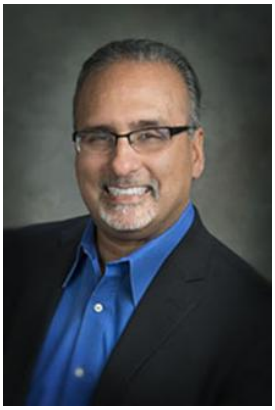
Regulations/Standards

Preparing for the New European Medical Device Regulations

Fri, 09/08/2017 - 9:28am by Bikash Chatterjee, Pharmatech Associates

The European parliament published new regulations for medical devices (MDR) and in-vitro diagnostics (IVDR) on May 5, 2017, capping almost eight years of negotiations between the European Union Council, Parliament, and Commission. Each regulation was published in the European Official Journal on May 25, 2017.



Bikash Chatterjee
Pharmatech Associates

The motivation to update the existing directives stemmed from inconsistent adoption by the European Union member states and an incident concerning fraudulent production of the Poly Implant Prothèse (PIP) silicone breast implants that highlighted weaknesses in the legal system in place at the time. This case damaged the confidence of patients,

consumers, and healthcare professionals in the safety of medical devices.

In addition, revision of the legislation was necessary to consolidate the role of the E.U. as a global leader in the sector over the long-term and to account for technological and scientific developments in the sector.

The new MDR will take effect three years from the publication date (May 26, 2020) and the IVDR will go into effect five years from approval (May 26, 2022). As a regulation and not a directive, the law will go into effect for all E.U. member countries and does not have to be adopted by each country's national authority. There is still work to be done before these new regulations are operational and it is expected that further supportive documents will be issued to standardize the necessary criteria to be fully compliant.

It may seem like a long time off before the new directives take effect, but the changes in these new regulations are significant and organizations with currently approved products and planned products for Europe will need time to prepare for them. Demonstrating compliance will require significant changes to the product development, manufacturing, quality assurance, clinical strategy, and data reporting systems and processes currently in place.

Key regulatory changes

Organizations with approved products or that plan to seek approval of a medical device or in-vitro diagnostic in the E.U. should pay particular attention to the following highlights.

Roles and responsibility of Notified Bodies

Sponsors can expect more scrutiny and surveillance. A Notified Body is an organization designated by an E.U. country to assess the conformity of certain products before being placed on the market. These bodies carry out tasks related to conformity assessment procedures

set out in the applicable legislation, when a third party is required.

All Notified Bodies will be re-designated under the new MDR/IVDR. In the case of specific high-risk medical devices, the new regulations have introduced a mechanism for scrutiny of a Notified Body's conformity assessment: i.e., Notified Bodies will have to notify competent authorities of certificates granted for such high-risk devices and the competent authority (and, where applicable, the European Commission) may, based on reasonable concerns, apply further procedures or request scientific advice from expert panels in relation to the safety and performance of any device.

Notified Bodies will also be required to have documented procedures regarding unannounced on-site audits of manufacturers and, when applicable, of subcontractors and suppliers. These obligations were recently emphasized following the February 16, 2017 Court of Justice of the European Union ruling, which stated that Notified Bodies are not under a general obligation to carry out unannounced inspections.

Device classification changes

The new regulations have expanded and changed device classifications, e.g., products for which a manufacturer claims only an aesthetic or another non-medical purpose (i.e., cleaning or sterilization) but are similar to medical devices, have been included into the scope of the new MDR. In addition, the definition of accessories has been enlarged, and the exception for custom-made devices has been narrowed.

Devices that are considered higher risk (including software that drives a device or influences the use of that device) have been re-classified as class III devices. Entirely new classification rules have been introduced for IVD medical devices, categorizing them into classes A through D. Manufacturers must assess all their devices and determine the applicable rules. The risk of different classification decisions by different E.U.

member states will be reduced, as the commission is given new powers to determine whether a specific product should fall within the scope of the MDR/IVDR.

Post-market clinical surveillance

By the end of the transition period, every manufacturer's post-market surveillance system must include a post-market clinical follow-up (PMCF), or, for IVD medical devices, a post-market performance follow-up (PMPF), to continuously update the clinical evaluation of the device, reflecting current non-binding MedDev guidance. For implantable and class III devices, manufacturers must draw up a "summary of safety and clinical performance" that will be validated by a Notified Body and made publicly available. Manufacturers must review their systems against the new MDR/IVDR, implement all new requirements, and train their staff.

Supply chain control and traceability requirements

The new regulations will demand much greater supply chain control. Notified Bodies will want to see evidence of a mechanism for quick access to pertinent technical data from suppliers and contract service providers during audits. Traceability has been emphasized in this new guidance and a Unique Device Identification (UDI) program must be implemented to allow any medical device to be identified and traced through the supply chain. Each participant in the supply chain, including distributors and importers, will have their own regulatory responsibilities. The UDI, along with a significant amount of data pertaining to vigilance and post-market surveillance, will be entered into an enhanced European Databank on Medical Devices (EUDAMED) and made publicly available to enable better-informed decisions of stakeholders.

Conclusion

The new MDR and IVDR are significant departures from the historical directives they are replacing. The changes do not grandfather programs and will become law across all member states at the end of the transition

period. Currently approved products and new submissions must consider the implications of these new regulations now during the transition period in order to be ready to align their programs with these new regulations.

Bikash Chatterjee is President and Chief Science Officer of Pharmatech Associates, a Hayward Calif.-based company that provides consulting and services to the regulated life science industry. Bikash has been involved in the biopharmaceutical, pharmaceutical, medical device, and diagnostics industry for over 30 years. His expertise includes site selection, project management, design, and validation of facilities for U.S. and European regulatory requirements.

RELATED READS

Better Safety and Traceability for Medical Devices

Brexit: The Aftermath for Universities and Students

EQUIPMENT

What Does the Brexit Mean for U.K. Science?

Europol Warns of New Terror Tactics, Fresh Threats to Europe

Forensic