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**Preparing for the future: The new European Union medical devices regulation**

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# Taking charge of the new medical device regulatory environment: From complex regulation to impactful change

## Summary

Since the 1990s, regulation of the medical device industry in Europe has been relatively unchanged. However, recent incidents, including the breast implant crisis and the hip replacements, have now prompted urgent regulatory and compliance reforms to the industry. Among the most significant of these are the European Commission's 2012 proposals for regulation on medical devices (EU MDR) and in-vitro diagnostics (EU IVDR). With the formal publication of guidance imminent, the proposals will give national regulators much more control and oversight of the medical devices industry—with adoption mandatory. If companies do not comply with these upcoming changes then this could possibly result in a company losing its license to operate.

The impact of this regulation can dramatically alter the operations of medical device manufacturers and even impact the composition of their existing as well as future portfolios. Cost of compliance will most likely be significant. It is critical that businesses take action now—to gain stakeholder buy-in, prepare their organisations, and start implementing changes.

This paper looks to understand the range of impacts the EU MDR will have on the industry—from change management to portfolio reviews to product labelling. We propose a series of steps manufacturers should take to address and mitigate the changes ahead. With careful planning, a successful transition to the new regulatory landscape is possible.

# Planning for the new EU medical devices regulation

## A plethora of regulatory changes

The Life Sciences sector is going through a period of unprecedented regulatory change (see figure 1), affecting organisations involved in pharmaceuticals, medical devices, and in-vitro diagnostics. Driven by a need to strengthen the regulatory platform across the European Union (EU) that aims to better ensure patient safety, new regulations are seeking to harmonise and simplify the rules by improving transparency and product traceability, demanded by patients and the public.

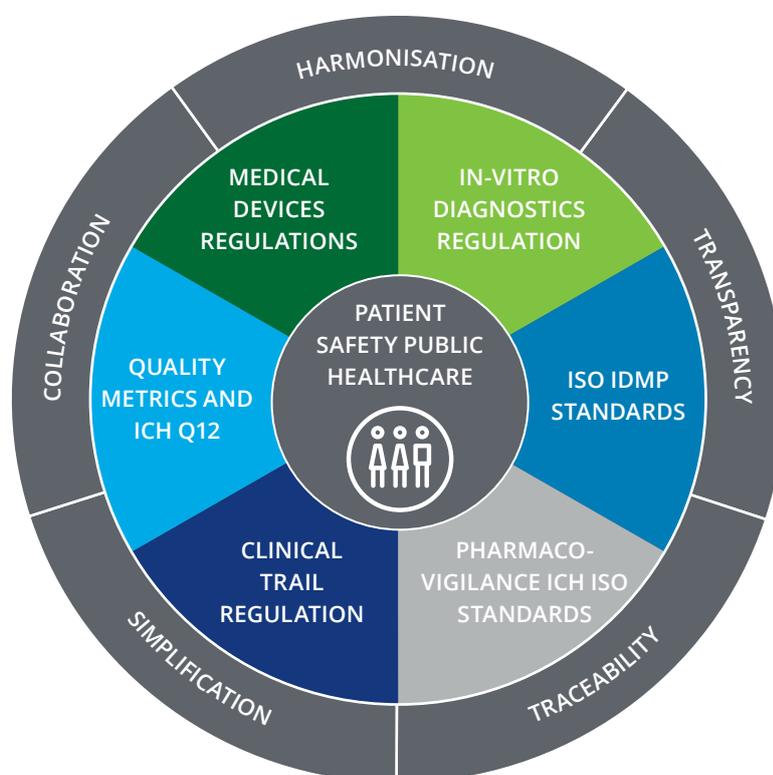


Figure 1: Change in regulatory landscape

It is important for medical devices companies to proactively prepare for these changes as their impact could be significant. These include impacts on their current and future revenue stream, especially as internal investment may be needed to prepare for these changes; on the prioritization of efforts within the organization; and on internal processes in terms of operations and getting a product to market.

## Context

On 26 September 2012, the European Commission adopted a Proposal for a Regulation of the European Parliament and the Council on medical devices (EU MDR) and in-vitro diagnostics (EU IVDR). These regulations, once implemented, will replace the existing three medical devices directives.

The aim of these new regulations is to ensure that products are effective and safe as well as can be freely and fairly traded throughout the EU. The existing rules that currently govern medical devices date back to the 1990s and have not kept pace with the significant innovations in technology and science.

A number of recent high-profile incidents such as the hip replacements and the breast implant crisis highlighted the urgent need for improvement in standards, processes and procedures and acted as catalysts for reform:

### **Hip Replacement Recalls**

In 2010, metal on metal (MoM) hip replacements were recalled due to high failure rates as the MoM device wearing down led to metal particles entering the bloodstream and soft tissues

### **Breast Implant Crisis**

In 2012, unexpectedly high number of women were diagnosed as suffering from ruptured breast implants leading to the breast implant crisis. The crisis took place as the French firm had been manufacturing implants using industrial grade silicone. The situation was made worse by poor record keeping, with women unable to find out whether they had received these implants or not

These separate incidents, highlighted the need for strengthening of the EU MDR and IVDR regulations and meant that regulatory reform was a matter of when not if.

These new regulations have been unfolding over the past decade and the benefits of the reforms will be realised by patients, healthcare professionals, manufacturers and will allow for national regulators to have much more control and oversight of the Notified Bodies and medical devices industry.

The new EU MDR regulation aims to create a new and improved landscape for the medical devices industry, with the following new guidelines:

- All medical devices will have to undergo an independent assessment of safety and performance before they can be marketed in the EU
- There will be greater transparency of information on the benefits for patients, residual risks, and a thorough assessment of the overall risk/benefit ratio will be necessary
- There will be clearer rules in place to enable standardisation and support simpler and less complex trading between EU member states; those that do not comply will be penalised
- The new rules support patient-oriented innovation and take particular account of the specific needs of the many small and medium sized manufacturers in this sector
- The EU MDR will place further responsibilities on “Notified Bodies” - those independent third parties that perform conformity assessments for medium and high risk devices. The Notified Bodies will be subject to heightened scrutiny from competent authorities and will need to be designated under the EU MDR, with the process of designation coordinated at a European level

To meet the new EU MDR vision, organisations will need to take a structured and well managed approach over the next 3 years depending on the product portfolio. A snapshot of the regulation timeframes is illustrated in the section below.

## Timelines to meet the EU MDR and IVDR compliance requirements

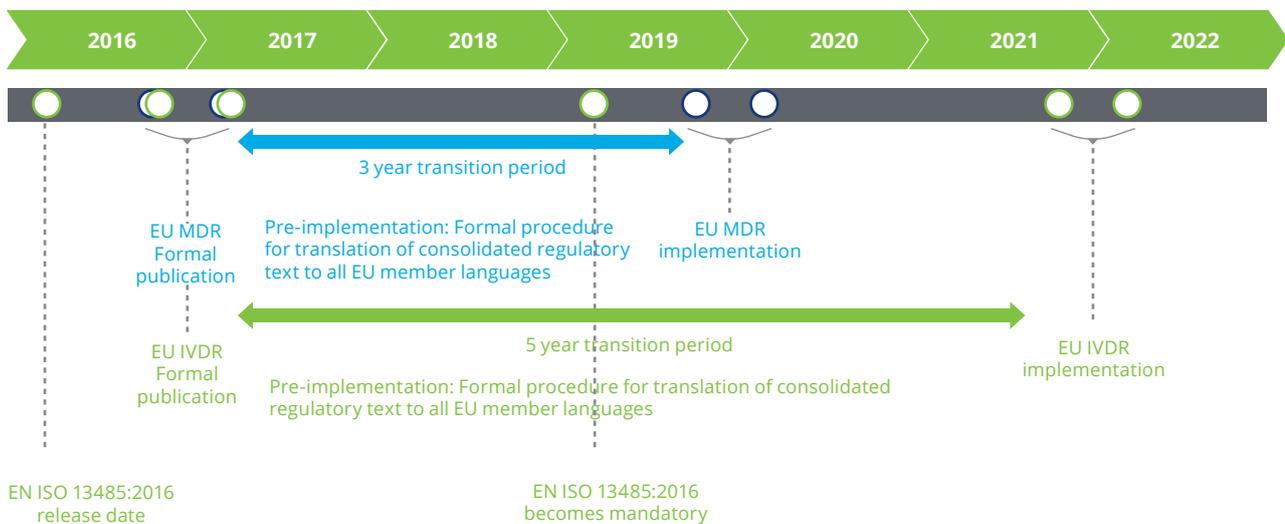


Figure 2: Medical devices and in-vitro diagnostics regulation timelines

The EU MDR is expected to come into effect in late 2019 or early 2020. Prior to implementation, there will be a formal procedure whereby the consolidated regulatory text is translated for all EU member languages. Formal publication is expected in late 2016 or early 2017. Once published there will be a three-year transition period. With respect to Notified Bodies, the designation process will start six months after the adoption of the regulation and have a phased transition period.

This paper is primarily focused on the medical devices regulation (EU MDR) and the requirements of the EU MDR apply in large to the medical device industry.

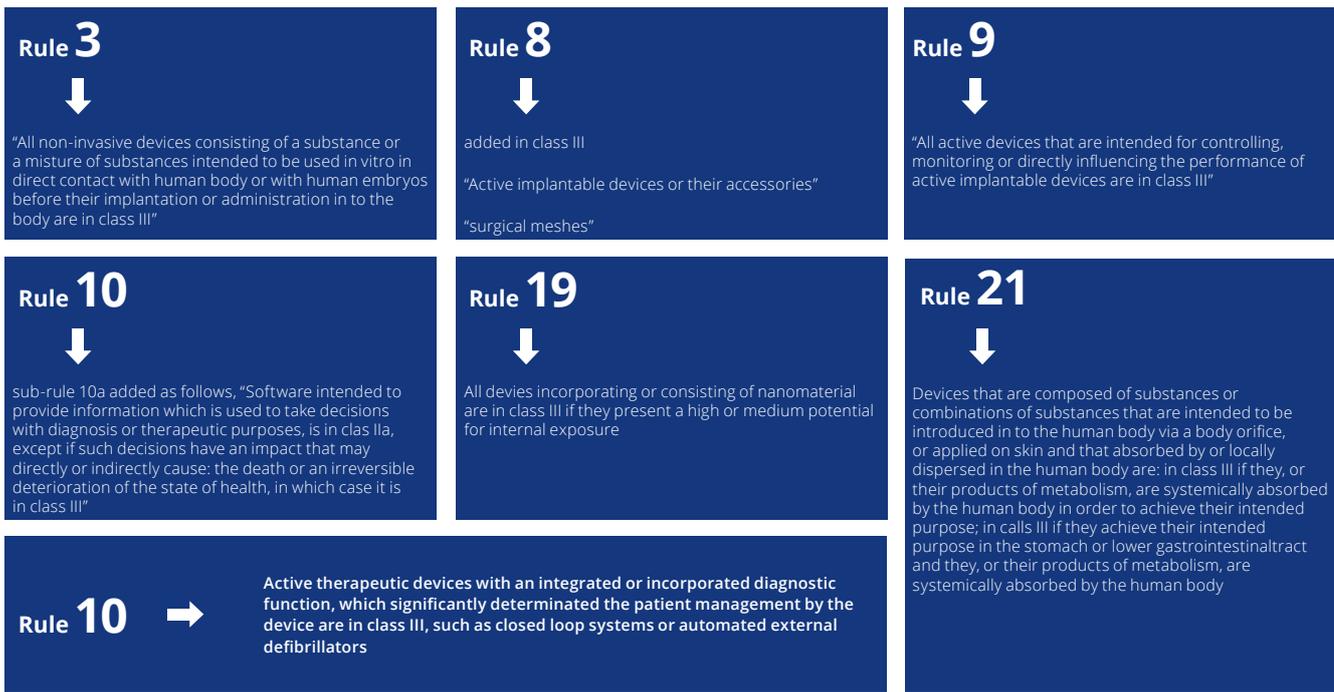
### Mitigating the impact of EU MDR

The combined impacts from EU MDR are significant to a medical devices company from a commercial, portfolio, R&D, process, and organisational perspective. Compliance will require an enterprise-wide approach, pulling together a multi-disciplinary and cross-functional governance and programme team. Tackling these new regulations in a siloed and functional way will not work and C-suite leadership must be fully aware of the changes the EU MDR will necessitate.

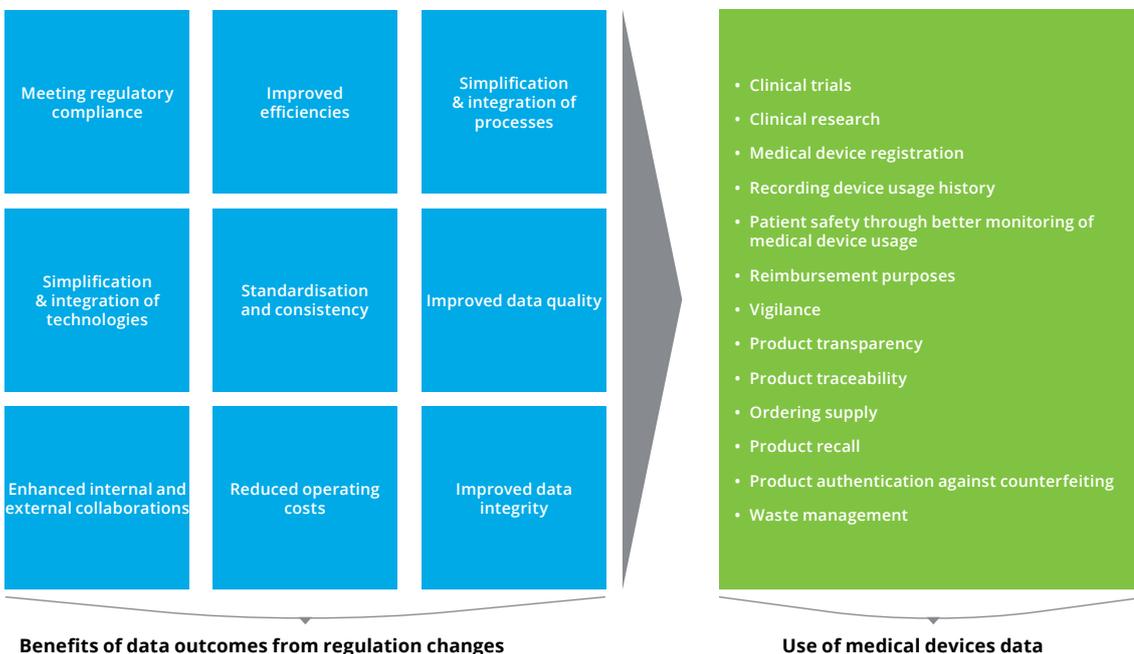
The impacts may even dramatically alter the composition of tomorrow's portfolios, with the cost of compliance possibly in the multi-millions. The EU MDR could ultimately force organisations to assess whether there is sufficient return on investment for a product to be viable. The effort involved with the changes may actually force companies to divest products, leading to increased merger and acquisition activity in the market. And if the requirements are not met within the defined timelines, it could mean withdrawing a product from the market.

The new regulation will also impact some devices, especially those that fall under class III systemically absorbed, class IIa (devices used on skin), class IIb default, other class II impacts (now added in class III as per rule 8) and software (this is no longer an active device).

Illustrated below in the table are new class III designations:



Business Case – In the context of shareholder value and potential outcomes:



## Recommended approach to the EU MDR compliance

The EU MDR will impact all device manufacturers, so what are the steps manufacturers need to take to mitigate this impact?

Given the scale and complexity associated with implementing the EU MDR changes it is important for manufacturers to adopt a structured enterprise wide cross-functional approach. We believe there are three key steps to implementing the EU MDR and gaining compliance (see figure 4).

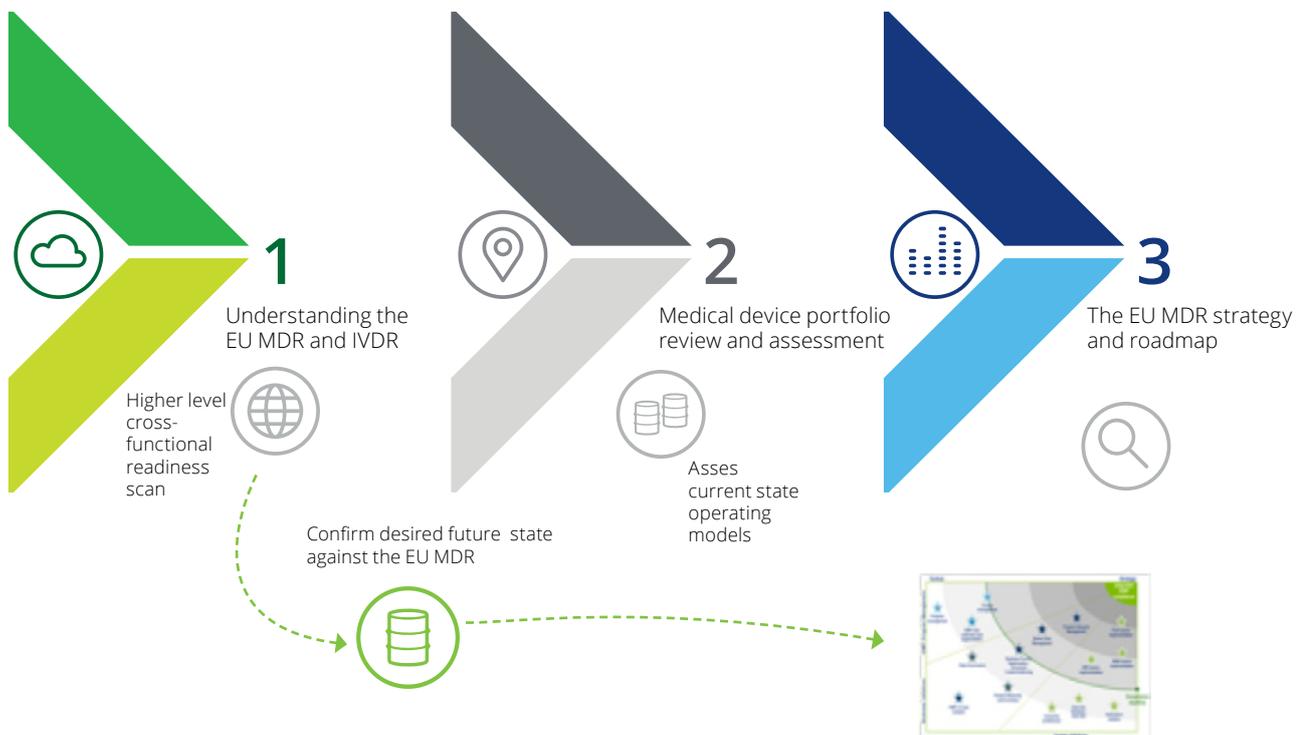


Figure 4: Recommended approach to implement the regulation changes

### Step 1 - Understanding the EU MDR and IVDR

As a medical device manufacturer, importer or distributor it will be critical to have a good understanding of the new regulations, the scope and full impact on the business. Many companies will have combination products and so both the changing pharmaceutical and medical devices regulations are relevant. Understanding the overlap and synergies with other applicable regulations and directives such as IVD, Clinical Trial Regulation (CTR) for human use, Falsified Medicines Act and Identification of Medicinal Product (IDMP) will be important.

### Step 2 - Medical device portfolio review and assessment

A manufacturer's portfolio of products will need to be fully reviewed and assessed against the new regulations and future requirements. For example, under the new directive, products that are classified as accessories could now be covered under the definition of a medical device. With the new requirements there also may be product lines for which the classification status will change or the oversight by the Notified Bodies will be heightened without an increase in classification. It will be important to understand whether these products will need to be up-classified in the future and the associated impact. Illustrated in the diagram below are some of the most critical areas that will require assessment (see figure 5).

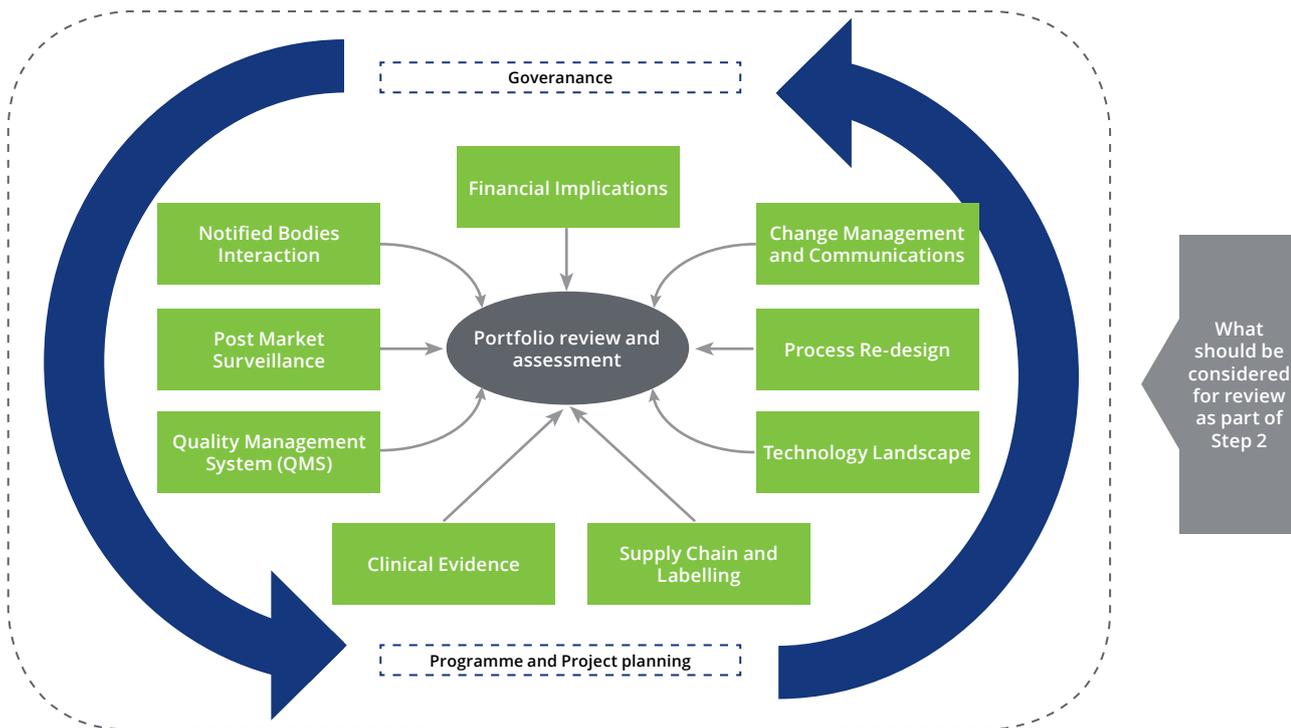


Figure 5: Key focus areas to consider during review and assessment stage

## Financial

These types of enterprise-wide regulatory-driven implementations are far-reaching and can require significant investment to plan and execute, especially for large and mid-size medical device organisations. It will be necessary to understand the percentage of potential revenue at risk and the potential need to look for buyers or acquisition opportunities. The partnering/outourcing landscape may change as a result and it may be necessary to evaluate other new alliances. It could mean organisational re-structuring, end-to-end process re-design, and systems implementation and integration. But more importantly, serious decisions may need to be made around the product portfolio to understand whether some products may need to be rationalised and divested. Adoption of the changes are not optional and non-compliance will have serious implications on a company's license to operate.

Key considerations: How many products will we rationalise or divest? What is the impact of this on revenue and what percentage of revenue is at risk?

## Governance

A change of this magnitude will require cross-functional leadership and governance, both at the time of the new regulation for the strategic aspects and on a continuing basis for the tactical and future implementation phases. The C-suite leaders will need to be very aware and become a driving force in the leadership and governance of this initiative.

## Programme and project planning

As medical devices organisations prepare to adapt and implement the new EU MDR, programme and project planning will be crucial for success. Understandably, it has been difficult to motivate the senior leadership in medical devices organisations to

realise the ramifications of upcoming change in regulation given that the implementation of the new EU MDR is three years away. However organisations will need to be well prepared for this change as it will impact many aspects of the product life cycle. Several tasks will need to be undertaken such as defining portfolio strategy and optimising portfolio, understanding the new clinical evidence required for certain products, optimising resource to be able to meet compliance requirements, adapting existing business processes to meet the new changes, building successful roadmap and performing gap analysis to understand current capabilities and future needs. In order to deliver such a complex programme, organisations will need strong leadership and programme management skills. Three years may seem like a long time, however given the complexity and enormity of the tasks involved organisations will need to start preparing for this change now.

### Change management and communication

Awareness of EU MDR will need to be cascaded across the enterprise from the C-suite down. Stakeholder engagement and training on EU MDR requirements will be necessary along with an understanding of changing needs for the business and the operational implications. Change management and effective communication will be critical as the organisation adapts to the changes. The diagram below (see figure 6) illustrates key disciplines of change management that should be considered when undertaking such a large and complex programme.

Key considerations: Are we prepared for the change? Do we have the right number of resources to ensure we meet compliance?

### Change Management Sub-Disciplines

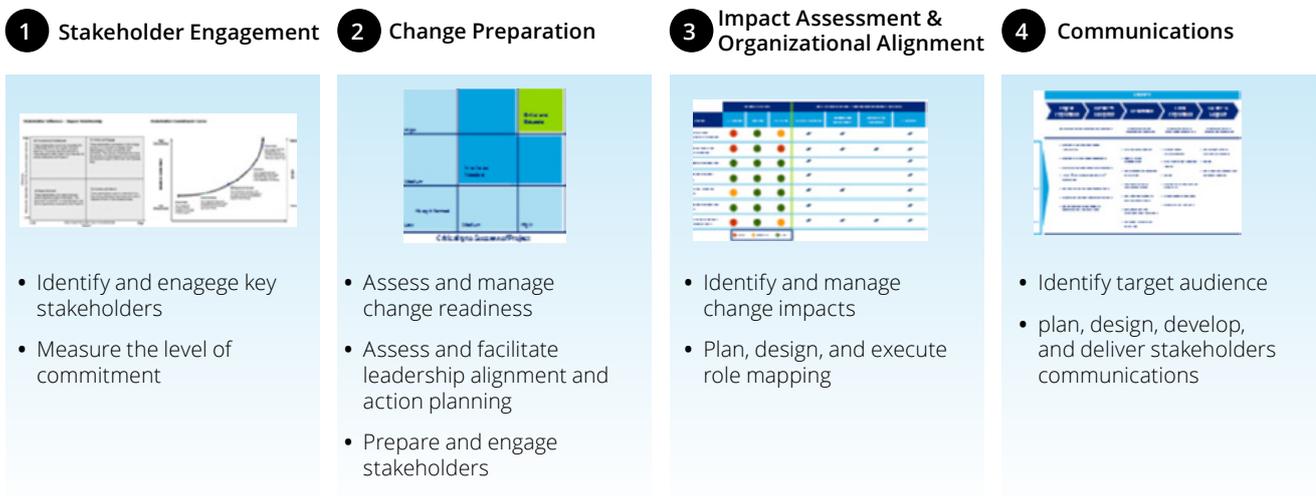


Figure 6: Disciplines of change management

### Process re-design

It is likely that today's processes will need to be re-engineered as a result of the new changes. The EU MDR requirements implementation plan will need to take in to account documented procedures to be created, approved, and implemented for new and existing processes. For example, considerations should include how many design centres there are, and whether they are aligned and consistent on the development of the technical files.

Key considerations: Do we have consistent processes and IT systems across the organisation? How many design centres are there, and are they aligned and consistent on the development of the technical files?

## **Technology landscape**

Consideration will have to be given regarding the suitability of the current systems landscape for the operational aspects of the new requirements. It will be important to understand if there is an opportunity for automation and integration enabling efficiencies by a new enterprise-wide technical architecture. Other considerations include what type of technologies can be evaluated and introduced to support the changes and how will the company interface with the Eudamed database (the electronic system for incidents reporting, field safety corrective actions, periodic summary reports, periodic safety update reports (PSUR), and trend reports). This database, as part of the new regulations, will be made available at an appropriate level to the public and healthcare practitioner (HCP) to improve transparency, enabling the public and the HCP to make informed decisions about medical device products.

Key considerations: Do we have the right architecture needed to implement this change? How complex are the technical file structures and do they have a consistent format?

## **Supply chain and labelling**

It will be important to understand how the current supply chain is managed, including manufacturer, importer, authorised representative, and distributor. There are significant implications on information on labels and it is possible that every label and instruction will need to be changed in line with EU MDR. Just this effort around the labelling alone will take considerable time, resource and planning. For example, will there be enough space on the label for the extra information needed? Additionally, the Unique Device Identification will need to be implemented and differences between the FDA and EU classification taken into consideration for products on the market globally.

Key considerations: What is the structure of our supply network? Are we ready to embrace and adapt the new electronic Instructions for Use (eIFUs)? How many resources shall be required to manage product label change in order to meet the new regulatory timeframe?

## **Clinical evidence**

The new EU MDR will lead to changes in the medical device development process due to new clinical evidence requirements. Additional clinical evidence will also be required for products already on the market. An understanding of the impact on R&D and ability to retain products on the market and launch products in the pipeline will be crucial.

Key considerations: For how many products in our portfolio will we need to generate new data? Does our portfolio include any class III or class II devices, ones that are most impacted? Is the process for managing and preparing clinical evaluation report (CER) robust to update CER annually?

## **Quality management system (QMS)**

Often due to mergers and acquisitions or other reasons, companies have more than one QMS. However, the EU MDR includes requirements for the QMS to be placed where the regulatory requirements come together to be implemented systematically throughout the life cycle of the device. Upgrading quality systems to the new regulatory environment may require significant investment as well as increased senior management involvement in both the upgrade process and ongoing management of the QMS. Additionally, as mentioned earlier, the publication of EN ISO 13485:2016 has a transition period of 3 years until March 2019. QMS will be the critical path for CE-mark approval.

Key considerations: How many QMS do we have in operation currently? Do we need to upgrade the QMS and how?

## Post-market surveillance

The EU MDR will bring about changes in requirements in the post-market area, including PMS planning and implementation, vigilance reporting, PSURs, and the handling field safety corrective actions. The timeline for adverse event (AE) reporting has decreased from 30 days to 15 days. Vigilance and PMS are in the responsibilities of competent authorities instead of Notified Bodies.

Key considerations: Are we well equipped in terms of resource to be able to report on AEs within the short timeframe set by the new regulation? Do we have the knowledge and skillsets to prepare for PSUR?

## Notified Bodies interaction



Figure 7: Changes related to Notified Bodies

Dependence on the EU MDR will place further responsibilities on the Notified Bodies, who will also be under heightened scrutiny from competent authorities. Changes within the Notified Bodies requirements will fundamentally change the way Notified Bodies interact with manufacturers. In order to help ensure impartiality and address the concerns raised by the safety issues resulting from the hip replacement and breast implant problems noted above, it is reasonable to expect more rigorous audits resulting in more cited non-conformities. In addition, the review of technical files and design dossiers by Notified Bodies may also result in more comments that must be addressed before the reviews are completed. Combined with the potentially longer lead times to schedule reviews and site audits resulting from the probable reduction in the number of Notified Bodies that obtain recertification under the new MDR, it is beholden on manufacturers to carefully assess go-to-market strategies, especially as they relate to moderate and high-risk devices. Given the number of Notified Bodies likely to seek designation, and the resources available for the designation procedure, the process to designate all Notified Bodies across the EU will be lengthy. There may be resource limitations during this process.

Key considerations: What are the changes related to Notified Bodies? How many products in the portfolio are certified by Notified Bodies and how does this impact us?

### Step 3 – The EU MDR strategy and roadmap

Once a full portfolio review and assessment has been performed around the current and future states, the gaps can be defined. These gaps would essentially be classified as strategical and tactical projects, prioritised based on business, legal, and regulatory drivers.

#### A deeper understanding of EU MDR

Functional Requirements and Impact

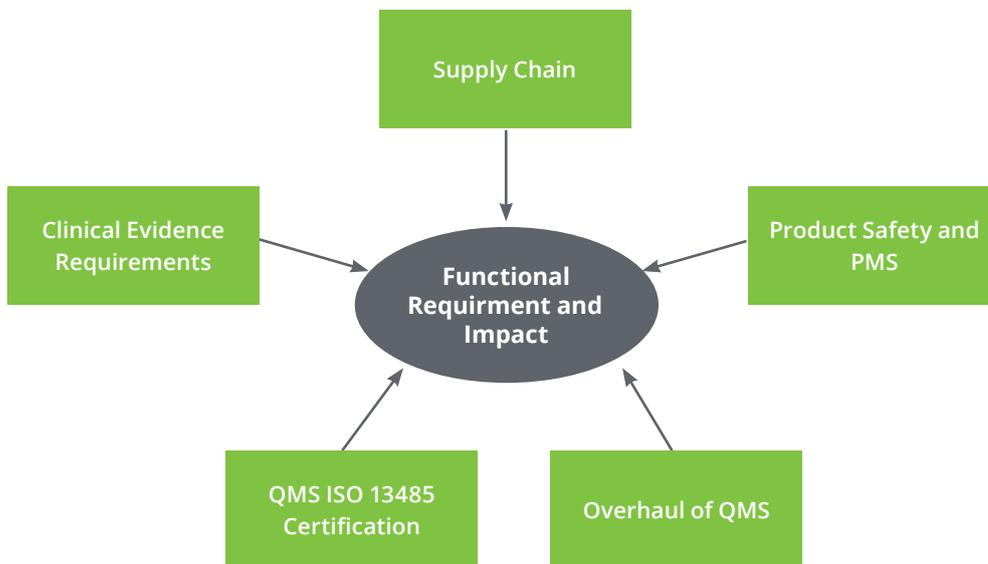


Figure 8: Key areas impacted as a result of functional requirements

#### Areas bear increased scrutiny

In addition to undertaking the steps recommended above, the following areas bear increased scrutiny. These are where changes will be felt the most and a deep understanding of the impacts is critical.

##### The supply chain

The new regulation around medical devices will strengthen the controls around traceability and transparency within the whole supply chain. Maintaining business continuity and ensuring products continue to flow to the EU market without disrupting the supply chain and distribution networks is extremely important, yet remains one of the most critical risks. New regulations in the EU region will require changes in manufacturing processes to enable the implementation of localised requirements. Without compliance with new regulations, companies will not be able to sell and distribute products to the EU region, causing significant disruption to their supply chain network. These impacts will range from changes to supplier agreements, increased scrutiny of supply chains through requirements, and disclosure of information to unannounced audits. This may result in increased supplier corrective action requests and may require a reassessment of suppliers. The MDR will definitely require an increased level of information retained, ready and available for inspection. To ease the burden where possible to manufacturers, the EU is cooperating with other regulators on some areas.

The diagram below (see figure 9) shows the impact on supply chain.

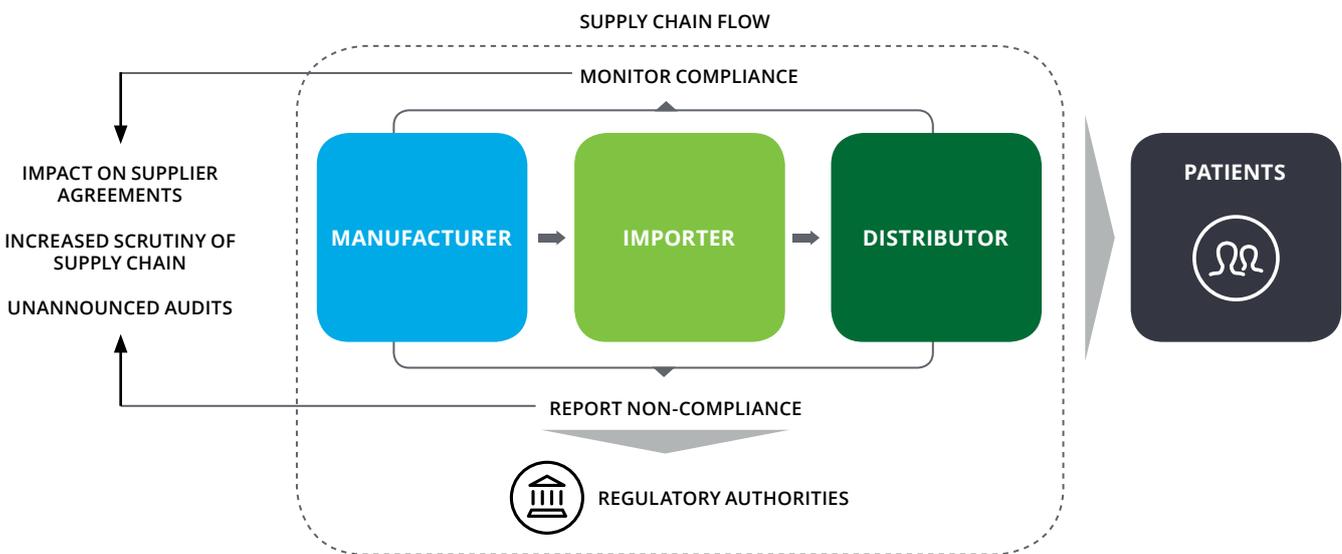


Figure 9: Supply chain compliance

While it is unclear if the Transatlantic Trade and Investment Partnership (TTIP) will go ahead in negotiating texts submitted by the EU, there is an emphasis placed on regulatory cooperation regarding medical devices. The TTIP Council aims to work closely with other regulatory agencies to reduce the duplication of effort and make devices more accessible. The International Medical Devices Forum (IMDRF) has been working with the EU and other global agencies (Australia, Brazil, Canada, China, Japan, Russia and the US) to produce a harmonised unique device identifier (UDI) guidance.

In the Council's proposal the new UDI requirements will be aligned with other systems such as the FDA's and those of other EU member states. The FDA is ahead at the moment and through guidance from the IMDRF has already implemented its own UDI requirements. Compliance is required for Class III and Class II medical devices already, with compliance for Class I due on 24 September 2018. The EU is set to follow the same process with a three-stage implementation with the highest risk Class III devices requiring UDI compliance first. In the United States, the submission of data is required to the global UDI database (GUDID) and the EU will enforce this submission through the Eudamed database.

UDI requirements include product data drawn from multiple sources. Many companies do not have clearly defined and consistent definitions for some or all of the data elements. In addition, lack of system integration across the product information ecosystem creates process inefficiencies, delays, and risks to data integrity during manual rekeying. UDI provides a foundation for systems and processes to enhance patient safety and traceability is one of the benefits. Traceability includes capturing the UDI along with transactional data associated with product movement through the supply chain to economic operators and healthcare caregivers. Capturing, storing, and reporting UDI for traceability supports post-market surveillance as required by the impending EU MDR regulation.

The European Commission will designate entities to assign UDIs. However, it is currently unclear as to what form these will take until such time the Commission states in the draft legislation that "GS1 AISBL (Global Standards One, Association Internationale Sans But Lucratif), HIBCC (Health Industry Bar Code Council), ICCBBA (International Council for Commonality in Blood Banking Automation) shall be considered as designated UDI assigning entities". This means that manufacturers will only be able to use coding standards provided by these entities.

An increased demand will be placed on manufacturers labelling and packing requirements through the MDR. According to FDA figures there has been a large increase in product recalls in the last decade of which 15 percent can be attributed to labelling errors. There will be requirements for manufacturers to have labels ready for immediate printing, thereby reducing the risk of a mass recall. In addition, companies must provide "instructions for use" (IFUs) that correspond to the format as defined by the EU MDR. The IFUs are available in several languages and require authoritative approval leading to significant effort for its management throughout the registration, production, and distribution process. The proposed procedures will enable the distribution process for appropriate IFU's, making sure they are available in the correct language and updated as required.

As a part of the new regulations, the EU proposes to adopt eIFUs as a faster method of communicating health and safety issues to HCPs. Currently, the EU is proposing to introduce timelines of only two weeks (15 days) for the integration of any health and safety changes into eIFUs and the presentation of the new version to the competent authority in a member country. This would mean that organisations will have to be prepared to be able to adapt to this short timeframe and deliver on any changes to IFUs.

Regulations within the EU will be a big step forward in terms of documenting medical devices. The regulations introduce new levels of complexity that are different from the regulations by the FDA or other regulating bodies for medical devices in other markets. Nonetheless, as per the regulations for health and safety on pharmaceutical products, it is expected that other markets will follow, introducing the similar regulations as proposed for the EU.

## **Product safety and post-market surveillance requirements**

One of the key drivers for the new MDR in the EU is to improve product safety due to recent scandals as mentioned previously. The new EU MDR mandates a substantial increase in safety obligations of manufacturers. The manufacturer is required to monitor more thoroughly the safety profile of the products placed on the market through implementation of a post-market surveillance (PMS) plan. Implementing and maintaining a risk management system throughout the lifecycle of a device is also needed. This requires identifying and analysing any known risks and implementing solutions to eliminate or control these risks. The reporting timeline of a serious event to a health authority is reduced to 15 days once the manufacturer has become aware of the event. For Class IIa, IIb and III device, a Periodic Safety Update Report (PSUR) is produced and is part of the technical documentation. The purpose of the PSUR is to present and summarise the post-market surveillance information, analyse, and present the benefit risk profile of the device within a defined period.

The post-marketing surveillance activities require volume, capacity, and capability assessment. Manufacturers that plan ahead and resource appropriately will be able to maintain up-to-date safety profiles of their devices and provide current product information to users in a timely manner.

## **Quality management systems**

Medical devices manufacturers are required to establish, document, implement, and maintain a quality management system (QMS) to maintain product conformity and quality and to achieve compliance with the provisions of the new regulations. To obtain the CE marking for a medical device, manufacturers are required to submit the documentation on QMS for conformity assessment by Notified Bodies, in addition to other technical documents, depending on the chosen route.

While ISO 13485 QMS is not a regulatory requirement under the EU Medical Device Directive, it is recognised as an internationally harmonised standard for designing a medical device QMS. This provides a framework to address management responsibilities, improve effectiveness of processes, and promote product conformity and quality as well as patient safety.

A new version of the ISO 13485 was published in April 2016.

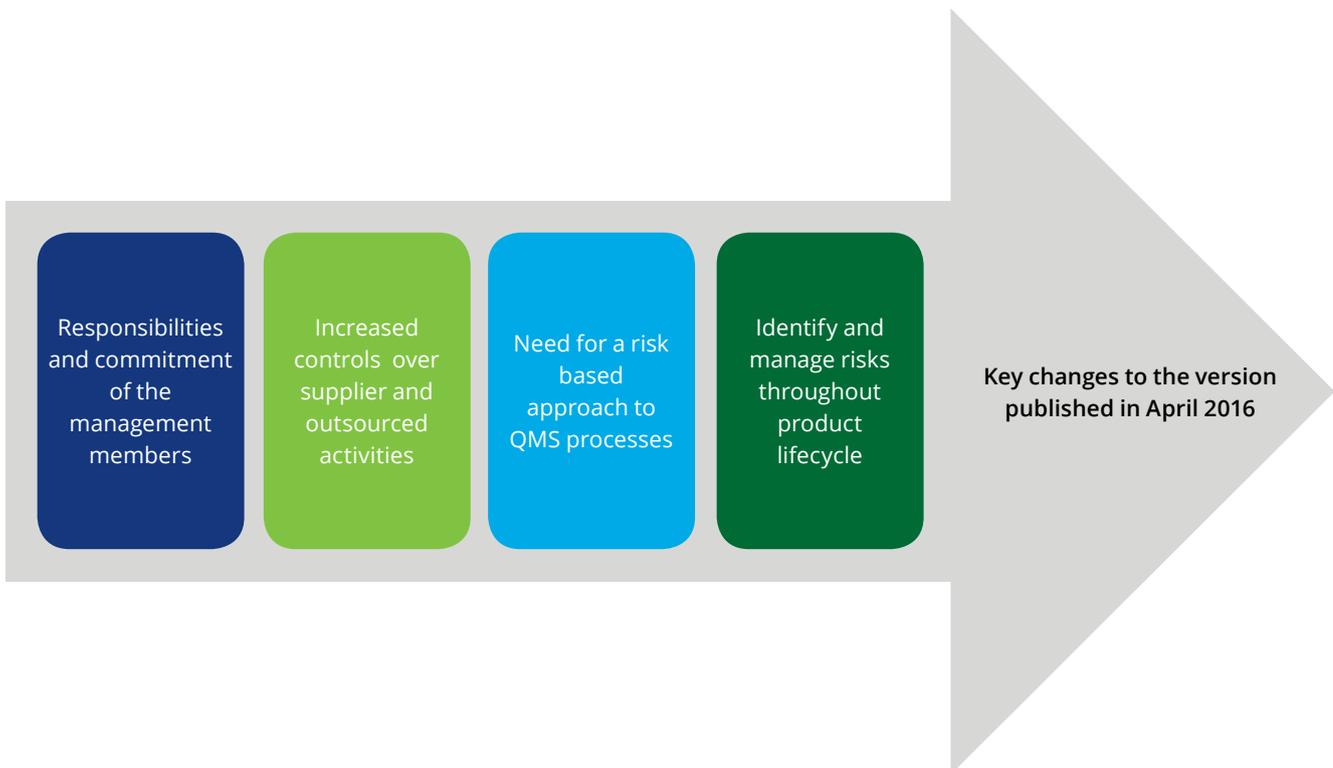


Figure 10: Key changes to ISO 13485

The key changes to the new standard include:

- Greater emphasis on the responsibilities and commitment of the management members;
- Increased controls over supplier and outsourced activities;
- The need for a risk-based approach to the QMS processes; and
- An emphasis on risk management throughout the product life cycle.

The QMS must comply with changing regulations to make sure that processes and procedures meet compliance expectations. It must also be designed to maintain and sustain short- and long-term quality across the MDR processes.

In addition to developing a strategy for meeting the regulations, the QMS should encourage quality beyond compliance. This means designing QMS processes to facilitate effective decision-making and to serve as the tools used to facilitate improved device quality, patient safety, improved outcomes, and customer satisfaction. The new Directive will drive changes across all elements of the quality program, including quality plans, quality manuals, and quality records. It will be important to maintain tight coordination between the changes to foster consistency across documents, eliminate redundancies, and empower the correct responsible individuals at each stage of the product lifecycle.

Companies need to understand the interconnectedness of all quality system documents (SOPs, trainings, work instructions, job aids). It is strongly recommended that a project management structure should be set up that manages the SOP updates and plans for the impact across the entire quality system. An analysis of the current QMS against the future requirements based on the new

ISO 13485 and the new medical device regulations should be conducted, assessing what impact the new regulations will have on the current business processes across R&D. For example, a process for planning, preparing, and submitting each of the technical files—including the clinical evaluation report, reaction monitoring reports (RMR), risk management plans (RMP), post-market surveillance (PMS) plans, periodic safety update reports (PSUR) and summary of safety & clinical performance—will be required. Implementation and training sessions for these new and/or revised processes should be planned. This will require substantial effort and resources to ensure a smooth transition and timely compliance with the MD regulation.

Given the many changes that will need to be made to the quality systems in order to comply with the new MDR, as well as ISO 13485:2016, companies should view changes as an opportunity to move to a state of “Quality beyond Compliance.” Under the new regulatory paradigm, quality can no longer be viewed in a silo and must be imbedded across both the product lifecycle and the organisation. Further, given the latest FDA initiatives and the focus on enhanced product quality, as evidenced in the work being done by the Medical Device Innovation Consortium (MDIC) and published in Agency guidance, these changes, if properly implemented, can enable companies to extract real business value from the QMS and the metrics derived therefrom. This could enable quality to become a true partner with business—not only improving product quality but also enhancing customer satisfaction and positively impacting the bottom line.

## **Clinical evidence requirements**

The new MDR will have a substantial impact on medical device clinical data requirements, both pre- and post-marketing. A Post-Market Surveillance (PMS) system will need to be optimised and maintained for all medical devices by the manufacturer, as described in Step 2 - Medical device portfolio review and assessment. The PMS system will need to include a Post-Market Clinical Follow-up (PMCF) to facilitate the gathering of quality, performance, and safety data throughout the device's lifetime. PMCF data will be required for high risk devices where long term performance and safety information is unknown or where CE marking is based on equivalence. For devices where long term influence data is available, PMCF could be avoided by providing this justification. Additionally, manufacturers of Class III or implantable medical devices will be required to write a Summary of Safety and Clinical Performance (SSCP), which will be validated by a Notified Body and publically available via Eudamed. PCMF data will be used to update the Clinical Evaluation Report (CER) and the SSCP, where applicable. For Class III and implantable devices already on the market, companies could start to focus on locating clinical evidence already gathered and update their CERs to reflect this data.

The inclusion of data sourced from clinical investigations will become mandatory for new Class III or implantable medical device applications following the implementation of the Medical Devices Regulation. The details of these clinical investigations will be stored in a system that is interoperable with the new clinical trials database for human medicinal products. The similarities between the medical devices regulation and the regulation on clinical trials on medicinal products for human use may allow organisations currently producing human medicinal products to use their existing clinical trial systems as a basis for the new medical device investigations. Other firms, however, may need to invest heavily in designing new clinical trial systems. Irrespective of other products marketed, all medical device manufacturers will need to assign personnel capable of analysing clinical investigations and PMCF data, either in-house or through a third-party contractor. Clinical investigations that commence before the MDR comes into effect will be able to continue, but must comply with the serious adverse event and device deficiency reporting guidelines set out in the new regulation.

Patient confidentiality requirements, for those involved in clinical investigations, will become more stringent after the new regulation is introduced. Early review of current data collection and storage policies to assess their alignment with the regulation may show inconsistencies that can be addressed before the regulation comes into force. In addition, organisations may use this as an opportunity to ensure databases are sufficiently secure, complying with both MDR and Data Privacy regulations.

The expected rise in clinical evidence requirements merits consideration when discussing resourcing and budgets, especially within organisations manufacturing Class III or implantable devices. Clinical investigation and maintaining a PMS system will demand initial investments and will require continuous resourcing and expenditure for implementation.

## Conclusion

The level of time and effort needed for defining the strategy and planning for implementation of these regulations is not to be underestimated. In order to assess the impact of these changes on the business and its commercial and R&D operating models, organisations will need to build a robust business case and strong project management capabilities with effective cross-functional stakeholder management.

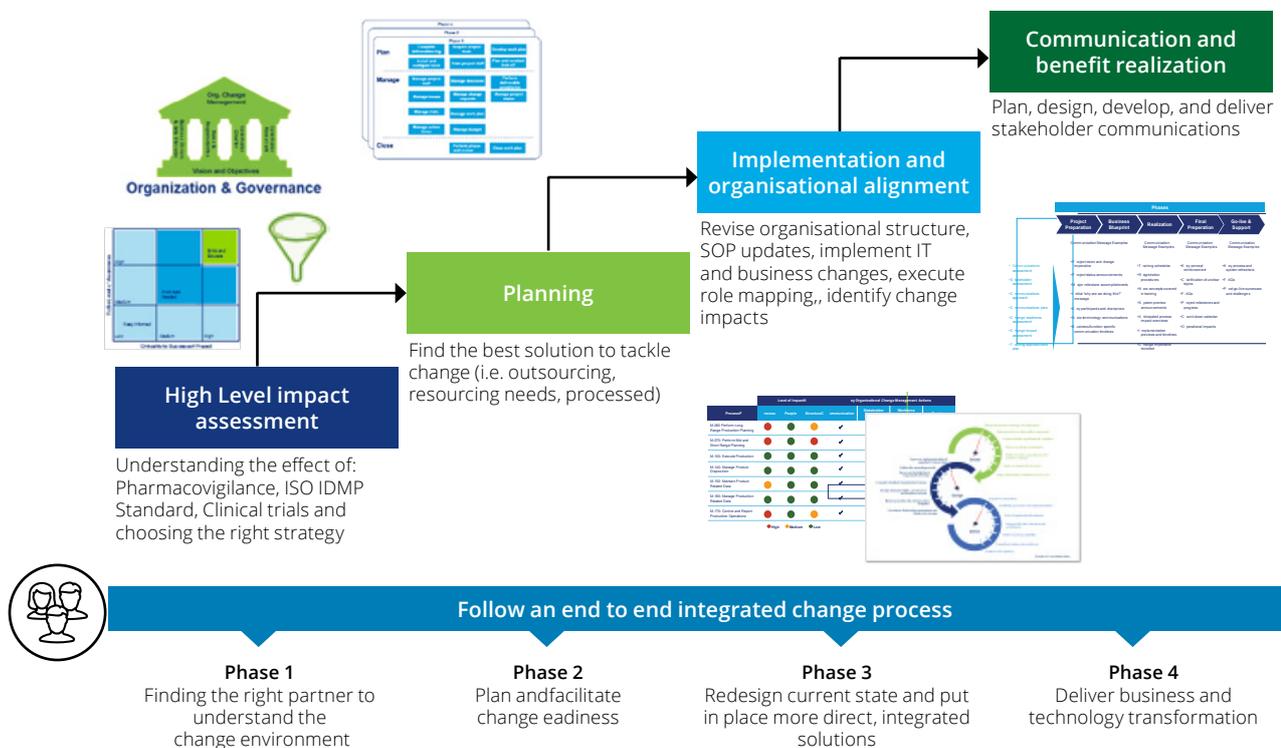


Figure 11: From taking the first step to delivering transformation

In order to develop the regulatory strategy for the implementation of the EU MDR a coherent sequence of activities will be critical. This will involve a multilevel approach: high-level impact assessment; planning; implementation and organisational alignment; and communication and benefit realization. While the process is a standard project management and business transformation programme, it offers the opportunity to go beyond compliance and make decisions on a company's current portfolio of products.

The understanding of the EU MDR requirements will be key to the ability to develop an implementation plan that ensures continuing regulatory compliance. Even more important, it will facilitate the ability to provide the EU market with safe medical devices that perform as intended.

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This includes the 28 official E U member states, plus Norway, Iceland, Lichtenstein, Switzerland, and Turkey by way of a Customs Union Agreement.

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