Mission of GCC_DR

To provide Gulf States with safe and effective medicines with reasonable price.
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
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.
Three meetings are planned

- The GCC Adverse Event Reporting System Symposium (VAERS).

- Bioequivalence Studies of Generic Pharmaceutical Products Workshop.

The GCC Adverse Event Reporting System Symposium (VAERS). 6-7 November 2007. Riyadh

- Prequalification of vaccines, WHO Perspective
- EU regulation for vaccines.
- Vaccine Safety, Immunogenicity, Efficacy, Monitoring.
- Vaccine quality control in GCC States.
- The need for vaccine vigilance.
- The vaccine vigilance from WHO and Industrial prospective
- Causality assessment tools.

- GCC guidelines.
- Bioanalytical methodology and validation
- Statistical analysis and acceptance criteria
- Special considerations for some drugs
- Biosimilars
- Inspections of bioequivalence centers and analytical laboratories

- A workshop on the evaluation of bioequivalence data and reports:
  - 1. Contents of bioequivalence data and reports
  - 2. How to evaluate bioequivalence reports submitted by pharmaceutical companies
  - 3. Evaluation forms and check list
  - 4. Examples of bioequivalence reports submitted for registration
2-3 December, 2007. Riyadh

- GCC, WHO and ICH guidelines
- Methodology, specifications, and acceptance criteria
- Selection of batches/bracketing and matrixing for multiple strengths
- Stability testing of oral dosage forms
- Stability testing of parenteral products
- Stability testing of topical products
- Some major factors that may influence product stability

- A workshop on the evaluation of stability data and reports:
  - 1. Contents of stability reports
  - 2. How to evaluate stability reports submitted by pharmaceutical companies
  - 3. Evaluation forms and check list
  - 4. Examples of stability reports submitted for registration