CEHTRA

Your Specialties, Our Expertise

Toxicology Expertise

CMC Support

- Safety Assessment: PDE, OEL/OEB, qualification of impurities, extractables-leachables, *In silico* assessment (QSAR)

Regulatory Dossiers

- Authoring nonclinical sections of CTA (IMPD), IND, IB & Briefing Documents
- Updating and making a critical review of nonclinical modules (CTD)

Preclinical Development

- Development plans, Study monitoring (protocol validation, study follow-up, discussion of the results), Gap analysis

Environmental Assessment

- Study monitoring, Preparation of the Environmental Risk Assessment (Phase I & Phase II), Defense of the Dossier

For the safety and efficacy of both human & veterinary pharmaceuticals, CEHTRA can support you in:

- The safety of your CMC activities (PDE, OEL/OEB, qualification of impurities)
- The drafting of your regulatory dossiers (nonclinical modules)
- The definition of your preclinical development plan
- The Environmental Risk Assessment (ERA) for your MAA dossier

Value-added Services

- Recognized Toxicologists & Ecotoxicologists Team
- *In silico* Methods: QSAR Support (Derek, Leadscope)
- Data & Bibliography Analysis
- Independence from CROs
- Dossier Defence
- A demonstrated expertise in the pharmaceutical field

Key Sectors

Biocides

Chemicals (REACH)

Cosmetics

Global Chemicals Notification

Industrial Hygiene

Medical Devices

Packaging

Pharmaceuticals

Plant Protection

REACH Authorisation

Key Contacts

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Key Services

Dedicated Support (Régie)

Endocrine Disruption

Poison Center Notifications

Representation Services

Trainings