

Questions & Answers

Call for Expression of Interest for ICH Training Associates

Last updated: 30 April 2019

1. **Question: Is it acceptable for the applicant to expand any sections when filling in the Response Form?**

Answer: Applicants should respect the character limit specified for each question and answer as precisely and concisely as possible. Please note that in Section 6 of the Response Form you may provide any relevant additional comment or support documents, for example information on expert knowledge of any additional ICH Guidelines, etc.

2. **Question: Is the training associates call only applicable for legal entities? Are there any positions available for individuals working for such an entity?**

Answer: Please note that further to the Terms of Reference for Training Associates, (Section 2.b. Eligibility Criteria), in order to be considered the organisation must be a legal entity which is a non-profit accredited training organisation/institution.

3. **Question: If an applicant is a division of a larger organisation which is the legal entity, please advise on who should submit the application?**

Answer: Applications may be submitted by a division so long as the legal entity to which the division belongs meets the criteria of being a non-profit accredited training organisation/institution and the application is submitted by an individual(s) with the legal capacity to sign on behalf of the legal entity. In any case, the legal entity should be clearly indicated in the application.

4. **Question: Should the applicant organisation include the Curriculum Vitae/resume of key staff/leaders from its organisation?**

Answer: This information is not necessary to provide. However, if an applicant considers this information relevant to its application, Section 6 of the Response Form allows the provision of additional information in the form of comment or support documents.

5. **Question: Regarding the development of Online Training Materials, what would be the terms of ownership for these materials and associated underlying source files?**

Answer: ICH plans to have ownership of the materials, including copyright and associated source files.

6. **Question: Regarding the development of Online Training Materials, where should these be hosted?**

Answer: ICH plans to host the materials directly on its own website www.ich.org.

7. **Question:** Regarding the development of Online Training Materials, what would be the responsibility of the training associate for the ongoing maintenance of these materials.

Answer: Future/ongoing maintenance of the Online Training Materials is not within the statement of work for this initial Call for Expression of Interest. However, organisations wishing to provide input on this may do so in Section 6 of the Response Form which allows inclusion of additional comment or support documents.

8. **Question:** How does ICH define “Case Study” in the context of the statement of work described?

Answer: A case study is considered illustrative material to demonstrate or emphasize key regulatory elements in the guideline; including help with implementation and application of the guidelines; e.g., real world or fictional drug development and registration examples.

9. **Question:** What kind of contract will be issued? What is the timing of the contract?

Answer: ICH is exploring contracting Training Associate(s) for an initial period of 1-year with an option to renew, potentially to start in 2019.

10. **Questions:** Who is the audience of the training?

Answer: The training audience would include regulatory, industry and associated stakeholders of ICH Member and Observer countries and regions, with some training potentially targeted at one group or the other (e.g. Regulator only training).

11. **Question:** Is it allowable to propose a train-the-trainer model?

Answer: “Train-the-Trainer” modules are not specifically addressed in the response form, however an applicant is free to offer any views regarding training models in Section 6.

12. **Question:** For an in-person training, who controls the curriculum and the speakers?

Answer: The Training Associate would be tasked to form a planning committee to develop a curriculum and confirm the Speakers for in-person training programmes, based on the needs stated by ICH.

13. **Question:** Will the developed training materials be posted publicly?

Answer: The developed training materials will be publicly available on the ICH website www.ich.org.

14. **Question:** While we understand that ICH will own the materials, can the Training Associate continue to use the materials it develops for research and education purposes?

Answer: ICH plans to have ownership of the materials, including copyright and associated source files. The continued use of training materials developed for ICH by the Training Associate has not been considered. Any views by applicants could be provided in Section 6 of the Response Form.