

APEC LIFE SCIENCES INNOVATION FORUM REGULATORY HARMONIZATION STEERING COMMITTEE



Version: Dec 2020

APEC Training Centers of Excellence for Regulatory Science (CoEs)

Checklist



APEC LIFE SCIENCES INNOVATION FORUM REGULATORY HARMONIZATION STEERING COMMITTEE



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.

Becoming a Candidate CoE Host Institution & Completing a CoE Pilot Program

 $\hfill\square$ Obtain the CoE Pilot Application Form on the RHSC website.

☐ Complete the CoE Pilot Application Form and submit it to the RHSC Secretariat.
$\hfill\Box$ Obtain the approval and recommendation of the PWA CoE Steering Committee, which may require further discussion or additional information.
☐ Develop a brief (5-10 min.) presentation to include organizational qualifications and a description of the proposed CoE Pilot Program, and present it to the RHSC.
☐ Obtain initial RHSC endorsement. Once endorsed, you are now a Candidate CoE Host Institution. This first endorsement is that of an institution's ability to satisfy the criteria laid out in Section B of the CoE Operating Model.
☐ In consultation with the PWA CoE Steering Committee, convene a CoE Program Committee to help (a) develop a pilot training program based on the PWA Training Objectives and Core Curriculum; (b) propose a timeframe for the pilot program; and (c) develop a post-course evaluation form.
☐ Schedule regular teleconferences with the CoE Program Committee; provide updates to the PWA CoE Steering Committee upon request.
$\hfill \square$ Identify appropriate speakers and facilitate communication between speakers to ensure a cohesive program is delivered.
□ OPTIONAL: If requesting APEC Harmonization Center (AHC) funding, obtain an application form on the AHC website, complete it, and submit by September 30 in the year prior to anticipated disbursement of funds.
☐ Obtain final approval from RHSC for the timing, training program, and evaluation form at least 8 weeks before the planned pilot. Once approved, begin participation selection and registration.



APEC LIFE SCIENCES INNOVATION FORUM REGULATORY HARMONIZATION STEERING COMMITTEE



This second approval is that of the actual pilot training program to be delivered; the RHSC may deem the PWA Steering Committee sufficient to approve the materials at this step. ☐ Conduct CoE pilot training. ☐ Convene the CoE Program Committee to discuss the outcome of the pilot and results of the postcourse evaluation, and report back to the PWA CoE Steering Committee. **Becoming a Formal CoE Host Institution** ☐ Complete a minimum of three (3) successful CoE Pilot Programs. ☐ With the approval of the PWA CoE Steering Committee, obtain the formal CoE application form on the RHSC website, complete the form, and submit it to the RHSC Secretariat. ☐ Develop a brief (5-10 min.) presentation for the RHSC to include organization qualifications, results of the three (3) CoE Pilot Programs, evidence to demonstrate ability and capacity to abide by the CoE Operation Model and Guidelines, and plans to ensure sustainability of operations. ☐ If RHSC endorsement is successful, a written letter of confirmation is provided by the RHSC Secretariat. You are now a Formal CoE Host Institution. ☐ If RHSC endorsement is not successful, detailed guidance is provided by the PWA CoE Steering Committee for the completion of one or more additional CoE Pilot Programs. ☐ Once RHSC endorsement is obtained, the RHSC Secretariat requests the input and signature from the Formal CoE Host Institution for the Memorandum of Understanding (MOU). ☐ Once the MOU is signed by the CoE Host Institution, the RHSC Secretariat requests the countersignature of the LSIF Planning Group Chair. ☐ The new Formal CoE Host Institution may now begin operating with support from the PWA CoE Steering Committee and its PWA Program Committee.