

Terms of Reference for Training Providers for an ICH Recognised Training Programme

Training Programme:

- The provider will develop the programme, agenda, training materials and secure appropriate faculty.
- ICH experts/participants/members should be included in the programme committee and/or on the faculty.
- The programme should be based upon the scientific and regulatory principles outlined in ICH Guidelines.
- Any appropriate training modalities may be used in the programme (live lecture, webcast, video, hands-on, pre-assigned reading, etc). It is highly suggested to use case studies in the curriculum.
- The provider should target participants representing regulators, industry and other stakeholders of ICH Guidelines from geographic regions/areas in need of the specific training.
- The ICH Training Subcommittee has the right to review the agenda with regards to programme content, objectives and faculty, and may review proposed training materials if requested.
- The provider is responsible for all logistics and administration of the programme.
- The course and all associated training materials will be in English. The organiser may consider translation services for some programmes.
- Training providers should post the following disclaimer on the agenda/programme: “The views and opinions expressed in this training session and associated training materials are those of the individual presenter and should not be attributed to the International Council for Harmonisation (ICH) organisation, its members, officers, employees, participants, observers or volunteers.”

ICH:

- The “ICH Recognised Training” logo may be used on an announcement of a programme that has been reviewed and endorsed by the ICH Training Subcommittee. (The ICH logo itself is only used on ICH-produced materials such as ICH Guidelines or slides developed by ICH working groups.) It may not be used on any other materials without express permission of the ICH Management Committee. Use of the “ICH Recognised Training” logo signifies that only this programme has been endorsed by ICH.
- A disclaimer must be signed by the ICH Training Programme Provider and submitted to the ICH Secretariat before the training logo will be released for use.
- Announcements of the programme may be posted on the ICH website.
- Announcements of the programme may be circulated by the ICH Secretariat to ICH distribution networks.

Funding:

- Funding will be the sole responsibility of the training provider.
- Cost recovery is allowed.
- Registration fees should be reduced or waived for regulatory participants and NGOs.

Analysis/Assessment:

- A post-course survey should be given to the participants—and faculty to assess the programme’s effectiveness in raising awareness/increasing uptake of ICH Guidelines and results reported back to the ICH Training Subcommittee. A subset of standard survey questions will be provided by the ICH Training Subcommittee.
- Outcomes will be periodically reported to the ICH Management Committee and Assembly.