

## APEC Harmonization Center Guidelines

### 1. Mandate

1.1 The APEC Harmonization Center (AHC) is established under the authority of the APEC Life Sciences Innovation Forum (LSIF) to provide a platform to address and solve priority concerns of APEC member economies on regulatory harmonization. In 2008, APEC Ministers specifically endorsed the AHC in the annual Ministerial Joint Statement:

*“Recalling our commitment to promoting regulatory reform and harmonization, we welcomed and endorsed the establishment of the APEC LSIF Harmonization Centre in Seoul as a key step forward.”*

### 2. Goals

2.1 Both APEC broadly and LSIF specifically have recognized the benefits of regulatory harmonization within APEC, including in the context of APEC’s trade facilitation and regional economic integration agendas. The AHC will provide a sustained way of advancing those agendas.

2.2 In this context, the AHC’s primary goals will include:

- **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 medical products and thus enhance health outcomes in APEC economies and facilitate the international trade of medical products.

### 3. Operations and Organization

3.1 As an LSIF organization, the AHC will engage with and seek input from representatives of government, industry, and academia.

3.2 The LSIF, through the Regulatory Harmonization Steering Committee (RHSC), provides strategic direction to the AHC in accordance with established regulatory priorities and programs.

3.3 The organizational structure of the AHC will include the following components:

- AHC Director: responsible for oversight of activities and events and for leading coordination between the LSIF Planning Group, the Regulatory Harmonization Steering Committee (RHSC), the AHC Secretariat, and the AHC Advisory Board.
- AHC Secretariat: responsible for coordinating day to day organization of AHC activities and serving as the administrative point of contact. The Secretary General oversees Secretariat activities, including international cooperation, and assists the AHC Director.
- AHC Advisory Board (AB): is responsible for providing technical input and professional expertise on the organization of specific curriculum and projects; develop training modules and securing appropriate trainers.

3.4 The AHC AB would be comprised of members representing a cross section of LSIF expertise.

#### 4. Scope of Activities

4.1 The AHC will report to and be guided by the LSIF. However, the initial scoping of its activities includes:

- **Conduct surveys and research** on harmonization policies and practices and identification of best practices and challenges;
- **Provide education**, including symposiums, workshops, seminars and fellowship programs to the full range of regulatory stakeholders;
- **Establish strong networks** for harmonization and mechanisms for information exchange among participants;
- **Maintain an e-Publication and website** to increase engagement and share information;
- **Develop and disseminate harmonization models** across the Asia-Pacific Region;
- **Support international cooperation** through organized collaboration between the groups represented in the AHC AB and through new initiatives with other international centres and institutions.

## ANNEX A:

### **APEC Harmonization Center Advisory Board (AHC AB)**

#### **1. Membership**

The AHC Director will act as a chair of the AB. The Chairs of the LSIF Planning Group, the LSIF RHSC and the RHSC subcommittee on training will participate in AB meetings given the need for close coordination of effort in achieving overall harmonization and training objectives.

AB members will be selected on the basis of their recognized ability to provide technical input and professional expertise on the organization of specific curriculum and projects; to develop training modules and to secure appropriate trainers across the range of topics under consideration by the AHC. Efforts will be made to ensure that the expertise and knowledge of board members is complementary and that members represent a cross section of LSIF constituents.

Towards this end, selection of candidates will take into account the need for:

- members from regulatory authorities of APEC economies with responsibility for the regulation of medical products, including pharmaceuticals and medical devices
- members from the medical products industry, including pharmaceuticals and medical devices
- at least one member from an academic or other educational institution within the APEC region
- appropriate geographic representation from across the APEC region
- knowledge and experience in scientific and regulatory affairs
- knowledge and experience in regional and international harmonization activities
- previous experience as a member of an advisory board or similar committee to an organization engaged in international regulatory policy, advocacy or training
- other exceptional requirements and experience that can ensure support for the specific objectives of the AHC.

In order to preserve as much flexibility as possible in the membership of the AHC AB, the above composition requirements are intended to establish minimum requirements and are not intended to be overly prescriptive. Accordingly, any one member of the AB can be used to satisfy one or more of the requirements listed above.

In exceptional cases, the AHC Director may authorize an individual with appropriate knowledge and expertise to participate in AB as an external expert.

#### **2. Representation:**

As the qualifications to serve on the AB suggest, Board members are asked to serve based on their own unique expertise and experience in an advisory capacity rather than as representatives of an organization. However, in certain circumstances, the obligations of some government agencies do not allow their staff to serve in an advisory capacity to any other organization except as an official representative of their employer. In these cases, it is understood that government representatives will take into account the official policies and positions of their home organizations in AB proceedings.

#### **3. Conflicts-of-Interest:**

Due to the unique role of the AHC AB, it is not anticipated that board members will be faced with an actual or potential conflict-of-interest while advancing the interests of the AHC. However, if an AB

member does become aware of an actual or potential conflict-of-interest, that member should so inform the Director of the AHC and subsequently abstain from participating in any portion of an AB proceeding in which that conflict-of-interest may arise.

#### **4. Functions**

Each board member is responsible for the following activities:

- providing technical input and professional expertise on the organization of specific curriculum and projects,
- developing training modules and securing appropriate trainers
- consulting with external experts on specific projects when necessary
- undertaking any other initiatives that contribute to the achievement of AHC goals and objectives.

Board members are expected to devote adequate time and attention to assigned tasks and duties and to conduct work via remote communication, including e-mail and teleconference. Face to face meetings of the AB may also be called by the AHC Director, as required. Efforts will be made to conduct such meetings in conjunction with other meetings or events in which a number of board members are likely to be present.

#### **5. *Ad Hoc* working groups**

*Ad Hoc* working groups may be formed at any time by the AB. *Ad Hoc* working groups shall have specific work products for short time (e.g. planning for the specific workshop).