Regulatory Expertise
Medical Device Software
Clinical Evaluation

QAdvis

QAdvis AB is based in Sweden with two offices, in Lund and Stockholm. We are 20 senior and expert consultants supporting clients worldwide, with an emphasis on Scandinavian and European companies.

QAdvis offer a complete range of multidisciplinary quality and regulatory services, ranging from initial device classification, software validation and clinical evaluations to post market surveillance.

Over the years, our team has successfully conducted a large number of expert assignments, thereby establishing partnerships and alliances with clients, industry, trade associations and an international network of expert consultants.

Find the easy way – work with us.

QAdvis is a team of expert professionals in compliance, quality, productivity and regulatory affairs for the MedTech industry.

We are a longtime trusted service provider for the medical device and in vitro diagnostic device industry. Our services include all regulatory aspects, such as setting up quality management systems, CE marking and technical files as well as risk management, clinical evaluation, compliance, software, training, interim management and regulatory affairs.

We are experienced active participants in several key international standardization committees and EU workgroups, writing standards and guidelines. With a thorough understanding of the industry we support our clients in turning complexity into simplicity.

Our employees are carefully chosen professionals, each with decades of MedTech experience, including extensive work at notified bodies. QAdvis has the tools and skills to safely bring your medical devices and in vitro diagnostic devices to domestic and international markets.

The regulatory reality is currently facing significant changes, with new medical device and IVD regulation in the EU as an example. Quality management systems according to the revised ISO 13485:2016 is also on the doorstep. We provide gap analysis, understanding, interpretation and implementation.

European Authorized Representative

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.

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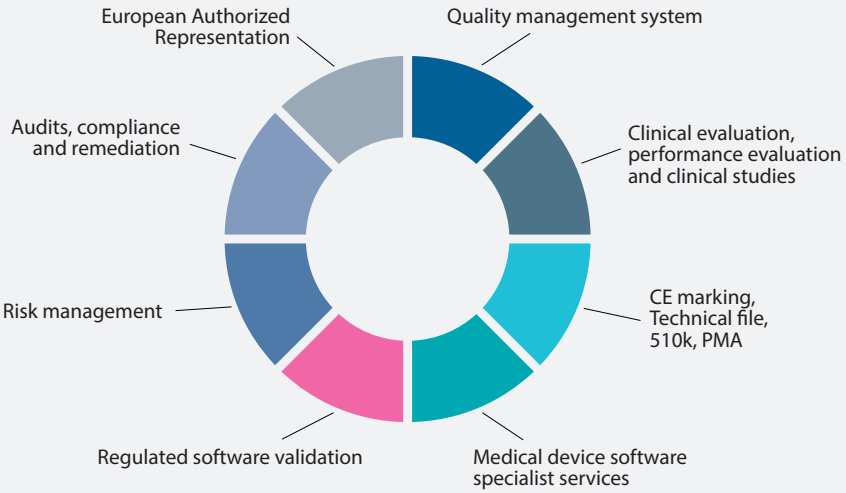

Eight reasons to choose **QAdvis**

1. Training Open course trainings, in-house training, seminars.

2. Expert competence Participates in workgroups for IEC 60601-1, IEC 62304, IEC 82304-1, IEC 80001-1, IEC/TR 80002-1, IEC/TR 80002-2, ISO 13485, MEDDEVs etc.

3. Clinical evaluations Experienced and highly qualified personnel to review or write CERs

4. One stop shop approach IVD, MDD, software, validation, technical file, registrations, risk management, biocomp, audits, due diligence, etc.

5. Software Unique competence in regulated software, for both medical devices and company infrastructure.

6. Network Excellent international network of contacts with Competent Authorities, Notified Bodies, standardization committees, MedTech industry associations etc.

7. International Our competence and knowledge cross borders, but they are always specific to your local requirements.

8. Reliable Our personnel embrace the value of being humble experts. Professional services delivered with integrity.

QAdvis

www.qadvis.com

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