MedQ
CONSULTANTS B.V.

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BRINGING YOUR MEDICAL DEVICE TO THE MARKET

Full Service Medical Device CRO

A single point of access for all your supporting Regulatory, Quality and Clinical Services

FIRSTLY

THANK YOU

FOR CONSIDERING US!

Full Service Medical Device CRO

MedQ consultants B.V. is a full service international Contract Research Organization (CRO) for the medical device industry.

We support medical device companies in a highly dynamic environment to cope with EU and global Regulations for all types of medical devices and classifications. The broad range of our services gives you the opportunity to tailor made your choice for support in line with your project and still have access to the full range of knowhow for assessing the impact of the project strategy on compliance with the regulations to avoid market access delay.

For those companies that do not have a presence in the EU, MedQ B.V. also can be your European Authorized Representative.

All services are aimed at providing an economical and practical approach in supporting your business throughout the entire duration of your project and life-cycle of your device. These services include:

- Regulatory compliance
- Technical Documentation for Market Approval
- Quality Management Systems
- Clinical trial strategy and support
- Authorized Representative

Our MedQ Consultants B.V team is specialized, experienced and highly competent in the processes for complying with the medical device directives and regulations.

Robin J.M. Lucchesi
René Roncken
Founders

CONTENT

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Our mission is to provide tailor made services to fit the need of the clients and maintain a high level of competence and experience throughout the duration of the projects.

For more information please contact us and we will get back to you

1 OUR SERVICE AREAS

MedQ Consultants B.V. provides a broad range of regulatory, quality, clinical and Authorized Representative services for the medical device industry in order to provide an economic and practical approach in supporting your business through the duration of the project and life-cycle of your device.

Regulatory Services

Quality Services

Authorized Representative

Clinical Strategy

Clinical Strategy

2 | REGULATORY
SERVICES

WE ARE OFFERING A FULL SET OF REGULATORY SERVICES

Our Regulatory Services will guide you through the various (inter)national and local regulations to assure compliance and access for the market of interest.

With the expansion of the markets on a global scale, regulatory compliance strategies require a broader approach and view point in order to scale your strategy to include the various country specific demands.

REGULATORY STRATEGY

Regulatory strategy is depending on the market you would like to enter. Continuous development of medical device laws has increased the detail of regulatory compliance and practical implementation of the requirements.

Technical documentation has become more detailed and standardized with required information.

MedQ Consultants B.V. can support you in:

- Regulatory strategy for the European and other global markets;
- Provide support for compliance against the regulatory market(s);
- Technical documentation;
- Market approval/release and access for the European market as well as globally;
- Being your Authorized Representative:
    - Authorized contact for non-EU companies;
    - Vigilance and Safety reporting;
    - Medical Device Market registration and Approval support.

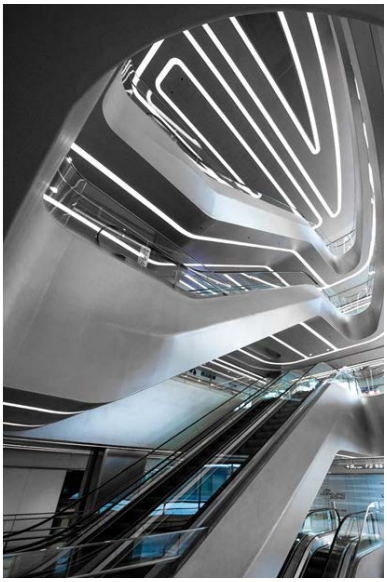
3 REGULATORY CONSULTING SERVICES

The most important element of getting your medical device approved is the implementation of a fundamental regulatory strategy and sound technical documentation. Our regulatory service provides you guidance and support to comply with the current medical device regulation(s) and market access requirements. With a tailor-made service package we can provide excellent and efficient support in preparing access to the European/global market

REGULATORY CONSULTING SERVICES

MedQ Consultants B.V. can support your regulatory requirements with:

- Regulatory strategy;
- Liaison for Notified Body, Competent Authority, European Commission;
- CE marking guidance;
- Prepare / review risk analysis;
- Prepare / review Essential Requirements;
- Declaration of Conformity;
- Instruction for Use / Labeling;
- Clinical evaluation report;
- Regulatory training;
- Being your internal regulatory employee / support;



MEDR-AR SERVICES B.V. EAR SERVICES

- When a manufacturer of medical devices is not established in a European Member State, it is a legal requirement to designate a European Authorized Representative (EAR).
- We are offering a set of Authorized Representative services under the Medical Device Regulation 2017/745 (MDR) to take responsibilities as mandated by the legal manufacturer.
- MedR-AR Services B.V. will provide you with a European Authorized Representative that will serve as a liaison between you, the European Commission and the National Competent Authorities
- MedR-AR Services B.V. can support you as EAR for:
  - Authorized contact with Authorities
  - Verify conformity of your Technical Documentation and Declaration of Conformity
  - Verify conformity of your labeling
  - Vigilance and Field Safety Corrective Action reporting
  - Medical Device market registration and approval support
  - Free Sale Certificate, including legalization

5 QUALITY SERVICES

The most important element of getting your medical device released /cleared is the implementation of a quality management system in compliance with the global requirements.

A sound quality management system in compliance with the (inter)national requirements will provide your company a structured method for your processes and aid in obtaining your certifications.
Thinking about expanding your business on a global scale, incorporation of an extended quality system including a wider range of compliance above just the local requirement might seem an additional burden at first but will result in an experienced workforce already working at a higher compliance level and as such are prepared for future challenges.

QUALITY STRATEGY & QUALITY CONSULTING SERVICES

Quality Strategy

Quality strategy is depending on the market you would like to enter and to the regional requirements. A custom-made service package will be set-up for implementing, certifying and maintaining a quality management system suitable for the medical device industry and applicable global regulation.
MedQ Consultants B.V. can support you in:

- Quality strategy for the European and other global markets;
- Selection of Notified Body;
- Implementation and certification of the quality system;
- Outsourced or subcontracted processes;

Quality consulting services

The most important element of getting your medical device released /cleared is the implementation of a quality management system in compliance with the global requirements.

Our quality service provides support to implement or enhance your quality management system for compliance with applicable regulatory requirements based on your global strategy and market approval requirements.

MedQ Consultants B.V. can support your quality management system (QMS) with:

- GAP analysis;
- Equipment qualification / validation;
- QMS development, support, review and/or maintenance according to ISO 13485 (EU), 21 CFR Part 820 (US) and/ or other global territories;
- Conduct / prepare audits (Internal audit, vendor audit, (pre)assessment audit);
- Prepare / support / attend certification assessment audits by Authorities;
- Process validation;
- QMS / audit training;
- Authority contact;
- Being your internal quality person / support;

4 CLINICAL SERVICES

We are offering a full set of clinical consultancy services

CLINICAL STRATEGY AND TRIAL SUPPORT

Our clinical strategy and trial support will provide you with a clinical strategy in line with the current expectations of the authorities to maintain state of the art clinical data.

Clinical data and clinical evaluation has become an ever more important pillar for showing your medical device safety, performance and efficacy. Increased demands on proper clinical data requires a proper clinical strategy planning.

CLINICAL STRATEGY AND TRIAL SUPPORT

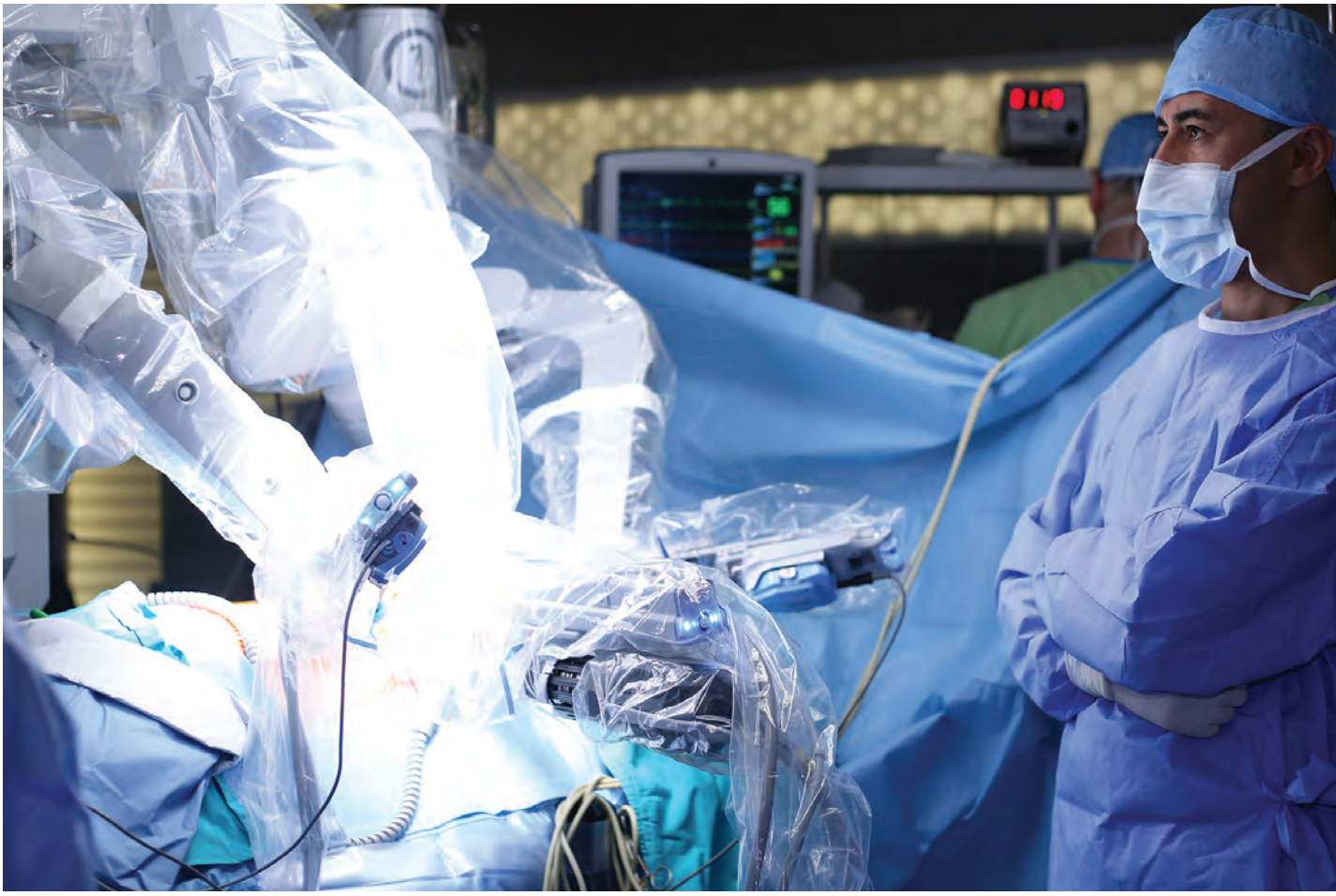
Clinical Strategy

Continuous development of medical device laws, influenced by globalization and harmonization, has increased the complexity of its interpretation and practical implementation.

Although the medical device directives and regulations have become more standardized with a more uniform structured approach, demands on the pre-clinical requirements and clinical strategy have increased.

MedQ Consultants B.V. can support you in:

- Finding the optimal clinical strategy for your device;
- Provide support in literature and state of the art review;
- Support in the clinical evaluation reporting;
- Assessment of your pre-clinical requirements;



CLINICAL TRIAL SUPPORT PRE- AND POST CE MARKING

The most important element of getting your medical device approved is the implementation of a fundamental clinical trial strategy. Our pre- and post-market clinical trial support service provides you access to guidance and support with the current medical device regulatory demands and market access requirements. By optimizing the trial setup, the trial conduct is optimized and avoids redundancy and cost. Having a sound clinical medical device trial strategy to support your clinical evaluation will benefit both your single market and (future) multi continent approach.

MedQ Consultants B.V. will assist you where needed in the preparation, conduct and management of your pre- and post-market clinical trials according to the European Regulation and country specific requirements.

MedQ Consultants B.V. can support your trial with:

- Pre-Market and Post Market Clinical Trial Management;
- Regulatory Submissions dossiers for the Ethics Committees and Competent;
- Authorities, Radiation Board as well as local authorities;
- Support on essential (country specific) documentation and preparation of Study Documentation Preparation/Review among others;
  - Clinical Investigation Protocol;
  - Investigator's Brochure, local dossiers;
  - Case Report Form (CRF);
  - Patient Information and consent forms;
- Clinical Site Selection, Qualification, Initiation, Monitoring, Close-out;
- Safety Reporting to Ethics Committee and/or Competent Authorities;
- Electronic Data Capture (EDC) system setup and support;
- Statistical Analysis clinical data;
- Prepare final clinical trial report;

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