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**Monitoring a
regulatory convergence**

Significant regulatory change
for medical technology

A call to action

In a global marketplace, regulatory change can result in fines, penalties, and loss of market access. Regulatory change can also emerge from outside your home market.

Consider medical technology. Companies in this sector are currently facing a triple witching hour. New regulations from the European Union (EU), Canada, and the United States (US) are being implemented simultaneously, and they will impact companies' bottom lines. Even medical technology companies with limited revenues and market share in the regulators' home geographies will be affected.

Changes to regulatory oversight will most certainly alter the competitive landscape. Global players need a well-developed and well-implemented plan to turn these regulatory requirements into a source of competitive advantage that will allow them to reap economic benefits. By embracing complexity, medical technology companies can seize opportunities to lead in the industry, effectively navigate new regulations, and disrupt through innovation.

Three regulatory change areas affecting your organization today

Requirements for three foundational medical technology industry programs are in flux and are expected to impact your company over the next three years. The changes are intended to enhance product quality and safety. They're also meant to give companies better insight into the entire product life cycle via improved quality metrics and a more efficient inspection process.

These changes have ramifications for all medical device companies operating in these and other markets. They could require strategic organizational and process transformation not only to ensure compliance, but also to avoid loss of revenue and market share.

Implications for your operations and bottom line

Failure to adequately prepare for these new and revised requirements could result in fines, penalties, and loss of market access, which can directly and negatively impact the bottom line.

Consider the current Canadian Medical Devices Conformity Assessment System (CMDCAS) program. As that program is phased out, companies that market in Canada will have to comply with the requirements of the Medical Device Single Audit Program (MDSAP). That's because Health Canada will soon require MDSAP audit reports from companies in order for them to obtain and maintain device licenses. It's also important for companies to not underestimate the efforts required to implement the ISO 13485:2016 and EU MDR changes.

But these mandatory compliance changes can also be an opportunity to increase efficiency. Risk-based approaches, when implemented correctly, allow the organization to spend time where it most matters to their stakeholders, while reducing time spent on non-value-added activity. Adoption of MDSAP will allow the organization to use a consistent methodology to fulfill its regulatory obligation for multiple local markets, reducing time spent on audits.

Proper planning, preparation, and implementation of the necessary changes can lead to market share advantages, improvements to operational and quality process efficiencies, and a positive impact on the bottom line.

Overview of regulatory changes

ISO 13485:2016

- Various updates that will necessitate an evaluation of and update to an organization's Quality Management System (QMS).
- Updates will require expansion of QMS elements across multiple functions, further involvement from senior management, and the need for additional resources, as well as time to both implement and maintain.

European Union Medical Device Regulations (EU MDR)

- The new EU MDR and associated In Vitro Diagnostic Regulation (IVDR) constitute a major change in regulations relating to the safety and performance of medical devices in the EU.

Medical Device Single Audit Program (MDSAP)

- A global harmonization effort among the US, Canada, Brazil, Japan, and Australia, which became operational on January 1, 2017.
- Health Canada has announced that as of January 1, 2019, it will terminate the current CMDCAS program and only accept MDSAP certificates.
- Additional markets and organizations, including the World Health Organization (WHO), Medicines and Healthcare products Regulatory Agency (MHRA), Health Products Regulatory Authority (HPRA), and European Union (EU), are expected to adopt this program.

Adopt a strategy to manage the complexity of these changes

Implementation of the regulatory changes outlined here began in 2016 and will be completed around 2020. The organizational, process, and mind-set changes required for compliance are substantial. This transformation will require significant investment in time and resources. Forward-thinking organizations will be pursuing strategies that formalize a road map for the following:

- Assessing the changes against the current state
- Closing gaps
- Coordinating with notified bodies

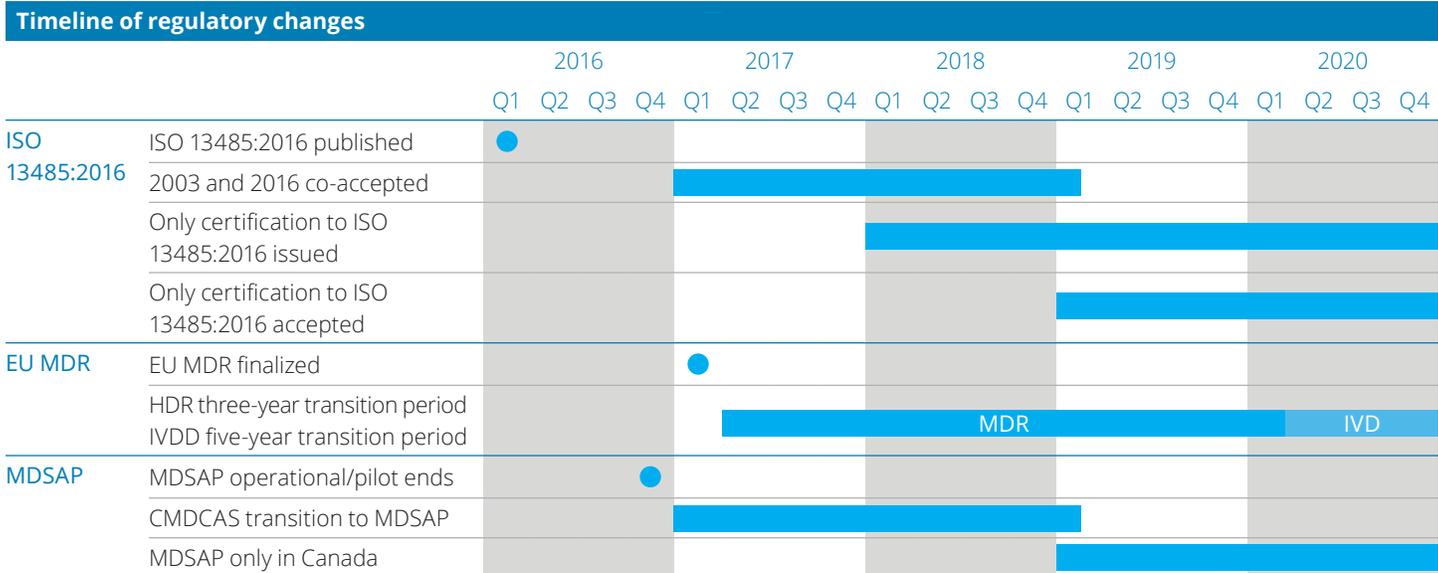
What's your plan to prepare for changes and capture benefits?

Significant changes to the regulations and standards regarding the breadth and scope of the QMS are already in play. Compliance with these changes requires careful and thorough planning to properly determine both the compliance timeline and the resources required to address these changes. If this transformation process isn't already underway, then urgent consideration is warranted as the timeline for implementation is relatively short.

Preparing a forward-thinking strategy will help to ensure your company's compliance, avoid massive operational disruptions, and enable your organization to capture benefits from the ongoing changes.

Advantages to manufacturers that participate in the MDSAP program

- **Reduction in the number of inspections and total time of inspection.** A typical regulatory inspection (not “for cause”) takes approximately 5 to 10 business days—with inspections that take several weeks not being uncommon. Regulatory inspections occur every two years, except for ISO inspections, which occur at least annually. For five regulatory agencies and an ISO audit, the time could be reduced from 15 to 30 days per year to just 10 days per year (see below).
- **More consistent inspections.** With only one inspection entity, the Auditing Organization, inspection of all QMS elements across multiple local regulatory requirements may result in better understanding of the applicability and suitability of the QMS to the regulations. Inspectors may see the “big picture” of the QMS with less need for explanation of the interconnectedness of the processes and fewer translation issues.
- **Less time responding to inspection outcomes.** Consistent, methodical inspections can mean higher quality findings. Functional areas that might receive slightly different findings from different auditors can instead respond meaningfully to a single comprehensive finding, instead of multiple smaller findings.



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