PHARMALEX

MEDICAL DEVICES FOR THE PHARMACEUTICAL INDUSTRY

PharmaLex's dedicated Medical Device team offers the breadth and depth of expertise to provide comprehensive support throughout the product life-cycle. 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 EU Medical Device Regulation (MDR) ensures high standards of quality and safety for devices being produced or marketed in Europe. This new regulation impacts a number of products within the pharmaceutical industry. The PharmaLex team is available to help you navigate these requirements, you can reach us at contact@pharmalex.com.

MEDICINE TO MEDICAL DEVICE RE-CLASSIFICATION

Many medicinal products do not contain a component that meets the definition of a medicinal product active substance (i.e. a substance that has a pharmacological effect). These products may be better considered as medical devices (if the action is purely physical). PharmaLex supports:

- Classification assessment
- Medical device technical documentation creation according to the MDR
- Quality Management System (QMS) updates
- Notified Body interactions
- Post-market continuous support

CO-PACKAGED MEDICINES AND DEVICES (PROCEDURE OR DOSING PACKS)

- Labelling review (to ensure compliance to both medicinal and medical device regulations)
- Medical device Importer / Distributor requirements (when using a delivery device from a 3rd party)
- Technical documentation and QMS updates for in-house manufactured devices

MEDICINE WITH AN INTEGRATED DELIVERY DEVICE COMPONENT

Article 117 of the MDR introduces the requirement to obtain a Notified Body Opinion (NBOp) for certain integrated delivery device components, even when the device component cannot be classified as a medical device in its own right, e.g., pre-filled syringes and auto-injectors. Any medicine Marketing Authorization Application (MAA) submission planned after 26th May 2021 (MDR date of application) may require a NBOp. This new requirement can lead to significant delays if not addressed well in advance of the MAA submission. PharmaLex supports:

- Classification assessment
- NBOp technical documentation creation
- Notified Body interactions

QP CONSIDERATIONS FOR DEVICE COMPLIANCE WHEN DISPOSITIONING COMBINATION MEDICINAL PRODUCTS

40+ nationalities

Provides you access to much needed and qualified resources locally and globally

1000+ highly skilled experts

33 offices in 21 countries

InnoPHLEX

DISCOVERY / NON-CLINICAL

CLINICAL DEVELOPMENT

AUTHORIZATION / APPROVAL

PRODUCT MAINTENANCE

SourcePHLEX

DELIVERING SUCCESS WITH CONFIDENCE

PHARMALEX IS A LEADING PROVIDER OF SPECIALIZED SERVICES FOR THE PHARMA, BIOTECH AND MEDICAL DEVICE INDUSTRIES

We guide you from early strategic planning activities and non-clinical requirements through clinical development, regulatory submission processes and post-approval / maintenance post-launch activities.

Our experts use **technology-enabled solutions** to support you through the entire product lifecycle. We deliver exceptional results – going above and beyond the standard to deliver tailor-made solutions worldwide.

The PharmaLex Group now has over **1000** employees, with **33** offices in **21** countries and more than **600** satisfied clients worldwide.

Stay **one step ahead** of essentials requirements needed by health agencies. Our knowledge accelerates your business success...

Knowledge. Accelerated.

CONTACT US

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STRATEGY & CONSULTING REGULATORY AFFAIRS PHARMACOVIGILANCE QUALITY MEDICAL AFFAIRS

1000+
SUBJECT MATTER EXPERTS WORLDWIDE

25+ YEARS
OF INDUSTRY EXPERIENCE

9/10
TOP PHARMACEUTICAL COMPANIES ARE OUR SATISFIED CLIENTS

40+ NATIONALITIES
ON STAFF, INCLUDING FORMER FDA AND EMA EXPERTS

50+%
OF OUR PROJECTS ARE GLOBAL