PHARMALEX
CONFIDENCE BEYOND COMPLIANCE

MEDICAL DEVICE REGULATIONS – MDR - (EU) 2017/745) AND IVDR - (EU) 2017/746

HOW CAN PHARMALEX HELP?

- MDR and IVDR gap assessments, analysis and remediation
- Classification review
- Drug-device combinations (Economic Operators, co-packed requirements, article 117)
- Clinical Evaluation/Performance Evaluation
- Clinical study strategy and design
- Instructions For Use (IFU) and labelling updates/review
- Technical documentation preparation and management
- Unique Device Identification (UDI) including Basic UDI-DI
- Notified Body (NB) selection
- Post-Market Surveillance (PMS) activities
- Quality Management System (QMS) support
- Notified Body Inspection Readiness and preparation.

PHARMALEX'S DEDICATED MEDICAL DEVICE TEAM OFFERS THE BREADTH AND DEPTH OF EXPERTISE TO SUPPORT COMPLIANCE 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. Our team members' experience include Regulators, Notified Bodies and Industry and cover a wide range of products.

DID YOU KNOW...
If you impact safety this does not preclude biosimilarity if it is an improvement (as long as efficacy is not impacted)

Clare Huntington

Director, Head of Medical Devices / IVD UK

Clare Huntington has over 12 years of medical device industry experience, including managing EU Technical Files, regulatory strategy, clinical trial submissions and post market surveillance including vigilance reporting. Prior to joining Pharmalex, Clare has held positions at the Medicines and Healthcare products Regulatory Agency, MedPass International, and Johnson & Johnson.

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REGULATORY TIMELINE

26 MAY 2017	26 MAY 2021	26 MAY 2022	26 MAY 2025 - 26 MAY 2027	1 JANUARY 2028	1 JANUARY 2029
Regulations enter into force	MDR fully applies (delay of 1 year)	IVDR fully applies	IVDs can be placed on the market under IVDD certificates/DoC (classification dependent)	Class III and IIb implantable devices (with exceptions) can no longer be placed on the market under MDD	Class Is, Im, IIa and remaining IIb devices, and up-classified class I devices can no longer be placed on the market under MDD

OJ Official journal of the European Union
NB Notified body
MDCG Medical Device Coordination Group
DoA Date of Application
COM European Commission
MDR Medical Device Regulation
IVDR In-Vitro Diagnostic Regulation

UK LEGISLATIVE CHANGES

Following Brexit, the UK is still in the process of drafting the new UK Regulation. Our team can support:

- Identifying the applicable requirements and guide clients through the ever changing landscape
- Act as UK Responsible Person and complete MHRA registration
- Advise on the differing rules applying to Northern Ireland.

INSIGHTS

Conditions to be met to qualify for the MDR extension

Conditions that must meet to be granted an extension as per the new Regulation (EU) 2023/607 regarding delays to MDR deadlines. These include:

- Devices must continue to comply with MDD/AIMDD
- There are no significant changes in the design and intended purpose
- Devices do not present an unacceptable risk for patients, users, third parties or public health
- Manufacturers must implement a QMS as described in MDR article 10(9) before 26 May 2024
- The manufacturer (or authorized representative) must have applied to a notified body for the conformity assessment of these devices, or the devices intended to replace them before 26 May 2024, with the agreement signed no later than 26 September 2024.

DID YOU KNOW...
In theory, the new EU MDR could be adopted by manufacturers of medical devices immediately after its entry into force in May 2017

ABOUT PHARMALEX

25+ YEARS
OF INDUSTRY EXPERIENCE

OVER 50%
OF OUR PROJECTS ARE GLOBAL

100% COVERAGE
OF ALL PRODUCT CATEGORIES INCLUDING MEDICINAL PRODUCTS, MEDICAL DEVICES, CONSUMER HEALTH AND VETERINARY

40+
HEALTH AUTHORITY MEETINGS PER YEAR WITH EMA/FDA/PMDA

95%
OF OUR PROJECTS PASSED SUCCESSFULLY THROUGH DEVELOPMENT PHASE WITHOUT MAJOR FINDINGS