
APEC Training Centers of Excellence for Regulatory Science Pilot Application Form

This form is used to request approval to become a candidate Center of Excellence (CoE) and to conduct a pilot for a RHSC Priority Work Area (PWA). Completed applications and supporting material should be sent to the RHSC Secretariat with copy to the PWA Champion Economy representative.

Candidate Information

Organization Name:

Physical Address:

CoE Contact Name:

CoE Contact Title:

CoE Contact Phone:

CoE Contact Email:

CoE Pilot Information

Priority Work Area (select one of the below):

- Multi-Regional Clinical Trials (MRCT)-Good Clinical Practices (GCP) Inspections
- Global Supply Chain Integrity
- Advanced Therapies (Cell, Gene, and Tissue-Based Therapies)
- Biotherapeutics (Biotechnological Products)
- Good Registration Management
- Pharmacovigilance
- Medical Devices

Do you plan to host training activities:

- In person, face-to-face
- Totally remotely
- Hybrid

Brief description of proposed pilot (this can be provided as a separate attachment):

- High-level outline (specifically state how the Core Curriculum will be used)
- Proposed timing and location
- Funding plan/assumptions

Do you hold formal CoE status for another PWA?

- Yes, for this/these PWA(s):
- No

If yes, the Organizational Qualifications section is not required.

Organizational Qualifications

Please provide information outlining your organization's qualifications relevant to the following CoE criteria. If you are part of a partnership with other organizations to provide CoE services, please provide contact and qualification information for the partner organizations as well. Information may be provided as a separate package or attachment.

- Trusted global educational/regulatory/science-setting organization and brand
- Ability to develop and deliver a training program with priorities set by the APEC RHSC
- Willingness to provide a full or part-time Director and appropriate staff to manage the CoE
- Ability & commitment to achieve objectives as agreed in the CoE Operating Model & Guidelines
- Ability to fund the administrative overhead over the life of the agreement (minimum 3 years)
- Demonstrated credibility in the topic area
- Location that provides, or the ability to travel to, a site easily accessed by participants -or- access to necessary remote training modalities
- Ability to provide qualified faculty; this could be visiting regulatory staff or other experts as required by the training program
- Ability to receive funding to support specific aspects of CoE training (e.g., to fund student travel)

Authorized Signatures

I certify that the information provided in this request is correct, and commit to carry out the CoE pilot activities in accordance with the CoE Operating Model and Guidelines.

Signature

Date

Printed Name and Title