

ICH Update in Fukuoka

ICH Project Committee

H.Saito

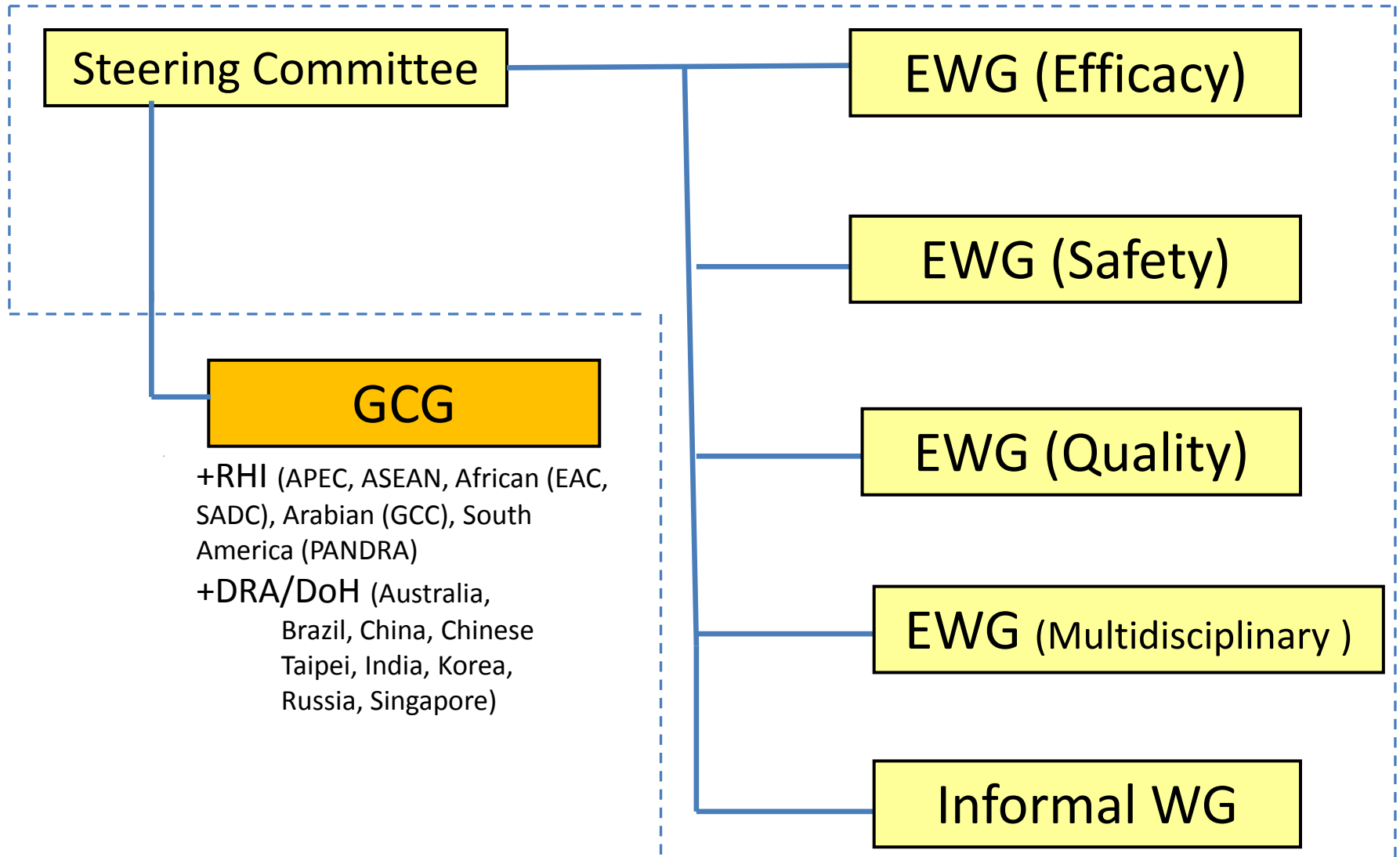
ICH Reform (Expand and Be wide)

- From International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
- To International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
 - Management Committee/Assembly (Legal Entity and Funding Scheme Fixed)
 - EU/US/Japan to Global
 - Involvement of other industries
- 2016 January : Assembly : 2015 December : Jacksonville (USA)

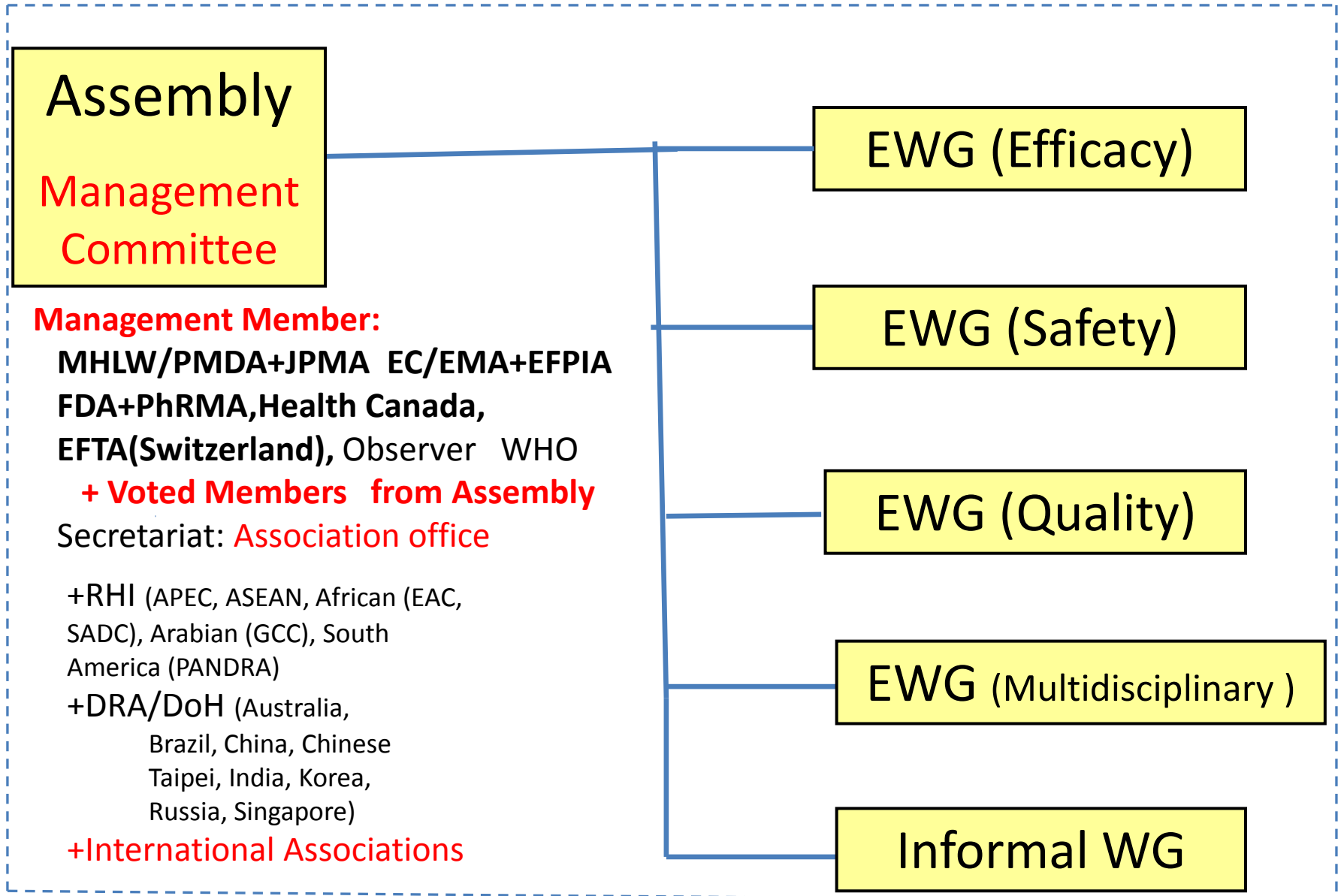
ICH Organization (Current)

Member: JP: MHLW/PMDA+JPMA Europe: EC/EMA+EFPIA USA: FDA+PhRMA
Health Canada, EFTA(Switzerland), Observer WHO

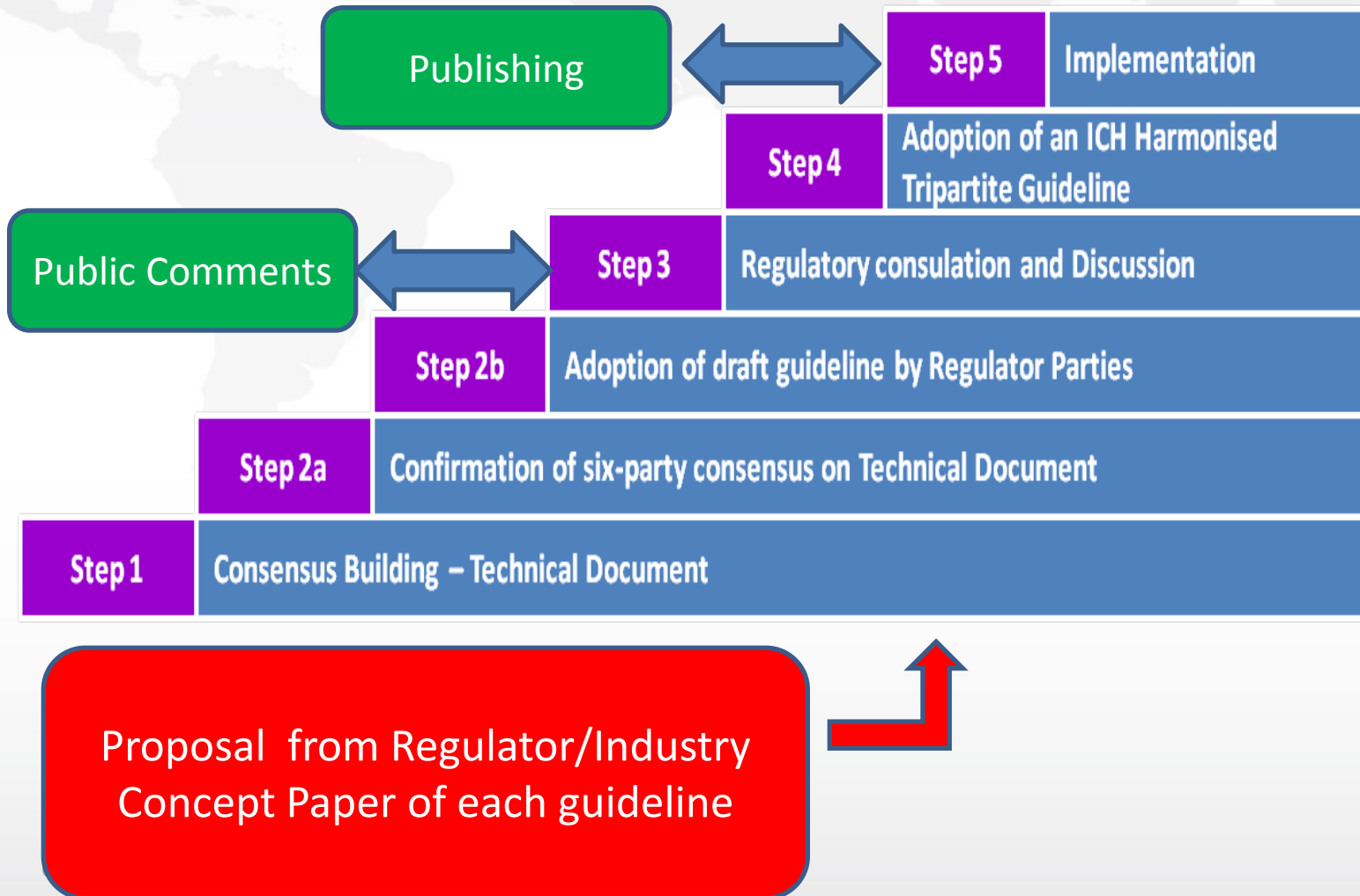
Secretariat: IFPMA



ICH Organization (Future)



ICH Process for new guideline



ICH Reform Activity

Concept

- From **Committee** to **Independent Assembly**
- From **US/EU/Japan** to **Global**
- From **registration** activity to **registration/maintenance** activities

Activity for ICH reform (Leader)

- Legal Entity TF (EMA)
- Funding TF (FDA)
- Membership TF (PMDA/MHLW)
- Transition TF (Swiss Medic)
- Communication & Outreach TF (JPMA)

Action Plan

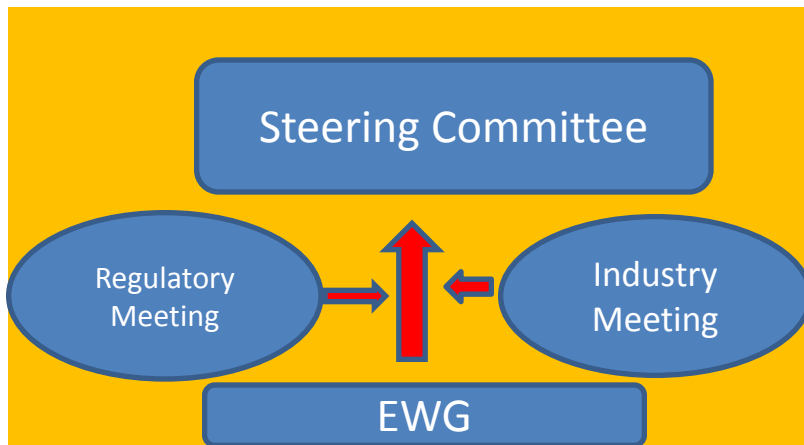
- ICH Association setting up (from Jan. 2016)
- IFPIA Office to independent Association Office

Mind Set

- **From Internal contribution to Global/Asia Contribution**

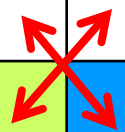
ICH Decision Making approach

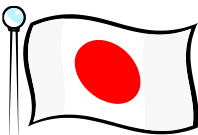
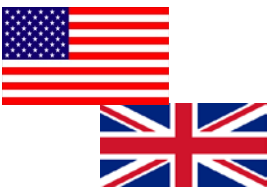

- **Consensus based decision making (Global Matrix)**
 - 6 party consensus based decision making depend on topics
 - Prevalent Regulatory meeting(FDA,EMA,PMDA/MHLW) and Industry meeting (PhRMA,EFPIA,JPMA)
 - Regional meeting (FDA:PhRMA, EMA:EFPIA, PMDA/MHLW:JPMA) meeting
 - Industry recognizes the importance and the need of involvement from early development phase.
 - Implementation is easier because of attending the discussion.
 - Industry contributes guideline training.



Japan Contribution in ICH activity

People	Idea
Good listener Encouraging Loyal Patient Team person Supportive	Enthusiastic People-oriented Demonstrative (feelings) Optimistic Confident Creative
Process	Action
Courteous Sensitive Accurate Concerned with quality Detailed Persistent	Decision-making Risk-taking Prodding others to action Independence Goal orientation Change orientation



	Primary	Secondary
	People	Process
	Action	Idea
	Process	Action

Myers-Briggs Type Indicator
 Pierre Casse, "Training the Intercultural Mind"
 Intec JAPAN Inc.

Viva!!! ICH

