TERANGA GROUPE

TECHNICAL & REGULATORY AFFAIRS

Do you need a technical & regulatory expertise ?
CEBIPHAR is your partner for the CMC part of your dossier.

Our core competencies:

- Regulatory intelligence
- Audits and writing of dossiers
- Consulting, technical & regulatory support for APIs, human and veterinary medicines

We have answers to your technical & regulatory needs, should they be planned or unforeseen

Product buying: technical & regulatory assessment of the CMC dossier.

Selection of a new API sourcing: technical & regulatory assessment of ASMF or scientific data

New product registration: data presentation & writing of MA dossier (Modules 3 and 2.3/Parts 2 and 1.C).

Clinical trial: writing of the IMPD dossier.

Troubleshooting

New site, process, method, packaging... : strategical support, variations, classification of variations & writing of the Quality part of the dossier.

Assessment of the industrial usage vs the MA dossier

Dossier update: compilation of initial dossiers, answers to authority questions & variations.

Support to protocol design: process or method validation, stability protocols.

Electronic submission: writing on your templates, electronic files in accordance with eCTD requirements, (V)NeeS.

Our assets

A regulatory experience combined with an analytical and galenic expertise

A sophisticated technical platform:

- physico chemistry laboratory
- microbiology laboratory
- stability storage infrastructure

CEBIPHAR

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