Update on GCC Region
ICH-GCG Meeting,
Yokohama, Japan
9 June, 2009

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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.
The Council of Ministers of Health (CMH)

Saudi Arabia, Kuwait, UAE, Oman, Bahrain, Qatar and Yemen

The Executive Board (EB).

The Executive Office General Director

GCC_DR Secretariat

GCC_DR Steering Committee

GCC States and Yemen and Working Groups
GCC Activities

- Participated in Webinar for S9 and Q8
- GCC CTD. Dubai 30-31 May 2009,
8th Middle East Regulatory Conference MERC
reflected on the journey that had taken place since the first MERC in 1996, in particular:

- The rapid developments in health care and medical science
- The regulatory environment changes over that time
- The continuing partnership between industry and regulators in bringing safe, effective, and high quality medicines to patients in the Middle East region
The key topics of the conference were:

- Local regulatory authorities’ views and key issues
- Pharmacovigilance
- Counterfeit medicines
- Innovation in the quality arena
- Common technical document and electronic submissions
- Evolving global legislation on medicines
- Health economics
ICH UPDATE
  – Dr. Yves Juillet,
PARTICIPATION OF REGIONAL HARMONIZATION INITIATIVES IN ICH-GCG
  – Professor Saleh Bawazir,
Towards Unified Arab CTD.

- Arab Union of the Manufacturers of Pharmaceuticals and Medical Appliances (AUPAM) discussed problems facing manufacturers in registering pharmaceuticals.
- The two-day conference aims at drawing a draft on standardizing criteria affiliated with registering medicines in an attempt to establish a joint Arab pharmaceutical market.
Harmonization of Drug Registration in the Arab Countries

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• Agreed to Adopt ICH CTD
• Agreed to use ICH guidelines as primary source when developing guidelines by AUPAM.
• Distributed booklet of E6 guideline translated in Arabic language
Two days workshop on CTD and eCTD
- Discussed GCC Module 1.
- Future development towards eCTD.