Regulatory Expertise
Medical Device Software
Clinical Evaluation

QAdvis

www.qadvis.com


We are longtime trusted providers of
MedTech quality management systems,
risk management, compliance, training,
interim management and regulatory affairs.

QAdvis AB is based in Sweden with two offices, in Lund and Stockholm. We are 20+ senior and expert consultants supporting clients both in Europe and worldwide.

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, technical files and CE marking, as well as risk management, clinical evidence, compliance, software, usability, cybersecurity, training, interim management and regulatory affairs.

We are experienced active participants in several key international standardization committees and EU commission work-groups, writing standards and guidelines. With a thorough understanding of the regulations we support our clients in turning complexity into simplicity, having a business perspective in mind.

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.

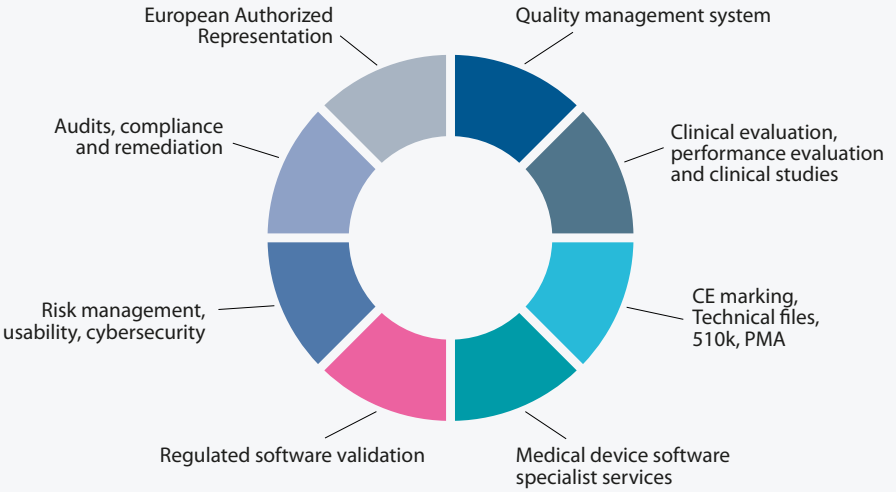
The regulatory reality is currently facing significant changes, with the new medical device and in-vitro diagnostic regulations in the EU as an example. Implementation of quality management systems according to the revised ISO 13485:2016 is another challenge. We provide support with gap analysis, interpretation, training 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.

ear@qadvis.com



Eight reasons to choose **QAdvis**

1. Source of competence Open courses, in-house training, seminars.

2. Subject matter experts 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, ISO 14971, MEDDEVs etc.

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

4. One stop shop approach MDR, IVDR, 510k, PMA, software validation, technical files, international registrations, risk management, biocomp, audits, due diligence, etc.

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

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

7. European Authorized Representation A Brexit safe European base in Sweden. Competent E.A.R. team who can truly support with all EU regulatory aspects and be a valuable European partner.

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

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