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European Authorised Representative Medical Device Software Clinical Evaluation

QAdvis

WHAT WE DO

QAdvis is a team of expert advisors in compliance, quality, productivity and regulatory affairs for the MedTech industry. Our services include:

- Quality management support
- System development
- Clinical evaluation
- Medical device software specialist services
- Regulated software validation
- Quality and regulatory consulting
- Training
- European Authorized Representation

We are long-time trusted providers of MedTech quality and system management, risk management, compliance, training, interim management and regulatory affairs. Offering a thorough knowledge and understanding of the industry, based on 30 years of professional experience, QAdvis have the tools to help take your MedTech innovations to domestic and international markets.

As compliance in the MedTech field is governed by rigidly specific requirements, developing and using a reliable quality management system is key to fulfilling and maintaining compliance. We support you in this process, using best practices based on three decades of projects in this field.

QAdvis offer complete European Authorized Representation services for non-EU companies entering the European market. We are an active member of the European Association of Authorized Representatives.

We also offer support for businesses entering the US market, conducting quality system regulation assessments, mock audits, evaluations and we help collect all the information required for FDA applications.

WHO WE ARE

QAdvis AB is based in Sweden and has two offices, one in Lund and one in Stockholm. We are more than a dozen senior and expert consultants. The company's background is in consulting and the medical device industry and it started as a separate business in 2013, the founding team bringing the expertise of more than 500 consultant assignments into the company.

Since then we have successfully conducted a large number of assignments and a number of long term agreements have been established, as well as partnerships and alliances with clients, industry and trade associations and regulatory companies. The majority of our clients are located outside Sweden.

CONTACTS

Nils-Åke Lindberg has been working in the international medical device industry for 30 years and has a thorough knowledge of quality assurance management and regulatory affairs. He has conducted numerous internal, external and supplier audits and works regularly with Competent Authorities and the Food and Drug Administration in the United States. He is an active participant of SIS/TK355, Medical Quality Management Systems and of EAAR, European Association of Authorized Representatives.

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Robert Ginsberg has more than 30 years of software development experience, with 24 years in medical device software. He has participated in more than 20 audits involving the Food and Drug Administration, the Medical Device Directive and others, is a Certified Lead auditor (ISO 13485 & QSR), co-author of IEC/ISO 62304, 82304-1, 80001-1, 80002-1, 80002-2 and a working member of Cenelek TK-62.

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