cencora
PharmaLex

Are you struggling to understand Companion Diagnostic requirements?

Ensuring you understand, plan for and implement applicable requirements is pivotal to a smooth commercialization of your product.

We have the know-how to support your companion diagnostic (CDx) project through its entire lifecycle, from idea generation all the way through registration and postmarket.

Regulatory requirements for CDx vary significantly by region. They must be aligned with a specific medicinal product (International Non-proprietary Name, INN) registration. This process necessitates dual expertise, we can manage the intricacies of CDx and their unique regulatory pathways in all major markets.

EU

- In Vitro Diagnostic Medical Device CE Marking IVDR (EU)2017/746
- Competent authority/EMA consultation procedure required for notified body CE marking (incl. Summary of Safety and Performance (SSP), Instruction for Use (IFU) and application form)
- Importer/Distributor requirements
- Competent authority clinical performance study (CPS) applications, ethics committee interactions / combined studies for CDx and medicinal product
- Authoring of device specific information for MAA dossier including SmPC

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)

Australia

- Classification and pathways determination
- TGA pre-submission meetings
- Priority review pathways
- Technical File Authoring
- Drug Applications
- Device Conformity Assessments and ARTG 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 all aspects of Pharmaceutical and In Vitro Diagnostic (IVD) medical device strategies.

Strategy Development: Including regulatory, distribution and consultations with the national competent authorities and contacts to conformity assessment bodies

Market Access Consulting: Reimbursement assessments, market research and evidence generation

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 CDx.

Clinical Development Support: Supporting compliance with both drug and device requirements for combined studies.

Global Logistics: Tailored transportation, storage and financial services

Manufacturing and Scale-Up Support: Addressing the complexities of manufacturing IVD assays which must be closely aligned with related drugs and are crucial for using those drugs safely (only when giving clear advantage and without causing any unnecessary side effects for patients).

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 CDx product's 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