What you need to know about Health Canada

UPDATES

As of October 1st, 2020, the use of the Regulatory Enrolment Process (REP) is mandatory for pharmaceutical, biologic and radiopharmaceutical drugs for human use. We can guide you with the transition to REP and with all the REP templates (RT, PI and CO) to be filed for each submission thereafter.

FLOWCHART

Master Files (types I-IV)

- Dossier ID request
- **eCTD** compilation and publishing
- **non-eCTD** compilation and publishing
- Document **formatting**
- Conversion to eCTD format

Pharmaceuticals and Biologics

- Dossier ID request
- **eCTD** compilation and publishing
- Document **formatting**
- Conversion to eCTD format
- Implementation and lifecycle of **REP**

Clinical Trial Applications

- Dossier ID request
- **Pre**-Clinical Trial Application Consultation Meeting (Pre-CTA)
- Clinical Trial **Application** (CTA)
- Clinical Trial Applications – **Amendments**

VALIDATION
(HC validation rules)

SUBMISSION
(CESG)

ASPHALION

Regulatory Services for Health Canada

- eCTD compilation and publishing for all Health Canada submissions (Master Files, Pharmaceuticals/Biologics and Clinical Trial Applications).
- Transition from non-eCTD to the mandatory eCTD format.
- Submission package fulfills all the strict requirements of the agency and validation according to the latest version of Health Canada validation rules.
- Submit to Health Canada on your behalf via the Common Electronic Submissions Gateway (CESG).

EXTEDO
eRegulatory Affairs

Regulatory Solutions for Health Canada

- eCTDmanager: eCTD compilation and publishing for all Health Canada submissions.
- eSUBmanager: Viewing and reviewing of archived and in-progress electronic submissions.
- eDOCSmanager: Manage all your regulatory documents in a secure document management system.

info@asphalion.com
info@extedo.com