German) in charge of the Radio transmission compatibility with the European army corps (Eurocorps) and Thomson (EADS).

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EDUCATION:

- Three year university degree, Physics and Optics, Lasers and Optic Fibers, Université Paris XI & Institut d'Optique Graduate School, Paris, France.
- Two year university degree, Physics and Mathematics, DEUG A, Université Paris XI, Paris, France (1987)

TRAINING:

- Australian & Taiwanese regulations
- Lead Auditor SCC (Health Canada)
- Lead Auditor IRCA
- ISO 9000 Version 2000 Training
- Auditor Laser Specialist (Cofrac)
- Lead Auditor ICA (Afnor)
- Telecom (ENST)
- Manufacturer training: Alcon USA, Zeiss, Dornier-MBB, Laser Industries, Cynosure, Amsco, HGM
- GPIB training: Labwindows, Labview (National Instrument)
- LNE Internal Training (MDD, Biocompatibility, Sterilization, et al)
- Medical Information Ophthalmology Surgery, Echography (Optimal Reading)