



# 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)



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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.