



Ufficio Attività negoziale e gestione patrimonio

## PUBLIC NOTICE

### CALL FOR EXPRESSION OF INTEREST

**for the initiation of a market investigation aimed at identifying Universities and/or public or private Research Institutes, with which to proceed with a direct award, pursuant to Article 50, paragraph 1, letter b) of Legislative Decree No. 36/2023, as amended, 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.**

## PREAMBLE

The Italian Medicines Agency (hereinafter referred to as the "Agency" or "AIFA"), through this PUBLIC NOTICE, published on its institutional website, in compliance with the principles of cost-effectiveness, efficiency, impartiality, rotation, equal treatment, transparency, and proportionality, and with the aim of promoting the widest possible participation, intends to acquire quotations for the direct award of the service indicated above, pursuant to Article 50, paragraph 1, letter b) of Legislative Decree No. 36/2023, as amended (hereinafter also referred to as the "Code").

## INVITATION

**Universities and/or public or private Research Institutes**, as better specified in paragraph 5 below, are invited to submit a quotation along with their training proposal, should they be interested in the direct award of the training services described in paragraph 2 below.

Any possible direct award will be carried out pursuant to Article 50, paragraph 1, letter b) of the Code. Therefore, this Notice does not constitute a call for tenders.

In any case, this Notice and the subsequent receipt of quotations with training proposals shall not be binding upon the Agency and shall not generate any rights or legitimate interests in favour of the interested parties.

The Agency reserves the right, at its sole discretion, not to proceed with the direct award, or to initiate further market investigations or procurement procedures, without any entitlement to claims from the parties concerned by this Notice.

## 1. CONTRACTING AUTHORITY

Agenzia Italiana del Farmaco – AIFA  
(P. IVA 08703841000 – C.F. 97345810580)  
Via del Tritone, 181 – 00187 Roma  
MAIL: [ufficiogare@gov.aifa.it](mailto:ufficiogare@gov.aifa.it)

## 2. SUBJECT OF THE CONTRACT

The training services subject to the potential contract include the planning, presentation, approval, and delivery of training courses addressed to the technical-scientific personnel of the National Competent Authorities (NCAs) in the pharmaceutical field located within the European Union.

CPV Code for training services: CPV 8052000-9.

This initiative is part of the Joint Actions included in the 2022 Work Plan (WP) of the EU4Health Programme 2021–2027 (<https://www.salute.gov.it/new/it/tema/politiche-sanitarie-internazionali/eu4health-programma-europeo-salute-2021-2027>), specifically within the framework of Project IncreaseNET (<https://www.aifa.gov.it/-/riunione-d-avvio-della-joint-action-europea-increasenet-del-programma-eu4health>), which involves AIFA and aims to strengthen the capacity and competencies of the European regulatory network, including with regard to innovative and emerging technologies in the pharmaceutical sector.

In particular, the initiative involves the provision of **two (2) training courses**, each falling under one of the thematic areas indicated below, along with the respective target audience and learning objectives to be achieved:

### Thematic Area 1 – Organ-on-Chip (OoC)

- **Target audience.**

Technical-scientific staff of NCAs involved in the clinical and non-clinical assessment of pharmaceutical dossiers within regulatory procedures.

- **Learning objectives and examples of potential content**

- Overview of the technology (e.g., definitions, single/multi-organ models, operating principles and technology applications, etc.)
- Understanding of technological features (e.g., microfluidic systems, biomaterials, biocompatibility, knowledge of the cellular environment and compatibility with physiological phenomena, predictivity and biological relevance, etc.)
- Awareness of reference standards and basic principles for technology qualification and method validation
- Potential applications in human medicine clinical and non-clinical development (e.g., *in vivo* PK simulation, disease modeling, pharmacological safety/toxicology testing, identification of sensitive biomarkers)
- Case studies (e.g., liver-on-chip and/or heart-on-chip and/or special population models, digital twins, etc.)

## Thematic Area 2 – RNA-based Therapeutics

- **Target audience**

Technical-scientific staff of NCAs involved in the assessment of quality and/or non-clinical aspects of pharmaceutical dossiers.

- **Learning objectives and examples of potential content**

### **GENERAL OBJECTIVES**

- a. General overview (e.g., RNA biology, classification, intracellular regulation, post-transcriptional modifications and their impact on folding, stability, and function; role of RNA in the regulation of cellular processes)
- b. Knowledge of RNA-based medicinal products and therapeutic applications (e.g., mRNA, siRNA, miRNA, ASO, aptamers, gRNA per CRISPR; mechanisms of action; chemical modifications for stabilisation and optimisation; case studies e.g RNA decoy, RNA sponge, etc.)
- c. Knowledge of current and emerging delivery systems (e.g., viral/non-viral delivery systems)
- d. Basic understanding of applied biocomputing (e.g., structure prediction, on-/off-target effects, molecular interactions)

### **SPECIFIC OBJECTIVES**

- e. Knowledge of pharmaceutical development, production, and quality control (e.g., production systems, scaling-up, analytical methodologies, stability)
- f. Knowledge of non-clinical development (e.g., *in vitro/in vivo* models, alternative approaches such as organoids, immunogenicity, biodistribution, case studies)

With regard to Thematic Area 2 (“RNA-based therapies”), the training proposal must cover all GENERAL learning objectives and at least one of the SPECIFIC learning objectives.

For both thematic areas, additional learning objectives and/or further elements deemed useful for presenting the training proposal may be included.

**Proposals may be submitted for one or both thematic areas.**

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Each course must meet the following **minimum requirements**:

- duration of between 8 and 12 hours;
- delivered in English;
- provided via e-learning; delivery of the recorded lecture to AIFA is required, preferably in SCORM 1.2 format.

The courses will be delivered via the platform of the European Medicines Agency (EMA) (EMA) EU Network Training Centre Learning Management System (EU NTC - LMS).

### 3. DURATION

The video recording of the lectures must be delivered by end of January 2026, unless otherwise indicated by AIFA.

### 4. CONTRACT VALUE

The maximum amount allocated for the implementation of each training course is € 15.000,00 (fifteen thousand/00), VAT exempt. Therefore, the total maximum amount, in case both courses are implemented, is € 30.000,00 (thirty thousand/00), VAT exempt.

### 5. ELIGIBILITY REQUIREMENTS

As foreseen by Project IncreaseNET, **only Universities and/or public or private Research Institutes**, based in Italy or in other EU Member States, are eligible to submit a quotation with their training proposal.

**The selected contractor must:**

- be registered, **by 22/09/2025**, in the MePA under the “SERVICES/Training services” category; registration in another e-procurement platform may be allowed upon prior authorisation from the Agency, subject to justification;
- meet the general requirements set out in Articles 94 et seq. of Legislative Decree No. 36/2023;
- have demonstrated proven academic and/or research activity in the thematic areas of interest specified in paragraph 2.

### 6. SUBMISSION PROCEDURE AND DEADLINE

Interested parties, as defined in paragraph 5 above, must submit their quotation using **exclusively Form A**, which forms an integral part of this Notice.

Form A must be digitally signed by the legal representative or, alternatively, by a duly authorised general or special proxy holder (in this case, the proxy must be attached, unless the powers are already indicated in the Chamber of Commerce registration).

Form A, duly completed and digitally signed, along with all required documentation, must be stored in a password-protected zip folder and sent as an email attachment by **12:00 PM on 22/09/2025 to the following address: [ufficiogare@aifa.gov.it](mailto:ufficiogare@aifa.gov.it)**

The email subject line must state:

**“QUOTATION FOR THE DIRECT AWARD OF TRAINING COURSES FOR TECHNICAL-SCIENTIFIC PERSONNEL OF EU NATIONAL COMPETENT AUTHORITIES IN THE PHARMACEUTICAL FIELD.”**

The body of the email must indicate:

- Attn: Dr. Paolo Foggi – Responsible for the procedure;
- the name and contact details of the submitting entity.

To preserve confidentiality, no information regarding pricing or training content shall be included in the body of the email.

Starting from 12:01 on 22/09/2025 and no later than 12:00 on 23/09/2025, the password for opening the zip folder must be sent to the same email address: [ufficiogare@aifa.gov.it](mailto:ufficiogare@aifa.gov.it)

The quotation shall remain valid for 180 days from the submission deadline.

Quotations submitted using formats other than Form A, received after the deadline, or sent to a different email address, shall not be considered.

Requests for **additional information or clarifications** must be submitted in writing to the Responsible for the Procedure, as identified in paragraph 9, no later than 12:00 on 11/09/2025, via email to: [ufficiogare@aifa.gov.it](mailto:ufficiogare@aifa.gov.it)

Any subsequent contract will be formalised pursuant to Article 50, paragraph 1, letter b) of the Code.

## **8. PERSONAL DATA PROCESSING**

Personal data provided will be processed exclusively for the purposes related to this procedure, pursuant to Article 13 of Legislative Decree No. 196/2003 and Article 13 of Regulation (EU) No. 2016/679. Participants may exercise the rights provided by said regulations. The Data Controller is AIFA, represented by its legal representative pro tempore, Dr. Robert Giovanni Nisticò.

Pursuant to Legislative Decree No. 33 of 14 March 2013 and Article 32 of Law No. 190/2012, participants expressly consent to the processing and publication on the Agency's website of the data relating to this procedure.

Submission of a quotation implies acknowledgment of the personal data processing terms outlined in the information notice available at the following link:

[https://www.aifa.gov.it/documents/20142/897150/Informativa\\_ex\\_art.13\\_GDPR.pdf](https://www.aifa.gov.it/documents/20142/897150/Informativa_ex_art.13_GDPR.pdf)

## **9. RESPONSIBLE FOR THE PROCEDURE**

Pursuant to Article 5 of Law No. 241/1990, as amended, the person in charge of the procedure designated by the Agency is Dr. Paolo Foggi, Head of Innovation and Pharmaceutical Strategy Department.

## **ATTACHMENT**

- **Form A** – Application template for submitting the quotation and training proposal.



Raffaella Cugini  
09.07.2025 13:02:15  
GMT+02:00

**The Director**

*Raffaella Cugini*

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