# 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.

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Signature Date

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Printed Name and Title