QUICK REFERENCE GUIDE

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 labeling 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

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.

Clare Huntington

Associate Director,
Regulatory Affairs – Medical Devices

Clare Huntington has over 10 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	DECEMBER, 2020	26 MAY, 2021	26 MAY, 2022	26 MAY, 2022	26 MAY, 2024	2024-2025
Regulations enter into force	Eudamed Actor Registration available	MDR fully applies (delay of 1 year)	IVDR fully applies	Full Eudamed database available	AIII devices to be placed on the market under MDR or IVDR - MDD, AIMDD or IVDD no longer accepted under any circumstances	MDD, AIMDD, IVDD devices already on the market can continue to be made available

BREXIT

Our UK medical device team are able to provide support in navigating the Brexit requirements.

- **Devices to be placed on the market from January 2021 should be registered with the MHRA (grace periods apply)**
- **A UK Responsible Person should be identified**
- **And then medical devices manufacturers should prepare for any required changes to documentation as required in order to comply with the UK Conformity Assessment requirements which must be met by June 2023**
- **The different rules applying to Northern Ireland should also be considered.**

INSIGHTS

Medical devices within the EU are currently regulated by 3 directives:

- Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) (1990)
- Council Directive 93/42/EEC on Medical Devices (MDD) (1993)
- Directive 98/79/EC of the European Parliament and of the Council on in-vitro Diagnostic Medical Devices (IVDD)

On 5 April 2017, 2 new Regulations on medical devices and in-vitro diagnostic medical devices establishing a modernized and more robust EU legislative framework to ensure better protection of public health and patient safety were adopted.

They entered into force on 25 May 2017 and will progressively replace the existing directives after a transition period.

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