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