PROCEDURE ON TRAINING ACTIVITIES:
SELECTION, PRIORITIZATION, COORDINATION OF RHI & DRA REQUESTS

BACKGROUND:

This procedure on training activities aims at improving the selection, prioritization and coordination of requests for training activities and capacity-building events from Regional Harmonisation Initiatives (RHI) and individual Drug Regulatory Authorities and Department of Health (DRA/DoH) considered during the GC session of the ICH meetings\(^1\). This procedure also aims at achieving greater transparency regarding events in which ICH experts are asked to participate.

The GC sessions were established as an evolution of the GCG that was created to facilitate the dissemination of information to non-ICH regions / parties concerning the operation, organization and products of ICH. With the adoption of a new framework for cooperation with non-ICH regions\(^2\), the GCG was engaged in a more active and interactive manner with non-ICH regions / parties. This new engagement promotes a better understanding of the underlying principles and intent of ICH Guidelines as well as the challenges faced by both RHI and individual DRA/DoH in their utilization.

The scope of activities undertaken by the GCG was embodied in the Mission Statement adopted by all parties in May 2005:

*To promote a mutual understanding of regional harmonisation initiatives in order to facilitate the harmonisation process related to ICH Guidelines regionally and globally, and to facilitate the capacity of drug regulatory authorities and industry to utilize them.*

In 2006, the GCG implemented a strategy for addressing the training and capacity\(^3\) needs of RHI and for ensuring the most effective use of resources, opportunities and the realization of desired outcomes.

The GCG defined principles and recommendations in responding to training requests. Whenever possible, training initiatives directed through the GCG should:

- Optimally, be regionally-based, with flexibility to consider nationally-based training, if deemed appropriate
- Be coordinated amongst ICH parties and RHI and leverage existing regional training activities and events
- Leverage the experience and resources of non-profit training organizations
- Be planned and reviewed on a periodic basis
- Take full advantage of appropriate training modalities/technologies.

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\(^1\) This procedure does not preclude the consideration by GCG of requests for training by DRA/DoH that are not participating in the GCG.

\(^2\) Revised GCG Terms of Reference, November 2003

\(^3\) *Strategy document on Training and Capacity-building*, endorsed by the ICH SC and GCG in June 2006
With the decision of the ICH Steering Committee in October 2007 to invite representatives of individual DRA/DoH to participate in the GCG it was agreed to extend the training strategy to also apply to requests from individual DRA/DoH. However, in line with the original principles of the training strategy it was agreed that regionally-based training events should be given a higher priority than country specific events.

In June 2013, the GCG adopted a new format. The GC sessions of the ICH SC were established to allow interactive discussions on implementation of ICH Guidelines in the ICH regions and beyond, and training as main focus.

PROCEDURE FOR ORGANISATION OF TRAINING:

1. TRAINING PLAN

RHI and individual DRA/DoH are encouraged to submit to the ICH Secretariat, one-month prior to the ICH meetings, an updated two-year training plan which would outline the overall training strategy relating to ICH Guidelines for the RHI/DRA/DoH and list any training events for which the ICH SC would be requested to consider providing speakers.

The training plan would be circulated to the GC members by the ICH Secretariat for discussion at the GC session of the ICH SC meeting. The two-year training plan will act as a supporting document to assist the ICH SC to prioritise training requests in the context of the overall training strategy of RHI/DRA/DoH.

2. SUBMISSION OF INDIVIDUAL TRAINING REQUESTS (STANDARD TEMPLATE)

All training requests should be submitted to the ICH Secretariat using a standard template (see below). For training requests RHI and individual DRA/DoH are asked to provide information on:

1. Sponsors:
   - Who organizes the training event
   - Is this event supported by a profit or non-profit organisation
   - Who is the primary contact for organisational aspects

2. Scope:
   - How does the training event fit into the overall training strategy of the RHI/DRA/DoH?
   - How would the RHI/DRA/DoH rank this training request among its most pressing needs
   - What are the learning objectives of this event

3. Target audience:
   - Is this a regional or a national event
   - Who may participate in the training (e.g., regulators, industry, academia etc…)
   - Are other RHI/DRA/DoH invited
   - What is the suggested profile of the participants (e.g., new to subject, intermediate knowledge or expert)

4. Practical information on the training event:
   - Programme:
     - Is there a draft programme already available?
     - Are the topics/issues on which the speakers should present already known?
   - Schedule:
     - When will the event take place?
     - How long will the event last
   - Speakers:
What are the expectations in terms of speakers (e.g., number of speakers needed, regulators/industry speakers, etc)?

5. **Funding:**
   How will the event (speakers, venue, development of conference materials etc…) be funded (e.g., grant, participant registration fee etc…)?
   What will the funding for ICH speakers cover (e.g., flights, accommodation, etc…, please note that ICH SC endorsement does not necessary mean that the ICH party pays its own travel expenses)?

Where necessary, the ICH Secretariat will provide assistance to RHI/DRA/DoH to complete the template. The ICH Secretariat will work with RHI/DRA/DoH to ensure that all requests contain the appropriate information before circulation for ICH SC consideration.

3. **REVIEW CRITERIA FOR THE ICH SC**

The ICH SC reviews requests based on the following criteria:

1. **Sponsors:**
   - Is the event leveraging the input of a training organisation?
   - Do the funding arrangements preclude participation of regulators?

2. **Scope:**
   - Is the event within the scope of the GC?
   - Is the training event integrated into the regional/national training strategy of the RHI/DRA/DoH?
   - What are the expected benefits for the RHI/DRA/DoH?
   - Does the event conflict with WHO or other training initiatives?

3. **Target audience:**
   - Is the training nationally or regionally based?
   - Does the event promote interaction, support and a common understanding of the ICH Guidelines amongst the countries and stakeholders within a given region?

4. **Appropriateness:**
   - Is the event appropriate to cover the objectives set by the RHI/DRA/DoH?

4. **PRIORITISATION BY THE ICH SC**

At the GC session of the SC meeting, the ICH SC will consider the two-year training plans and requests for training. Prioritisation would be based on assessment against the review criteria outlined above.

5. **ORGANISATION OF TRAINING**

In general the host RHI/DRA/DoH is responsible for the organisation of training events. It should be noted that the role of the ICH Secretariat extends only to acting as a point of contact between the host and the ICH parties/experts involved in the training.

As a principle it should also be noted that following all GC-endorsed training events training materials/presentations from the event will be made available for re-use on the ICH Public website (see also Section 7).

   – **Development of agenda and program:**
     Once a training request is approved by the ICH SC, the ICH SC will nominate an

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4 As a principle regionally-based training events should be given a higher priority than country specific events.
ICH lead party or lead parties. The host RHI(s)/DRA/DoH is responsible for developing the draft programme with input sought from the ICH lead party/parties. Work should progress via e-mail exchange and, if necessary, tele/webconferences. The ICH Secretariat will periodically monitor the progress of GC-actioned training requests.

- **Selection of ICH experts:**
  Once the type of expert(s) required has been decided the ICH Secretariat will work with the ICH Coordinators to identify the expert(s) to participate in the training event. The role of the ICH Coordinators is to identify speakers within their party and region. The ICH Secretariat will also keep a record of the ICH experts who participated in RHI/DRA/DoH training events.
  As a general rule, the rapporteur of the topic of the training event should be consulted during the development of the event.

- **Logistics/Conference Management:**
  The host RHI(s)/DRA/DoH is responsible for the meeting logistics e.g., organisation of venue – organisation of equipment for meeting rooms etc…; identification of hotel(s) - making block booking if appropriate; sending invitations to speakers; collection of abstracts/CVs; printing of program, background documents etc…; promotion of event - development/releasing of announcements; organisation of translation - translation of documents, interpreters; organization of registration of participants - name tags etc..
  Coordinating with the ICH Secretariat, the host should ensure that the ICH experts nominated as speakers are provided with all the necessary information on the event logistics.

- **Information on ICH:**
  Training that has been endorsed through this training procedure should normally include the ICH logo in all promotional material (this does not exclude the additional use of other logos). Those speaking on ICH topics should consider to use the ICH logo on their slides as appropriate.
  To frame the ICH training event an ICH expert participating in the event should be asked to present on ICH in general. The slides for this presentation will be provided by the ICH Secretariat and consist of a general set of slides with background information on ICH and the GC-related activities.

6. **ASSESSMENT AND FEEDBACK**

   It is important to monitor and evaluate the training outcomes in order to assess whether training objectives were achieved and to identify lessons learnt for future events. Therefore the host RHI(s)/DRA/DoH is requested to submit a short report on the event to the ICH SC. ICH speakers may provide feedback as appropriate and will also be advised of any important feedback from the host RHI(s)/DRA/DoH that would be of help for future presentations.

7. **LEVERAGING RESOURCES FOR TRAINING**

   In order to better leverage resources the GC members should take into consideration the following points for GC training events:

   - Could training materials and programmes developed for previous training events be reused.
   - In cases where stand-alone training is requested (i.e., not part of a bigger event) could the training be conducted remotely by webinar.
   - Could some training events be opportunities for a “train the trainer” approach i.e., other RHI/DRA/DoH could send participants who would be trained and could then return to their regions to give training.
The presentations/training materials will be for reuse and for posting on the working area of the GC, and where appropriate on the ICH public website. Any errors identified in the presentations/training materials should be corrected before posting on the working area of the GC/ICH public website. Following GC-endorsed training events, speakers/trainers involved in the events will be asked to sign a standard form provided by the Secretariat granting ICH and the host RHI/DRA/DoH permission to publish their training materials/presentations on their respective websites.

**Submission of Requests (Standard Template):**

For training requests RHI and individual DRA/DoH are asked to provide information on:

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