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 05/09/2025

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.

Question 3

With reference to the digital signature to be affixed to Form A and the attached documents, it is requested to clarify whether the documents must be signed in PAdES format or CAdES (.p7m) format.

Answer 3

It is hereby specified that it is possible to digitally sign either in PAdES (PDF) format or in CAdES (.p7m) format.

Question 4

Could you please clarify the requirement for MEPA registration for lecturers? Does this refer to a third-party service where the relevant department will manage the funding?

Answer 4

The call is addressed to Universities and/or Research Institutes, whether public or private, and not directly to individual lecturers.
In order to use the MEPA e-Procurement System, the University/Research Institute must register on the platform by accessing the portal www.acquistinretepa.it and following the instructions provided therein.
As specified in paragraph 5 "Requirements for invited entities," the Contractor must be registered on MEPA under the category “SERVICES/Training Services,” or alternatively, on another digital procurement platform (PAD), provided prior authorization has been granted by AIFA where the conditions are met.
The Electronic Marketplace of the Public Administration (MEPA) is an online platform that allows Public Administrations to purchase goods and services from duly registered Economic Operators.

Question 5

An Economic Operator (EO) reported being unable to register on MEPA, since the MEPA portal does not manage VAT groups (i.e., autonomous entities operating under the same VAT number). The EO requested "your guidance and authorization in order to proceed with registration on other platforms with the aim of finalizing the training proposal."

Answer 5

As specified in paragraph 5 “REQUIREMENTS FOR INVITED ENTITIES” of the relevant Notice, registration on a different digital procurement platform (PAD) is permitted, provided prior authorization is granted by AIFA where the conditions are met.
For entities unable to register on MEPA, registration is authorized on the “SINTEL - e-procurement platform” managed by Aria S.p.A., available at the following link: https://www.ariaspa.it/wps/portal/Aria.
Instructions for registration on the SINTEL platform are attached.
In such cases, together with the financial quotation, a proper self-declaration must also be provided — issued pursuant to and in accordance with Articles 46 and 47 of

Presidential Decree No. 445/2000 — declaring the impossibility of registering on the MEPA portal and the underlying reasons.