Prof. Saleh Bawazir
Gulf Cooperation Council (GCC)
Representative
Vice President for Drug Affairs
Saudi Food and Drug Authority
Riyadh, Saudi Arabia
GCC
The Cooperation Council for the Arab States of the Gulf

Bahrain
Kuwait
Oman
Qatar
Saudi Arabia
United Arab Emirates
and Yemen as member in Health Council.
Mission of GCC_DR

To provide Gulf States with safe and effective medicines with reasonable price.
GCC RHI

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 Activities

- The 39th Meeting for GCC_DR

The 39th Meeting for GCC_DR
Riyadh, Saudi Arabia.

1. The GCC Stability Guideline.
   - The GCC_DR will review the guideline based on the WHO Stability Guideline final version.

2. Under license, Contract Manufacturing and Technology Transfere.
   - Several suggestions and proposals were discussed.
   - A draft paper will be developed and discussed in the next meeting.

3. Update of GCC_DR registration Requirements.
   - Package Insert translation
   - Time for appeal for rejected products.
The 39th Meeting for GCC_DR
Riyadh, Saudi Arabia.

4. GMP Inspection
   - Review of inspection procedures
   - Nomination of inspectors

5. Requirements of Central Reregistration of manufacturers
   and Pharmaceutical products.
   a. Manufacturing license and GMP certificate from DRA
   b. Declaration form
   c. Pay Re-registration Fee
   d. Re-inspection if needed
The 39th Meeting for GCC_DR
Riyadh, Saudi Arabia.

   - Proposed by SFDA
   - A greed to discuss in special meeting.

7. CTD
   - Training for Staff
   - Proposed to enforce CTD starting January 2010.
The 39th Meeting for GCC_DR
Riyadh, Saudi Arabia.

8. Single Entry Point for GCC.
   - Member States update the committee on preparation progress.

9. ICH Update
   - Prof. Bawazir present to the GCC_DR an update of ICH and GCG.

10. Training Programs.
    - The committee approve the proposed training program on biotechnology products and biosimilars.
8TH MIDDLE EAST
REGULATORY CONFERENCE
MERC 2009
January 20-21, 2009 - Bahrain
THANKS...