Mission

The AHC was established in order to contribute to trade facilitation and economic integration in the APEC region. AHC’s mission for that includes:
1. Facilitate regulatory convergence in the region and beyond
2. Enhance quality, safety and efficacy of medical products
3. Promote collaboration and information sharing among APEC members
4. Support access to the best practices and international guidelines

Organization

APEC Leaders’ Meeting

APEC Business Advisory Council

Ministerial Meeting

Sectoral Ministerial Meeting

Senior Officials’ Meeting

Senior Finance Officials’ Meeting

Committee on Trade & Investment

Budget & Management Committee

Economic Committee

SOM Steering Committee on ECOTECH

APEC LSIF

APEC RHSC

APEC Harmonization Center

AHC Director

Is responsible for overseeing AHC’s activities and events and leading coordination among LSIF, RHSC, AHC Secretariat, and AHC Advisory Board. The AHC Director is performed by Director General of the NIFDS, the MFDS.

AHC Advisory Board

Is responsible for providing technical input and professional expertise on the strategic direction of AHC’s activities, and assistance for development of training module and inviting appropriate experts.

AHC Secretariat

Is responsible for administrative works and serves as a focal contact point of AHC. The AHC Secretariat is currently supported by the Korea Pharmaceutical and Bio-Pharma Manufacturers Association(KPBMA).
The APEC Harmonization Center (AHC) was established in 2009 with 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 region.

AHC Activities

In cooperation with the international organizations including LSIF, RHSC, WHO, ICH and IPRP*, the AHC is focusing on capacity building and regulatory harmonization based on international guidelines.

Workshop

The AHC has hosted 37 workshops, where approximately 9,100 regulators and industry participants were provided with training and discussed regulatory harmonization. AHC’s support for participation of 11 travel eligible economies (311 trainees) has significantly contributed to the regulatory harmonization of medical products in the region.

<table>
<thead>
<tr>
<th>Date</th>
<th>Workshop Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>11. 2013</td>
<td>AHC and RHSC Awareness Workshop</td>
</tr>
<tr>
<td>11. 2014</td>
<td>AHC-AHWP Joint Workshop</td>
</tr>
<tr>
<td>11. 2015</td>
<td>AHC-ICH Ofﬁcial Integrated Implementation Training Workshop for ICH Q8/Q9/Q10</td>
</tr>
<tr>
<td>11. 2016</td>
<td>AHC and RHSC Awareness Workshop</td>
</tr>
<tr>
<td>11. 2017</td>
<td>AHC Biotherapeutics Workshop</td>
</tr>
<tr>
<td>11. 2018</td>
<td>AHC and RHSC Awareness Workshop</td>
</tr>
<tr>
<td>11. 2019</td>
<td>AHC Biotherapeutics Workshop</td>
</tr>
<tr>
<td>11. 2020</td>
<td>AHC and RHSC Awareness Workshop</td>
</tr>
<tr>
<td>11. 2021</td>
<td>AHC Biotherapeutics Workshop</td>
</tr>
<tr>
<td>11. 2022</td>
<td>AHC and RHSC Awareness Workshop</td>
</tr>
<tr>
<td>11. 2023</td>
<td>AHC Biotherapeutics Workshop</td>
</tr>
<tr>
<td>11. 2024</td>
<td>AHC and RHSC Awareness Workshop</td>
</tr>
</tbody>
</table>

Website

Many training resources are available at AHC’s website to ensure an easy access to various training materials and achievements of AHC’s efforts for regulatory harmonization. The AHC provides not only workshop video clips and presentation materials, but also AHC’s research and annual reports.

Research

The AHC conducts various research projects in order to identify areas where regulatory harmonization is needed and take actions in response to the needs. For example, the AHC has published reports on drug approval system of 21 APEC member economies since 2015 (available on AHC website). A survey on ICH guideline implementation among APEC member economies was conducted in 2014, and the survey report was published and is also available on the website (www.apec-ahc.org).

The AHC and the International Council for Harmonisation (ICH) developed ICH guideline E2: Pharmacovigilance training programs together. Following that, the AHC also developed ICH guideline (ICH Q8, Q9 and Q10) training programs and Biotherapeutics online course which started to be provided since 2017. The AHC will continue to expand training programs based on priorities in the APEC region.

*World Health Organization (WHO). International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). International Pharmaceutical Regulators Programme (IPRP)