The AHC was established to provide a sustained way of advancing APEC’s trade facilitation and regional economic integration:

1. By facilitating regulatory convergence in the region and beyond
2. By enhancing quality, safety and efficacy of medicinal products
3. By promoting collaborative actions and information sharing
4. By supporting access to the best practices and international guidelines

The AHC, in partnership with APEC Regulatory Harmonization Steering Committee (RHSC), is operated under aegis of APEC Life Sciences Innovation Forum (LSIF) in order to provide platform for regulatory priorities among APEC member economies. The AHC is operated and supported by the National Institute of Food and Drug Safety Evaluation (NIFDS), the Ministry of Food and Drug Safety (MFDS), Korea.

AHC Mission & Organization

APEC Harmonization Center
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AHC Mission

By facilitating regulatory convergence in the region and beyond

AHC Advisory Board
Is responsible for providing technical input and professional expertise on the strategic direction of AHC events for developing training modules and securing appropriate trainers to be used as resources for strengthening the AHC and its specific projects.

AHC Director
Is responsible for overseeing activities and events and leading coordination among LSIF, RHSC, AHC Secretariat, and AHC Advisory Board. The Director of AHC is performed by Director General of the National Institute of Food and Drug Safety Evaluation (NIFDS), the Ministry of Food and Drug Safety (MFDS), Korea.

AHC Secretariat
Is responsible for administrative point of contact and organization of the AHC’s day-to-day activities. The Secretary General is an overseer of the Secretariat’s activities including international cooperation, and assists the AHC Director. Duties of AHC Secretariat are performed by the Korea Pharmaceutical Manufacturers Association (KPMA).
The APEC Harmonization Center (AHC) was established in 2009 after the endorsement of the APEC ministerial-level talks and summit as an official and permanent organization, specialized in training. The AHC is in pursuit of APEC’s trade facilitation and regional economic integration by promoting a higher level of international regulatory harmonization in the APEC region.

**AHC History**

09. 2005

Ministers and officials at the LSIF recommended APEC Leaders to endorse the “capacity building for the harmonization of standards and regulatory practices for medical products and services according to international best practices where the need is most pressing and obstacles are the greatest” by the AHC in Seoul as a key step forward.

08. 2008

Korea proposed the establishment of the AHC at the LSIF meeting in Peru.

11. 2008

APEC Ministers specifically endorsed the AHC in the LSIF meeting in Peru.

06. 2009

The AHC was established in the MFDS.

**AHC Activities**

The AHC has hosted 28 workshops, where approximately 8,000 regulators and industry participants were provided with training and discussed ways to achieve regulatory harmonization. By supporting participation of 11 APEC travel eligible economies (215 trainees) for training, the AHC has contributed to the regulatory harmonization in the APEC region.

**AHC Workshop**

01

In cooperation with the international organizations including LSIF, RHSC, WHO, IFPMA, ICH, and IGDRP, the AHC is working to enhance capacity building in the health industry and harmonize with international regulations by providing various training for APEC regulators and industries in the medical product area.

**AHC Website**

02

To ensure easy access to various training materials and achievements of regulatory harmonization that the AHC is working on, related data are available at the AHC website. The AHC provides not only workshop video clips and presentation materials, but also AHC research reports and annual reports.

**AHC e-Learning Center**

03

In 2016, the AHC opened e-Learning Center to ensure capacity building of regulators and expansion of regulatory harmonization training opportunities in the APEC region.

The AHC has proposed a joint development of ICH guideline training program to the International Council on Harmonization (ICH) and is jointly developing online training program under the agreement with the ICH. After conducting pilot training program for ICH pharmacovigilance guidelines (ICH E2 series), the AHC is now planning to expand the program to a number of topics in the future.

**AHC Research**

04

The AHC conducts various research projects in order to pioneer areas in need of regulatory harmonization and to seek measures. On the basis of the research on pharmaceutical regulatory framework of APEC economies, the AHC plans to publish regulatory requirements of each economy, through its website which will be continuously updated in the form of report. Moreover, a survey on ICH guideline implementation status in each APEC economy and its priority training areas was conducted by the AHC and the report results are also available at the website. The AHC will continue its efforts to achieve regulatory harmonization through research activity.