

APEC Harmonization Center



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How to involve

2015 APEC Harmonization Center Biotherapeutics Workshop

July 1-2, 2015 | Songdo Convensia, Incheon

About AHC



About AHC

About AHC

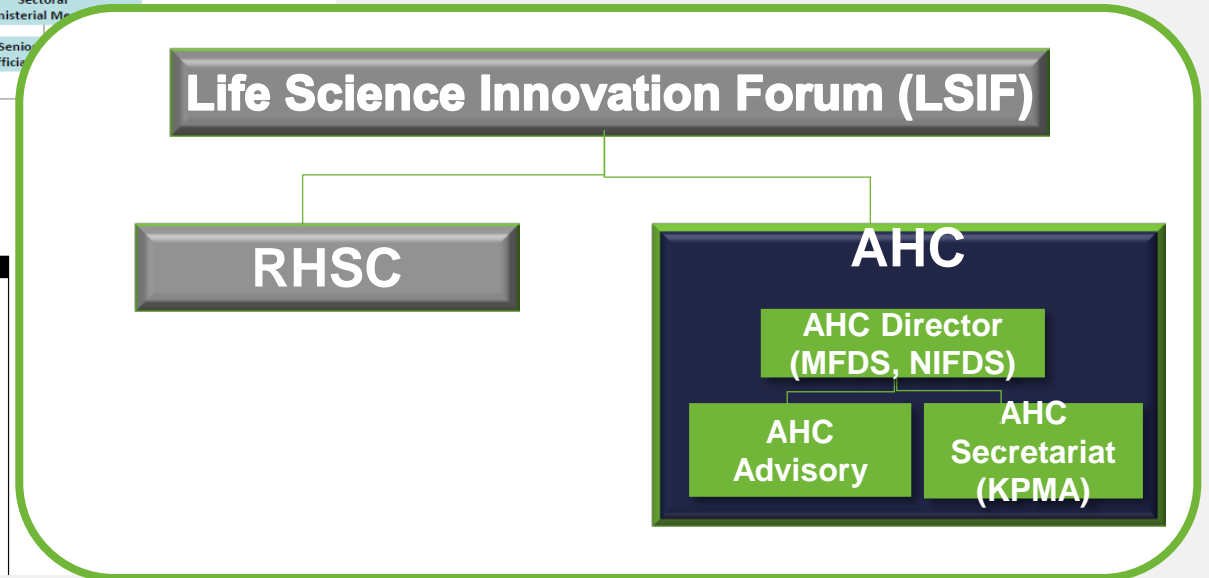
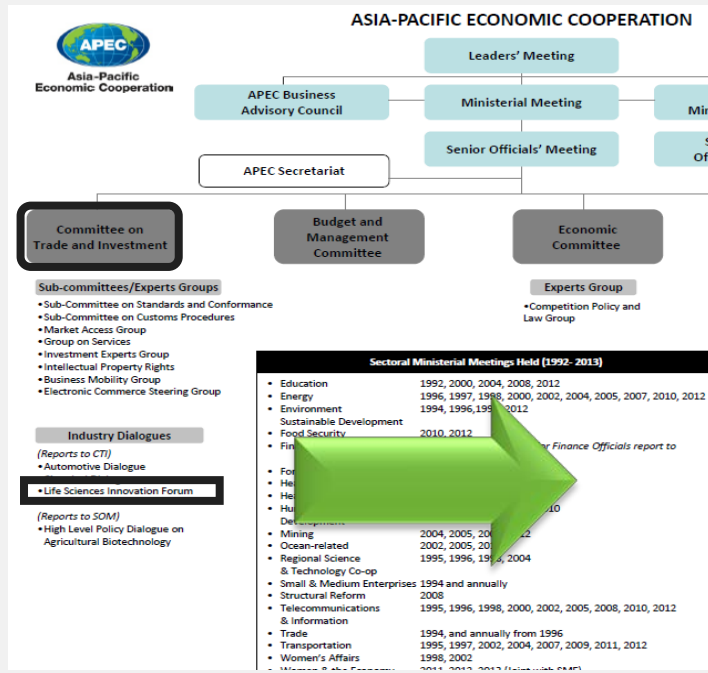


Background

 Objective Strategic Approach

The **APEC Harmonization Center (AHC)** was established to **provide a platform** to address and solve priority of APEC member economies **on regulatory harmonization**.

2008. 8.	Korea proposed the establishment of the AHC at the 4th LSIF in Lima, Peru
2008.11.	APEC Ministers specifically endorsed the AHC in the annual Ministerial Joint Statement
2009.6.	Established at the MFDS, Korea (under the authority of APEC LSIF)



Objective

About AHC

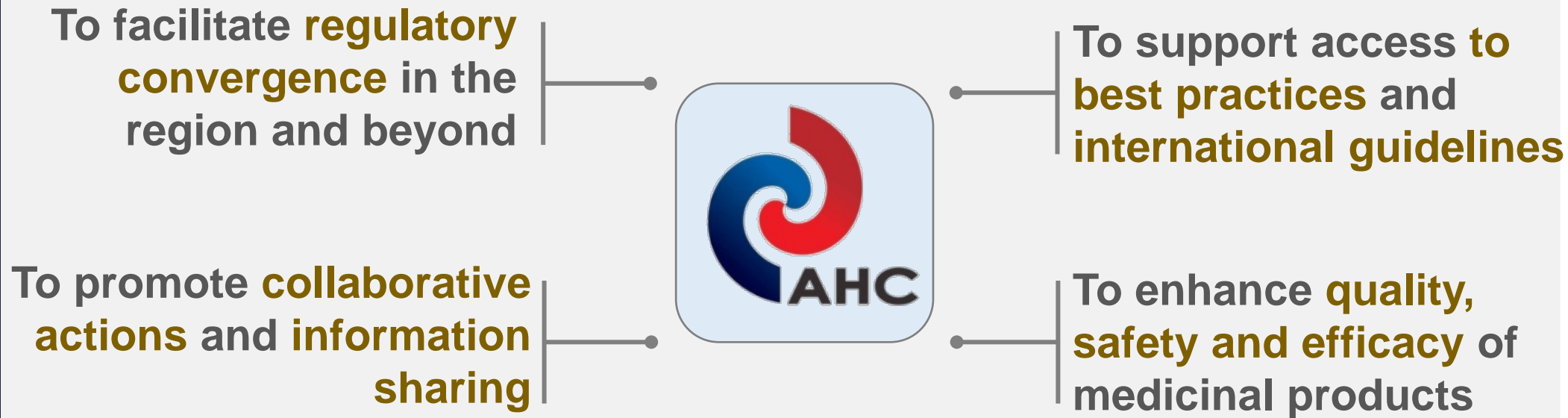
 Background

 Objective

 Strategic Approach

Vision

Regulatory Convergence in the APEC



Strategic Approach

About AHC

 Background

 Objective

 Strategic Approach

Cooperating Globally with
APEC LSIF Regulatory Harmonization Steering Committee (RHSC)
and other international organizations

Broadening AHC Activities
Center of Excellence (CoE)

Face to Face
Training

Hosting Workshops

Research

Research Projects on
Pharmaceutical Regulatory
Framework (APEC)

Online Training

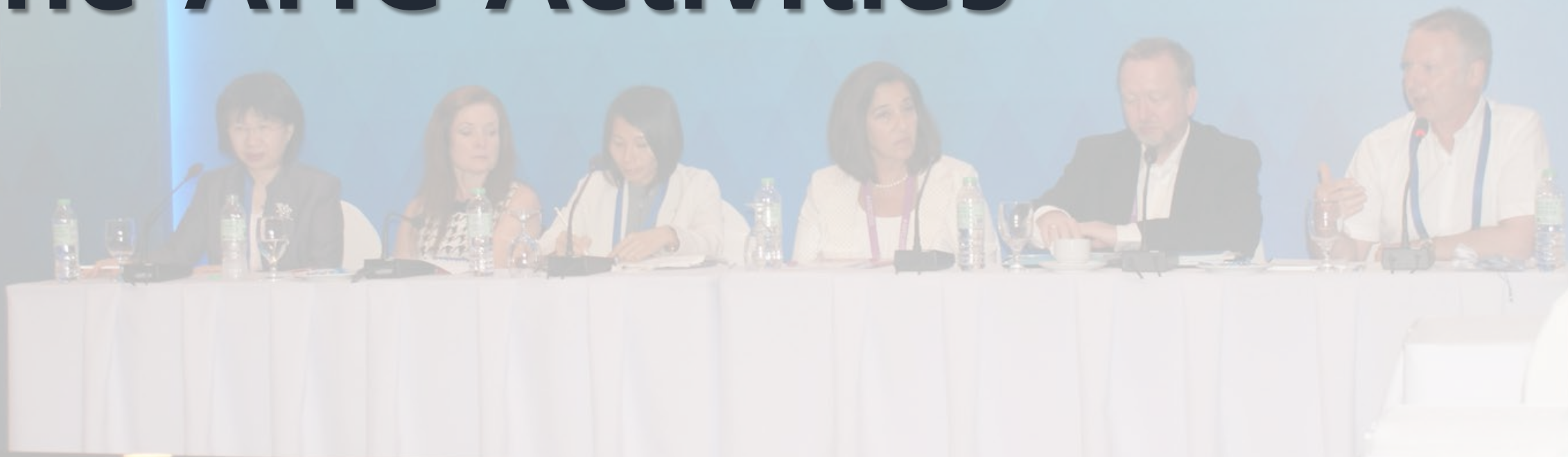
- AHC Workshop Videos and Presentation Materials
- Research Papers



APEC LSIF Training Program on Global Medical Product
Integrity and Supply Chain Security Workshop

July 27 - 28, 2018 Cebu City, Philippines

The AHC Activities



Workshops

The AHC Activities


 Workshops

 Research

 Online Training

1

AHC supports **RHSC PWAs** (Priority Work Areas) and devotes to **regulatory convergence** in the APEC.



**Pharmacovigilance
and Medical Device
Vigilance**



**Medical Product
Quality and Supply
Chain Integrity**



**Good Registration
Management**



**Advanced
Cell and Tissue
Therapy**



**Multi-Regional
Clinical Trials and
Good Clinical
Practices**




Biotherapeutics

2

AHC selects topics that are needed in regulatory convergence such as Generic Drugs and Medical Device.

Workshop

The AHC Activities

 Workshops

 Research

 Online Training

 Network






The AHC Workshops (2009~2016.3.)

-  **28** workshops, **8100** attendees
-  **109** speakers from **25** countries
-  **223** trainees from **11** APEC travel eligible economies





Achievements

-  Regulatory gap analysis
-  Training on the basis of recommendations from gap assessment
-  Training for regulators from APEC travel eligible economies




Future Plan– Center of Excellence (CoE)


-  The RHSC agreed to explore the establishment of CoEs to ensure sustainable platform for promoting regulatory convergence
-  The AHC takes role to coordinate CoEs

Workshop – 2016 plans

The AHC Activities

 Workshops

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1

Medical Product Integrity and Supply Chain Security Workshop
Feb 20 - 24 (5 days), Lima, Peru

2

Biotherapeutics CoE Pilot
Late Jul, Northeastern University, United States

3

Medical Product Integrity and Supply Chain Security Workshop
Aug, Lima, Peru

4


Pharmacovigilance and Medical Device Vigilance Workshop
Early Sep, Seoul, Korea

Research – Implementation Status on ICH Guideline

The AHC Activities

 Workshops



 Research

 Online Training




Object

-  Survey on **ICH Guidelines** Implementation Status to identify **training needs**

Method

-  Conducted **16 countries** and received responses from **8 governments** and **5 industry**.
-  Investigate to the implementation status of **Quality, Efficacy, Safety, Multidisciplinary**.

Pharmaceutical Regulatory Framework in APEC

-  The order of average percentage **implementation** of guideline was **Efficacy>Safety> Quality> Multidisciplinary**.
-  The order of **education needs** was **Quality> Efficacy>Safety>Multidisciplinary**.
-  Most people preferred online training and small group workshop.

Research – Implementation Status on ICH Guideline

The AHC Activities

Workshops

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ICH Guideline Survey Result Report

Contents

- I. Abstract
- II. Introduction
- III. Result
 - 1. Current status of ICH Guideline implementation
 - 1.1. Quality
 - 1.2. Safety
 - 1.3. Efficacy
 - 1.4. Multidisciplinary
 - 2. Needs of education by country
- IV. Conclusion

Reported by:

Yoonjee Lee, Minseung Jung
From AHC secretariat (April, 2015)

References

- Magdalena Bayne, Neil McAuliffe (2014, Dec). The impact of the changing regulatory environment on the approval of new medicines across six major authorities 2004-2013. Centre for Innovation in Regulatory Science
- WHO TDR Results (2013 report). WHO
- Anderson C, McLaurine JAN & Walker SR (2014). Adoption of the ICHES Guideline in Asia Pacific (excluding Japan). CMC International
- Dr Caroline Nadey, EFPIA, IFPMA, PMSOA (2000, Jan). The Value and Benefits of ICH to Industry, ICH

II. Introduction

The ICH guideline is an ongoing work that was first introduced in 1990, bringing together experts and regulatory authorities of the USA, EU and Japan. The purpose of this guideline is to establish single set of technical requirements for the registration of new drug products, and therefore to

I. Abstract

The ICH guideline which was introduced in 1990 have four parts of Quality, Efficacy, Safety and Multidisciplinary. Its aim is to guideline drug harmonization over the world. According as part of the ongoing study to develop on-line education program, AHC surveyed the introduction of ICH guideline.

The survey was conducted in both online and paper to improve response rate, of which 13 respondents provided data.

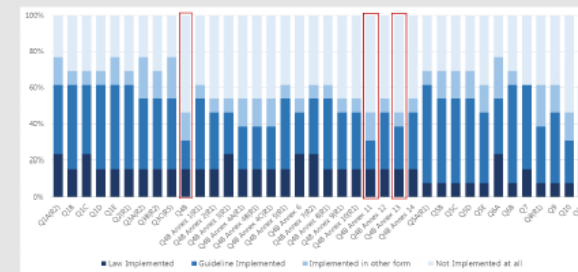
As a result, the order of average percentage implementation of guideline was Efficacy>Safety>Quality>Multidisciplinary. Whereas the order of education needs was Quality>Efficacy>Safety>Multidisciplinary. It is supposed that Quality is the most urgent part as a basic guideline.

Other result showed that respondents prefer online program and small group workshop training program.

Therefore, it is recommended that AHC may make those training programs especially on Quality the first for the harmonization of drug regulation in the APEC region.

ICH Guideline Survey Result Report, 2015, AHC secretariat

Fig2. Implementation Status (Quality)

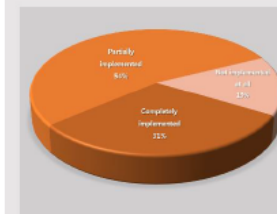


Safety

When asked the implementation status of each economy, 4 out of 13 responded "completely implemented", 7 as "partially implemented" and other 2 as "not implemented at all" (Fig 3).

The implementation status amongst the APEC economies was surveyed as the following (Fig 4). The graph shows there is no significant variations among individual guideline, therefore suggesting most are well incorporated into economies. The average implementation level in Safety calculated was 74% and the least implemented guideline was S10 of 62%.

Fig3. Implementation Status (Safety)



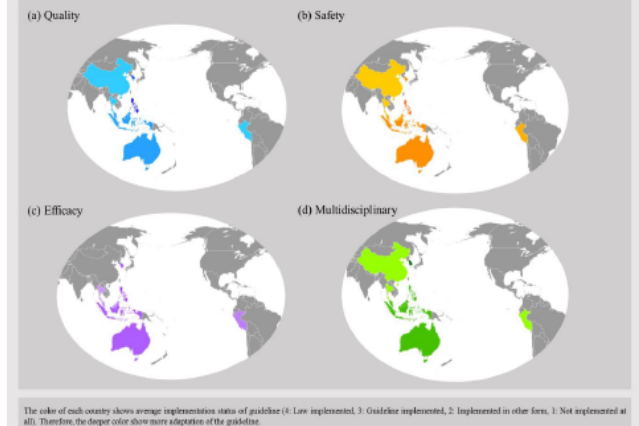
The average time taken in implementation claimed by the Governments for Safety guideline widely varies from less than 6 months to more than 4 years, and the industry answered from 2 years to more than 4 years category.

For the reason of delay, "Need of time to prepare or change regulatory system in order to implement the guideline" stood out as the main reason with 42%. Then "Lack of understanding of the guideline to implement immediately" followed with 26%. "Time to translation into their own language" also followed very closely with 21%.

ICH Guideline Survey Result Report, 2015, AHC secretariat

2. Needs of education by country

Fig9. Implementation Status



Which education is needed by country

Figure 9 portrays the average implementation status of APEC member economies of each area: Quality, Safety, Efficacy and Multidisciplinary. The color scheme was calculated by scoring the implementation status of each specifying guideline with 4 being law implemented and 1 being not implemented at all. Therefore, the paler the color is, the less implemented of guideline as a whole.

In part of Quality, the Philippines scored the highest on average implementation status and Korea and Brunei also showed high score. On the other hand, China, Peru, and Thailand showed low average implementation status. In the part of Safety, no economy scored the maximum. Indonesia, Malaysia, Australia, and Brunei scored high among the respondents especially compared to China and Thailand. The Philippines again scored the highest in Efficacy, while Malaysia and Thailand scored the lowest. No economy scored maximum in the part of Multidisciplinary either, and China and Thailand scored the lowest. Based on all these outcomes, China stood out as the economy with urgent need in education for all areas, while the Philippines in average scored the highest in the most of the four parts.


Online Training

www.apec-ahc.org

The AHC Activities

 Workshop

 Research

 Online Training

Online Training

- AHC Workshop Video Clips and Presentation Materials
- APEC RHSC CoE Pilot Videos and Presentation Materials

Research

- Survey Result Report on the Implementation of ICH guidelines



The APEC Harmonization Center



About AHC

AHC Activities

E-learning

Centers of Excellence

Resource

All



APEC LSIF Training Program
on **Global Medical Product Integrity**
and **Supply Chain Security**

In Focus




E-Learning Center

www.apec-ahc.org

The AHC Activities

 Workshop

 Research

 Online Training

AHC Workshops and CoE Pilot

- Workshop Information
- Speakers
- Workshop Videos
- Presentation Materials

Research Papers

- ICH Guideline Survey Result Report



The APEC Harmonization Center

About AHC

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E-learning

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E-learning

ICH Online Program

Workshops

Workshops

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Biotherapeutics

- 2009 Biosimilar
- 2012 Biosimilar
- 2013 Biotherapeutics
- 2014 Biotherapeutics
- 2015 Biotherapeutics

Resource

News

RHSC PWA

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Network

The AHC Activities

-  Workshop
-  Research
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The AHC cooperates with International organization, regulatory agencies, and industries to enhance the global network to promote regulatory harmonization without having duplication efforts.

How to involve?

www.apec-ahc.org

Thank you

Please contact AHC Secretariat at ahckorea@kpma.or.kr