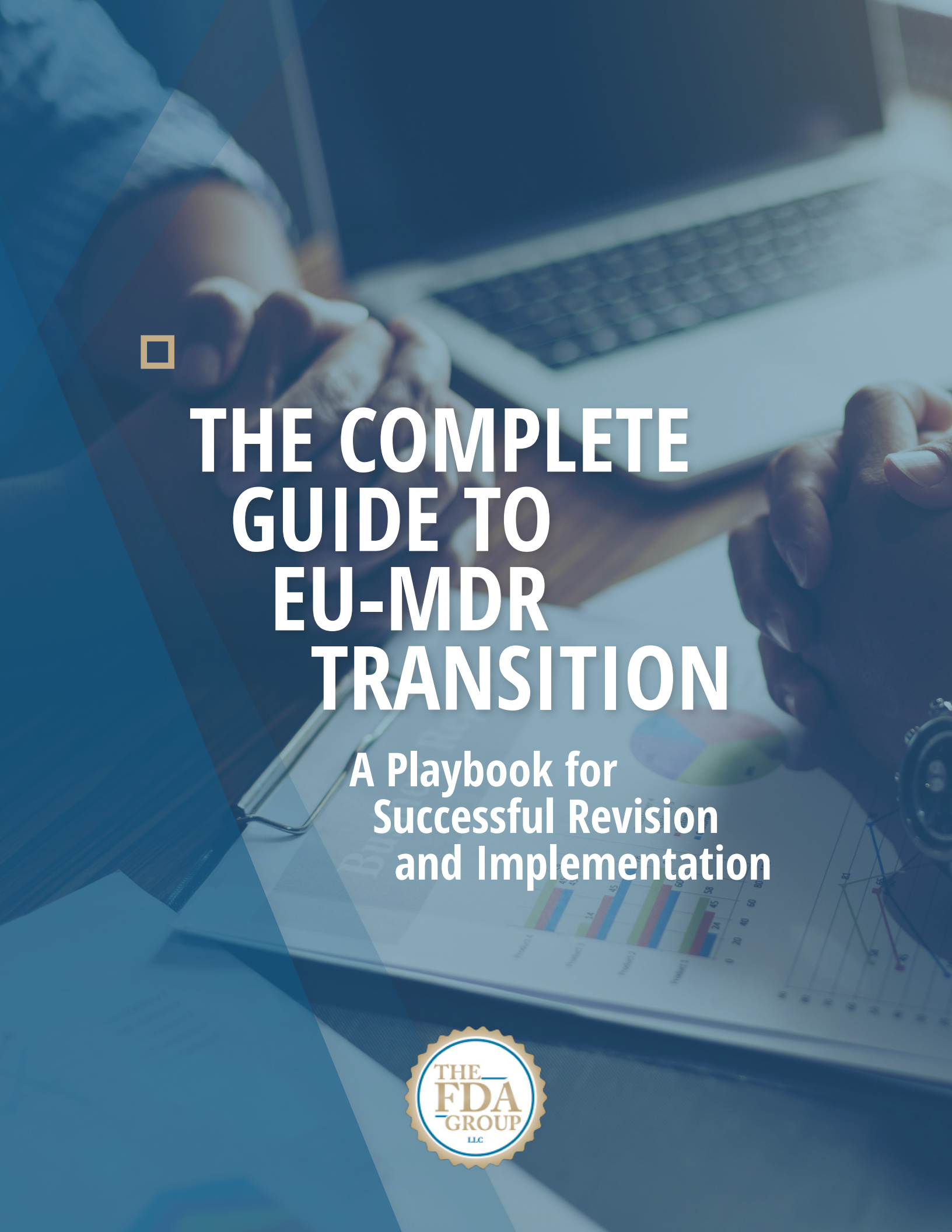


THE COMPLETE GUIDE TO EU-MDR TRANSITION

A Playbook for Successful Revision and Implementation

THE FDA GROUP LLC

TABLE OF CONTENTS

INTRODUCTION

The release of the new Medical Devices Regulation (EU-MDR) in the Official Journal of the European Union in May of 2017 marked the start of a three-year transition period for manufacturers, suppliers, Notified Bodies, and national Competent Authorities to comply with the new Regulations set to take effect in May of 2020. The scale of the changes made is significant, putting pressure on all impacted parties to closely examine the MDR, assess the impact it will have on their own organization, and implement compliant processes and procedures accordingly.

After May 2020, non-compliant companies will likely lose their CE-mark certification as well as access to the European market. Non-compliant Notified Bodies, similarly, may lose re-designation.

Since MDR's release in 2017, many regulatory experts have published and circulated resources aimed at helping companies understand the new rules and adjust their organizations accordingly. While many of these resources are extremely useful, we set out to offer something different—and hopefully even more useful—with this in-depth guide. In addition to highlighting some of the major elements of this new Regulation that will likely require action on the part of regulated companies, we also present a process for transition that can be adapted to suit your organization's specific needs.

It's important to note that given the scale of the these changes, it may be useful—and even necessary—to enlist the help of a third party consultant capable of lending a perspective informed by prior experiences and a thorough understanding of MDR to create your transition plan and bring it to life throughout all impacted areas of your organization.

Contact The FDA Group today to learn more about how we can help you transition to MDR compliance effectively and efficiently.

START THE CONVERSATION »

Let's begin with a look at the five basic questions surrounding the MDR:

1. What are the major themes?
2. What specific changes are coming?
3. How will they be implemented?
4. Who will be affected?
5. What needs to be done (and by who)?

WHAT ARE THE MAJOR THEMES IN MDR?

1. A broad transition from pre-approval to life-cycle approach

The MDR shifts regulatory focus away from the pre-approval stage (largely established by the MDD) to a life-cycle approach aligned closely with other international standards including those recognized by the US Food and Drug Administration (FDA). This change is exemplified by the inclusion of MEDDEVs. In general, this will likely result in less flexible interpretations by the industry as well as the authorities and Notified Bodies.

2. A greater emphasis on clinical trial data and evaluation

Under MDR, equivalence will be more thoroughly interpreted, likely making it much more challenging to demonstrate clinical safety or performance for medical devices.

3. Greater supervision over Notified Bodies

The document currently states that Notified Bodies will be strictly supervised, however it is still unknown whether intended sanctions against a Notified Body in violation of MDR requirements could be implemented against the will of a Member State in those circumstances. The Regulation clearly states that the qualification requirement for auditing and reviewing Notified Bodies will be significantly increased.

4. Clinical investigations will be expected for implantable Class III devices

In general, Notified Bodies will no longer accept the equivalence approach under MDR, with some exceptions. Clinical investigation requirements will not apply to devices that have been lawfully placed on the European market in accordance with the AIMDD and MDD where they demonstrate conformance based on

sufficient clinical data and applicable Common Specifications (CS), or are of a specific family specified (see Article 61). Notified Bodies will require high quality investigations and compelling clinical evidence in most cases.

5. More transparent review timeframes

The MDR will provide more detail and solidify provisions from previous guidance and standards to enhance review time transparency.

WHAT ARE THE MAJOR CHANGES EXPECTED IN MDR?

- The new regulation is four times longer, and contains five more annexes than its predecessor, the Medical Device Directive (MDD).
- The word "safety" appears 290 times in the MDR. The MDD, by comparison, uses it only 40 times.
- Significant changes in wording used in the new law will require companies to rationalize their portfolios and perform a global impact assessment in order to implement the necessary changes to remain compliant.
- Annex I, General Safety and Performance Requirements, identifies new conditions that will need to be addressed for most legacy devices (CE marked under the MDD). Existing products must be recertified in accordance with the new regulations.
- The new rules will require most companies to update clinical data, technical documentation, and labeling.
- Unique Device Identification (UDI) will be implemented to help track devices throughout the economic operator supply chain and will be required on all labels.
- While the scope of the MDD did not encompass medical purpose devices and AIMD, these are both included under MDR.
- The definition of medical device will be broadened to include non-medical and cosmetic devices not previously regulated. Examples include products for cleaning, disinfection or sterilization of devices as well as contact lenses, liposuction equipment, or epilation lasers.
- Manufacturers will need to generate and provide more in-depth clinical data to prove safety and performance claims including tighter equivalency standards.
- Manufacturers will need to report all incidents, injuries and deaths into an EU portal that will centralize relevant data so that patients have access to more safety-related information. Reporting for incidents that did not result in death or serious deterioration in health is moved to 15 days from 30 days.

- Companies undergoing transition will need to revisit core processes including the quality assurance, risk management, and postmarket expectations. These will require careful review, planning and updating to re-implement in compliance with new requirements.
- Reclassification of many medical devices to a higher risk class and a new classification for reusable surgical devices requiring notified body oversight.
- IVDs are now classified into four risk classes that will require Notified Body review for about 90% of the devices, up from the current 10%

HOW WILL THESE CHANGES BE IMPLEMENTED?

- Medical device companies have until 2020 to fully implement these changes. It's important to note that since many of the new regulations are significantly transformative, European governance has been strengthened to ensure that the regulations are enforced and upheld. The Medical Devices Coordination Group (GCDM) has been created, which will be responsible for enforcing the regulations by invoking a 'scrutiny mechanism' that will allow them to review a Notified Body assessment of high risk devices.
- The role of Notified Bodies will grow. They will carry out random audits, sample checks and testing.
- Additionally, manufacturers must appoint at least one person responsible for regulatory compliance who will ensure that the new regulations are being adhered to. They will be the equivalent of a Qualified Person in the pharmaceutical industry.

WHO WILL BE AFFECTED BY THESE CHANGES?

These changes will have the greatest impact on medical device manufacturers responsible for implementing and upholding significant changes to their manufacturing and testing processes. As previously noted, Notified Bodies will also have additional responsibilities related to testing and assessment.

It's important to note that these changes aren't unfolding among regulating authorities and the industry alone. Patients and customers will ultimately feel the effects of these changes through better access to health and safety data while possibly being restricted from various products as the stricter regulations may create a short-term filter to market availability.

For medical device companies, the changes prompted by this transition may seem overwhelming at first glance. Without proper guidance, it can be difficult to know where to start and how to plan the next move. Company leaders will inevitably have many questions about how this will impact their organization and the patients who rely on their products. How should they prepare? Which internal processes need to be updated? What new documentation must be created? What are the priority items?

To help you answer these questions and orient yourself toward smart action, we've created this step-by-step guide to EU-MDR transition. Whether you're looking to improve your current program or build one from the ground up, this resource something for everyone.

Before jumping into transition, the following sections call attention to sections of the Regulation that will likely require change as well as specific changes to classification, the forthcoming EUDAMED entity, and clinical evaluation.

KEY SECTIONS OF NOTE

The sections listed below will have a major impact on quality system documentation, technical files, and other duties. We recommend highlighting these in the Regulation.

Article 10: General obligations of manufacturers	**Article 29:** Registration of devices
Article 12: Change of authorised representative	**Article 30:** Electronic system for registration of economic operators
Article 15: Person for regulatory compliance	**Article 31:** Registration of manufacturers, authorised representatives and importers
Article 18: Implant card and information to be supplied to the patient…	**Article 32:** Summary of safety and clinical performance
Article 19: EU declaration of conformity	**Article 51:** Classification of devices
Article 27: Unique Device Identification System	**Article 52:** Conformity assessment procedure

Article 53: Involvement of notified bodies in conformity assessment procedures	**Article 87:** Reporting of serious incidents and field corrective actions
Article 54: Clinical evaluation consultation procedure for certain class III and IIb devices	**Article 88:** Trend reporting
Article 61: Clinical evaluation	**Article 89:** Analysis of serious incidents and field corrective actions
Article 62: General requirements regarding clinical investigations conducted to demonstrate conformity of devices	**Annex IX:** Conformity Assessment based on a QMS and on assessment of TF
Article 83: Post-market surveillance system of the manufacturer	**Annex X:** Conformity Assessment based on Type Examination
Article 84: Post-market surveillance plan	**Annex XI:** Conformity Assessment based on Product Conformity Verification
Article 85: Post-market surveillance report	**Annex XIV:** Clinical Evaluation and post-market Clinical Follow-up
Article 86: Periodic safety update report	**Annex XV:** Clinical Investigations

DEVICE CLASSIFICATIONS

Ten of the major classification changes are highlighted below.

- Devices intended to be introduced into the body through an orifice or applied to the skin—and absorbed or locally dispersed in the human body—will be classified as Class III.
- Nanomaterial devices (Microelectromechanical systems [MEMS]) will become Class III.
- Total and partial joint replacements will become Class III.
- IVF and ART non-invasive devices may be Class IIa or IIb.
- In vitro contact with cells and/or embryos returning to the body will be Class III.
- Reusable surgical instruments will no longer be self-certified Class I devices, but the newly-created Class IR.

- AIMD accessories will be Class III.
- Devices that record diagnostic images will be Class IIa.
- Spinal implants will be Class III.
- Apheresis devices will be Class III.

In addition to classification changes, MDR lists specific types of products that, although not serving a "medical purpose," will fall under the Regulation addressed in a Common Specification (Article 1, Annex XVI). These include the following items:

- All contact lenses
- All implants for cosmetic or anatomical modification
- Facial and other dermal or mucous membrane fillers
- Invasive laser equipment
- Pulsed light equipment
- Liposuction equipment

EUDAMED

EUDAMED is an official central European databank accessible only to competent authorities. Further details can be found in Article 14a (MDD 93/42/EEC). Article 33 presents the obligations for medical device manufacturers which start from the date of application.

CLINICAL EVALUATION

Some of the most significant regulatory changes affect clinical evaluation for devices. Perhaps the most fundamental of these changes is the inclusion of a definition for the term itself—something not provided in the MDD.

According to the MDR, a clinical evaluation is a systematic and planned process to continuously generate, collect, analyze, and assess the clinical data pertaining to a device in order to verify the safety and performance, including clinical benefits of the device when used as intended by the manufacturer.

MDD CLINICAL REQUIREMENTS (ANNEX X)	MDR CLINICAL REQUIREMENTS (ARTICLE 10)
As a general rule, confirmation of conformity with the requirements concerning the characteristics and performances referred to in Sections 1 and 3 of Annex I, under the normal conditions of use of the device, and the evaluation of the side-effects and of the acceptability of the benefit/risk ratio referred to in Section 6 of Annex I, must be based on clinical data.	Manufacturers shall conduct a clinical evaluation in accordance with the requirements set out in Article 61 and Annex XIV, including a PMCF.  Confirmation of conformity with relevant general safety and performance requirements set out in Annex I under the normal condition of the intended use of the device, and the evaluation of the undesirable side-effects and of the acceptability of the benefit-risk ratio referred to in Sections 1 and 8 of Annex I, shall be based on clinical data providing sufficient clinical evidence, including where applicable relevant data as referred to in Annex III.

What does "clinical data" mean?

MDD DEFINITION

"Clinical data" is the safety and/or performance information generated from the use of a device.

MDD CLINICAL DATA SOURCES

1. Clinical investigation(s) of a particular device; or
2. Clinical investigation(s) or other studies reported in scientific literature, of a similar device with demonstrated equivalence; or
3. Published and/or unpublished reports on other clinical experience of either a particular device or a similar device with demonstrated equivalence.

MDR DEFINITION

"Clinical data" is information concerning safety or performance that is generated from the use of a device.

MDR CLINICAL DATA SOURCES

1. Clinical investigation(s) of a particular device, or
2. Clinical investigation(s) or other studies reported in scientific literature, of a similar device with demonstrated equivalence; or
3. Reports published in peer reviewed scientific literature on other clinical experience of either a particular device or a similar device with demonstrated equivalence; or
4. Clinically relevant information coming from post-market surveillance, in particular the post-market clinical follow-up

MDR "CLINICAL PERFORMANCE" DEFINITION

"Clinical performance" is the ability of a device, resulting from any direct or indirect medical effects which stems from its technical or functional characteristics, including diagnostic characteristics, to achieve its intended purpose as claimed by the manufacturer, thereby leading to a clinical benefit for patients, when used as intended by the manufacturer.

MDR "CLINICAL BENEFIT" DEFINITION

"Clinical benefit" is the positive impact of a device on the health of an individual, expressed in terms of a meaningful, measurable, patient-relevant clinical outcome(s), including outcome(s) related to diagnosis, or a positive impact on patient management or public health;

MDR TRANSITION: AN OVERVIEW

With the clock ticking toward 2020, MDR transition should be a high priority for device companies currently marketing products—or planning to market products—in the EU. Again, due to the significant changes in the language used in the forthcoming regulation versus the MDD, this transition process should begin with a comprehensive gap assessment led by experienced compliance experts who know exactly what to look for.

Given that the MDR does not grandfather legacy products and presents limited allowance on the short-term continuation of supplies to the EU market following the formal transition, portfolio revision and a global impact assessment will also be needed for many organizations.

Once these initial product decisions and process steps are taken, transition largely becomes a matter of training staff and implementing the changes needed. We've broken this down into seven essential steps along with insight into how an experienced quality and compliance specialist can play vital role in your transition.

1. PLAN AND SCOPE YOUR TRANSITION PROGRAM

Understanding the breadth required of your MDR transition program from a purely practical perspective is an essential first step. This will inform the budget needed to build out project teams and layout tasks in front of them.

While scoping and planning a project like this may not seem particularly new or challenging to those leading your transition, be cautious to avoid presenting the false impression that MDR doesn't depart significantly from MDD in key areas. Downplaying the differences sets a dangerous tone and can degrade the sense of urgency needed to execute your plan effectively.

While it's true that like the MDD, the MDR requires companies maintain a full quality system and technical files for each product marketed in Europe with pre-market reviews carried out by the same Notified Bodies, these similarities shouldn't cast a shadow on the essential changes just mentioned, as well as one of the most important changes at the foundation of the regulation:

The legal bases of MDR will switch to a central EU regulation, replacing directives instructing individual countries what to include in their laws.

The stated goal of this change is to help Notified Bodies and boost supply chain control, however, manufacturers should expect regulators to demand much more precise clinical data in support of the safety and performance of devices within their intended use.

For those leading the transition team, make sure to include the following three action items in this critical first phase:

1. **Make sure your entire project team reads the "whereas section" before article 1.** This explains the specific goals of the law in clear and practical terms and should be used as a starting point for planning next actions.
2. **Make sure your entire project team studies the 35 pages of instructions addressed to the Notified Bodies.** This will help everyone understand what Notified Bodies will be looking for. These instructions can be backwards-engineered to serve as a checklist when preparing for assessment.
3. **Use the quick-guide below to help you meet the stricter requirements for quality and clinical data.** The MDR presents major changes to technical product validation that should be closely studied. To help device companies take steps toward meeting stricter requirements for this data, regulators have updated the guidance for current legislation to align more closely with MDR expectations. The main components of this change are summarized below.

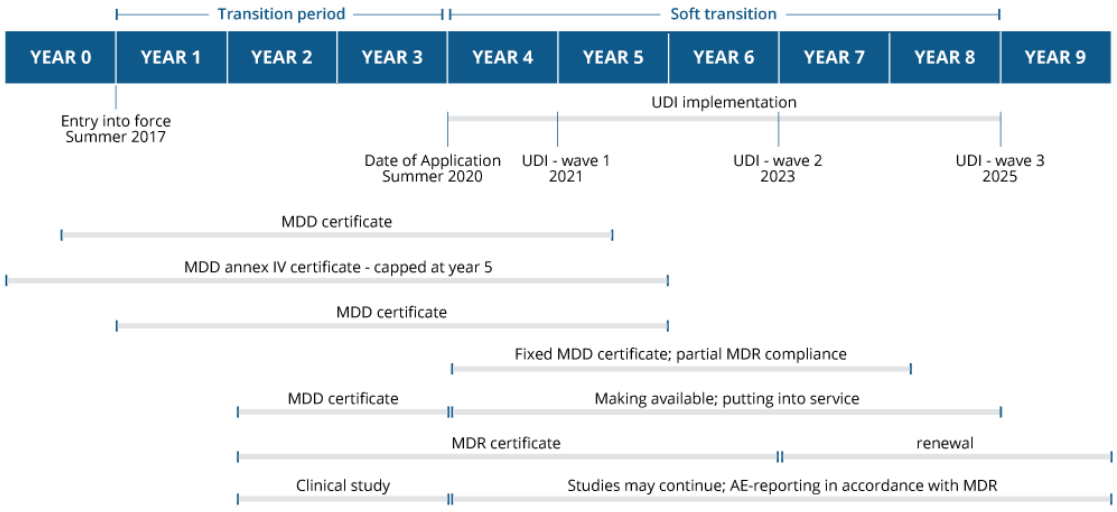
Guidance MEDDEV 2.7.1 rev

- A Clinical Evaluation Report now applies for all classes of devices
- Benefit risk in intended use/target group
- Usability requirements must now be included
- Clinical data must now be integrated in lifecycle management
- Clinical evaluations must now be conducted before and after clinical studies
- Regulators will expect larger patient numbers in studies
- Expect a stronger focus on the analysis and appraisal of data
- Evaluators will be subject to qualification
- Updates must be made annually, every two years and five years

Along with enhancing clinical safety and performance, the MDR also makes key changes to Notified Bodies in order to focus their attention (and that of manufacturers) on compliance. Following the removal of 30 Notified Bodies and a significant reduction in scope of those remaining to focus on core areas of importance, device companies should prepare themselves accordingly.

Under MDR, Notified Bodies will have greater assessment powers and stronger systems for coordinating with authorities, who in turn, will have stronger supervision over these assessors. These changes pose important questions for device companies, chiefly: How do these changes *practically* impact my system?

A look at the broader MDR timeline shows that systemic change will be an almost decade-long process, broken into increments, with many of the more system-wide changes occuring during the soft transition phase from 2020 through 2025.



2. CONDUCT A THOROUGH AND COMPREHENSIVE GAP ASSESSMENT

As with any gap assessment, the better project teams can prepare for them, the faster and better they can be completed. For MDR transition specifically, there are three core questions to ask of your technical documentation:

1. **Will this product still be covered by the MDR?**
2. **Will any products not currently marketed under MDD be covered under MDR?**
3. **Will classifications change?**

For most companies, this process should lend itself to summarizing and organizing high-level gap indications using color coding, similar to many other assessment applications. Teams should gather important certificate information to ensure important dates and deadlines are accounted for during transition.

After calculating the costs of bringing your system into compliance (and any potential ROI that can be derived from doing so), teams should carefully examine all changes related to the quality management system (QMS). This is area that most companies will identify a number of upgrades and additions, and similarly, will likely come under heavy regulatory scrutiny. While the transition period allows for ample time to make these changes, being thorough in identifying and planning for change often requires the assistance of an experienced third party consultant who knows the Regulation inside and out.

Contact The FDA Group today to learn how our large staff of quality and compliance experts can help you successfully and efficiently bring your QMS into compliance under MDR.

START THE CONVERSATION »

Once gap assessments are complete, your attention should turn to the Notified Bodies. There are four key questions to ask in preparing your system for assessment:

1. **Will your stated positions on product reclassification stand up to scrutiny?**
2. **Is the same true of your plan to file for exclusions?**
3. **Is your clinical data ready for discussion?**
4. **Have you used post-market surveillance and post-market clinical follow-up appropriately?**

3. EXAMINE YOUR PORTFOLIO AND MAKE KEY DECISIONS

Following gap assessment, a difficult and likely turbulent process stands before you. Although data has been a powerful decision-making tool up until now, the task of examining the company's portfolio and making product-related decisions for the broader EU market may pose significant internal challenges and require

well-reasoned justifications based on much more nuanced arguments. This is why gaining buy-in and meaningful commitment from the board as well as company leaders in all essential functions as early as possible is absolutely critical.

The primary task of ensuring your clinical data is sufficient enough to support clinical indications is apparent as it relates to this transition. However, what is often less apparent are the supply chain factors that can cause a cascade of costly other necessary actions.

Insufficient contractor data and/or an unwillingness to cooperate with new initiatives required to become MDR-compliant may force changes in suppliers and vendors. This can present costly challenges on its own, and depending on the circumstances, may require significant time, energy, and resources to overcome.

This is just one example of how any change to the portfolio can create a web of complex issues which must be handed carefully. Given that one company's portfolio assessment may look wildly different than another's, this phase of the project should be considered in the context of your own organization and dealt with accordingly.

At this point, timelines for the transition project should be made taking all relevant calculations into consideration, including the four key questions below:

1. **What is the time and resource investment needed to upgrade the QMS?**
2. **What products can continue to stay on the market given current clinical data?**
3. **What, if any, products can be paused given relevant factors and dependencies?**
4. **How do signed contracts affect the necessary supplier changes?**

Assessing the global impact of your changes is an important step as well. While it's especially true for device companies based in the EU, the majority of all companies require CE and ISO certifications as they provide market access in many other jurisdictions. In transitioning to MDR, carefully catalog all dependencies on CE certifications to avoid serious issues affecting market access elsewhere in the world.

4. DEVELOP AN ENTERPRISE-WIDE ACTION PLAN

Once all portfolio-related decisions have been made, it's time to bring stakeholders, structure, and dependencies together to broaden the scope of the project for company-wide participation in new compliance initiatives.

Depending on the size and scope of your transition plan, you may choose to establish additional project teams to handle coordination between departments and divisions while the others focus squarely on implementation.

Answer the following questions when deciding how to expand your program throughout your organization:

- **What should be implemented centrally, and what should be left to individual business units and divisions?**
- **How will accountability be established between the two?**
- **What will be handled by the legal producer versus subcontractors?**
- **Is now the time to integrate particular subcontractors into the company?**

Foundational changes like those prompted by MDR require teams invest just as much time and energy in coordinating as they do developing the plan itself. Each phase of your project should be completed on-schedule to ensure delays don't compound into massive last-minute emergencies.

Your ideal deadline for core implementation should fall within the year prior to the formal deadline. The remaining time can then be used to address subsequent changes that may be necessary—particularly within the QMS and any technical documentation where changes may have been made between central and local control.

5. SUPPORT YOUR TRANSITION WITH EFFECTIVE TRAINING

The transition to MDR will likely pose training challenges common among every transformative program. Informing and educating your project team can be difficult enough. How do you scale this to the entire company?

While training, too, lends itself to each company differently, we've summarized an effective structure to mold around your company's specific needs.

1. Generate initial and ongoing program awareness

Awareness is critical in the early stages of MDR transition and beyond. Develop a means of keeping stakeholders updated on project progress through regular updates at key milestones. Extend this communication to your supply and distribution chain as well. Action-sheets, short video updates, webinars, and routine meetings are all great delivery formats.

2. Divide project-level training into two phases

Before your transition teams begin working on a new project within the transition plan, break training sessions down into workshops that present the regulations and connect them to the initiatives laid out in the project. Focus these training engagements on inspiring action and cooperation around core goals.

Subsequent training sessions should focus on comparing old procedures to new ones and connecting the differences to the reasons that prompted them. Make sure an appropriate level of training is presented at the board level as well. This provides important context into the actions being taken and can help projects stay on track.

3. Reiterate key points

Repeating the most important takeaways is one of the most reliable ways to ingrain them in the minds of everyone. Pull out key messages and hit them home though sharepoint presentations, internal newsletters, and regular meetings.

6. IMPLEMENT YOUR TRANSITION PROGRAM

When fully prepared, it's time to bring your systems into compliance with the MDR. Again, accounting for the variability in how this will apply to each company, we've offered a templated, step-by-step process to work from:

1. Develop a governance structure

This should consist of a primary project manager under the direction of a steering committee. From there, workflows and project-specific teams can be organized to accomplish the specific goals of transition within their respective functional areas. For most companies, these functional area categories should be Quality, Regulatory, Operations, Supply Chain, Legal, and R&D. These teams will likely be responsible for developing new documentation, creating or revising procedures, and other related tasks—all under the lens of quality management. The specific goals for each team are explained below.

2. Build your teams

Once a governance structure is in place, build out your project teams in each functional area with a designated MDR Lead to manage representatives from each area. Identify who will be responsible for certain tasks at the most granular

level possible—keeping everything linked to a team leader in charge of oversight. For larger multifaceted companies, this process can take time. Make sure to leverage all the resources at your disposal and avoid inadvertently putting goals at risk by stretching your teams thin.

PROJECT TEAM RESPONSIBILITIES:

- Understand the changes and implications of MDR on their business unit and its function within the broader organization
- Track progress and adapt to pending changes related to EUDAMED, UDI, common specifications, etc.
- Collect current state information to understand the impact of MDR on products, quality system processes, certification status/timelines
- Develop business unit plans for gap assessment, remediation, process changes, and product submission impacts
- Launch newly-developed business unit plans by conducting new activities, producing new deliverables, reporting on status, and escalating issues

3. Write up project charters

The result of your enterprise-wide transition plan should be a number of individual project charters, each following a step-by-step workflow from initial kick-off to confirmation and effectiveness checks. Included in each charter should be a clearly-written definition sheet which lays out goals, project milestones, a timeline, team members, and budget. The progress of these projects should be controlled by the chief project manager who can relay statuses directly to the steering committee. We've highlighted the important activities for each business unit below.

QUALITY TEAM ACTIVITIES

- Thoroughly review the current QMS
- Revise all QMS processes to take a risk-based approach
- Develop and document processes for managing new and changed requirements
- Conduct computer system validation (CSV) for all impacted software systems
- Upgrade to EN ISO 13485:2016 & MDSAP
- Integrate changes with other QMS requirements in 21 CFR 820

REGULATORY TEAM ACTIVITIES

- Review product portfolio (as explained above)
- Determine each device's classification status under MDR
- Determine if any invasive cosmetic devices fall under MDR
- Connect with Notified Body to arrange for transition
- Conduct a gap analysis of technical documentation
- Review and update risk management files
- Review and update clinical evaluation reports and related documentation
- Plan clinical equivalence protocols
- Establish systems for regularly reviewing technical documentation
- Establish systems for new post-production PMS, vigilance reporting and PMCF obligations

OPERATIONS TEAM ACTIVITIES

- Document and plan for current certificate expiry and renewal
- Manage any labeling changes necessary
- Develop a practical plan for implementing UDI
- Identify, prioritize, and manage time-critical operations

SUPPLY CHAIN ACTIVITIES

- Review the the distributor network
- Review OEM and OBL agreements
- Support Economic Operators with required transactional arrangements
- Manage suppliers' ENO ISO 13485:2016 certification and transition

LEGAL ACTIVITIES

- Closely review all possible product liability issues, include OEMs and OBLs
- Examine required insurance requirements
- Establish systems for device complaints processed by third parties

R&D ACTIVITIES

- Carefully set and manage launch dates for new product development according to transition milestones and date of application

4. Develop communication plan and issue status reports

Routine status reports documenting the progress being made on each charter will help the steering committee focus on progress and set priorities as needed, in addition to serving as an aid for communicating project status to senior managers and company leaders.

You should also develop a communication plan for use at the program level as well as in each division and business unit. Make sure to adapt the following messages to their corresponding audiences:

- What is the MDR?
- Why was it released?
- When will it be implemented?
- How will it impact the organization as well as customers, products, and the quality system?
- What is the company doing?
- What is needed from the particular audience?
- What measures are in lace to ensure issues are escalated and addressed transparently?
- What are the positive outcomes to expect following transition?

7. CONDUCT EFFECTIVENESS CHECKS AND AUDITS

The result (in terms of tangible output) of each project charter should be verified through individual effectiveness checks on each sub-task within the broader transition program. To supplement this further, conduct a series of audits to identify remaining gaps and fill them ahead of any official inspection.

Performing these, along with a series of mock audits with the help of an experienced third party auditor not only goes further in assessing the new state of compliance, but also prepares staff for the newly-modified Notified Body audits that will bring increased scrutiny in the areas of compliance.

Finally, a management review should be conducted to provide closure on implementation with final confirmation that the transition effective and quality management processes can effectively maintain compliance in the future.

A TIMELINE FOR TRANSITION PLANNING AND IMPLEMENTATION

2016 - 2017
Gap Assessment & Planning

2017 - 2019
Implementation

2019 - 2020
Verification & Improvement

2020 & beyond
Routine Internal & Mock Audits

NEW QUALITY SYSTEM MANAGEMENT (QMS) REQUIREMENTS

Device manufacturers will now document information on the following items:

- All systems for any reclassified devices or devices new to the scope of certification
- Economic Operators Registration as described in Article 30 and Single Registration Number (SRN) as described in Article 31
- The new role of Person Responsible for Regulatory Compliance as described in Article 15
- Agreement with EU Authorised Representative i.e. written mandate (Article 11), SRN (Article 11), and including Person Responsible for Regulatory Compliance (Article 15), QMS (Article 8)
- Importers i.e. SRN (Article 31), QMS (Article 13)
- Distributors i.e. QMS (Article 14)
- Strategy for Regulatory Compliance (Article 10) Unique Device Identification and Registration (Article 27, 29) Handling communication with regulatory authorities, Notified Bodies, Economic Operators
- Agreement with Importers / Distributors, including evidence of having met Article 13/14 respectively
- A process to identify Safety & Performance Requirements (SPR). See more below

QMS Requirements will be assessed for all existing CE Certifications from May 26, 2020. This includes:

- New vigilance reporting requirements compared to MedDev 2.12.1 (15 days maximum to report)
- New post-market clinical follow-up requirements compared to MedDev. 2.12-2 (more frequent updates)
- Registration of Economic Operators including Single Registration Number (Article 31)

- Process and/or procedure for communicating with Commission/Member States to obtain SRN
- Systems for Market Surveillance described in Article 93
- System for Serious Incident, Field Safety Corrective Action and Trend Reports described in Articles 87 and 88
- Systems for PMS Plan and Report described in Articles 84 and 85
- Systems for Periodic Safety Update Report described in Article 86

GETTING MANAGEMENT ON-BOARD

Conveying the importance of implementing a comprehensive MDR transition program and securing the necessary resources from management can be a challenge. This internal communication plan should begin with a high-level overview clearly and concisely presenting the key changes and how they impact your organization. Avoid framing this as a simple series of problems and solutions. Instead, anticipate fears and pushback, explain the changes coming, and offer a way to implement those changes in a way that addresses those fears and pushback from the very start.

Take, for instance, the number of reports that will be required for clinical evaluation. Most of these changes relate to documentation or recordkeeping. This means you'll have to use additional resources to create those, without changing the way business is conducted. Decision-makers are typically much more likely to devote resources when a clear connection can be made to achieving compliance in the context of how things are currently done. Managers want to ensure regulatory personnel understand what that path toward change looks like, and are armed with the tools to solve problems up front. This is one area where gap assessment planned and led by an experienced third party consultant can identify gaps that may not be apparent to internal personnel.

Keep in mind that management might not have the bandwidth to stay in tune with system and process changes at a detailed level. Perhaps they aren't aware of how risk management will need to be implemented a slightly different way, or may not realize that specific new reports will need to be created and maintained. The clinical evaluation report and post-market clinical follow-up reports as well as everything else that will have to be noted may incur some new costs. However, once implemented, these items should be comparatively easy to maintain. Make sure everyone understands the initial non-recurring expenses and how they connect to important activities related to transition.

TRAINING

The MDR coincides with looming deadlines for ISO 13485:2016 and the Medical Device Single Audit Program (MDSAP), so it's no surprise management teams and regulatory professionals are inundated with work. Looking at timelines for each of these programs, MDR sits largely at the end of the series and, in some ways, presents the most strict new regulations. Those in charge of implementing MDR will likely have been trained in ISO 13485:2016 and the MDSAP already, however they should be careful to assess training gaps that may exist between the MDR and these other regulations.

In addition to being able to audit to these requirements, MDR-specific training should be focused on business-side changes, too, with special attention given to greater liability pressure. Determine what your contracts will need to look like in the future with all economic operators, such as Notifying Bodies, Authorized Representatives, and distributors in Europe.

HOW AND WHERE THIRD PARTY EXPERTS OFFER VALUE

- **Planning and project management**

  The breadth of change prompted by MDR will demand smart, efficient project management to ensure activities are successfully completed on schedule. This is one role perfectly suited to the perspectives and prior experiences of a third party compliance expert. From this high-level perch, a consultant can draw on their talents to both establish a transition plan and see it through to completion by applying best practices and guiding project teams each step of the way.

  An expert-written transition plan can easily be reformatted into a project checklist and set to a timeline based on reasonable expectations that are informed and supported by first-hand experience rather than estimates.

- **Project timing**

  Third party experts can also ensure you avoid a potential regulatory disaster due to poor timing by taking several situation-specific factors into account. For instance, it's important that companies schedule auditing activities with their Notified Body not with the compliance date in mind, but the date by which evidence for compliance will be obtained by the Notified Body. If your Notified Body typically audits during the month of March, for example, and the

implementation is required by May, you should be able to proceed as usual given the buffer period you may need to put corrective actions in place. If, however, audits are conducted in October, you'll have six months before the requirements must be implemented, but will need to be audited six months prior. An outside consultant will be able to put his or her finger on a particular spot on the calendar to start and end transition based on your Notified Body's typical audit pattern.

- **Gap assessment & portfolio rationalization**

  Experienced consultants arrive with an arsenal of checklists and guidelines to conduct a thorough gap assessment. Consultants can also be a valuable resource when rationalizing your portfolio, especially for the 80% of IVD companies that will need to change their classifications and have documentation reviewed by a Notified Body. Similarly, device changes will requires reviews in order to maintain their certification.

- **Training**

  While consultants aren't typically seen as trainers, they can play an important role in educating staff both in changing requirements as well as the impact it will have on specific areas and individual roles. Third party experts can combat the often unrealized myopia that can naturally develop within internal teams and demonstrate new, more efficient ways to improve your processes.

FINAL THOUGHTS AND NEXT STEPS

There is no doubt the regulatory landscape of Europe is changing.

With the implementation of the MDR, the intense focus on legal manufacturers will shift to the broader supply-chain and levy higher expectations for responsibility at every level. Along with the specifics of transition we've touched on here, it's critically important for all stakeholders to align themselves with these new norms and ensure all agreements are updated to reflect changes in compliance expectations.

As with the broader regulatory trends throughout the world, the importance of continuous improvement will only grow for those marketing products in Europe. New rules geared to increase transparency will bring both new challenges and opportunities for the industry.

For most companies, the changes clinical data requirements will present the most significant changes as they will need to demonstrate sufficient clinical data for products and for each clinical claim and for each intended use. The Notified Body system will quickly shift into compliance-focused gear and, by all indications, will broaden and tighten their oversight over the industry.

The cure to this complexity starts with ensuring everyone is armed with the knowledge and tools needed to understand the new regulations and orient themselves within them. Contact us today to power your transition program with the help of a knowledgeable third party regulatory compliance expert.

Interested in working alongside experienced Quality professionals to plan and implement your MDR transition program?

CONTACT THE FDA GROUP FOR A FREE CONSULTATION »