

# Steps to Conducting an APEC RHSC CoE Pilot Program and Formalizing an APEC CoE

## CHECKLIST

The following steps, at a minimum, must be followed in order to host an APEC CoE pilot program and then become a formalized CoE. Refer to the “APEC LSIF RHSC Training Centers of Excellence for Regulatory Science-Operating Model and Guidelines” for more information.

### Hosting a CoE Pilot Program



1. Contact the Priority Work Area Champion Economy to notify them of your interest in hosting a pilot Center of Excellence (CoE) training in their respective work area.

#### Priority Work Areas (PWA):

- *Multi-regional Clinical Trials (MRCT) and Good Clinical Practices (GCP) Inspections*  
Japan (MHLW/PMDA) and Thailand (TFDA): add Contact names and [email](#)
- *Global Supply Chain Integrity*  
US (FDA): add contact name and [email](#)
- *Advance Therapies*  
Singapore (HSA): add contact name and [email](#)
- *Biotechnology Products*  
Korea (MFDS): add contact name and [email](#)
- *Good Registration Management*  
Chinese Taipei (TFDA) and Japan (MHLW/PMDA): add contact names and [email](#)
- *Pharmacovigilance*  
Korea (MFDS): add contact names and [email](#)
- *Medical Device*  
Korea (MFDS), United States (FDA), Japan (PMDA) and email



2. Contact the APEC Harmonization Center (AHC) through AHC website at [www.apec-ahc.org](http://www.apec-ahc.org) to notify them of your interest in hosting a pilot Center of Excellence training, specify the specific work area in the email and subject line.



3. Obtain the CoE pilot application form through AHC website at [www.apec-ahc.org](http://www.apec-ahc.org) (AHC website) or the PWA Champion Economy.

- 4. Start the application process in consultation with the PWA CoE Program Committee. If a program committee has not yet been established the CoE hosting institution is encouraged to develop one consisting of the PWA champion economy, RHSC members, industry and academic partners.
- 5. Submit the CoE Pilot application form to the RHSC leadership and relevant PWA Champion Economy, through the AHC website. Application notifies the RHSC of a desire to become a candidate CoE hosting institution and to host a pilot in the specified PWA.
- 6. Upon invitation from the RHSC leadership, develop a brief (5-10 minutes) description of plans for the program for presentation at an upcoming APEC LSIF RHSC meeting (SOM1, February; SOM3, August). Presentation may be given by the PWA Champion if the applicant is unable to attend the RHSC meeting in person.
- 7. Obtain endorsement and approval from the RHSC to proceed with pilot application process
- 8. After endorsement for the pilot application is received, using the PWA core curriculum for the respective work area, develop a pilot training program in consultation with the PWA CoE Program Committee.
  - Schedule periodic teleconferences with the PWA CoE Program Committee; provide updates to the RHSC leadership upon request.
  - Identify appropriate speakers and facilitate communication between speakers to ensure a cohesive program is delivered.
- 9. OPTIONAL: While developing the pilot training program, if requesting AHC funding, obtain an application form through the AHC website. Applications for AHC funding are due by September 30 the year prior to disbursement of funds.
  - Work with AHC in filling out the funding application.
  - Submit proposal for funding.
- 10. Propose a timeframe for the potential pilot in collaboration with the PWA CoE Program Committee and share it with the RHSC leadership, the PWA Champion Economy and the AHC.
- 11. Obtain approval from RHSC for the timing of the planned pilot. Once a proposal is finished (step 8), share the proposed training program with the PWA CoE Program Committee and RHSC for discussion at least 8 weeks before the planned pilot.
- 12. Develop a post-course evaluation form in collaboration with the PWA CoE Program Committee.

- 13. Obtain final approval from the RHSC for the training program
- 14. Conduct APEC LSIF RHSC CoE pilot training as approved from the RHSC leadership and PWA Champion.
  - Considerations:
    - Schedule the pilot program around availability of the PWA Champion, , PWA CoE Program committee, and/or RHSC leadership, in order that they can attend to provide feedback
    - Be sure all participants, including faculty and observers, provide a post-course evaluation form.
- 15. Convene the PWA CoE Program committee to discuss the outcome of the pilot. Determine if additional pilots are required. Report outcome back to the PWA champion economy.

***\*\* Once approved, the participation selection and registration can begin for the hosting institution \*\****

***\*\*\*The candidate CoE hosting institution should consult and adhere to “APEC LSIF Training Centers of Excellence for Regulatory Science - Operating Model and Guidelines” \*\*\****

### **Becoming a Formal CoE**

- 1. Complete the pilot program(s) as described above. A minimum of one pilot program must be conducted before applying to become a formal APEC CoE.
- 2. Consult the document, “APEC LSIF RHSC Training Centers of Excellence for Regulatory Science-Operating Model and Guidelines”, to ensure the candidate hosting institution meets the criteria. This should be done in collaboration with the PWA CoE Program committee.
- 3. Request a formal CoE application form from the RHSC leadership or AHC.
  - The institution requesting recognition as a full CoE may complete the application form with or without consultation the PWA CoE Program committee
- 4. Submit the completed application through AHC website, with all accompanying documents to the RHSC leadership, PWA champion economy and PWA CoE program committee.
- 5. The RHSC leadership will then invite the requesting institution to present at an upcoming RHSC meeting (SOM1, February; SOM3, August).

- Provide the results of the pilot(s), evidence of its ability to meet the selection criteria as detailed in the “APEC LSIF RHSC Training Centers of Excellence for Regulatory Science-Operating Model and Guidelines”, and plans to ensure sustainability when it commences operations (staff, funding, etc.).
- 6. The RHSC opens the floor to discussion, and a subsequent vote of the institution’s ability to serve as a CoE.
  - If it is determined the institution is not yet ready, the RHSC and PWA CoE Program Committee will provide detailed guidance to the requesting institution so that it may conduct subsequent pilots.
  - If the requesting institution is endorsed as a CoE a written letter of endorsement will be provided.
- 7. After endorsement, the RHSC leadership, LSIF advisor, and the endorsed CoE hosting institution develop a MoU based on the “CoE MoU Template”.
- 8. RHSC leadership sends the approved draft (step 7) to the LSIF planning group, requesting approval for the LSIF Planning Group Chair to sign the MoU.
- 9. If no further edits are requested for the LSIF planning group, they sign the MoU along with the host institution.
- 10. The now official CoE hosting institution, with support from the PWA CoE Program committee, may begin operating. This program committee will be involved with the continuing operation of the CoE. Note: The CoE may seek to serve as a CoE for other topic areas by undertaking the same steps outlined above.