

APEC Harmonization Center

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AHC Vision

Establishment of the Best Harmonization Model in the Asia-Pacific Region through achieving goals:

Supporting access to the **best practices and guidelines** for regulatory harmonization

Promoting collaborative actions and wide **information exchanging activities** among participants

Promoting the conduct of **clinical trials** that meet international standards

Enhancing the quality, safety, and efficacy of therapeutic products and thus enhance health outcomes in APEC Economies and facilitate the international trade of therapeutic products

AHC Logo

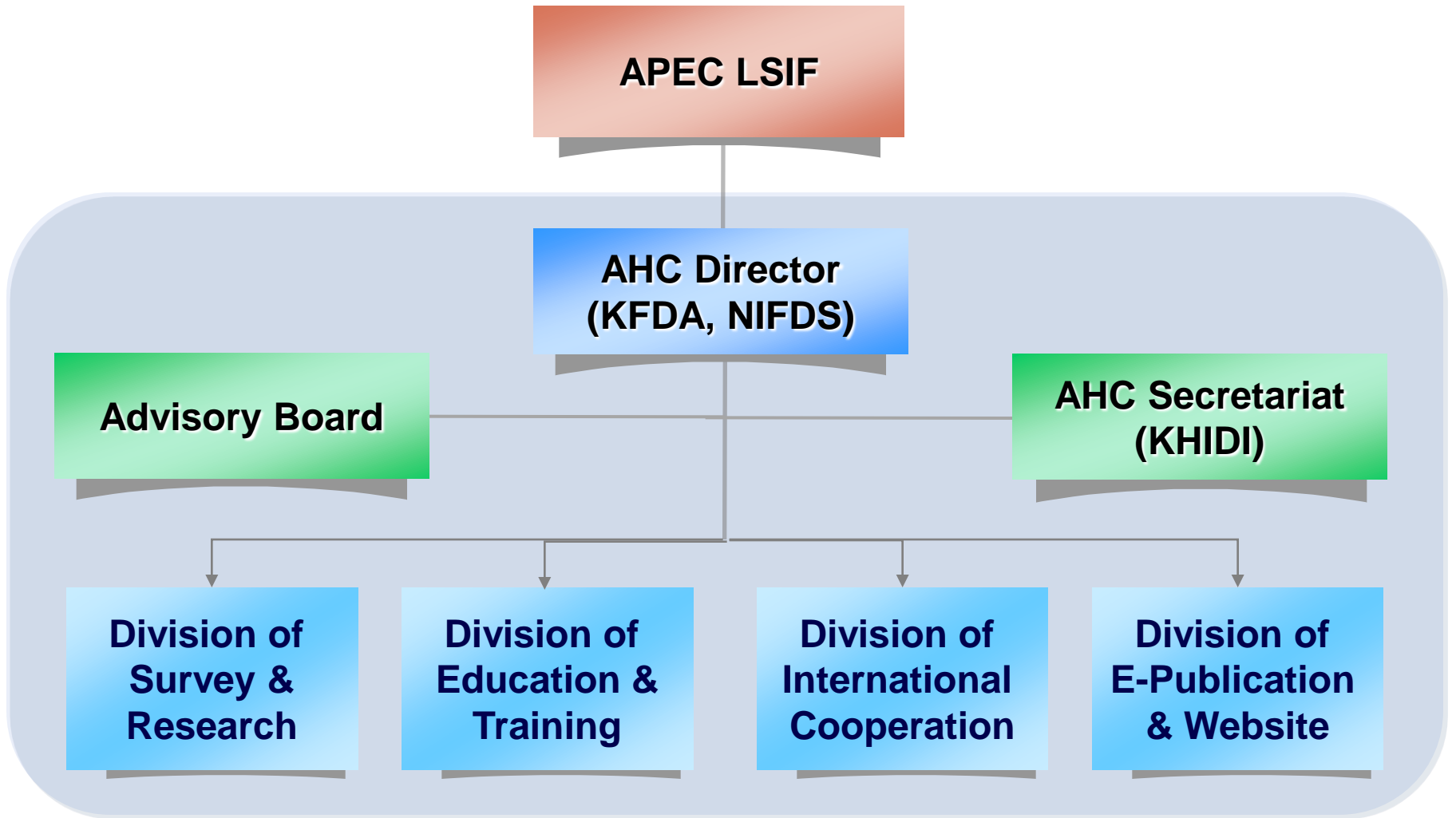


- **The Red and Blue arms joined in the center** represent a critical connection of the Asia Pacific Region
- **Joint effort to harmonize** starts from the core and extends out to bring out the harmonization between the **East and West of the Asia Pacific Region**
- AHC will be active in continuing the successful progress of **international regulatory harmonization initiative** within the APEC region

Scope of AHC Activities

Surveys & Research	<ul style="list-style-type: none">• Conduct Surveys and Research on Harmonization Policies and Practices• Identification of Best Practices and Challenges
Education & Training	<ul style="list-style-type: none">• Providing Educational Programs : Symposiums, Workshops, Seminars, and Fellowship programs
E-Publication & Website	<ul style="list-style-type: none">• Publishing and Web Posting: AHC Newsletter, Compendium of the events and training programs of AHC
International Cooperation	<ul style="list-style-type: none">• Establishing networks and Exchanges: Organized Collaboration between the groups represented in the Advisory Board and other international organizations

Organization



Inauguration Ceremony of AHC

- **Date: June 15, 2009**
- **Venue: Grand Hilton, Seoul**
- **Participants**
 - About 600 from 17 economies
(Government, Industry and Academia)
- **Inaugural Ceremony**
 - Performance(Sand Animation), Message from the President of Korea, Remarks, Reception



Multi-Regional Clinical Trial Workshop

- **Date: June 15 ~ 18, 2009**
- **Title: Multi-Regional Clinical Trials (MRCT) Seoul Workshop**
- **APEC Self-funded Project (2009/CTI2/LSIF/005)**
- **About 600 Attendees:**
 - **17 Speakers**
 - **AHC supported Trainees** from Malaysia, Peru, Philippines, Thailand, Vietnam.



Multi-Regional Clinical Trial Workshop

Program: **6 Plenary** & 4 Breakout Sessions

- **Plenary 1: The Value and Challenges of Multi-Regional Clinical Trials**
- **Plenary 2: Intra-Regional Efforts to Streamline the Conduct of Clinical Trials: The Tripartite Initiative and the ASEAN PPWG**
- **Plenary 3: ICH: Overview**
- **Plenary 4: Multi-Regional Clinical Trial Design Issues that Clinical Researchers Should Understand in Order to Succeed**
- **Plenary 5: Operational Aspects**
- **Plenary 6: Regulatory Guidance/Perspectives/Issues**

Multi-Regional Clinical Trial Workshop

Program: 6 Plenary & 4 Breakout Sessions

- **Session 1: Regional Specific Issues**
- **Session 2: Site Management, Data Management and Good Clinical Practice**
- **Session 3: Multi-Regional Clinical Trial Design Issues that Clinical Researchers Should Understand in Order to Succeed**
- **Session 4: Specific Therapeutic Areas**

Multi-Regional Clinical Trial Workshop

GMP and Clinical Site Visit

- GMP Pharmaceutical Ware Visit: Yuhan Co.
- Clinical Site Visit: Asan Medical Center



MRCT Workshop-Recommendations(1)

▪ Training

- **Create RHSC subcommittee** on training
- **Identify the needs and areas of interest** by survey and assessment
- **Identify qualified trainers**
- **Develop Training Methods:** Face-to-face programs, webinars

MRCT Workshop-Recommendations(2)

- **Develop Guidance**

- Perform prospective research and data collection
- Create Principle documents

- **Create Repository of Information**

- Create a **repository of regulations** for the better understanding of the different regulations
- Consider **Common language**

MRCT Workshop-Recommendations(3)

▪ Promote Dialogue

- Promote dialogue on MRCT
- Provide a forum to increase collaboration among industry, academic and regulatory scientists to enhance awareness of the issues

▪ Develop Common Templates

- Develop **Reporting and Reviewing Templates** to ensure acceptability of MRCT data

Biosimilar Workshop

- **Date: September 16 ~ 18, 2009**
- **Title: APEC Harmonization Center Biosimilar Workshop**
- **Venue: Grand Conference Room, COEX, Korea**
- **About 400 Attendees:**
 - **9 Speakers**
(Asia, North America, Europe)
 - **AHC Supported Trainees** from
Indonesia, Malaysia, Peru,
Philippines, Thailand, Viet Nam.



Biosimilar Workshop

Program: 3 Sessions (Sept. 17)

- **Session 1: The Opportunities and Challenges of Biological Medicine**
- **Session 2: Regulatory Issues for Biosimilars**
- **Session 3: Regulatory Landscape on Biosimilars**
- **Summary & Next Steps**

GMP ware visit & Seoul Tour (Sept. 18)

- **Pharmaceutical Ware: Celltrion Co.**



Biosimilar Workshop- Recommendations

- **Promote Dialogue on Biosimilars**
- **Sharing Information**
- **Access and Cost Issues**
- **Training**

Next Steps

Education & Training

▪ Workshops in 2010

- The AHC will continue to serve as a forum for education & training for the capacity building
- The AHC will develop programs and annual training plans directed by the AHC Advisory Board and under guidance of the APEC RHSC and LSIF

Survey & Research

- The AHC will conduct survey and research to assess the training needs and current situation of the APEC countries

Next Steps

E-Publication & Website

- Post training materials on the AHC website
- Develop new website for repository of Information, Database

International Cooperation

- Strengthen cooperation with governments, industry and academia (both APEC and non-APEC)
- Confirm members of the Advisory Board experts from international harmonization organizations including ICH, GHTF, and others

Next Steps

- **Other activities under guidance of the APEC LSIF RHSC**
 - e.g. mapping out existing harmonization models and capacity building
- **Continue to Discuss and Consider the Recommendations raised from the workshop**
 - Collaborate work of the AHC Advisory Board and the RHSC will promote regulatory capacity building

Outcomes

- First step towards the **sustained, long-term capacity building activities**
 - AHC Workshop provided the medium for sustained, long-term capacity building activities that will contribute to regional economic integration
- **Strengthening friendship and Network** among the participants from the APEC and non-APEC economies
- **Received high interests and supports** from Regulatory Authorities, Industry, and Academia for its Regulatory Harmonization initiative within the APEC region

Concluding Remarks

- **AHC** seeks support from the ICH-GCG in future training and capacity building activities
- **AHC welcomes the suggestions on the training needs and areas** from ICH-GCG members
- **AHC welcomes** other interested governments, institutions, corporations and foundations **to work cooperatively with the AHC**



Thank You

KFDA 식품의약품안전청
Korea Food & Drug Administration