ICMRA’s Role in Capacity Building: Where are Gaps and Overlaps?

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<td>☐ Grants/Research Funding</td>
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1. Bi-lateral
   1. A-few-people sent to another country

2. Personnel dispatch/exchange for OJT

2. Seminar-type (one to multi-countries’ trainees)
1. Many parties’ great efforts in Capacity Building, but always felt “not enough”

2. Little coordination among the providers; leading to duplications & gaps, but where?

3. Difficult to compare programs

“GMP training by country A makes GMP training by country B redundant?”

- Target products (chemicals, biologics, solid, injections, gas?)
- Target trainees (self-claimed/objective basic, intermediate, advanced, regulators, inspectors?)
- How far apart the trainings (time and location)
The ICMRA is a voluntary, executive-level, strategic coordinating, advocacy and leadership entity of regulatory authorities that work together to:

- address current and emerging human medicine regulatory and safety challenges globally, strategically and in an ongoing, transparent, authoritative and institutional manner
- provide direction for areas and activities common to many regulatory authorities’ missions
- identify areas for potential synergies
- wherever possible, leverage existing initiatives/enablers and resources

ICMRA will provide a global architecture to support enhanced communication, information sharing, crisis response and address regulatory science issues.
ICMRA member

1. Australia (TGA)
2. Brazil (ANVISA)
3. Canada (HPFB-HC)
4. China (CFDA)
5. Europe (EMA and DG-SANCO)
6. France (ANSM)
7. Germany (PEI)
8. Ireland (HPRA)
9. Italy (AIFA)
10. Japan (PMDA and MHLW)
11. Korea (MFDS)
12. Mexico (COFEPRIS)
13. New Zealand (Medsafe)
14. Nigeria (NAFDAC)
15. Singapore (HSA)
16. South Africa (MCC)
17. Switzerland (Swissmedic)
18. United Kingdom (MHRA)
19. United States (FDA)
20. World Health Organization (WHO) - observer

(As of November, 2014)
ICMRA Priorities in specific regulatory fields

Working Groups (2013-)

1. GMP inspections (UK)
2. Generic drugs (Australia)
3. Capacity Building (Japan)

Three priority Areas (2016-2019)

1. Supply Chain Integrity (EU)
2. Pharmacovigilance (Australia)
3. Crisis Management (Brazil).

Members:
Europe (EMA), Italy (AIFA), Korea (MFDS), Switzerland (Swissmedic), United States (FDA), WHO
Questions

1. Requests received from other authorities
2. Capacity building activities actually provided to other authorities
3. Requests that the ICMRA member made to other countries’ authorities
4. Training seminars provided to other authorities’ regulators in the past 24 months
Acknowledgement: Cooperating Organizations

Australia (TGA)  
Brazil (ANVISA)  
Canada (HC)  
EU (EMA)  
France (ANSM)  
Germany (PEI)  
Ireland (HPRA)  
Italy (AIFA)  

Japan (PMDA)  
Korea (MFDS)  
Mexico (COFEPRIS)  
Singapore (HSA)  
Sweden (MPA)  
Switzerland (Swissmedic)  
United Kingdom (MHRA)  
WHO
Results (1)

On Bi-lateral trainings

1. A-few-people mission to another country
2. Personnel exchange for OJT
Recipients of Training

- Africa, 21 (13%)
- Europe, 25 (15%)
- Asia-Pacific, 42 (25%)
- North America, 7 (4%)
- South America, 42 (25%)
- WHO/Other International Organization, 30 (18%)

Total: 174
Who supplied to whom? (excluding EMA)

There seems to be “hub” authorities in each region.
EMA supplied to whom?
Mismatches in the supply and demand: Asia-Pacific

**Requested or Providing Regulatory Authorities**

- **Demand**
  - North America, 4
  - Asia-Pacific, 21
  - Europe, 52

- **Supply**
  - North America, 4
  - Asia-Pacific, 15
  - Europe, 27
  - South America, 1
Mismatches in the supply and demand: Central & South America

Field of Training

Supply
- Review, 7
- Inspection, 9
- Others, 28
- Safety, 1

Demand
- Review, 9
- Inspection, 4
- Others, 12
- Safety, 2
On Seminar-type trainings
WHO was the largest supplier of “seminar-type” training.

- WHO/Other International Organization, 110 (75%)
- Europe, 18 (12%)
- Asia-Pacific, 9 (6%)
- South America, 8 (6%)
- North America, 2 (1%)
- Africa, 0 (0%)
Summary

(1) Regional “hub” especially in bilateral supply/demand of capacity building.

(2) Some gaps exist between supply and demand

(3) Seminar-type trainings are mainly by WHO.
Some ideas
1. The hub authorities should be well aware of
   1. Providers of trainings in the region and what they
      provide, and
   2. Demand in the region.

2. The hub authorities can coordinate the regional capacity
   building activities in cooperation with other providers,
   collectively meeting the region’s demand.
Within East Asia alone there are many providers of training for regulators.

- Overlapping efforts?
- Room for coordination?

- WPRO
- Regulatory Authority
- APEC CoE
- APEC Harmonization Center
“Match Making” for Staff Dispatch/Acceptance/Exchange

- Currently no mechanism to pool and match wishes between countries.
- A system of matchmaking can fill this gap.

Wanna send GMP inspectors for OJT Country A

Send us Review Instructor Country C

Can accept 5 trainees Country B

Ready to accept GMP inspector Country D
WHO could consolidate its Database on Seminar-type trainings including those provided by others.
1. Assessment of fitness to demand/ Assessment of effectiveness (for individual and for country)

2. Cost/benefit analysis to justify the resources
Thank you very much for your attention! Danke für Ihre Aufmerksamkeit!

Ask