cencora
PharmaLex

Are you confident in your combination product requirements?

Ensuring you understand, plan for and comply with applicable requirements is pivotal to commercializing your product.

We have the know-how to coordinate combination product registrations and to support them through the entire lifecycle

Regulatory requirements for combination products vary significantly by region, and registration frequently necessitates a dual assessment approach. We can manage the intricacies of borderline products and navigate unique regulatory pathways in all major markets.

USA

- Requests For Designations (RFD/ Pre-RFD)
- FDA pre-submission meetings
- Investigational Device Exemptions (IDE)
- Authoring of device-specific sections within module 3 for INDs, NDAs, and BLAs
- Device-led applications (e.g. 510(k), De-Novo, PMA)

EU

- Notified Body opinion under MDR Article 117 and GSPR compliance assessments /Declaration of conformity
- Device CE Marking (MDR)
- Importer/Distributor requirements
- Clinical trial applications
- Authoring of device specific information for MAA dossier

Australia

- TGA pre-submission meetings
- Boundary product determination
- Priority review pathways
- Device Conformity Assessments
- Drug Applications

Global support in simplifying the path to full market access

Technical documentation development | **Quality Management Systems** | **Post-market surveillance and support**

We have the expertise to support you in navigating dual regulatory pathways involving both pharmaceutical and medical device regulation.

Regulatory Strategy Development: Including consultations with the national competent authorities and contacts to Notified Bodies

Technical documentation development: Support in development and compilation of product technical files for all classes of products.

Quality Systems Management: Tailored to support the unique requirements of combination products.

Clinical Development Support: For trials involving combination products, supporting compliance with both drug and device requirements.

Manufacturing and Scale-Up Support: Addressing the complexities of manufacturing products that combine pharmaceuticals and devices.

Post-market surveillance: Support through the entire product lifecycle including change management, surveillance, license holding, vigilance and recalls.

Your trusted partner in leading the way for your combination product's classification and regulatory approval strategy across the globe

25+
years of industry experience

200+
experienced local representatives support our global coverage

9/10
of the top pharmaceutical companies are our clients

60%
of our client base are small and midsize enterprises

50+%
of our projects are global

Have the right expertise by your side

www.pharmalex.com

Contact us