ASSOUS Didier

69008 LYON
Tel : (+33) 6 11 95 20 00
Email : d.assous@tna-part.com

SENIOR CONSULTANT
REGULATORY AFFAIRS AND QUALITY
CE MARKING MD and PPE
CE CERTIFICATION AUDITOR

HIGHER EDUCATION

1979	**Engineer** I.N.S.C.I.R. in Rouen (76)
1987	**D.E.S.S.** Business and Administration Management – IAE Grenoble (38)

PROFESSIONAL EXPERIENCE

Since Jan. 2021,	**TNA & Partners (77) – European Representative for MD and PPE** **Co-founder** Responsible for the evaluation of Technical Documentation

Since Jan. 2020,	**WTT-PROD (Spain) - Production of water treatment installations for the pharmaceutical industry** **Co- founder** Responsible of Regulatory Compliance

Since Jan. 1991,	**ADAQ Conseil - LYON (69)** **Sole Manager and senior consultant** Regulatory Affairs and Quality Management for Medical Device manufacturing companies and healthcare establishments Time-shared Regulatory Affairs and Quality Manger

September 1990 May 1981	**HBS – SOGEME in Valence (26)** **Quality Manager** in a production company of around 1000 people for mechanical assembly, ultrasound control, special machine manufacturing. **Laboratory manager for physico-chemical tests**

September 1979 - April 1981	**PEC ENGINEERING in Osny (95)** **Deputy tests engineer**

MAIN AREAS OF SKILLS

➢ **Assessment of the Technical Documentation MD all classes**

All fields of Medical and Electromedical Devices

➢ **CONSULTANT DM Quality and CE Marking since 1995**

All fields of medical and electromedical devices using the following technologies:

Mechanics – electronics – Plastics – Chemistry - Welding – Surface Treatment - Non-woven - …

➢ **Audits and evaluations**

Second and third party auditor skills
Auditor certified by the Institute for the Certification of Auditors (I.C.A.) No. 154 in 11/1993
CE Marking and Quality Systems Auditor according to EN ISO 13485 for Medical Devices on behalf of Gmed (French Notified Body) since 1998
ISO 9001 and EN ISO 13485 Certification Auditor for the AFNOR Certification Body between 1993 and 2015

➢ **Regulatory Affairs and Quality Manager on a part-time basis since 2005**
Skills: *Development of all CE Technical Documentation for class I to IIb products (including in particular Risk Management File, Biocompatibility Files, Sterilization Validation Files, Sterile Packaging Validation File, bibliographic clinical evaluation, suitability for use file).*
Quality and Regulatory Affairs Manager for:
- Manufacturer of nasal spray (Class IIa)
- Manufacturer of dental burs (Class IIa)
- Manufacturer of dialysis water production plant (Class IIb)
- Manufacturer of cancer cell detection product (Class IIa)
- Manufacturer of medical electrostimulation devices (Class IIa)
- Manufacturer of sterile (Class Is) and non-sterile (class I) non-woven fabrics
- Manufacturer of medical masks (Class I and IIa)

➢ **Trainer in Quality management and risk management in industrial settings and with healthcare establishments**
Trainer for Paul Sabatier University, EUROPHARMAT, CAFOC, Nîmes University Hospital, Mantes la Jolie University Hospital

MAIN PROFESSIONAL TRAINING from 2019 to 2021

ISO 19227 version 2018	EN ISO 11607-1 & 2 version 2019	Règlement Européen 2017/745/UE
Directive 93/42/CEE	Série EN ISO 10993	EN ISO 13485 version 2016
ISO 9001 version 2015	EN ISO 11135-1	EN ISO 17665-1
EN ISO 62366	EN ISO 15378	EN ISO 22716

RECOGNITION

Certification Auditor CE and EN ISO 13485 Marking on behalf of the French NOTIFIED BODY GMED for 22 years

Certification Auditor CE Marking and EN ISO 13485 on behalf of the Luxembourg NOTIFIED BODY SNCH from 2012 to 2015
Certification Auditor ISO 9001 and EN ISO 13485 for the French organization AFNOR from 1993 to 2015
Trainer for the Scholarly Society EUROPHARMAT, relating to the use of Medical Devices in hospitals from 2004 to 2015