

**IncreaseNET\_PUBLIC NOTICE - CALL FOR EXPRESSION OF INTEREST for the provision of training courses addressed to the technical-scientific staff of National Competent Regulatory Authorities in the pharmaceutical field located within the territory of the European Union.**

**Q&A up to 29/07/2025**

**Question 1**

Is it possible to submit a training proposal with a duration that differs from the one specified in the notice?

**Answer 1**

The duration of 8 - 12 hours for the training event was defined based on an estimate of the time presumably needed to achieve the learning objectives. Additionally, this timeframe was considered appropriate in proportion to the maximum budget available to cover the costs of each course. Any deviations from the established minimum requirements, if adequately justified, may nonetheless be subject to comparative evaluation alongside the submitted training proposals.

**Question 2**

In Module A, it is required to specify "Any knowledge and/or previous experience in the pharmaceutical regulatory field". Should this information refer to the designated Contact Person, or can it pertain to any member within the proposing organization, even if they are not part of the teaching staff responsible for delivering the course? What supporting documents should be attached?

**Answer 2**

As detailed in the bullet points contained in the "Any knowledge and/or previous experience in the pharmaceutical regulatory field" section of Module A, the Proposing Entity is required to specify whether it has within its organization a structure or individuals with expertise in the pharmaceutical regulatory field. Such individuals are not necessarily required to be part of the teaching staff; however, it is advisable to indicate whether or not they will be involved in the development of the training proposal. If they are involved, it is recommended to specify their contribution (e.g., teaching, scientific input in the course design without direct teaching involvement, etc.).

The same applies to the presence of structures or individuals with "any previous collaborations with regulatory authorities" and/or "experience in delivering training courses or other educational events in the pharmaceutical regulatory field."

It is recommended to attach any documents deemed useful to demonstrate the expertise and previous experience in the regulatory field, which may also include detailed self-declarations from the individuals concerned.

It should be noted that the presence of any knowledge and/or previous experience in the pharmaceutical regulatory field is not a mandatory requirement for submitting a proposal;

however, it may be taken into account for comparative evaluation among the training proposals received.