EU MDR

On May 5, 2017 the EU MDR (Medical Device Regulation) was published in the EU Official Journal. This date starts the three-year mandatory transition period where the MDR will replace the MDD (Medical Device Directive). The expanded scope of the MDR combined with the timeframes for compliance is compelling medical device companies to focus significant attention on transition strategies and will require substantial hands-on work.

NEW FOCUS

Significant changes to the requirements include:

- Classification changes
- Increased clinical evidence
- Increased scrutiny of technical documentation
- Responsible Person – regulatory compliance on-staff or outsourced
- Post-market surveillance, vigilance, surveillance
- Significant changes to the Economic Operators and their responsibilities
- Unique Device Identification (UDI)
- General safety and Performance requirements
- (Significant increase in responsibility of the Authorized Representative

TIMELINE

The regulations entered into force on May 26, 2017 and will apply after May 26, 2020. Medical device manufacturers with multiple products and products in the new product pipeline should conduct an impact assessment, assess gaps and create an implementation plan by the end of 2017. For smaller or single site manufacturers, an implementation plan by May 2018 should allow time to transition to the new regulations.

R&Q CAN HELP

R&Q can guide your transition to the EU MDR. From strategic planning to hands-on support our services deliver business-balanced solutions that are right for your business. Our support services include:

- **MDR Impact Assessment**: Assessment of the requirements of the MDR as they relate to your products. This includes review of the device's classifications and the associated regulatory and quality system requirements.
- **MDR Quality System Gap Assessment**: Gap Assessment between your quality management system and the quality system requirements of the EU MDR.
- **Design Document Gap Assessment**: Gap assessment between your existing design documents (e.g. design dossier and technical file) and EU MDR requirements.
- **Gap Response Plan**: A comprehensive response plan to address the identified gaps including quality system, design dossier / technical file updates; clinical evidence; post- market surveillance activities, including EUDAMED database; testing activities; labeling change; and general safety and performance requirements.
- **Clinical Evaluation Reports**: CER management including plan and justify the amount of clinical evidence required for the device and post-market surveillance plans; create a clinical evaluation plan, conduct both state of the art and clinical literature searches; summarize findings and assess the need for post-market clinical follow-up.

Additional services on back...
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R&Q CAN HELP (CONT.)

- **Mock Audit – EU MDR**: On-site mock audit of design documentation and quality management systems focusing on MDR requirements to prepare for Notified Body inspections. This includes author a report to summarize the findings; define and prioritize the risks; and provide recommendations on mitigating the risks.
- **Notified Body Submission / AI Response**: Regulatory support and guidance to prepare documents and manage correspondence for Notified Body submission including any requests for additional information.
- **Post-market Surveillance Services**: Develop post-market surveillance plan including periodic safety update report (PSUR); vigilance reports; trend reports; and EUDAMED database updates.
- **Training**: On-site overview training of EU MDR including new requirements, timelines, specific requirements for your class of device, engaging with key stakeholders, clinical evidence strategies, and industry best practices for implementation of the MDR.

WHY R&Q?

R&Q exists to help you bring more safe and effective medical devices to market. Leveraging our deep industry experience, we provide solutions that help you improve the world. Drawing on our expertise across the entire medical device product lifecycle, we are uniquely positioned to present a range of strategic and tactical options and execute on the solution that best suits your individual regulatory and quality needs.

REGULATORY

Worldwide Regulatory Strategy, 510(k), PMA
EU and Canadian Entrance
Rest-of-World Support
UDI Compliance
Regulatory Counsel
Acquisition Regulatory Due Diligence

QUALITY SYSTEMS

Quality System Development
(ISO13485/QSR/CMDR)
Internal Auditing
FDA Inspection Preparedness/Assistance
Quality System Improvement Projects
Acquisition Integration

DESIGN ASSURANCE

Design Quality Assurance and Engineering
(Software, Electromechanical, Disposables)
Design Verification and Validation
Human Factors/Usability
Safety Risk Management

PRODUCT QUALITY

Supplier Quality and Audits
Process Validation/Qualification
Manufacturing Site Transfer
Manufacturing Quality Process

POST-MARKET SURVEILLANCE

Form 483, Warning Letter, Consent Decree
Strategy and Remediation Support
CAPA and Complaint Monitoring/Leadership
Safety Risk Monitoring
Recall Decisions
Design History File

REMEDIATION

Proactive and Reactive
Best Practice Strategic and Tactical Solutions
Gap Assessment and Process Improvement
Hands-on Guidance for Optimizing Quality Systems
Project Team Assembly
Root Cause Analysis and Corrective Action

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