

Perspective from Regional Harmonisation Initiative (RHI)

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Agenda

- ❖ Setting the Stage
- ❖ Lessons Learned
- ❖ Influence in Regional Harmonisation
- ❖ Potential Development

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.



ICH Global Cooperation Group

- ❖ ICH SC In March 1999 notice a growing interest in ICH by non-ICH parties in ICH guidelines and operations.
- ❖ Six parties were invited and the GCG was formed .
- ❖ Facilitates dissemination of information on ICH activities, guidelines and their use



ICH Global Cooperation Group Mission Statement

“To promote a mutual understanding of regional initiatives in order to facilitate harmonisation processes related to ICH guidelines regionally and globally; and to strengthen the capacity of drug regulatory authorities and industry to utilize them.

Osaka, November 2003: An Important Milestone

- ❖ Endorsement by ICH SC of new Mandate and Terms of Reference that call for
 - The **ongoing participation** of regional harmonization initiatives
 - Greater **transparency**



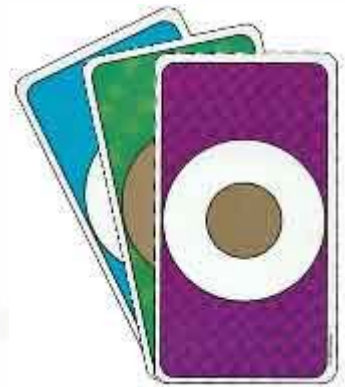
ICH Global Cooperation Group -2

- ❖ RHI representatives may attend any technical expert working group and SC meetings
- ❖ Strategy on training and capacity-building in development
- ❖ RHIs invited to nominate expert to Quality Systems expert working group

Lesson 1

Harmonisation the Magic Word

Harmonisation is the name given to the effort by industry to replace the variety of product standards and other regulatory policies adopted by nations in favor of uniform global standards.



“The establishment, recognition and application of common standards and regulatory measures”

— WTO SPS Agreement

Lesson 2

ICH

- ❖ Conference or Forum or Coalition
- ❖ Mechanics and process of ICH
- ❖ Effective management and administration
- ❖ Structured Meetings.
- ❖ Commitment of all parties



Lesson 3

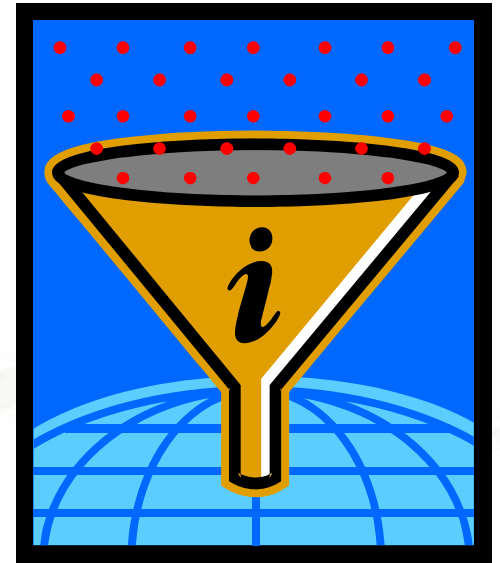
Pharmaceutical Industry and DRA Friends or Foe

- ❖ Joint participation of regulators and industry
- ❖ Establish two-way dialogue, collaboration
- ❖ Commitment of regulators to implement harmonized guidelines
- ❖ Periodic reassessment of regulatory gaps

Lesson 4

Guideline the Guidelines

- ❖ Guideline must be value- added and implementable
- ❖ Building Scientific Consensus
- ❖ Agreeing on Draft Text
- ❖ Consulting with Regional Regulatory Agencies
- ❖ Adopting Harmonized Guidelines
- ❖ Implementing Guidelines.



Lesson 5

Capacity Building and Information Sharing

- ❖ Facilitates dissemination of information on ICH activities, guidelines and their use
- ❖ Discussions on possibilities for increased participation in ICH activities
- ❖ Solicited views on ICH draft guidelines and topics of interest
- ❖ More focused interactions under discussion
- ❖ Important new training opportunities identified

Influence in Regional Harmonisation -1

- ❖ Spread the message for harmonization.
- ❖ Better understanding and implementation of the ICH guidelines.
- ❖ Better interaction between ICH regions and RHI countries.



Influence in Regional Harmonisation - 2

- ❖ Methodology of the guidelines development.
- ❖ Gain more prospective on adoption of guidelines.
- ❖ ICH can reach non ICH regions much easier through RHI.



Potential Development -1

- ❖ Structured dissemination of information on ICH activities, guidelines and their use
- ❖ Progress towards more productive and transparent relationship with regional harmonisation initiatives
- ❖ Greater inclusion of RHI experts on technical working groups



Potential Development -2

- ❖ Regional special sessions to discuss the ICH-GCG meeting outcomes.
- ❖ ICH and RHI mini symposiums on step 2 technical guidelines.
- ❖ More technical experts from ICH-GCG to help RHI .
- ❖ ICH representative to be invited to regional forum.



Conclusion

- ❖ Paradigm shift from:
 - information-sharing to active engagement.
 - Regional Thinking to Global picture
 - Guidelines to Broader regulatory issue
 - Secrecy to Transparency.

THANKS...
For Your Attention

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