QAdvis

QUALITY MANAGEMENT SYSTEM DEVELOPMENT EXPERT ADVICE TRAINING

EUROPEAN AUTHORISED REPRESENTATION

WHAT WE DO

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

- Quality management support
- System development
- Quality and regulatory consulting
- Training
- European Authorised Representation

We are longtime 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 is an active member of the European Association of Authorised Representatives, offering support and legal EU representation for non-EU companies who want to enter the European market.

We also offer support for foreign businesses entering the US market, conducting mock audits, Quality System Regulation assessments, evaluations and collecting 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. The company started as Synergus AB in 2007 and branched off as a separate business in 2013, with a history of more than 500 expert assignments. In the beginning of 2014, a number of long term agreements had already been established, including Dako/Agilent, Contura, Sensidose and Antrad. Further partnerships and agreements have successfully been established, with a majority of the clients being 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 a 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, 80001-1, 80002-1, 80002-2 and a working member of Cenelek TK-62.

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