Quality, Regulatory Affairs, Medical Device & IT

When you need advice or support regarding market access, regulatory requirements or quality assurance for medical and in-vitro diagnostic devices and systems, HELEN SANDELIN can support you. It can concern CE marking, FDA submissions, classification, regulatory strategy, notified body or competent authorities communication, quality management systems, risk management or compliance to standards for medical and diagnostic devices including electrical equipment and software.

Helen has more than 15 years of experience as an operational and strategic senior consultant with focus on communication to deliver customer value and meeting expectations. Helen is an open minded, structured and target oriented person with many ideas. She is a communicative team builder with strong ability to work towards defined objectives both individually and with teams.

In her role as trainer, Helen has met both beginners and management teams in medical device and IVD industry, teaching and training them in quality and regulatory subjects with focus on patient risks, dialogue and problem solving.

Helens technical experiences are based on software and system design and development, but enlarged to also include clinical and scientific data, electronic hardware, material evaluations, usability aspects and product validation. To result in a complete and compliant Technical Documentation for the devices developed under pre-determined procedures.

She has worked with, among other things, the following products; ECG, patient monitoring systems, ventilators, dental implants, patient record systems, sterile products, surgical procedure packs, wound care dressings, medical beds, medical information systems, alarm systems, IVD reagents, IVD instruments and software including AI.

TOOLS & METHODS

- Market access, approval, clearance and registration; CE-marking , 510(k), etc.
- Risk management
- Define and implement processes – QMS incl. software development
- Product audit & reviews
- Audit and compliance assessment:
  MDD,MDR, IVDD, IVDR, PPE, QSR, ISO 13485, ISO 9001
  ISO 14971,
  IEC 60601-1 standards
  IEC 62304
- Education and Training
- Facilitation methods

LANGUAGES

- Swedish – mother tounge
- English – fluent

EDUCATION

- B Sc in Electrical Engineering and Computer Systems, Chalmers University, Göteborg, 1995

Courses & certificates

- IRCA certified Lead Auditor for ISO 13485, ISO 9001
- Member in IEC TC 62 - Medical Electrical Equipment
- Member in ISO TC 210 – Health Informatics

EMPLOYMENTS

- Mediteq, 2007 -
- Castra Group AB, 2006 - 2007
- Breas Medical AB, 2003 - 2006
- Cap Gemini AB,1998-2003
- Ortivus AB, 1995 -1998

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