



Dominique de KERMADEC BONNET

Senior Consultant, IVD Specialist

Dominique joined the Emergo Group team in 2010 and is stationed at Emergo Group's office in Paris and is a member Emergo Group's team in Europe. She brings to Emergo Group a comprehensive understanding of international quality system, regulatory and product compliance issues during her 7 year tenure at French Notified Body LNE/G-MED.

EXPERIENCE:

- **Certification Project Manager** (assessor and auditor), LNE / GMED – 2005 to 2011:
 - Auditor for voluntary and/or regulatory certification of quality management systems, according to ISO 9001 and ISO 13485 standards, European Directives for medical and *in vitro* medical devices, and International regulations (Canadian, Taiwanese regulations).
 - Technical assessor: examination of technical files for issuance of an EC certificate, supervisor of batch release processes for CE marked *IVD* medical devices.
 - Other activities: participation in customer meetings, organization of audits; involvement in internal quality, regulatory or training committees, including internal trainings (i.e. ISO 14971: 2007 training).
- **Registration Manager**, Ortho-Clinical Diagnostics France - 2000 to 2005
 - Putting in compliance the quality system and the products files with the *in vitro* diagnostic European Directive.
 - Follow up of subcontractors: monthly visits to help them to conform to *IVD* regulatory requirements.
- **Regulatory Affairs Assistant**, Ortho-Clinical Diagnostics France – 1997-2000
 - submission of technical files for registration in France : Virology, Immuno-Hematology, Haemostasis, Immunology and Biochemistry reagents manufactured by the manufacturing subsidiaries of OCD Group
- **Quality Assurance Assistant**, Pharmacie Centrale de Hôpitaux – 1994 to 1996
 - Management of raw material files according to pharmaceutical GMPs and French regulation for registration of drugs, follow up of the quality system.

AREAS OF EXPERTISE:

Devices:

- Wound dressings
- Injectable devices (wrinkles filling material, viscoelastic solutions)
- Ophthalmic use solutions
- Dental accessories
- *In vitro* diagnostic devices : Immuno-Hematology, Virology, NAT, Infectious diseases, Haemostasis, Biochemistry, Immunology, radio-immunology



EDUCATION:

- Engineer in Chemistry, option Organic and Industrial Chemistry, Ecole Nationale Supérieure de Chimie de Clermont-Ferrand, France
- Ph. D in Organic Chemistry, Research Center in Organic and Biological Chemistry, URM 485 of CNRS, Clermont-Fd, France
- Skills Certificate « Certificat de compétences ISO 9001:1994 », Conservatoire National des Arts et Métiers, Versailles, France
- Units of the Pharmaceutical Techniques Engineer qualification (pharmacology, formulations, drugs families....), Conservatoire National des Arts et Métiers, Paris, France

TRAINING AND CERTIFICATIONS:

- CMDCAS Program and Taiwan Auditor
- JQA Japanese regulations training
- W&T GMP requirements training
- LNE internal trainings: MDD, biocompatibility, clinical evaluation, sterilization, combined devices, US GMP, metrology, REACH, process validations....
- INTS trainings: IH, Virology, Molecular Biology (examinations included)