Medical Device Regulations Transition Support

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PHARMALEX

OUR MEDICAL DEVICE EXPERTS PROVIDE A RANGE OF SUPPORT

PharmaLex's dedicated Medical Device team offers the breadth and depth of expertise to provide comprehensive support throughout the product lifecycle. We employ proven methodologies and hands-on support to optimize and customize Quality and Regulatory solutions which are delivered on time, in budget and with the highest quality.

The Medical Device Regulation (MDR - (EU) 2017/745) and In-Vitro Diagnostic Regulation (IVDR - (EU) 2017/746) present a significant challenge for medical device manufacturers. Our highly professional and experienced medical device team are available to provide support as required. Examples of some of the MDR/IVDR services we can provide are:

- MDR and IVDR gap assessments, analysis and remediation
- Scientific Advice Meeting management for devices and drug delivery cases
- Medical device classification review
- Clinical Evaluation/Performance Evaluation Plan and Report (CEP, PEP, CER, PER)
- Clinical study strategy and design
- Instructions For Use (IFU) and labelling updates/review
- Technical documentation preparation and management, including General Safety and Performance Requirements (GSPR)
- Creation of a Unique Device Identification (UDI) system including Basic UDI-DI
- Expert-led, pan-European Notified Body (NB) selection for selected device types
- Post-Market Surveillance (PMS)
    - Creation of PMS and Post-Market clinical follow-up plans
    - Vigilance reporting
    - Summary of Safety and Clinical Performance (SSCP)
    - Periodic Safety Update Report (PSUR)/Post-Market Surveillance Report creation
- Updates to the Quality Management System (QMS) to ensure MDR/IVDR compliance
- Notified Body Inspection Readiness and support
- Training