



Fabio de Pasquale

Senior QA/RA Consultant

EXPERIENCE:

- QA and Regulatory Affairs Manager, StarFish Medical – 2003 to 2006
- Quality Assurance Consultant, (various clients), 2003
- Product / Project Manager, Hydroxyl Systems Inc., 2002 to 2003
- Licensing Officer, Canadian Nuclear Safety Commission, 1993 to 2001
- Nuclear Safety Specialist, National Nuclear Research Centre (Switzerland), 1989 to 1993
- Post Graduate Student, Centre for Nuclear Studies (France), 1987 to 1988

AREA OF EXPERTISE:

Devices:

- Implantable
- Heart valves
- Animal tissue based devices
- Cardiovascular
- Software (PACS)
- Ophthalmic, dental
- Dental
- Body contouring
- IVDD
- Tele-monitoring
- X-Ray
- Ultrasound
- Laser
- LED
- Wound dressing
- Rehabilitation system
- Radiology
- Neuro-stimulators

Disciplines:

- Quality assurance compliance (QSR/GMP, ISO 13485:03, and 21 CFR Part 11 Compliance)
- QMS design, audits and gap analysis
- International regulatory strategies development (FDA 510(k) & PMA, CE Mark, Canadian MD Licence)
- Clinical study design, management and monitoring (IDE, ITA, etc.)
- Product design and transfer to manufacturing strategies
- Risk Analysis and Quality Plans development
- Product labeling compliance



- Laboratory testing (electrical safety, EMC, biocompatibility, etc.) and international marking and registration
- European Ecology Directives Consulting ((RoHS & WEEE)

EDUCATION:

- MBA in Engineering Management University of Ottawa, Canada 1999
- M.Sc. in Mechanical Engineering University of Pisa, Italy 1988

TRAINING and CERTIFICATIONS:

- ISO 13485:2003 Internal Quality Auditor Training – BSI Product Services
- Attended: Integrating Quality in Clinical Trial Conference (by US-FDA)
- Attended: The Essentials - US, EU, and Canadian Regulatory Affairs Course (by RAPS)
- Attended: ISO 13485;2003 Internal Auditor Course (by BSI Management Systems)

AFFILIATIONS:

- Member of the Regulatory Affairs Professional Society (RAPS)