



## David Houot

*QA/RA Consultant*

Prior to joining Emergo Group, David worked with French Notified Body LNE/G-MED as a medical devices certification project manager within the implantable and invasive medical devices unit. He has extensive experience in technical file assessment and was a lead auditor for CE marking worldwide. David has expert knowledge in ISO 9001, ISO 13485, the European Medical Devices Directive and many other European harmonized standards, as well as global regulatory knowledge on medical device regulations for USA, Canada, Australia, New Zealand, Taiwan and Japan. David is a member of S95R committee (Sterilization, Disinfection and Sterilizers) at AFNOR (French Agency for Standardization). Education: One-year postgraduate degree in "Safety of the Industrial and Medical Systems" (quality, security, reliability); Four-year university degree in Science and Technology "Biological and Medical Engineering."

### **EXPERIENCE:**

#### **Medical Devices Project Mgr. /Lead Auditor/Assessor/In Charge of Teaching, LNE/G-Med – 2002 to 2010**

LNE/G-MED – Notified Body N°0459 - Medical Certification Division, Implantable & Invasive Medical Devices Unit, Laboratoire National de Métrologie et d'Essais in Paris.

#### **Quality Insurance Assistant, Jonzac's Hospital – 2000 to 2001**

300 beds.

#### **Research Position, Public School of Nancy – 1999**

#### **Internship Dess, Hospital Jean Monnet – 1998**

330 beds.

#### **Internship, Maîtrise de Sciences et Techniques – 1994 to 1995**

Ergotherapy Department of North-East CRAM in Nancy ( Regional Case of Sickness Insurance).  
Orthopedic and Traumatologic Surgery operating suite of the Central Hospital in Nancy.

### **AREA OF EXPERTISE:**

- Quality systems audits organization and conduction (worldwide) for a certification body accredited by COFRAC.
- Thorough knowledge of standards: ISO 9001(2000), ISO 13485 (1996 and 2003).
- Involvement in defining objectives to improve and develop internal organization.



## David Huout, continued...

- Customers handle in the field of medical devices in a regulatory (medical devices directives) and voluntary environment (ISO 9001, ISO 13485)
  - contracts, quotations and certificates handle, clients/clinical experts liaise, files submission to certification committee.
- Assessment of medical devices CE marking technical files.
- Lead auditor for CE marking (worldwide).
- Expertise in European regulation (Medical Devices Directives), Canadian (Medical Devices Regulation, Accademia Qualitas certificate), standards to secure and maintain medical devices sterility, and many other European harmonized standards. Knowledge of other regulations: USA, Australia / New Zealand, Taiwan, Japan (JQA certificate).
- Project leader: Improvement of internal organization between departments: conducted working group problems identifications, proposals and scheme monitoring.
- In charge of teaching : Design and conduction of training in the field of medical devices sterilization (Ethylene oxide, Radiation, Moist heat).

### EDUCATION:

- One-year postgraduate degree (Diplôme d'Etudes Supérieures Spécialisées) in "Safety of the Industrial and Medical Systems" in Nancy (quality, security, reliability), 1998
- Four-year university degree in Science and Technology (Maîtrise de Sciences et Techniques) "Biological and Medical Engineering" in Nancy, 1995
- Two-year university degree in technology (Diplôme Universitaire de Technologie) "Electric Engineering and Industrial Data processing" in Nancy, 1993

### AFFILIATIONS:

- Member of S95R committee at AFNOR (French Agency for Standardisation)
  - Sterilization, Disinfection and Sterilizers.

### LANGUAGES:

- English
- German