Regulatory Collaboration Principles In GCC States (GCC-DR)

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Presentation Outlines

- The GCC for the Arab States on the Gulf
- The executive Office for HMC
- Drug Registration Initiative GCC-DR
- Advantages and Challenges
The Gulf Cooperation Council (GCC)

- Saudi Arabia, Kuwait, Oman, United Arab Emirates, Bahrain and Qatar.

- Total population estimated at 37.5 million inhabitants.

- The GCC is a co-operative organization in different domains including health.

- The various councils of ministers of the participating countries meet twice a year.
The Cooperation Council for the Arab States of the Gulf (GCC)

Bahrain
Kuwait
Oman
Qatar
Saudi Arabia
United Arab Emirates
and Yemen as member in Health Council.
The Gulf Cooperation Council For Health Ministers

- Coordinate activities and communications between the Ministers of Health of member countries.

- Organizing conferences, seminars, and training.

- Procurement programs of pharmaceutical products, hospital sundries and equipments of high quality.

- Conducting field surveys and research.

- Assessment of the existing systems and strategies in the health fields.
The Executive Office (SGH)

- Established in 1976.
- Executive board chaired by the executive director.
- Health minister’s council.
- Advisory committees.

**Functions:**
- Group purchasing.
- Central drug registration.
- Health policies.
- Medical research.
The Council of Ministers of Health (CMH),

- The highest level of authority in the organizational framework,
- Meets twice a year, and oversees approval of all guidelines and policies adopted by the GCC-DR Steering Committee.
- The CMH consists of Health Ministers from each of the Gulf Cooperation Council Member States including Yemen
- The CMH holds twice-yearly 2-3 day meetings
Drug Registration Initiative
GCC-DR

- Drug registration (GCC-DR) was approved on 15th May, 1999.

- Program Secretary is located in Riyadh, Saudi Arabia at the Executive Office for Health Ministers.

- The GCC-DR committee consists of two members nominated by each state.
Mission

The mission of the GCC-DR is to provide Gulf States with safe and effective medications with reasonable price.
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 States and Yemen and Working Groups

GCC_DR Steering Committee
Scope of GCC Drug Regulatory Activities

- Pre-marketing evaluation.
- Marketing authorization.
- Post-marketing review.
- GMP inspection
- Technical guidelines
The GCC-DR Steering Committee

- Responsible for the products registration and selection and prioritization of topics,

- the assignment of guideline drafting and approval.

- The Steering Committee is composed of 2 members from each of the Member States, including Yemen.

- The Steering Committee holds a minimum of four meetings per year,
The GCC-DR Secretariat

- Facilitating the activities of the harmonization initiative through administration, coordination and communication.
- Receiving and reviewing registration files for completeness
- Preparing the agenda of Steering Committee meetings.
Norms and procedures

- The GCC-DR harmonization process is governed by standard practices and operating procedures.

- These procedures relate to:
  - the registration process for products and companies.
  - procedures describe file flow
  - the selection and prioritization of topics,
  - implementation of guidelines,
  - working groups and secretariat,
  - funding.
Harmonization process -1

- The GCC-DR primarily uses ICH guidelines as the basis for developing regional guidelines.

- Other international guidelines including WHO, as well as selected regional (e.g., EU, American sub-regional) or

- National technical documents are also used as basis for harmonization and as reference material.
Harmonization process -2

- Once developed by a working group, a draft guideline is circulated to all member states for comment.

- The draft document is also posted on the website to solicit comments from stakeholders.

- The working group reviews all comments received, and recommends the adoption of the guideline to the GCC-DR Steering Committee.

- Once adopted by the GCC-DR Steering Committee, the General Director of the Executive Office will submit the guideline to the CMH for final approval.
GCC Executive Office – GCC-DR SC

Prioritisation and selection of topics to be addressed by GCC-DR SC

SC selects expert WGs and monitors performance

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

GCC-DR SC adopt the guidelines and send to CHM for approval
Communications -1

- An updated web page is available as the main source for the public to get information on GCC-DR.

- Both draft and final guidelines are published online, and the public is invited to submit comments by e-mail.

- Comments are reviewed by the technical working groups.
Communications -2

- Presentations and promotions in national and international congresses or conferences.

- Meetings with healthcare professionals, industry associations, individual companies and/or the media.

- In addition, the GCC-DR Secretariat organizes workshops on specific topics.
Training

- There is no officially structured training program within the Initiative.

- Each Member State is normally responsible for providing training for their regulators.

- In addition, the Executive Office organizes training in the areas of GMP and PMS
Sources of Funding

- The activities of the GCC-DR harmonization initiative are financed by established quotas of contributions from Member States,

- Fees obtained from both company and product registration.

- The GCC-DR initiative operates through cost recovery, and is audited by a certified accounting firm.
Process of File Submission

- File must be submitted to GCC-DR secretariat at the Executive Office.
- Payment of required fees.
- Registration officer reviews the file for completeness.
- Products list and copies of files are forwarded to member states for review.
Reviewing Process - 1

First Stage:
- Received files are submitted to GCC-DR members for reviewing.
- Two members are designated to submit an evaluation report.
- Evaluation reports are discussed and approved.
- The executive director approve the minute of the meeting.
Reviewing Process - 2

- Second Stage:
  - Company is informed of the GCC-DR primary decision.
  - QCL requirements and product samples must be delivered to designated lab after payment of fees.
  - The QCL report is submitted to the GCC-DR for final approval.
  - Registration certificate is issued and the company is instructed to complete the registration process in each country.
Reviewing Process - 3

- **Company registration:**
  - Company profile is evaluated for primary approval.
  - The company is notified of the committee decision and instructed to prepare for GMP inspection.
  - The inspection team is appointed and the company is contacted to arrange for the visit.
  - The company registration will be decided upon completion of inspection.
Reviewing Process - 4

- GMP inspection:
  - A team of 3 inspectors will be appointed.
  - The company must pay inspection fee.
  - Inspection report must be submitted within 2 weeks of visit completion.
Advantages

- Permanent Secretariat
- Structured Meeting
- Efficient Operation
- Regulatory Harmonization
- Improve Capacity Building
### Challenges

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HRH Crown Prince Thanks SFDA & Employees
On the Advent of Being the First Organization in the Middle East to Win “Business Processes Management Award”

In a remarkable letter from HRH Prince Sultan bin Abdul Aziz bin Saud, Chairman of SFDA Board to H.E the Chief Executive Officer of Saudi Food & Drug Authority Dr. Mohammed bin Ahmed Al Kanhal, thanking him and ..more

H.E the Chief Executive Officer of Saudi FDA Welcomes the General Manager of Yemeni Standards Organization

H.E the Chief Executive Officer of Saudi FDA, Dr. Mohammed bin Ahmed Al Kanhal welcomed at his office yesterday the General Manager of Yemeni Standards & Quality Control Organization, Engineer..more

SFDA Warns about “Nab’a Health Potable Water”
assured the importance of developing a lawful base that covers all sectors of the
Many Thanks for your attention

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