cor science

MedTech Consulting

- Quality Management
- Regulatory Affairs
- Development

RESEARCH & DEVELOPMENT: FOR THE SUCCESS OF YOUR MEDTECH PROJECT

Would you like to have your project checked for feasibility as soon as possible? Are you looking for an experienced partner with whom you can reliably create a Class III medical device? Do you want to implement the phase-gate process and develop more efficiently? Benefit from our many years of experience in development services.

SHORTER TIME TO MARKET

SECURITY FOR YOUR PROJECT

HOW WE SUPPORT YOU:

- Requirements engineering (System footprint workshop)
- Proof of concept for hardware and software
- Feasibility studies
- Layout, software and algorithm reviews
- Insulation diagrams (HV)
- Reviews of complex systems at sub- and system level
- Creating proof of verification
- Prefabricated, customizable development solutions
- Cybersecurity concepts
- Test stands and test automation

QM & REGULATORY AFFAIRS: WITH US YOU CAN MASTER THE MDR APPROVAL PROCESS

Do you want to transfer a MedTech product from the MDD to the MDR? Do you need help from experts because the regulatory issues seem to be never-ending? As an MDR-certified manufacturer and supplier, we know the processes for approving medical devices inside out and will support you in getting your device approved.

EFFICIENT MDR TRANSITION

OPTIMIZED PROCESSES

HOW WE SUPPORT YOU:

- Consulting on, set-up or remodeling of a pragmatic ISO 13485-compliant QM system
- Creating and maintaining technical documentation
- MDR gap analyses
- MDR transition
- Approval strategies for active medical devices of all classes
- Approval support for CE, FDA
- Internal mock audits and supplier audits

OUR CONSULTING PROCESS IN 4 PHASES

MDR-COMPLIANT DEVELOPMENT

PREPARATION

- GAP ANALYSIS
- FEASIBILITY STUDIES

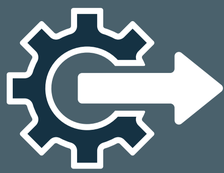
REVISION

- RISK ANALYSIS
- REVIEW OF RESULTS

PLANNING

- EVALUATION
- PROJECT PLANNING

INTEGRATION



- TEAM OF EXPERTS
- PROJECT HANDOVER

YOUR BENEFITS

OPTIMIZING STARTING CONDITIONS

We analyze your QM system or product idea, bringing over 20 years of expertise as a MedTech manufacturer to the table when doing so.

MINIMIZING RISKS

We identify potential risks to your project and provide you with pragmatic solutions during reviews to avoid delays.

REDUCING COSTS

We integrate processes tailored to your needs, saving you manpower and development time.

REDUCING TIME TO MARKET

With the support of our experts and our customizable solutions, you can get your product onto the market more quickly.

AN EXPERIENCED PARTNER AT YOUR SIDE

In-depth technical know-how, regulatory compliance, tried-and-tested processes: successful MedTech projects have complex requirements. So it is good to have a partner at your side who has been a development service provider and manufacturer of complex, safety-critical medical devices for over 20 years.

From conception, project management to development and transfer to series production – our MedTech experts will be there to advise you at every stage of the project.

„We are glad to have an experienced service provider like Corscience by our side, who have such comprehensive technological and regulatory expertise.”

Jacob Christensen
CEO OOONO Medical A/S

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