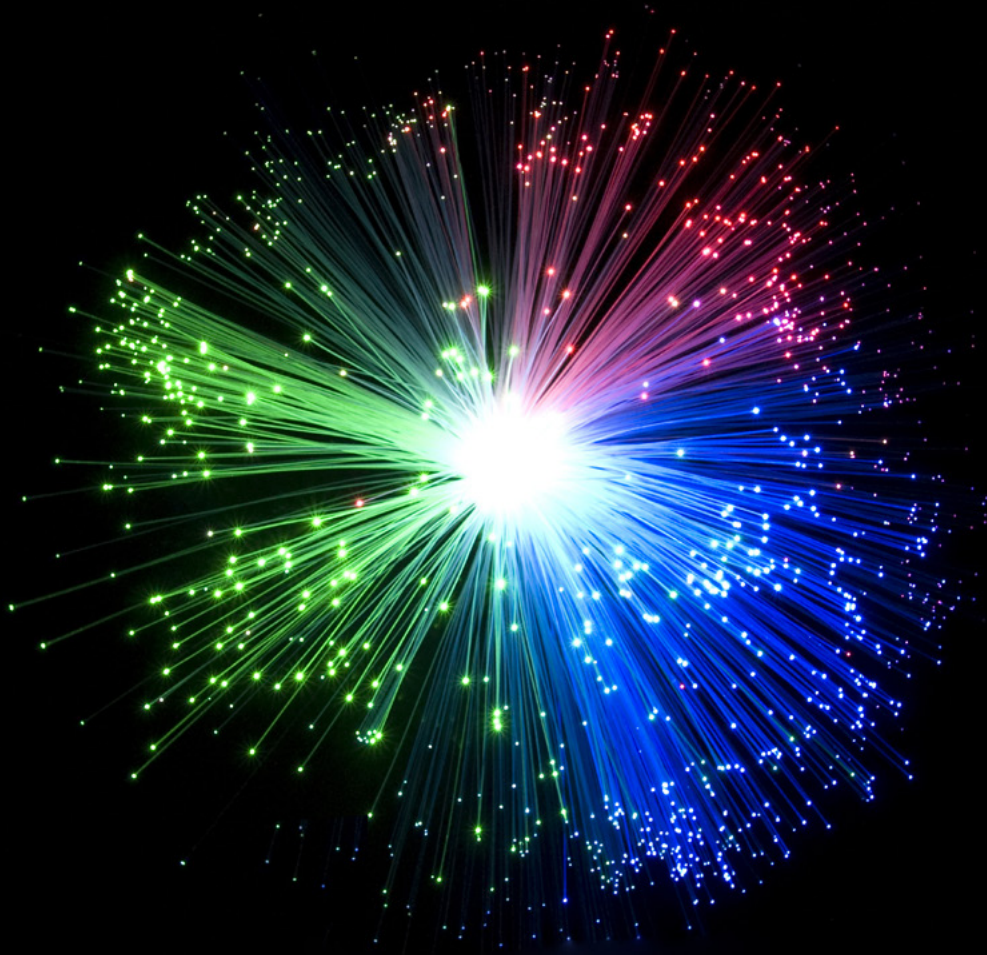


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The bigger picture

Impact of EU regulatory change on the
global life sciences industry

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Summary

The life sciences industry operates in one of the world's most regulated environments. Life science organisations must navigate and comply with a highly complex set of global, regional, country, and industry-specific directives and regulations; as well as industry standards and codes that span a drug or device's developmental and commercial lifecycle.

Recent and ongoing European regulatory changes are anticipated to be among the most significant yet for the global life sciences industry. Every pharmaceutical, biotechnology or medical technology (medtech) company that currently sells or sponsors products in the European Union (EU) will be impacted by these changes, which aim to strengthen the regulatory platform within the drug development and surveillance process, and achieve further harmonisation across the EU. The new and updated EU legislation is expected to drive enterprise-wide changes for life sciences companies, impacting current organisational structures, governance, processes, and technology.

Managing current operating models and future regulatory requirements will test a company's abilities to respond in a coordinated, cost-efficient, and timely way. There will be a need for more cross-functional collaboration and improvements in data management and data integrity.

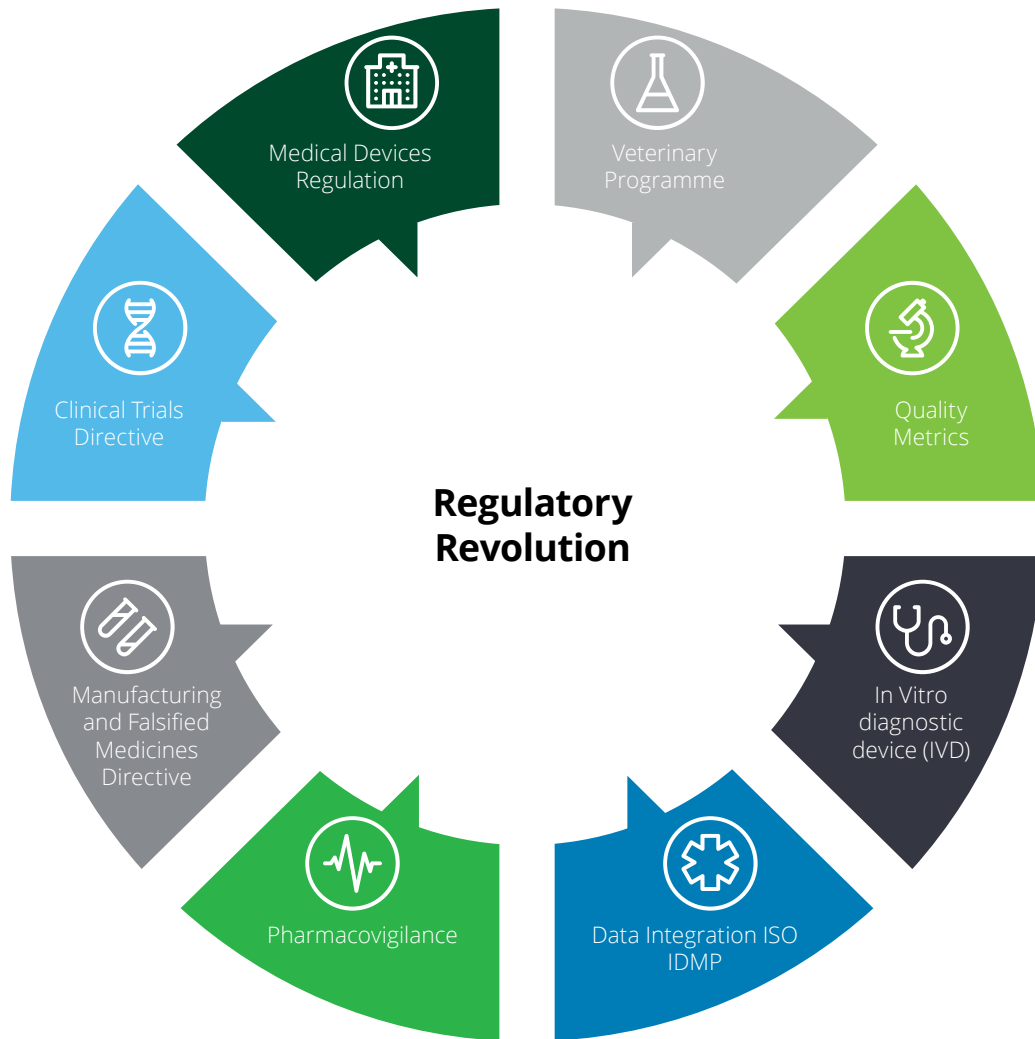
The regulatory compliance models which life sciences companies employ to maintain their operating license typically have evolved organically over time in response to new legislation. Today's compliance functions are often siloed, in part reflecting the business function they support.¹ Many organisations lack overarching compliance strategies and governance, which may result in:

- Potential non-compliance (e.g., some areas receive incomplete or no oversight)
- Duplicated efforts, redundant processes and/or structures
- Lack of standardisation
- Difficulty attaining a holistic, enterprise-wide view of compliance efforts
- Compromised ability to respond nimbly to emerging regulations or compliance issues.

In managing their response to the industry's complex regulatory environment, leading companies are looking well beyond addressing basic, functional-level compliance requirements. For example, obtaining a better understanding of compliance structures and enterprise-wide activities allows companies to identify opportunities to rationalise and simplify compliance operating models. Ultimately, the goal should be to mitigate the most intrinsic industry risks, such as safety concerns and drug supply interruptions.

Some large and complex regulations, such as Identification of Medicinal Products (IDMP), have been years in the making and will be rolled out in a phased approach, which gives companies time to plan for compliance. However, IDMP and other new regulations should not be dealt with singly or in isolation; companies need to be aware of and understand each regulation's requirements in the context of other new and/or updated laws that are part of the EU's regulatory revolution (Figure 1). This is because a new set of regulations will impact a number of functions within a pharma company and inputs from these functions will be required to implement the changes required.

Figure 1. EU regulatory changes impacting the life sciences industry



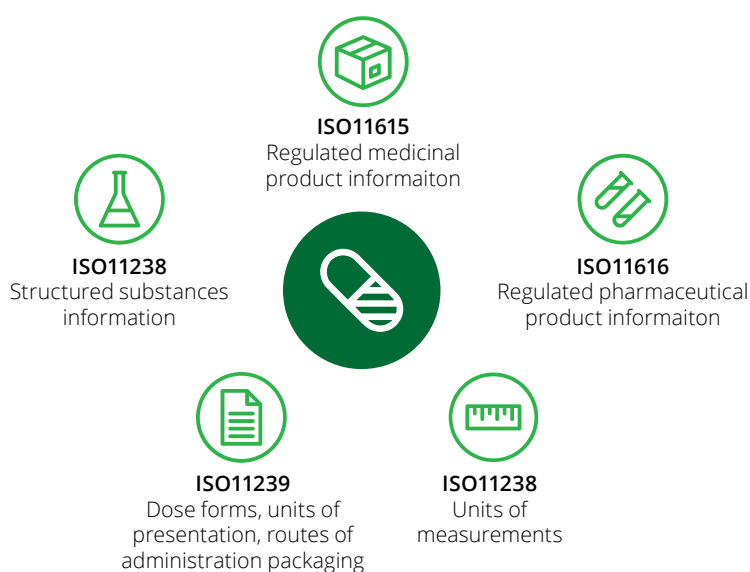
Life sciences companies will have to comply with regulatory initiatives which may overlap and offer business-building synergies across industry segments (e.g., biopharma, medtech, veterinary) and product lifecycle stages.

Based on Deloitte's experience in helping companies manage regulatory change, we estimate that life science companies will need to invest in significant programmes over the next few years to implement the changes necessary for full compliance. By taking a proactive approach to tracking and monitoring the regulatory developments and understanding their independent and combined impacts to the business, companies can be well-equipped to comply in a timely manner, differentiate themselves in the marketplace, and be part of defining tomorrow's regulatory platform. This paper looks at the regulations that are in train and are expected to be implemented over the next few years, and poses considerations and next steps for all life sciences companies that supply products to the EU.

Identification of Medicinal Products (IDMP) Data Standards

The IDMP data standards² are being developed and implemented by the International Organisation for Standardization (ISO), regulators, trade associations and other stakeholders in response to a worldwide demand for internationally harmonized specifications for medicinal products. IDMP consists of five standards (Figure 3) allowing for the definition, characterization, and unique identification of regulated pharmaceutical products across their lifecycle, from early clinical development through marketing authorization, ongoing management, changes and, ultimately, withdrawal.

Figure 2: IDMP is composed of five standards



Under the IDMP standards, pharmaceutical companies will be required to electronically submit detailed product data and maintain it on an ongoing basis. In doing so, this will:

- Help facilitate the creation of global drug dictionaries and product dossiers
- Link product and safety information across global regulatory agencies
- Increase the industry's signal detection capabilities to quickly identify product risks and issues, including coordinating product recalls
- Connect critical product information within health care systems.

Becoming IDMP-compliant will drive pharma organisations to make significant changes to current product-related processes and systems, ushering in a new era of cross-functional collaboration and paving the way for transformational benefits beyond compliance.

Business impacts

If not already doing so, organisations will need to:

- Assess IDMP readiness and understand its magnitude;
- Create awareness and alignment among executive stakeholders and cross-functionally (commercial R&D and supply chain);
- Plan and secure funding, executive sponsorship, and resources;
- Understand the evolving regulations, implementation guidelines and iterations;
- Understand the timeline and consequences of not meeting regulations;
- Understand the IDMP data model and where data resides in the organization;
- Be proactive and have a comprehensive strategy to ensure a smooth transition to IDMP requirements;
- Develop a comprehensive internal communication plan.

Medical Devices Regulation

In June 2016, the European Parliament and the Council of the European Union reached an important milestone by adopting the far-reaching EU Medical Devices Regulation,³ which is expected to be finalized in Q2 2017. There have been increasing calls for greater control and stringent monitoring of medical devices in the wake of the PIP breast implant scandal,⁴ a widespread hip replacement recall, and other incidents which have highlighted the current system's regulatory weaknesses. The new regulation aims to safeguard prompt and timely access to innovative devices for both patients and medical professionals, improve coordination between EU member states, and re-establish public confidence.

The Medical Devices Regulation introduces requirements that place greater responsibility on EU member states and alters many facets of the medical device business. Relevant organisations will have three years to implement the broad cascade of new rules for virtually all types of medical device products. The significant changes introduced by the regulation are:

- **Scrutiny process:** The European Commission (EC) will be able to review recommendations for CE Marking prior to approval.
- **Common technical specifications:** The EC's ability to create common technical specifications (CTS) will be expanded to all devices.
- **Review of notified bodies:** Only newly created Special Notified Bodies will be able to issue CE Certificates for high-risk devices such as implants.
- **Audits for notified bodies:** Notified Bodies will be audited for compliance with the new regulations jointly by two Competent Authorities (i.e., the regulatory body for each member state).
- **Unannounced audits by notified bodies:** Manufacturers will be subject to unannounced audits by Notified Bodies. In vitro diagnostic (IVD) manufacturers will experience the most significant changes under the new law. Currently, only one in five IVD products requires Notified Body involvement, but expected changes will require 80 percent of these products to have Notified Body involvement.
- **Reclassification of medical devices:** Spinal implants, devices that control and monitor active implants, nanomaterials, aphoresis machines, and combination products will be reclassified as Class III devices requiring design dossiers.
- **Identification and traceability of devices:** A Unique Device Identification (UDI) system will be required for labelling, and the European Databank on Medical Devices (Eudamed) will be expanded. Manufacturers will need to provide a summary of safety and clinical performance for class III devices and also for implants of lower classification.
- **Clinical evaluation and investigations:** The new regulation will put in place a regimen for clinical investigations. It will introduce new concepts relating to clinical evaluation and clinical investigation, as well as a mandatory post-market and clinical follow up (PMCF) and periodic safety update reports.
- **Post-market surveillance (PMS), vigilance, and market surveillance:** Under the regulation, PMS and vigilance requirements will be revisited. Manufacturers will consequently need to amend their PMS and vigilance procedures.
- **Change in format of technical files:** Formatting of declarations of conformity and technical files will be revised under the new regulation. The new format requires manufacturers to create a summary document for each section instead of providing complete protocols and reports.

These changes from a directive to a regulation seek to deliver better harmonization among EU member states and are a clear move towards improving the patient safety profile to better reflect the medical device area. Manufacturers will need to carefully consider the impact and the financial implications of the new and more stringent requirements for medical devices and plan early for a transition to the new regulation.

Business impacts

Companies will need to:

- Develop and implement a transition strategy for affected devices, including a gap analysis of: existing technical files against new requirements and re-registration where required; the quality management system (QMS) as well as current clinical evaluation, post-market clinical follow-up method, and clinical investigation plans against new requirements
- Select and mandate persons responsible for regulatory compliance
- Prepare for revision and relaunch of standard operating procedures (SOPs) including training requirements
- Prepare for new relabeling and repackaging requirements, and traceability systems for the supply chain



Clinical Trials Regulation

The new Clinical Trials Regulation,⁵ which came into force at the end of May 2016, replaced the Clinical Trial Directive 2001/20/EC. It was acknowledged that the directive contributed to a significant decline in the number of clinical trials conducted across Europe, and increased the administrative burden and the time to launch new trials by 90 percent.⁶ The directive was broadly criticised by patients, researchers, and industry for its disproportionate regulatory mandates, including high costs and a lack of harmonised rules for multinational clinical trials.

The new regulation seeks to provide a single, unified system for trial sponsors and member states which, in turn, will enable harmonization with the enhanced EudraVigilance legislation (see next section) and provide a simplified solution for submitting both Suspected Unexpected Serious Adverse Reactions (SUSARs) and Adverse Safety Reporting (ASRs).

Patient safety is at the heart of the Clinical Trials Regulation, which has been given a further boost by the linkages provided by the Clinical trials (CT) portal, which introduces far-reaching changes for clinical trial sponsors and member states alike. It also seeks to increase transparency of clinical trials results, data, and their outcomes. The regulation mandates that the EMA has to deliver, update, and maintain a number of IT platforms and systems to improve how clinical trials are applied for, assessed, and monitored in the EU.

The EU-CTR regulation will be binding for all member states and will, therefore, confirm identical rules throughout the EU. Member states will no longer implement the directive in their national legislation; instead, an EU regulation will automatically apply to all interventional trials in Europe. This provides a welcome level of consistency. Intrinsic simplifications brought by the new regulation include:

- Streamlining the procedures for assessing and authorising clinical trials, removing duplication and reducing delays in launching new clinical studies
- Introducing a lighter regulatory regime for trials conducted with medicines that are already authorised and which pose only minimal risk compared to normal clinical practice
- Simplifying reporting requirements, sparing researchers from submitting largely identical information on the conduct of the study to various bodies
- Formally recognizing co-sponsorship, which acknowledges that a trial can be led by more than one organisation
- Introducing the concept of a single decision on a clinical trial, which will replace the previous separate approvals given by the National Competent Authorities and Ethics (NCAE) Committees. This also subsequently reduces administrative burden on the Member States Concerned (MSC), particularly the elected Reference Member State (RMS).

The EU will host a centralised solution for clinical trials applications (The CT Portal and Database), which aims to harmonise clinical trials which are performed in different Member States through a single application submission. The EU CT portal and database should be available for independent audit by August 2017. If the systems pass the audit, the regulation will go into effect in October 2018.

In addition to the primary change of repealing the clinical trial directive and moving to the new regulation, there are also changes to the Good Clinical Practice (GCP) Commission Directive 2005/28/EC⁷ and the Good Manufacturing Practice (GMP), Commission Directive 2003/94/EC.⁸ Both directives, to the extent that they concern investigational medicinal products, will be replaced by the respective new acts:

01. Implementing act on the detailed arrangements for the inspections procedures, including inspector qualifications and training (Defined in Article 78(7) of the regulation (EU) No 536/2014 on clinical trials on medicinal products for human use)
02. Delegated act on principles and guidelines of GMP and detailed arrangements (Defined in Article 63(1) of the regulation (EU) No 536/2014 on clinical trials on medicinal products for human use).

Changes instigated by the directive will become applicable in early October 2018. There will be a transition period of at least three years from when the regulation becomes effective to when the existing EudraCT is decommissioned. During the first year, clinical trial studies can be entered in both new and old systems. Companies will be allowed the full three years to make significant modifications and assessments, either before the regulation became effective or in the first year after it became effective if the sponsor opted for the old system (EudraCT).

The new Clinical Trials Regulation offers greater increased transparency into clinical trials and their outcomes. Which aims to address the growing demand for access to clinical trial information from researchers, patients, and health care professionals. However, for life science companies, disclosing clinical trial information requires a huge cultural shift, given that they operate in a very competitive, high-risk/high-reward environment. Over the last few years, an increasing number of life sciences companies have adopted a more open and transparent policy for their clinical trial outcomes, irrespective of whether the results are positive or negative.⁹ As a result the life science and health care sectors have benefited from more thorough analyses of trials, better explanations of treatment outcomes, and help in identifying additional uses for products.

To discourage unfair commercial use of the trial outcomes data, the EMA has defined a clinical reports publication process, with onscreen reports available for any user with a simple registration process; and downloadable clinical reports available only to identified users. Both situations will be governed by dedicated terms of use.¹⁰

Business impacts

Companies will need to:

- Prepare and conduct training on new SOPs, adapt clinical trial application processes and implement a suitable system for notifications
- Monitor member state-level implementation, as each may need to adapt national systems to achieve a 'single opinion.'

Enhanced EudraVigilance System

Updated EU pharmacovigilance legislation that came into effect in 2012 introduced significant changes to electronic reporting requirements for suspected adverse reactions. This was done in order to support better safety monitoring for medicines and provide a more efficient system for regulators, manufacturers, and health care providers. In response, the new legislation requires the EMA to enhance EudraVigilance to deliver simplified reporting, better quality data and improved searching, analysis, tracking functionalities, and implement the new ISO International Conference on Harmonisation (ICH) standard on individual case safety report (ICSR) (27953-2:2011). Implementing the new ICSR standards will require significant efforts including system upgrade, business process review and providing training to the database users.

Business impacts

Companies will need to:

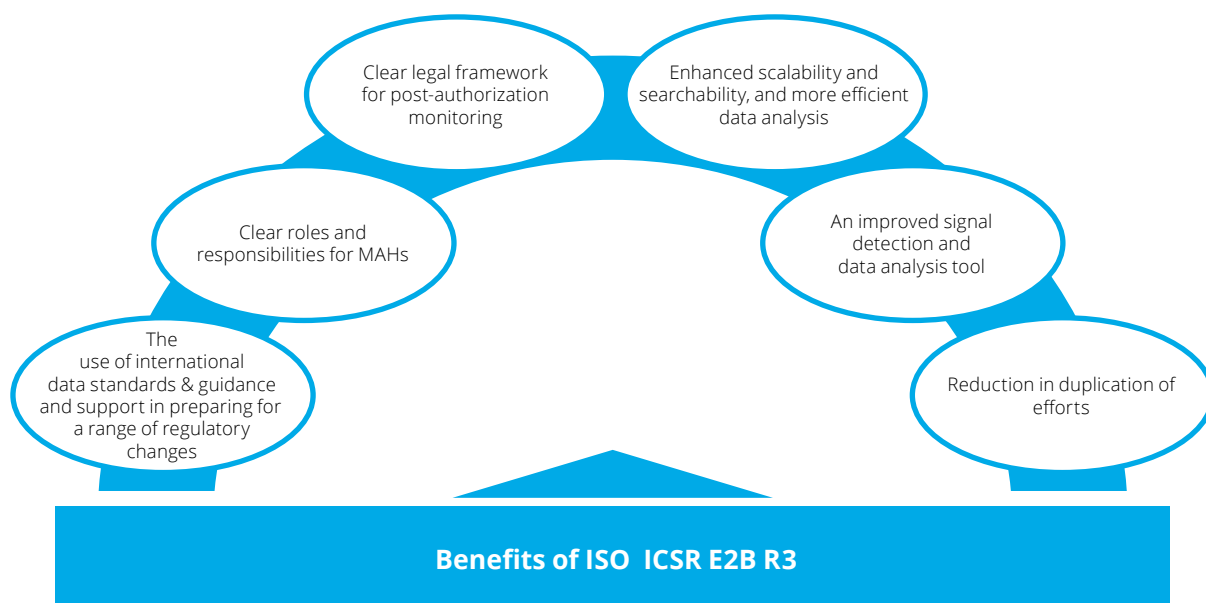
- Move from the current ISO ICH E2B R2 standards for electronic reporting of ICSRs to ISO ICH E2B R3 standards.
- Future use of ISO IDMP terminologies, once available, in the submission of ISO ICSR messages
- Centralisation of ICSR reporting in the EU and forwarding of national cases to the relevant NCA.¹¹

Planned changes to clinical trial reporting requirements include:

- Use of ISO ICSR E2B R3 standards in the reporting of Suspected Unexpected Serious Adverse Reactions (SUSARs)
- Use of ISO IDMP set of standards and terminologies, once available, in the submission of ISO ICSR messages
- Development of a standard, web-based structured form for SUSARs reporting by sponsors to EudraVigilance; this form would be ISO ICSR E2B R3-compliant.

Following the move to simplified reporting and the implementation of the ISO E2B R3 standard, industry stakeholders are expected to see a number of benefits (Figure 4):

Figure 4: Benefits of ISO ICSR E2B R3



Falsified Medicines Directive

The serious health threat posed by falsified medicines led to the EU adopting Directive 2011/62/EU,¹² which is often referred to as the Falsified Medicines Directive (FMD), which became applicable across the EU in January 2013. To avoid making EU legislation overcomplicated, a system exists for delegating to the EC limited powers to make minor changes to laws. This is on the provision that these laws do not affect the “core” legislation decided by European Parliament and the Council. Therefore, in parallel to the core legislation for the FMD, the EC started work on a Delegated Act ((EU) 2016/161) to ensure uniformity and standardization of key safety features required by the legislation.

The adoption and subsequent publication (in February 2016) of this Delegated Act begins a three-year timeline for implementation at EU member state level. With targeted implementation set for 2019. The IDMP Task Force is working on how IDMP product data can be linked to the FMD. For example, there is a possibility that IDMP can use a product’s Global Trade Item Number (GTIN) as part of the FMD. It also has been recommended on FMD to integrate the European Medicine Verification System (EMVS) with IDMP’s master product and organisational data.

Business impacts

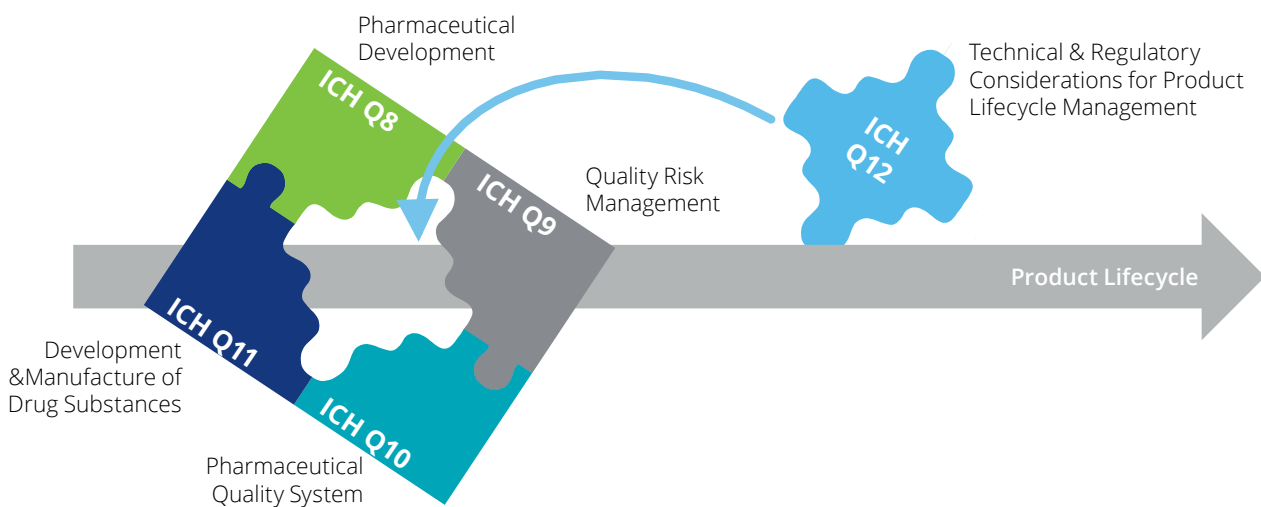
Under the FMD, all life science manufacturers, parallel traders, re-packagers and contract manufacturers will have to make sure they have adapted their packaging lines and systems to comply with the delegated act by the deadline. They will also need to manage and exchange the highly complex set of product information and serialisation data with their supply chain business partners. More specifically, this includes:

- FMD diverse rules for Active Pharmaceutical Ingredient (API) producers, guidelines for GMP of active substances, logos for online pharmacies, and on-package authenticity features known as safety features
- The safety feature regulations impose the greatest challenge for data management as well as transaction processing challenges for all stakeholders across the supply chain, with on-package authenticity features coupled with new serialization, compliance reporting, and verification regulations
- FMD requires serialization at the saleable pack or secondary level.
- MAHs have two primary reporting and notification requirements under FMD: product master data and serialized product pack data
- FMD provides for verification of safety features, including the serialized product identifier, at least once before the product leaves the supply chain and is dispensed to the patient. This can be a highly complex process if the supply chain involves wholesale distributors or parallel importers.

ICH Q12

The definitions on properties and product methods for drug substances have been published in the ICH quality guidelines Q8-Q11. These guidelines describe standards for the substances' chemical, biological, and physical properties. However these guidelines do not capture the product lifecycle, particularly in regards to changes in the production process. ICH Q12¹³ aims to fill this gap in the guidelines by allowing more productive and efficient management of Chemistry, Manufacturing and Controls (CMC) post-approval changes while promoting continual improvement, strengthening quality, and facilitating reliable product supply (Figure 5).

Figure 5: ICH Q12's role in drug production process



ICH Q12 adoption will occur in phases and will affect:

- Regulatory Dossier – Improve post approval changes by gaining efficiency and ensuring continued support of products
- Pharmaceutical Quality System (ICH Q10) – Improve knowledge and change management systems
- Post-approval Change Management Plans and Protocols – Establish criteria for managing and submitting post-approval changes.

ICH Q12 adoption is expected to benefit patients, pharmaceutical/ biotech companies, and regulators through continual improvement of post approval processes. Potential benefits include:

- Improved reliability of the pharmaceutical supply through CMC change management processes across the product lifecycle
- More standardized and useful regulatory dossiers
- Enhanced use of regulatory tools for Post-Approval Change Management Protocol
- Increased manufacturing efficiency and continual manufacturing process improvements
- Reduced product variability
- Support for risk-based regulatory oversight.

Although not all regulatory authorities may adopt the ICH guideline directly, ICH Q12 will surely impact regulatory requirements globally.

Business impacts

Companies will need to:

- Plan to implement global dossiers with defined design parameters (e.g., critical quality and process parameters across all regions).
- Prepare for global alignment within the regulatory affairs team and designate a single global product owner and/or global CMC owner.
- Implement a repository that stores product-specific and region-specific regulatory agency commitments and summaries of relevant global guidance and reporting categories.

Annex 21 – Importation of Medicinal Products

Medicinal products manufacturing is increasingly taking place outside of EU supply chains and is becoming larger and more complex due to industry globalisation. These trends increase the risk of counterfeit and unsafe products entering the EU health system.

The FMD described earlier confers product security responsibilities to manufacturers and importers in three important areas:

- Importers must hold manufacturing authorisations (MIA) in the EU
- Medicinal products must be tested and certified by a Qualified Person
- Importers are obliged to comply with GMP.

As a consequence, more than one license might be needed if various manufacturing sites are involved.

Regulators and industry stakeholders have requested clarity on requirements for importers. In response, the GMP/GDP Inspectors Working Party is planning to implement a new Annex 21 to the EU GMP guidelines. These guidelines aim to address medicinal products which are manufactured in these countries and imported into the EU, and the issue of multiple licenses being required if various sites are involved. The main goal of Annex 21 is to provide additional guidance on the GMP requirements that are of particular relevance to importers and on the extent those requirements apply to the different entities involved in importation activities.¹⁵

It is anticipated that the potential duplication of import testing for products at the country level will be clarified. A repetition of quality testing is not anticipated to increase public health protection. On the contrary, it could potentially have a negative impact in delaying batch release, reducing shelf life and, therefore, increasing the risk of potential drug shortages. Duplicated import testing is not deemed to prevent the entry of counterfeit products but has been recognized as a significant burden on national competent authorities and industry.

The status of this Annex's progression is unclear but when distributed, it is anticipated that the new guideline should provide clarity on import requirements and negate the need for double testing upon importation.

Business impacts

Companies will need to:

- Assess whether more than one licence might be needed, if various manufacturing sites are involved in producing a drug
- Check the definition of "an importer" after the guidance is finalised.

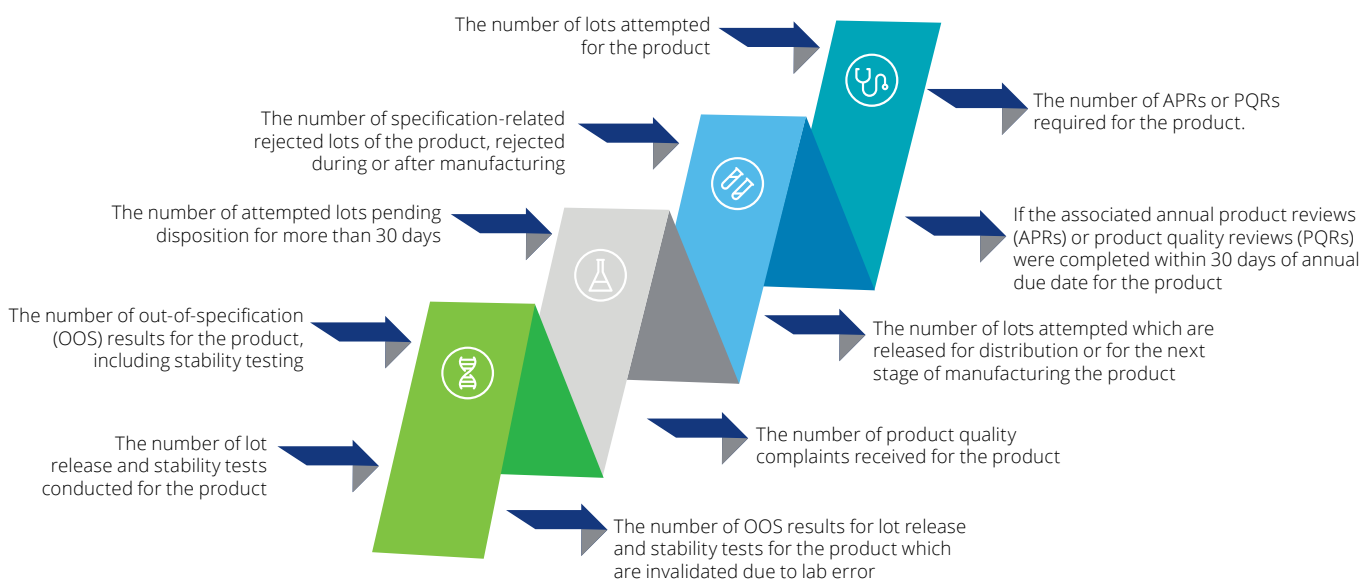
Manufacturing Quality Metrics

Multiple quality issues continue to be a concern and challenge for regulators in the EU and around the globe as they continue to concurrently issue recalls and warning letters.

In July 2015, the U.S. Food and Drug Administration (FDA) released draft guidance for the pharmaceutical industry, "Request for Quality Metrics: Guidance for Industry."¹⁶ This set of measurements is designed to confirm that pharmaceutical manufacturers produce quality medications and drive continuous improvement throughout a product's lifecycle. The reach of this guidance extends beyond the United States, and will impact life sciences companies that engage contract manufacturing organisations (e.g. labs, sterilizers and packagers) in the processing and preparation, of a drug product or API used in the manufacturing of a drug product.

The FDA currently uses quality metrics as part of its process validation lifecycle and pharmaceutical quality system (PQS) assessment. The guidance outlines FDA's authority to require owners and operators of such pharmaceutical establishments to provide upon request records and information that the FDA may inspect. Specifically, the FDA will request 10 baseline quality metrics as part of its analysis (Figure 6):

Figure 6. Quality metrics



In June 2016, the FDA released the technical guide for implementing the draft guidance, "Quality Metrics Technical Conformance Guide."¹⁷ This guide outlines the recommended data the industry should submit to the FDA and clarifies FDA expectations for the quality of the metrics required.

Industry standardization would help to ensure that metrics collected by the FDA could be defined and measured accurately and efficiently – currently, companies and even departments within companies might collect data in different ways and use different terminology and definitions. This can make it difficult to identify and compare quality issues between firms, and, the FDA has acknowledged the importance of industry's input and agreement in standardization.

In addition to the quality metrics, there has been a proposal around a set of optional parameters focusing on quality culture. These center on creating metrics in three areas:

- Senior management engagement metrics to quantify whether senior managers who possess the means (resources and authority) to implement a change are involved with quality assessment, as well as the level of knowledge-sharing within the organisation
- Corrective and preventative action effectiveness metric to highlight quality systems relying solely on retraining. It will also give a clear picture of the overall levels of corrective and preventative actions an organisation takes
- Process capability or performance metrics to examine the enabling of statistical process controls.

Business impacts

Companies will need to:

- Review and align internal processes and IT systems to prepare and extract data for external reporting by product and by site; 100% traceability is required
- Estimate costs required for adjusting IT systems
- Assess and prepare for optional metrics including senior management engagement, CAPA effectiveness and process performance

Veterinary Product Proposals

The EC has released two new proposals for regulation by the European Parliament (EP), which could replace the current combined EU regulation for human and veterinary medicinal products (Regulation (EC) No 726/2004). The Proposal,¹⁸ which is subject to change, is scheduled for adoption in mid-2017 and implementation within 24 months of adoption.

The new legislation is designed to increase the availability of veterinary medicinal products (VMPs) throughout the EU while reducing administrative burden. It also will address the risk of antimicrobial resistance (AMR) by managing the availability of antimicrobials for use in animals. While the proposal makes many minor changes to the existing legislation, the following areas have the greatest potential impact to the EU veterinary pharmaceutical industry:

- Authorisations to manufacture, import, or export a VMP will require the VMP's intermediate products and excipients, as well as its active substances to undergo scrutiny
- A marketing authorisation (MA) for a VMP shall be valid for an unlimited period of time, with the exception of MAs for limited markets (Article 21 of the proposal for the regulations of the EU on veterinary medicinal products dated 10 Sept 2014) and under exceptional circumstances (Article 22), which require renewal after three and one years, respectively. Thereafter, MAs for limited markets and under exceptional circumstances may be granted for an unlimited period at the discretion of either the competent authority or the Commission
- All applications for centralised marketing authorisations will be electronic and will adhere to the format made available
- Information on product packaging may consist of pictograms agreed to be common throughout the EU
- The period of technical data protection will be increased for most species
- Homeopathic VMPs will be required to be registered and subject to fulfilment of the new criteria.

Business impacts

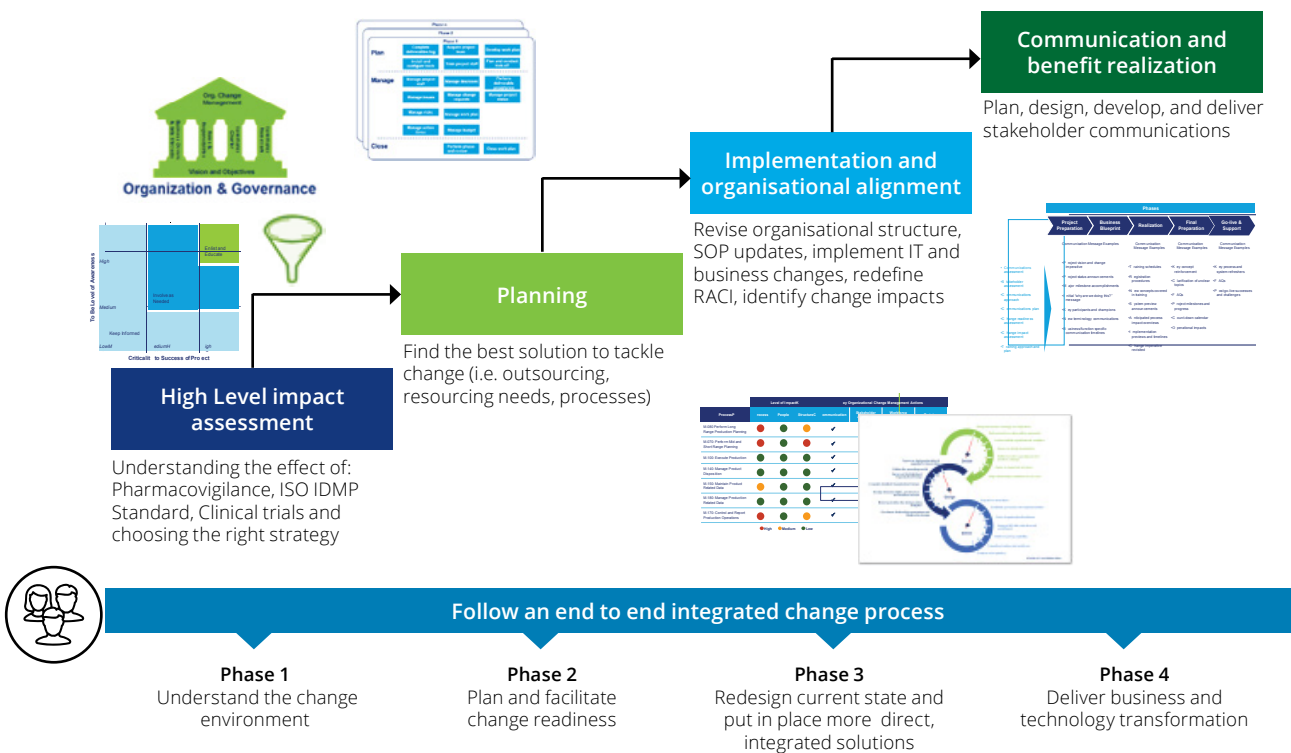
Companies will need to:

- Identify the potential for collaboration within the industry to develop centrally available modules required for veterinary-specific systems
- Assess the VMP proposals' impact on the ISO IDMP standards
- Adhere to new requirements to integrate eSubmission data into the product database (MAHs).

What should life sciences companies be doing now?

The EU life sciences regulatory landscape is evolving quickly and irrevocably. Significant transformations are imminent and several proposed longer-term initiatives are underway. It is important, therefore, that companies track and monitor legislative and industry developments, as the changing environment holds significant license-to-operate implications for life science companies that supply or look to supply products to the EU. Although timelines continue to fluctuate, manufacturers, distributors, providers, and other stakeholders should continually evaluate the individual and collective impacts of new regulations and take a proactive approach to managing regulatory change (Figure 7).

Figure 7. Taking charge of the regulatory environment



Regulatory change is not just a concern for R&D departments; its reach can span an entire organisation. While upgrading or establishing cross-functional regulatory governance is challenging, doing so can provide the operational alignment and compliance culture executives need to manage the complexities of a harmonised and increasingly complex global regulatory landscape. It can also help organisations differentiate themselves from their peers by articulating to patients the rigor invested in the development, manufacture, and distribution of products aimed to deliver improved health and quality-of-life outcomes. Such a stance can help build company value and provide an opportunity to address some of the reputational issues facing the pharmaceutical industry.

The changes in EU life sciences regulations are being made to improve knowledge; to standardise, simplify, and align regulations and procedures; and to increase efficiency and reliability for manufacturers, distributors, service providers, Notified Bodies and member states – with the ultimate goal of protecting and improving patient safety.

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End Notes

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