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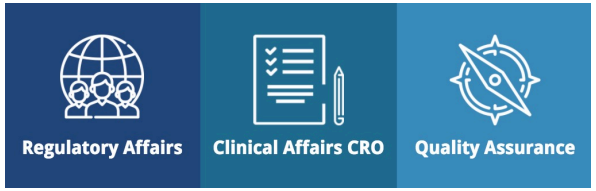
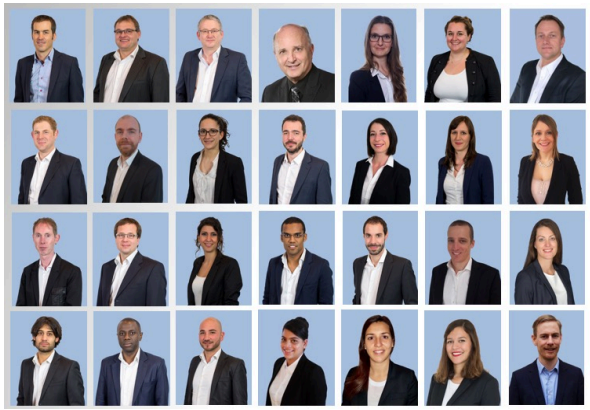


Leading Swiss **Consultancy Service**

Exclusively supporting Medical Devices and IVD compliance with international regulatory requirements



A Structured **Team of Experts**

Efficiently supplying Regulatory and Quality expertise along the entire product lifecycle, from idea to market, from market to profitability

Switzerland, Lausanne, Olten
Germany, München, Erlangen, Tuttlingen
Denmark, COBIS Copenhagen, Aarhus
Belgium, Brussels, Charleroi, Gent
USA, Boston

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Regulatory & Clinical **Pathway Development**

In the focus of MDR 2017/745 and IVDR 2017/746 implementation, the pathway for your product may present difficulties and hidden challenges. We support you with the following key activities:

- Identification of the applicable regulations and standards
- Determination of the clearance sequence for different jurisdictions in the world
- Integration of specific requirements in the Quality Management System
- Determination of applicable requirements for scientific and clinical evidence
- Structured communication with Regulatory Bodies and Competent Authorities.

MDR and IVDR transition require a strategic approach – not only for new products but also for the currently marketed medical devices. Some of the regulatory changes do not allow “grandfathering”. Medidee guides you towards the most economic pathway.

Implementation of **Quality Management Systems**

Obtaining market clearance in any of the leading jurisdictions is always a combination of scrutiny of technical documentation and verification of the effectiveness of a quality system. Rely on us for:

- ISO 13485:2016 conversion programs
- Integration of multiple requirements (Directives, MDR, IVDR, ISO 13485:2016, USA QSR, Japan Ord. 169, Brazil RDC 16/2013)
- Setup of a compact and clear process oriented documentation
- Training throughout the certification process
- Interaction with Notified Body and FDA
- Debugging, reshuffling and cleaning up of existing QMS
- Readiness for MDSAP - Medical Device Single Audit Program

Medidee is following state of the art IMDRF & MDSAP Guidance. Our sub-system based approach ensures straightforward integration of GMP requirements, easy and safe use in daily routine and efficiency of the QMS as a tool for corporate management.

Internal **Audit programs**

We contribute to your internal audit program by:

- Developing a risk management based audit program
- Planning and executing audits on your behalf
- Catching up the backlog of internal audits
- Training your staff on effective auditing

We help you turning your internal audit program into an effective tool for stimulating the CAPA and the management subsystems.

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Technical Documentation – **Submissions**

Whether your medical device is an active implant, an IVD or a classic medical device, **compliance with the essential principles** of safety / performance / effectiveness must be demonstrated.

The evidences are assembled during the design, development and industrialization in a comprehensive technical documentation – whether this is for CE mark, US FDA clearance / approval or compliance with any other regulatory framework.

Medidee assists you in:

- Defining a **Quality Plan** including required validations prior to market introduction
- Planning and conducting **V&V activities** for product and related manufacturing processes
- Setting up the technical documentation according to the latest MDR and IVDR requirements and applicable guidance
- Preparing for international submissions

Medidee may drive the project for you and/or assist your team in completing the required tasks.

Clinical **Evaluation – MEDDEV 2.7/1 Rev. 4**

Medidee has cumulated experience with **clinical evaluation** and **performance evaluation** for > 100 Medical Devices and IVD over the past decade. We support submissions for pilot & pivotal studies.

We assist you with:

- Development of the Clinical Investigation Protocol (CIP), the Investigator Brochure (IB), Patient Informed Consent forms, Case Report Forms (CRFs) according to ISO 14155 and applicable guidance
- Submission to Ethics Committees and the notification to Competent Authorities in any European Union member state
- Statistics and safety reporting
- Medical writing for **Clinical Investigation Reports** and **Clinical Evaluation Reports**

A trustful relationship with leading Notified Bodies promotes open discussions on expected clinical evidence and facilitates controlled regulatory outcomes.

Risk Management **- EN ISO 14971**

The benefits of a medical device shall outweigh any risks inherent with the use.

Medidee supports the risk management at the company, use, design or process levels from the early stages through the entire product lifecycle. We specialize in the smart integration of Risk Management into your QMS in connection with usability engineering, process validation and change control.

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Verification and **Validation (V&V)**

Biocompatibility **ISO 10993**

Knowing what needs to be done and who can execute is key. We work with GLP labs in Europe and the U.S.A.

Packaging, transportation, **shelf-life validation**

Together with your engineers we develop an evidence-based approach based on ISO, EN, ASTM and other applicable standards. For physical testing, we team up with GLP testing partners.

Innovative / resorbable materials

When it comes to innovative devices based on animal, vegetal or human source raw materials resulting from bio-technologies, we help identifying and negotiating a pathway with Competent Authorities and Notified Bodies.

Sterilization **processes**

Whether your product requires Steam, ETO or Radiation sterilization, Medidee helps you structuring the setup and validation of safe and effective processes.

For devices allowing **reprocessing**, we support the documentation of IFUs and the proper **validation** by the facility of our partners.

Software & Firmware lifecycle **EN 62304**

We help you preparing the changes of software classification related to MDR 2017/745 and IVDR 2017/746. Whether the software is embedded in medical devices or standalone software, we support you down to the organization of software development and testing.

The validation of software used in production processes or for Quality Management is a specialty. A multidisciplinary team provides the necessary competences and a safe project approach.

Usability **EN 62366**

A brief look into the MAUDE user experience database confirms that usability is crucial for product safety. We help you structuring risk management file, usability testing including formative and summative studies and IFU documentation. We support the integration of EN 62366 in your QMS.

Active Medical Devices **IEC 60601 standards family**

Substantiating fulfillment of the essential principles for safety and performance / effectiveness for Active Medical Devices requires often extensive involvement of 3rd party test houses in the Verification & Validation (V&V) of the Device.

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Medidee has the engineering knowledge and testing experience to navigate through the 60601 standards family, considering national deviations for accessing markets in the EU, USA, Canada and others. We assist your engineers in reviewing e.g. insulation schemes, risk analysis and **pre-testing** of your devices run by our experts prior the submission to test houses.

Active Implant **Medical Devices**

Medidee is specialized in coaching the long development towards a clinical investigation by helping the Client interpreting the wide requirements of the 45502 standard seriee.

Marketing & **Post Marketing**

Post Market Surveillance **- PMCF**

PMS incorporates a proactive and a reactive part. The medical device manufacturer drives the proactive part by gathering targeted data. To support that, we establish PMS plans for Europe including **PMCF** if required, depending on the necessity for data to continuously demonstrate fulfillment of the essential principles of safety and performance.

Vigilance & **Reporting**

The reactive part of PMS, also called **vigilance** or **medical device reporting**, requires the setup of a lean process for capturing and handling events communicated by the field.

We assist you in **implementing, validating** and **training** vigilance procedures and periodic reporting procedures as e.g. PSUR under the MDR and IVDR.

European Authorized **Representative**

EC REP

We assist you effectively in your compliance efforts to continuously meet the applicable regulatory requirements of the European Union once your device is on the market by providing tailor made services for Post Market Surveillance and reporting to regulatory authorities.

Contact **us**

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Offices **in**

Switzerland, Lausanne, Olten
Germany, München, Erlangen, Tuttlingen
Denmark, COBIS Copenhagen
Belgium, Brussels
USA, Boston

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Supplier **controls**

The technological complexity of devices and IVD requires division of tasks impacting safety and performance of a product along a supply chain.

The control of suppliers and subcontractors is in the focus of regulatory scrutiny by Authorities and Notified Bodies.

Setting up and maintaining the resources for a compliant supplier control program internally is a challenge for SMEs.

You can rely on Medidee for:

- Planning and execution of compliance audits according to ISO 13485, QSR, JPAL, RDC 16/2013 within the shortest lead times anywhere on this planet
- Catching up the backlog in your supplier audit program
- Executing supplier qualification audits during the design & development phase
- Getting your staff on speed for system audits / product audits / process audits
- Developing supply and quality agreements

ISO 13485
BSI certified company