Gulf Cooperation Council (GCC)
Regulatory Services

Updates

Gulf Cooperation Council countries (Bahrain, Kuwait, Oman, Qatar, Saudi Arabia and the United Arab Emirates) have implemented eCTD format for submissions as per the following schedule:

- Saudi Arabia (July 17th, 2016)
- United Arab Emirates (October 1st, 2017)
- Oman (January 1st, 2015)
- Bahrain (November 1st, 2016)
- Qatar (September 1st, 2019)

GCC countries follow the GCC eCTD specifications, common for the entire region. This includes a specific Module 1.

Asphalion ensures that eCTD submission will always follow the most updated Module 1 specifications and validation rules (current Module 1 version for GCC Countries is v1.5).

When needed or required, Asphalion can give you support on preparing physical media to be exchanged with the Regulatory Authorities (CD/DVD or paper copies).

Registration procedures

- National Procedure in one specific country
- Centralized Procedure in all GCC countries simultaneously through the Central Gulf Committee for Drug Registration

Submission Types

Most relevant are:

- ASMF
- MAA (Biological, Generic, New chemical Entity or Radiopharmaceuticals)
- Reformatting from any format to eCTD (Baseline)
- Renewal
- Variation (Type 1 or Type 2)

ASPHALION
Knowledge from experience

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EXTEDO
eRegulatory Affairs

EXTEDO's Regulatory Solutions for GCC:

- eCTDmanager: eCTD compilation and publishing for GCC submissions.
- eSUBmanager: Viewing and reviewing of archived and in-progress electronic submissions.
- eDOCSmanager: Manage all your regulatory documents in a secure document management system.
- SafetyEasy: Reporting and management of all serious and nonserious adverse events.

For further information, please contact: info@asphalion.com | info@extedo.com