

Terms of Reference

Call for Expression of Interest for ICH Training Associates

1. Presentation of ICH

a. ICH

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH, www.ich.org) is a non-profit association under Swiss law, with a permanent Secretariat based in Geneva, Switzerland. ICH is unique in bringing together the regulatory authorities and pharmaceutical industry to discuss scientific and technical aspects of pharmaceutical development, registration and maintenance. ICH's mission is to achieve greater harmonisation worldwide to ensure that safe, effective, and high-quality medicines are developed and registered in the most resource-efficient manner. Harmonisation is achieved through the development of ICH Guidelines involving regulatory and industry experts.

b. Guidelines

ICH has produced Guidelines on more than 60 technical topics, divided in 4 topic areas: Efficacy, Quality, Safety and Multidisciplinary. All ICH Guidelines are published on the [ICH website](http://www.ich.org).

In the ICH Assembly Rules of Procedure, the ICH Guidelines are classified by importance into so-called "Tier 1", "Tier 2" and "Tier 3" Guidelines:

- Tier 1 ICH Guidelines comprises E6, Q1 and Q7;
- Tier 2 ICH Guidelines comprises E2A, E2B, E2D, M4, M1;

Tier 3 ICH Guidelines comprises all other remaining ICH Guidelines. Prioritised Tier 3 Guidelines with regards to training needs are: E2 (E2C(R2), E2E, E2F), E5, E17, M3(R2), M7(R1), M8, Q3 (Priority Q3C), Q5 (priority Q5E), Q6 (A & B), Q8-11 as a package, S6 (R1).

It is the aim and intention that all ICH Regulatory Members implement all ICH Guidelines in their respective jurisdiction, with implementation of the Tier 1 ICH Guidelines already being a condition of Membership admission into ICH, and Tier 2 implementation being expected within 5 years of ICH Membership.

c. Training

With the aforementioned expectations for ICH Regulatory Members, as well as ICH Regulatory Observers interested in becoming Members, there is high interest in training on ICH Guidelines to assist implementation efforts. ICH is not a training organisation and has been actively considering in recent years how best to address the training needs of its Members and Observers.

For the more recent ICH Guidelines, the ICH Working Groups (WGs) who have developed them have been tasked to develop *Step 4* training presentations upon finalisation of their Guidelines, with some WGs being tasked to assist implementation with the development of comprehensive sets of training and support documents. The aim is that such materials are available to all stakeholders on the ICH website.

For established ICH Guidelines (where the responsible ICH WG has long since been disbanded), as well as for the delivery of in-person training across ICH's global constituency on all ICH Guidelines, ICH faces more of a challenge to meet the training needs of its Members and Observers.

Recognising the substantial training expertise of other non-profit organisations/institutions, ICH would like to explore formal engagement of such organisations/institutions to help it address these needs.

ICH intends that initial awards made in this area will be for training programs in English, but expects that in future years training will be expanded to other languages considering the broad membership of ICH parties.

2. Call for Expression of Interest

a. Statement of work

ICH would like to explore the possibility of contracting appropriate accredited non-profit training organisations/institutions, initially for 1-year with an option to renew, to assist ICH in its efforts to address in a strategic manner the training needs of its Regulatory and Industry Members and Observers.

As part of an initial scoping exercise to enable the structuring of such work, ICH would like herewith to solicit expressions of interest from eligible non-profit accredited training organisations who would have the capability to fully or partially address the statement of work described below. ICH would also like to understand what budget estimation might be required to support such work.

It is not necessary that responding organisations/institutions could provide the full scope of work as ICH may select to engage more than one organisation/institution. This would be with the intent of ensuring an appropriate geographic coverage in view of ICH's global constituency, as well as engagement of organisations/institutions with the most expertise in training on particular ICH Guidelines.

Statement of work for this call for Expression of Interest is:

❖ *Develop Online Training Materials*

Develop comprehensive online training materials in English on Tier 1, Tier 2 (*excluding M1*) and/or Prioritised Tier 3* ICH Guidelines which would be owned by ICH.

❖ *Develop a Case Studies Library*

Develop a library of Case Studies in English on Tier 1, Tier 2 (*excluding M1*) and Prioritised Tier 3* ICH Guidelines which would be owned by ICH.

❖ *Deliver In-Person Training Courses*

Offer in-person training courses in English in the regions of ICH Regulatory and Industry Members and Observers and/or at the organisation's/institution's own in-region facilities on Tier 1, Tier 2 (*excluding M1*) and Prioritised Tier 3 ICH Guidelines, which should be without a registration fee for participants.

❖ *Provide Consultation Services to ICH*

Provide input, advice and expertise on an ad hoc as needed basis to ICH, its Training Subcommittee, its Secretariat and its WGs which may include: providing educational expertise and course development support to ICH technical experts in development of their own high-quality training materials; reviewing technical content of training materials; assisting in the production of final training materials (voice-over recording at studio, etc); addressing training-related questions or requests received by ICH; etc.

b. Eligibility criteria

Eligibility criteria for this call for Expression of Interest are:

- A legal entity which is a non-profit accredited training organisation/institution;
- Proven record of having completed multiple successful trainings in regulatory sciences;
- Recognized expertise and experience in development of remote training curriculum and course content at the targeted level (e.g., university undergraduate introductory and advanced levels per technical content in Guideline);
- Ability to direct training efforts to regulators at various levels of maturity;
- Expert knowledge of ICH and ICH Guidelines or documented institutional expertise relevant to ICH Efficacy, Quality, Safety or Multidisciplinary topic areas.

* Complementary to existing ICH Training materials available on ICH website.

c. Conduct of the call

The call for Expression of Interest for the pilot phase closes on: 3 May 2019. Interested organisations/institutions should fill and return the completed Response Form to the ICH Secretariat (training@ich.org) no later than the aforementioned deadline.

Organisations/institutions are invited to respond to the questions in the Response Form as precisely and quantitatively as possible and to provide any additional document they consider appropriate in this context. A free comment section is available at the end of the form to provide additional information.

Please note that Expressions of Interest submitted will be shared with Representatives of ICH Members and Observers, who would be responsible for taking under consideration the Expressions of Interest received. In reviewing the Expressions of Interest, particular attention will be given to the organisation/institution's demonstrated experience and past performances for similar training activities, its proven expert knowledge of ICH or of topics relevant to ICH Efficacy, Quality, Safety or Multidisciplinary topic areas, its technical capability in delivering online and in-person training courses, the geographical area covered, and budget estimation considered necessary to support the statement of work.

d. Limitations of this Call for Expression of Interest

Be advised that a response to this call for Expression of Interest is for scoping purposes only, and is not to be construed as a commitment on the part of the ICH to award a contract, nor does the ICH intend to pay for any information submitted as a result of this call. The ICH will not reimburse respondents for any cost associated with submission of the information or reimburse expenses incurred to interested parties for responses to this announcement.