GCC RHI

Gulf Central Committee for Drug Registration.

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Glossary

- CMH, Council of Ministers of Health
- EB, Executive Board
- GCC, Gulf Cooperation Council for Arab States on the Gulf.
- GCC-DR, Gulf Central Committee for Drug Registration.
- GCC_DR SC, GCC_DR Steering Committee
- GD, General Director
Mission

To provide Gulf States with safe and effective medicines with reasonable price.
Organizational Structure

1. The Council of Ministers of Health (CMH)
   - Saudi Arabia, Kuwait, UAE, Oman, Bahrain, Qatar and Yemen

2. The Executive Board (EB).

3. The Executive Office General Director

4. GCC_DR Secretariat

5. GCC_DR Steering Committee
   - GCC States and Yemen and Working Groups
GCC-DR SC

- 2 members nominated by each state
- 2 consultants/advisors nominated by Executive Office (no voting rights) for total of 14 members
- Committee chairman nominated for period of one year.
- *Permanent, full-time secretariat*
- *Administration, coordination, communication.*
- Responsible for reviewing and approving of registration of pharmaceutical companies and their products, technical regulations and guidelines and administrative roles.
**Norms and Procedures**

- Description of file flow.
- Description of policy and procedures of each step of registration for products and companies.
- Selection priorisation of topics
- Solicitation of comments from stakeholders
- Approval/implementation of technical guidelines
- Responsibilities of decision-making body, working groups and secretariat
- Funding
Harmonisation Process

GCC Executive Office – GCC_DR SC

Prioritization and selection of topics to be addressed by GCC_DR SC

SC selects expert WG’s to meet and monitors performance

WG’s analyze topics and develop proposals or adapt int’l standards

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GCC_DR SC lead implementation & adoption of documents in jurisdictions
Technical Documents

- GMP standard
- Bioequivalence guidelines
- Stability guidelines
- GLP guidelines
- Postmarket surveillance guidelines
Topics under discussion

- Pharmacovigilance
- Biosimilars
- Sera and Antivenum
- Vaccines
- Blood products
- Radiopharmaceuticals
- Clinical trials
Participants in the Symposium on Food Regulation Call For a Lawful Base That Covers All Sectors of the Food Authority

Participants in the Symposium on Food and Drug Regulation (Present and Outlook) assured the importance of developing a lawful base that covers all sectors of the
Drug News

**French health authorities ban cosmetics containing vitamin K1 (phytonadione)**
The French Health Products Safety Agency (AFSSAPS) has announced a temporary ban on all cosmetic products containing vitamin K1 (INCI name: phytonadione; common name: phylloquinone; CAS: 84-80-0)...[more]

**FDA Warns Consumers About Dangerous Ingredients in "Dietary Supplements" Promoted for Sexual Enhancement**
The U.S. Food and Drug Administration (FDA) is warning consumers not to purchase or consume Zimaxx, Libidus, Neophase, Nasutra, Vigor-25, Actra-Rx, or 4EVERON. These products are promoted and sold on web sites as "dietary
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