Regulatory Affairs by ELC

Drug registration in the European Economic Area

Applicants can register pharmaceutical products in the European Economic Area (European Union + Iceland, Liechtenstein, Norway) via:

- National procedure (1 EEA member state),
- Decentralised procedure (several EEA member states)
- Centralised procedure (all EEA member states)

GMP certification

The manufacturer of a finished product needs to receive the GMP certification from an agency located in the EEA

Batch release & batch testing (BR/BT)

Mandatory for any registration of a product manufactured outside of EEA

EEA pharmacovigilance system

The applicant must set up a pharmacovigilance system in the EEA, appoint a EUQPPV and a deputy, prepare a risk management plan to be included in the dossier and start a global literature monitoring for the product of interest.)

EEA dossier

- A registration in the EEA requires preparation of the common technical document CTD as per ICH (International Council for Harmonisation) guidelines.
- The CTD, organised in 5 modules, contains all the information related to the medicinal product, manufacturing process, clinical and pre-clinical data and is required to be submitted in the eCTD format by an EEA entity.

MA holding

For registration in the EEA, the MA holder and applicant must have a legal entity in the EEA

MARKETING AUTHORISATION APPLICATION

- The MA application can be submitted to one, several or all the EEA member states, depending on the type of application.
- In certain Member states a local representative might be required.

How can ELC support your project?

ELC can guide you through the process and support you fulfilling all the regulatory and pharmacovigilance requirements before, during and after approval, offering:

regulatory strategy - dossier preparation, due diligence and gap analysis - BR/BT site in the EEA - translation and readability testing - MA holding – submission management - end-to-end pharmacovigilance

To find out more: info@elc-group.com

Concept to Compliance

www.elc-group.com