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

During product design she can lead projects or perform verification, validation, requirement management, software and system design review, configuration management, change management, labelling and product documentation as well as all other items associated with Technical Files and Design Dossiers.

Helen has the ability to work both operational to perform activities or strategically to develop and implement processes and procedures to support the activities listed above. Activities and processes are often included into a (quality) management system.

After more than 15 years of experience from product and system development in IT, telecom and medical device industry, she has specialised into quality and regulatory affairs for medical device industry. Her technical experiences are based on software and system development, but enlarged to also include electronic hardware, material evaluations and verification. Some of the product types she has worked with are; ECG, patient monitoring systems, ventilators, dental implants, patient records, sterile products, surgical procedure packs, medical beds, medical information systems and alarm systems.

Helen is an open minded, structured and goal oriented person with a lot of ideas. She is also a communicative team builder with strong ability to work towards defined objectives both individually and with teams.

QUALIFICATIONS

Quality and Regulatory Affairs for medical devices and systems.

Tools & Methods

- Market approval and clearance;
  CE-marking , 510(k), etc.
- Risk management and patient safety analysis
- Define and implement processes
- Product audit & reviews
- Audit & compliance assessment:
  MDD, QSR, ISO 13485, ISO 9001
  ISO 14971,
  IEC 60601-1 standards
  IEC 62304
- Quality assurance of medical device software
- Education & Training
- Facilitation methods

EDUCATION

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

Courses & certificates

- Lead Auditor Training
- Member of IEC TC 62 - standards for medical electrical equipment

LANGUAGES

- Swedish – mother tounge
- English – fluent

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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