cencora
PharmaLex

Add excellence to APIs and excipients

We help you manage CEP submissions, CMC authoring, and EDQM regulatory requirements.

Our Drug Substance Service support offers specialized expertise to navigate the complex landscape of regulatory approvals

- Support in navigating the regulatory approval process for your drug substance, e.g. CEP, DMF, ASMF
- Support in resolving delays or issues with CEP submission, CMC authoring, or meeting revised EDQM requirements
- Communication with both API manufacturer's clients and European authority EDQM
- Support for requirements regarding impurities like nitrosamine formation, elemental impurities, fate and carry-over of impurities
- Registration of drug substance information in different regions e.g., KASA, CEP 2.0, international DMF/ASMF sub requirements
- International DMF - rethinking data management considering the new CTR/CTIS portal

Are you aware about the Revised EDQM/CEP application forms?

Streamline the regulatory process | **Meet the timelines** | **Accelerate time-to-market for API**

We have the expertise to support you at every step of the regulatory process, from development to post-approval regulatory activities.

- In-depth knowledge and experience in CEP submission and revision/ renewal procedures at EDQM
- Proficiency in CMC authoring tailored to specific regulatory requirements
- Expertise in navigating EDQM requirements and ensuring compliance
- Proven track record of successfully guiding clients through the regulatory approval process
- Control strategy support to ensure the quality of the API
- Authoring support to meet assessors' expectations for a clear understanding of the substance's specification and manufacturing process

Let us be your trusted partner in managing global regulatory requirements and staying updated with changing regulations

25+
years of industry experience and knowledge

9/10
of the top pharmaceutical companies are our clients

50+%
of our projects are global

200+
experienced and certified local representatives support our global coverage

API Active Pharmaceutical Ingredient
CEP Certificate of Suitability to the monographs of the European Pharmacopoeia
EDQM The European Directorate for the Quality of Medicines & HealthCare
CMC Chemistry, Manufacturing, and Controls
DMF Drug Master File
CTR Clinical Trial Regulations
CTIS Clinical Trial Information System

Have the right expertise by your side

www.pharmalex.com

Contact us