

# ***Overview of ICH***

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# ICH

**INTERNATIONAL  
CONFERENCE ON  
HARMONIS/ZATION**

of

Technical Requirements  
for the Registration of  
Pharmaceuticals for Human Use

# ICH Background

- Unique harmonization project involving the regulators and research-based industries of US, EU and Japan—started in 1990
  - WHO, Canada, and EFTA are observers
- Well-defined objective: to improve efficiency of new drug development and registration process
- Accomplished through the development and implementation of harmonized guidelines and standards

# Expert Working Groups

**SAFETY**

**EFFICACY**

**QUALITY**

**MULTIDISCIPLINARY**

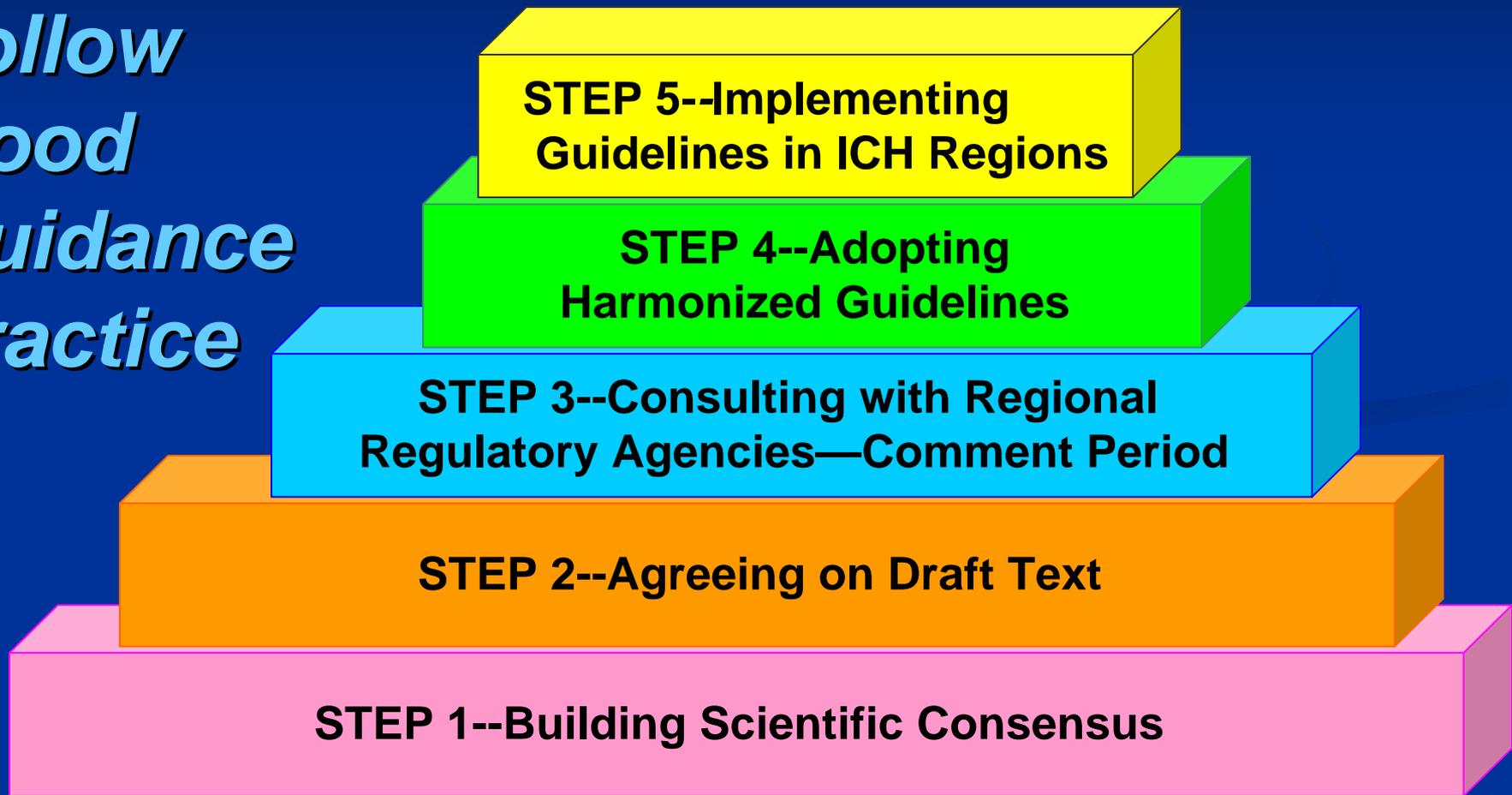


**STEERING COMMITTEE**

Monitors and Facilitates EWGs

# ***Steps of ICH Harmonization***

***Follow  
Good  
Guidance  
Practice***



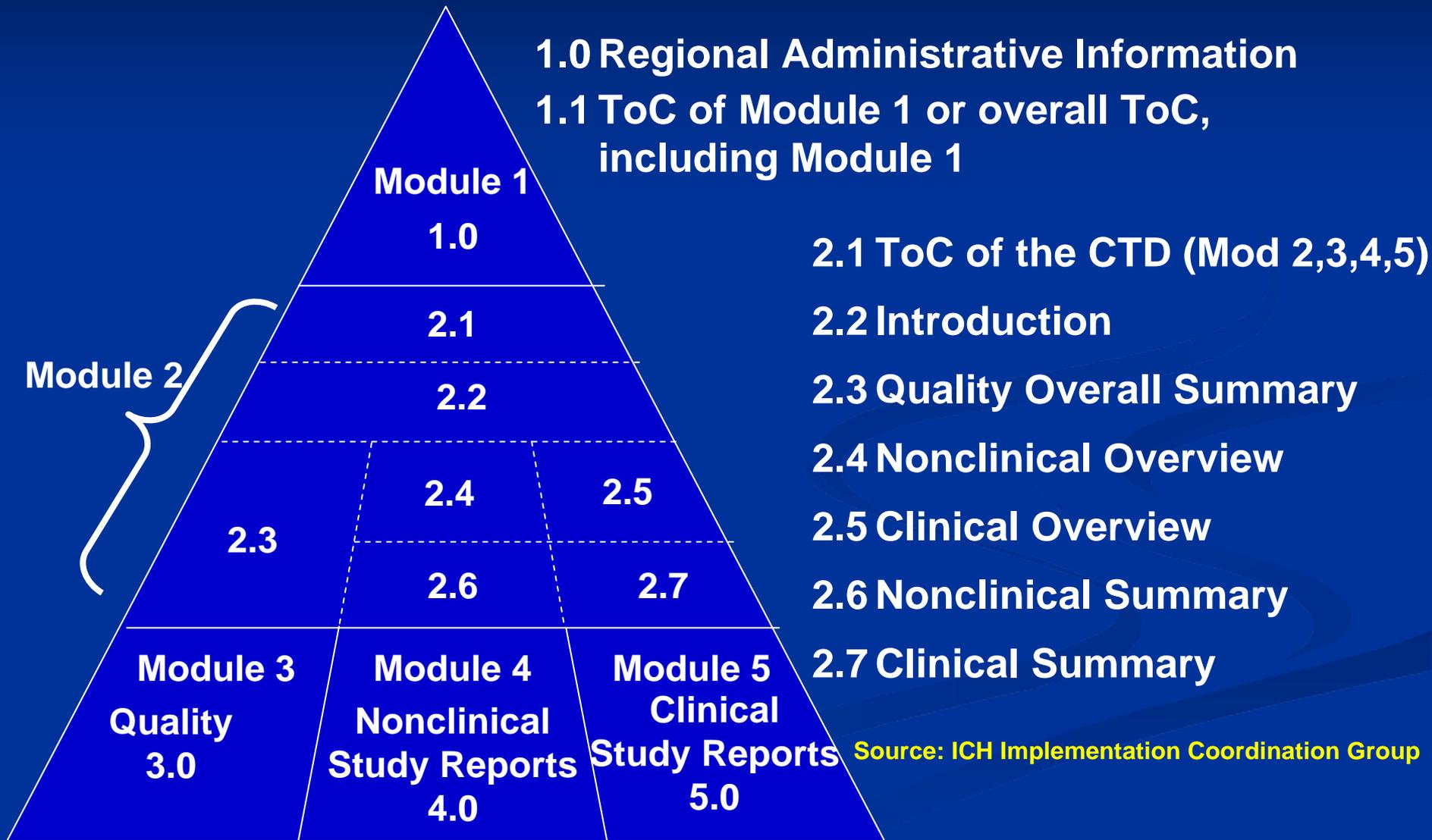
# Over 50 ICH Guidelines

- **Efficacy** – 14 topics/18 guidelines
- **Safety** – 8 topics/16 guidelines
- **Quality** – 10 topics/24 guidelines
- **Medical Dictionary** – MedDRA
- **Electronic Standards** – ESTRI, E2B
- **Common Technical Document** – CTD

Guidelines extend over entire product life cycle

Extend beyond new drugs: OTC and Generics

# ICH CTD



# ICH: Keys to Success

- Well-defined process
- Effective management and administration
- Limited number of players with common focus
- Comparable regulatory, technical and financial capacity
- Commitment of all parties

# International Conference on Harmonisation—Transparency

ICH-1: Brussels 1991

ICH-2: Orlando 1993

ICH-3: Yokohama 1995

ICH-4: Brussels 1997

ICH-5: San Diego 2000

ICH-6: Osaka 2003



# Results of Transparency

- Relevance of ICH guidelines and standards:
  - High quality scientific documents available to non-ICH parties
  - Serve as educational/reference material
- Increased interest by non-ICH countries in implementing ICH Guidelines and the CTD as a submission format

# Shift in Focus

- Initial focus on **information-sharing**
- Soon became clear that more active **engagement** was necessary to respond to increasing interest in ICH and ICH guidelines
- Resulted in creation of new mechanisms
  - Global Cooperation Group (GCG)
  - Newly established Regulators Forum
  - Regional ICH outreach meetings

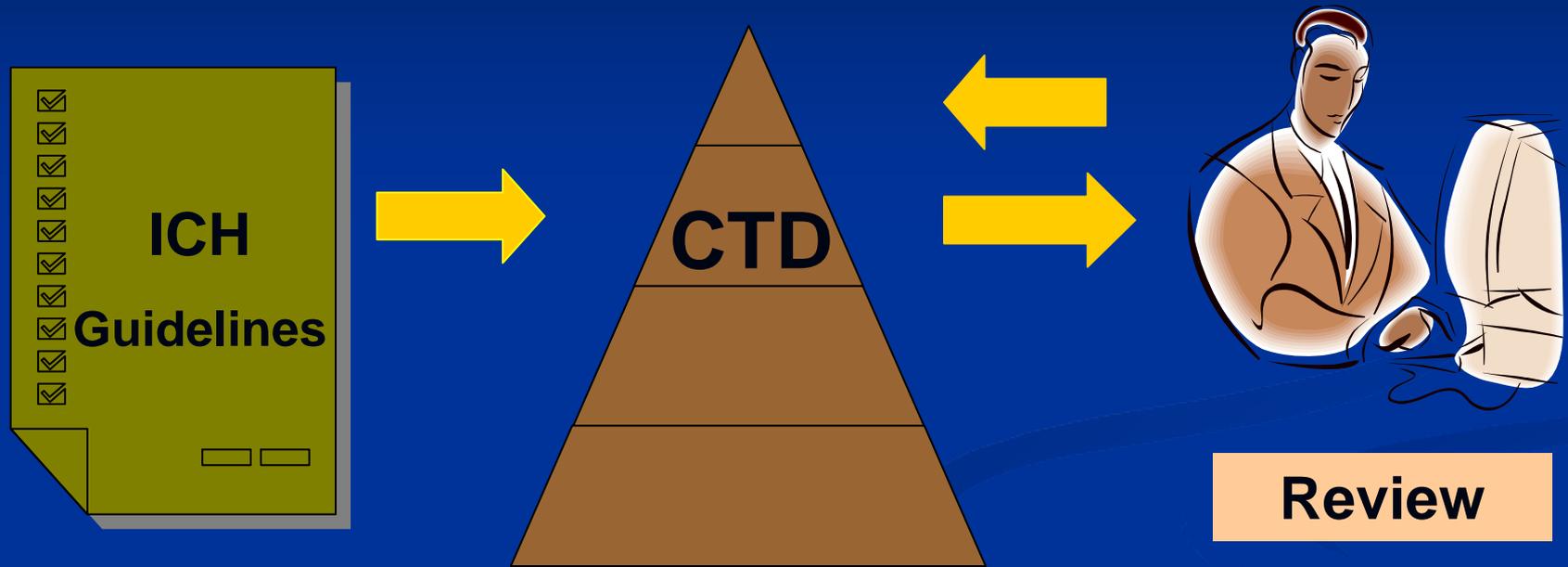
# ICH Global Cooperation Group

- Created in 1999 to address increasing interest by non-ICH parties in ICH guidelines and operations
- Facilitates dissemination of information on ICH activities, guidelines and their use
- GCG underlying principle: ICH will not seek to impose its views--rather, GCG will serve as resource for information
- Four brochures published on ICH and GCG, available at ICH website [www.ich.org](http://www.ich.org)

# ICH Regulators Forum

- ✧ The ICH SC endorsed the establishment of a Regulators Forum
- Created to promote discussion and sharing of best practices among regulatory authorities on issues related to the implementation of ICH guidelines and impact on regulatory systems
- The Regulators Forum will complement activities and objectives of GCG

# Focus on Implementation of ICH Guidelines



Easier to develop standardized reviewer e templates  
Influences Good Review Practices (GRPs)  
Focus on implementation

# Conclusion

- ✧ The geographical face of international drug development and trade is rapidly changing
- ✧ Interest and use of ICH guidelines reflects this change
- ✧ ICH is committed to responding to needs of regions and countries interested in implementing ICH guidelines
- ✧ Success dependant on collective effort and spirit of cooperation

**Thank you for your  
attention**