.....the practical approach

The roadmap to EU-MDR Implementation

Stay in compliance throughout the transition into
the new regulations

Europe - Amsterdam (HQ) | USA - Boston - San Francisco | China - Nanjing

Qserve Roadmap to EU-MDR compliance

- Scope and Plan
- GAP Assessment
- Portfolio Rationalization
- Global Impact Analysis
- Master Compliance Roadmap
- Regulatory Training
- Implementation of Roadmap
- Effectiveness Check
- **EU-MDR Compliance**

Introduction

The availability of the text for the new European Medical Device Regulation (EU-MDR) allows manufacturers to start considering the impact on their activities, and what they will need to do to be compliant with the revised requirements. This MDR will overhaul some of the basic principles with which you have been working, under the Medical Device Directive (MDD).

To succeed in complying to the new MDR timely, the following elements are key:

Structural approach

▼

Planning

▼

Regulatory knowledge

Implementing the MDR requires a structural approach, since the transition to new MDR CE certificates can last over several years.

The uncertainties that follow the introduction of the MDR can be minimized by implementing Qserve's EU-MDR roadmap, that can be tailored to the specific needs of manufacturers. Qserve is currently using this roadmap in MDR implementation projects.

Planning for implementation of these requirements is a classic project management activity to identify: what must be done, in what order, by whom, by when, at which budget, and how the process will be monitored.

Ultimately, the roadmap will lead to effective and efficient compliance ensuring business continuity.

White Paper MDR

- For more information on the transition periods, please see the whitepaper MDR.

  www.qservegroup.com/whitepapers

1.   Scope and Plan

A quick-scan of critical impact elements should be prepared to identify key MDR changes and potential actions.

The approach is based on interviewing key people at the manufacturer, in combination with a quick scan (360°) on elements in the MDR that are time critical. Based on this assessment, the scope of the implementation project is set.

Part of the interactions can take the form of group discussion sessions as needed, to ensure optimal efficiency.

The plan defines scope, timelines, methods, resources, structures, and tools and will be presented to the decision makers in the company.

Tools to use:

- Checklists (before, during and after implementation)
- Interviews
- Benchmarks

2.   GAP Assessment

Before starting, the GAP assessment templates must be aligned with the final plan. Training sessions will be organized, targeting specific areas that are impacted by the MDR. The use of the GAP assessment templates will be explained, if applicable, in such sessions. GAP assessments will be performed by cross functional teams, depending on the size of your organization.

Impact assessment checklists will include device, clinical and QMS related issues, addressing all aspects of the MDR.

The assessment results are gathered in a master impact matrix, making it possible to prepare overviews showing the impacts from different angles, e.g. per productgroup or Business Unit (BU).

Tools to use:

- Impact assessment checklist; product
- Impact assessment checklist; QMS
- Impact assessment checklist, clinical
- Master impact matrix

3. Portfolio Rationalization

The product GAP assessment forms the input for a strategic plan, while detailing portfolio management from compliance background.

This plan will outline the strategies per device family, including cost breakdown. Advice will be provided per device family to remediate or retire. The Notified Body situation will be assessed, including strategic options if applicable.

The gaps and impact lists across the various projects within the program will provide input to a financial impact assessment on a product level. It will define what needs to be done to achieve full compliance. This includes the impact on a product level, especially of gaps in clinical data and consequential measures to address those issues. This 3 to 8 year remediation/retire costs, on product family level, will form part of the portfolio analysis.

Tools to use:

- Product portfolio analysis template
- Remediation/retire cost budget template

4. Global Impact Analysis

How does your EU certification influence registrations in other regions? What impact do new certificates or change of a Notified Body have on your global registrations?

Following the achievement of portfolio rationalization for the EU market, the focus will shift towards worldwide registrations of your product. Is your CE certification the basis for registrations in Asia, South Africa, or Australia?

The impact on your global registrations can be significantly and the Global Impact Analysis will help as basis to start discussions with your local offices, local representatives, and/or distributors.

The starting point is to continue registrations worldwide. Together with your registration team, we work with the Global Impact Analysis template to provide a plan, country by country.

Tools to use:

- Global impact analysis template

5.   Master Compliance Roadmap

Based on the Master Impact Matrix, the business organizational structure of the manufacturer and the plan, a 'roadmap' with parallel projects, referred to as charters, will be designed.

Included in the roadmap is structure for the program governance and reporting/ metrics (i.e. project management reports). Each project will have a reporting tool ('charter definition sheet') wich will be used by the overall programmanager and steering committee to oversee the progress of the (implementation) plan.

Each project starts with a workshop and utilizes the results of the GAP assessment as input to define a charter with detailed deliverables, which may well be prioritized to optimize use of resources available to the program. Each charter format will define:

- **Objective**
- **Plan, team and scope**
- **KPI's**
- **Milestones / timelines**
- **Budget and resource planning**

An overall Program manager, with the support of the core team, ensures alignment and harmonization between projects, sites and business units.

The core team is involved from the beginning, overseeing responsibilities such as training, coordination, monitoring, balancing, alignment, and communication. The core team works together with BU's, taskforces, and steering committee.

Steering Committee

A steering committee, which will include a Qserve board member and the overall program manager, will implement a governance model to include:

- Standard charters format
- Standard reporting per charter to the steering committee (KPI's and risk assessment metrics)
- Monthly steering committee meetings (managing progress, resources and objectives)
- Centrally organized training
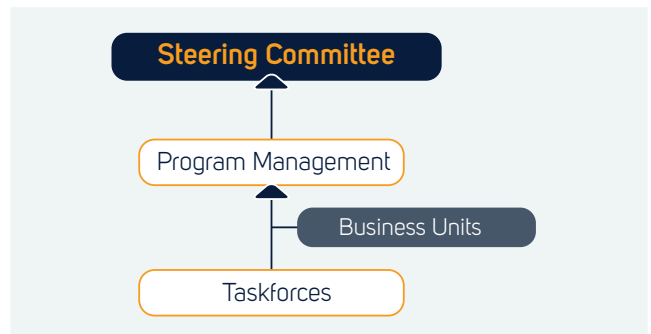
An important element for the implementation plan is the early debate with Notified Bodies. The reason is two-fold; first to create buy-in from Notified Bodies for the transition plan, and secondly, to secure resources, readiness and timelines within the Notified Bodies.

Tools to use:

- Project definition sheet.
- Steering committee report
- Master implementation plan template

Budget and resource planning

Before the implementation can begin, a budget and resource plan must be established. Estimating that implementation will take approximately 2-3 years, this needs to be reflected in the financial planning.

The overall 2-3 year cycle is in general as follows;

The Master Compliance Roadmap foresees within the step 'roadmap to implementation' the overview of charters. Each charter includes a budget to address the gaps.

For the cost overview of each individual gap, the Master Impact Matrix provides insight. The portfolio analysis report will provide details regarding the remediation costs per product family. After a decision to remediate or retire, the overall budget per product (and subsequently BU) will be known.

From the Impact Analysis and structure of defined projects, detailed budget and resource allocation can be prepared.

The Master Impact Matrix will form the input for the following budget and resource allocation:

- Detailed QMS changes including remediation cost breakdown
- Provide a calculation of costs to address the gaps and the resource requirements to implement the changes
- 3-year transition/execution budget plan by product and BU

The resource requirements to implement the changes can be derived in the step 'Roadmap to Implementation', detailing the number of charters.

Experience dictates that the MDR implementation can be a substantial process, therefore critical allocation of resources will be discussed prior to implementing the MDR.

Tools to use:

- 3year transition/execution budget plan template.
- Resource Requirements Template

6.   Regulatory Training

Training is an essential element of the roadmap program, as it is used to educate the 'new norm' in the early phase of the plan.

Training styles and tools can differ, depending on the size and culture of the organization.

Workshop content will vary, and include training employees on how to conduct parts of GAP analysis, while other sessions will address specific subjects of the MDR.

As charters begin, training ensures that employees are properly aligned with the new regulations.

7.   Implementation of Roadmap

The projectcharters are the deliverable of the implementation roadmap. Each charter follows a standard workflow of steps from kick-off to effectiveness checks.

The charters have a charter definition sheet with objectives, budget, milestones, team members and timing and follows a standardized working method.

Progress and opportunities within the charters will be organized and controlled by the overall program manager, in combination with the steering committee. Status reports on the charters will assist the steering committee in maintaining their focus on key priorities & business continiuty and in addition, will support communication on program status to the stakeholders in your company.

Tools to use:

- Specific in-house workshops
- Detailed workshops MDR transition training formats

Tools to use:

- Charter progress sheet
- Charter status dashboard

"Invest in knowledge, train your staff"

8.   Effectiveness Check

The verification of the projectcharters output is an effectivity check, This will be performed as internal audit or mock audit and will lead to finetuning of the implementation.

9.   EU-MDR Compliance

The final check for compliance with the MDR will be performed by your Notified Body. After audit preparation is completed, and having successfully followed the roadmap, compliance can be assumed. Following the described structrural approach and planning will ensure compliance control & business comtinuity.

Tools to use:

• Audits: internal, Mock and Unannounced

Tools to use:

• Notified Body audit checklist (before and during)
• Onsite expert help during audit (Qserve)

Sustain EU-MDR Compliance

Included in the roadmap, will be a detailed description of the compliance after the transition, ensuring continued compliance. The delegated and implementing acts of the MDR will be introduced over time, and will have to be included in your current system. Notified Body audits, MDSAP inspections, changes to your product portfolio will impact your organization during and after the MDR Implementation project. Qserve can assist here as well, by providing an open hot line for questions.

This can be of any scope:

• Annual updating of Clinical Evaluation Reports (CER) based on the requirements of
  MEDDEV 2.7.1, rev 4 or latest revision.
• Support for applicable delegated & implementing acts.
• Product changes with Notified Body.

Qserve MDR Implementation Model

STEPS	TOOLS	DELIVERABLES
1. Scope and Plan	Interviews, benchmarks, checklists	Plan defining scope, timelines, methods, resources, structures, and tools including presentation to stakeholders
2. GAP Assessment	Impact assessment checklist for product, clinical and QMS	Master Impact Matrix
3. Portfolio Rationalization	Product Portfolio Analysis template and remediation/retire cost budget template	Report Product Portfolio Analysis including budget impact
4. Global Impact Analysis	Global Impact Analysis template	Global impact report country by country
5. Master Compliance Roadmap	• Master Implementation Plan template • Project charter definition sheet • Resource requirements template • Steering committee report	• Master Implementation roadmap • Governance model including project charters
6. Regulatory Training	• Specific in-house workshops • Detailed workshops MDR transition formats	Alignment on changed SOP's, and MDR compliance
7. Implementation of Roadmap	• Projectcharter progress sheet • Projectcharter status dashboard	Implementation of the different charter projects
8. Effectiveness Check	Audits	Resolve any discrepancies
9. EU-MDR Compliance	Notified Body Checklist	Continued Compliance

About Qserve

Our mission is to support al medical device manufacturers with a practical approach, translating existing regulations to understandable requirements. We serve to guide manufacturers in gaining a maintaining compliance for their safe and qualitative medical devices.

Qserve's global team combines their regulatory knowledge and experience in the medical device industry, sharing more than 500 years' worth of combined expertise in the medical field.

The combination of regulatory knowledge and device experience, together with our willingness to go the extra mile for our customers, is what makes us your global partner for Medical Device Regulatory Compliance.

December, 2016

Your Global Partner Medical Device Regulatory Compliance

Clinical
Evaluation

Regulatory
Compliance

Global
Registration

Training

Quality
Assurance

Auditing

qservegroup.com