



Global Harmonization Center

# **Global Harmonization Center (GHC)**

## **Proposal Submission Guide**

### **(International Training Programs)**

# GHC Proposal Submission Guide for International Training Programs

## 1. Purpose

: This Submission guide outlines the process for submitting, reviewing, and approving proposals for international training programs hosted by the Global Harmonization Center (GHC).

The purpose is to ensure transparency, consistency, and fairness throughout the proposal process while supporting proposals that advance GHC's mission of regulatory harmonization and capacity strengthening.

## 2. Scope

: This guide sets out the process for submitting and reviewing proposals for international training programs organized by the Global Harmonization Center (GHC) in the field of medicinal product regulation.

Proposals may include suggested training topics, co-hosting arrangements, or other program concepts for the following year's training activities. These programs are primarily intended for government officials from national regulatory authorities.

GHC serves as the Host organization for approved programs and leads their planning and coordination. Programs may be co-hosted with the proposing organization, provided that the proposal demonstrates equitable roles and shared contributions to implementation.

## **3. Roles and Responsibilities**

### **(1) GHC Secretariat**

The GHC Secretariat shall:

- Lead the planning and coordination of approved training programs.
- Oversee the proposal submission and review process in accordance with this guide.
- Consult with the GHC Advisory Board, as necessary, during the review process.
- Finalize decisions and communicate outcomes to the relevant organizations.

### **(2) Proposing Organization**

The Proposing Organization shall:

- Prepare and submit the Proposal Form in accordance with this guide.
- Ensure that the proposal aligns with GHC's mission and objectives.
- Secure the necessary resources for program delivery, unless otherwise agreed in advance.
- Designate a focal point for communication during the review and implementation process.

### **(3) GHC Advisory Board**

The GHC Advisory Board may:

- Provide advice on submitted proposals, including the proposed topics, approach, and potential impact.
- Share views on current regulatory trends or issues of interest and may suggest possible topics for future programs.

## 4. Submission Guidelines

: Proposals shall be submitted by email using the official “Proposal Form” provided by the GHC Secretariat.

- The completed Proposal Form shall be attached to the submission email and sent to: [ghcteam@korea.kr](mailto:ghcteam@korea.kr)
- Receipt of the proposal will be acknowledged via email to the same address used for submission.
- Proposers may refer to Annex 1 prior to submission

## 5. Review Timeline

: The proposal process consists of four stages: Call for Proposals, Submission, Review, and Decision Notification. The indicative timeline below is provided for reference and may be adjusted as required by the GHC Secretariat.

Stage	Description	Indicative Timeline
<b>Call for Proposals</b>	Announcement is made on the GHC website.	Usually in early November
<b>Submission Deadline</b>	Proposals shall be submitted within 30 days from the announcement date.	e.g., If announced on 1 November, the deadline is 30 November
<b>Review Period</b>	GHC reviews the proposals. Consultation with the Advisory Board may take place where necessary.	Approximately one month (e.g., December)
<b>Decision Notification</b>	Final decision is communicated to the proposing organization.	Normally by end of January of the program year

## 6. Review Criteria

: Proposals will be reviewed based on the following criteria.

### 1) Alignment with GHC's Mission

- The proposal aligns with GHC's mission by advancing regulatory harmonization and supporting capacity-building that reflects current regulatory needs.

### 2) Impact and Relevance

- The proposal provides value across authorities by addressing shared regulatory needs or challenges, not a narrow or country-specific issue.

### 3) International Cooperation

- The proposal facilitates case sharing, best practice exchange, joint discussions, or other forms of collaborative engagement among regulatory authorities.

### 4) Feasibility

- The proposal is to implement within the available resources and proposed timeline, with a clear and structured plan.