



Form A – APPLICATION TEMPLATE FOR THE SUBMISSION OF A QUOTATION AND TRAINING PROPOSAL

Please complete the following sections for one or both of the thematic areas of interest.

Fields marked with an asterisk () are mandatory and must be completed for the quotation to be accepted, as specified in the Notice.*

Each attached document must be numbered and included in a list to facilitate identification and review by AIFA.

<p>* The undersigned _____ born in _____ on _____, Tax Code _____ (ID document _____ issued on _____ by _____), residing in _____, in the capacity of _____ and legal representative of _____, with registered office in _____, address _____, certified email (PEC) _____, tax code _____, VAT no. _____, phone number _____, by virtue of the powers granted under _____,</p> <p style="text-align: center;">[or]</p> <p>The undersigned _____ born in _____ on _____, Tax Code _____ (ID document _____ issued on _____ by _____), residing in _____, acting as proxy holder of _____, with registered office in _____, address _____, certified email (PEC) _____, tax code _____, VAT no. _____, phone number _____, by virtue of general/special power of attorney with certified signature issued on _____ by Notary Public Dr. _____, Notarial Deed No. _____ dated _____, executed in _____</p>
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within the context of the 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 personnel of National Competent Regulatory Authorities in the pharmaceutical sector located within the European Union.

Declares

also pursuant to Articles 46 and 47 of Presidential Decree No. 445/2000, and fully aware of the civil and criminal liability and consequences in case of false or misleading declarations,

1. to submit the quotation as:

** (check the relevant box)*

- ☐ University
- ☐ Research Institute

** (check the relevant box)*

- ☐ public
- ☐ private

** (check the relevant box)*

- ☐ Italian
- ☐ foreign entity established within the territory of the European Union

2. to have no grounds for exclusion as per Articles 94 et seq. of Legislative Decree No. 36/2023;

3. to meet all the eligibility requirements set forth in paragraph 5 of the Public Notice launching the above-mentioned Market Investigation;

4. ** (check the relevant box/boxes)*

- ☐ to be already registered in MePA under the “Services” tender, “Training Services” category
- ☐ not to be registered in MePA under the “Services” tender, “Training Services” category, and aware that the contract cannot be awarded without such registration by 22 September 2025 or registration, if previously authorised by AIFA, in an alternative Digital Procurement Platform (PAD);

5. ** (check the relevant box/boxes)*

to be submitting the quotation and training proposal for:

- ☐ THEMATIC AREA 1 – Organ on Chips (OoC)
- ☐ THEMATIC AREA 2 – RNA-based Therapeutics

6. to be aware that the submission of this quotation does not constitute a contractual offer, does not create any legal entitlement or obligation, does not entail the preparation of rankings or the award of scores, and does not bind AIFA in any way, which reserves the right to suspend, amend, or cancel the procedure at any time. Therefore, the undersigned waives any right to claim or demand in relation thereto;
7. to consent to the processing, including by electronic means, of the personal data provided, in accordance with Article 13 of Legislative Decree No. 196/2003, as amended, and Article 13 of Regulation (EU) No. 2016/679, exclusively for the purposes related to the conduct of this procedure.

ESTIMATED COST STATEMENT ACCOMPANIED BY THE TRAINING PROPOSAL

THEMATIC AREA 1 - Organ on chips (OoC)
Applicant's experience
<ul style="list-style-type: none">○ Contact point <i>[Applicant's full name]</i>:○ Role:○ Contacts: e-mail telephone
<p>* It is hereby declared that the Institution of affiliation, as well as the instructors intended to be engaged for the delivery of the training course, possess experience in academic and/or research activities within the scope of Thematic Area 1 (Organ-on-Chips). As evidence thereof, the following documentation is attached to this form:</p> <ul style="list-style-type: none">○ * Curriculum vitae of the instructors <i>[Please note that, where duly justified, integrations or modifications in the composition of the teaching staff will be permitted, provided that the individuals proposed possess skills and/or experience equivalent to those of the originally proposed staff]</i> It is specified that the curricula vitae must be submitted in the European format, dated and signed, and must include authorisation for the processing of personal data pursuant to Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 and Legislative Decree No. 196 of 30 June 2003, as amended (Personal Data Protection Code). They must also expressly authorise full disclosure and reproduction of the CV in the event of a request for access to the documents related to this procedure.○ Other documents <i>[please specify and number the attached documents]</i>

<p>Any knowledge and/or previous experience in the pharmaceutical regulatory field:</p> <p><input type="checkbox"/> Applicant is endowed with a structure or experts in the pharmaceutical regulatory field <i>[specify and number the documents to be attached]</i></p> <p>.....</p> <p><input type="checkbox"/> Previous collaborations with Authorities in the pharmaceutical regulatory field <i>[specify and number the documents to be attached]</i></p> <p>.....</p> <p><input type="checkbox"/> Experience in delivering training courses and/or other educational events in the pharmaceutical regulatory field <i>[specify and number the documents to be attached]</i></p> <p>.....</p> <p><input type="checkbox"/> Other <i>[specify and number the documents to be attached]</i></p> <p>.....</p>	
Training course	
<p>* Training course title:</p> <p>* Duration: <i>[specify a duration between 8 and 12 hours]</i></p> <p>* Cost estimate:<i>[costs must be within 15.000,00€, VAT exempt]</i></p>	
<p>The training course will be delivered in English and provided via e-learning.</p>	
<p>Description of the delivery method of the educational offer and any value-added elements useful for the final score attribution by the evaluation Committee <i>[describe the methods of delivering the training in terms of presence of the instructor/narrative voice, availability and types of any educational materials, possible presence of pre-/post-assessment tests, modes of interaction with learners, etc.]</i></p> <p>.....</p>	
<p>Learning objectives and examples of possible contents</p>	<p>Contents <i>[for each learning objective please briefly describe the content of related learning modules. Add additional lines as needed]</i></p>
<p>a. * Overview of the technology <i>(e.g., definitions, single/multi-organ models, operating principles and technology applications, etc.)</i></p>	1.1
	1.2
	1.3
<p>b. * Understanding of technological features <i>(e.g., microfluidic systems, biomaterials, biocompatibility, knowledge of the cellular environment and compatibility with physiological phenomena, predictivity and biological relevance, etc.)</i></p>	2.1
	2.2
	2.3
<p>c. * Awareness of reference standards and basic principles for technology qualification and method validation</p>	3.1
	3.2

	3.3
d. * Potential applications in human medicine clinical and non-clinical development (<i>e.g., in vivo PK simulation, disease modeling, pharmacological safety/toxicology testing, identification of sensitive biomarkers</i>)	4.1
	4.2
	4.3
e. * Case studies (<i>e.g., liver-on-chip and/or heart-on-chip and/or special population models, digital twins, etc.</i>)	5.1
	5.2
	5.3
f. Optional/additional learning objectives [<i>please list any additional learning objective below and describe related contents in the column at side</i>]	6.1

TEMATIC AREA 2 – RNA therapeutics

Applicant's experience

- Contact point [Applicant's full name]:
- Role:
- Contacts: e-mail telephone

*** It is hereby declared that the Institution of affiliation, as well as the instructors intended to be engaged for the delivery of the training course, possess experience in academic and/or research activities within the scope of Thematic Area 2 (RNA Therapeutics). As evidence thereof, the following documentation is attached to this form:**

- *** Curriculum vitae of the instructors** *[Please note that, where duly justified, integrations or modifications in the composition of the teaching staff will be permitted, provided that the individuals proposed possess skills and/or experience equivalent to those of the originally proposed staff]*
It is specified that the curricula vitae must be submitted in the European format, dated and signed, and must include authorisation for the processing of personal data pursuant to Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 and Legislative Decree No. 196 of 30 June 2003, as amended (Personal Data Protection Code). They must also expressly authorise full disclosure and reproduction of the CV in the event of a request for access to the documents related to this procedure.
- **Other documents** *[please specify and number the attached documents]*

Any knowledge and/or previous experience in the pharmaceutical regulatory field:

☐ **Applicant is endowed with a structure or experts in the pharmaceutical regulatory field** *[specify and number the documents to be attached]*

.....

☐ **Previous collaborations with Authorities in the pharmaceutical regulatory field** *[specify and number the documents to be attached]*

.....

☐ **Experience in delivering training courses and/or other educational events in the pharmaceutical regulatory field** *[specify and number the documents to be attached]*

.....

☐ **Other** *[specify and number the documents to be attached]*

.....

Training course	
* Training course title: * Duration: [specify a duration between 8 and 12 hours] * Cost estimate:[costs must be within 15.000,00€, VAT exempt]	
The training course will be delivered in English and provided via e-learning.	
Description of the delivery method of the educational offer and any value-added elements useful for the final score attribution by the evaluation Committee [describe the methods of delivering the training in terms of presence of the instructor/narrative voice, availability and types of any educational materials, possible presence of pre-/post-assessment tests, modes of interaction with learners, etc.]	
Learning objectives and examples of possible contents	Contents [for each learning objective please briefly describe the content of related learning modules. Add additional lines as needed]
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)	1.1
	1.2
	1.3
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.)	2.1
	2.2
	2.3
c. * Knowledge of current and emerging delivery systems (e.g., viral/non-viral delivery systems)	3.1
	3.2
	3.3
d. * Basic understanding of applied biocomputing (e.g., structure prediction, on-/off-target effects, molecular interactions)	4.1
	4.2
	4.3
SPECIFIC objectives	
e. Knowledge of pharmaceutical development, production, and quality control (e.g., production systems, scaling-up, analytical methodologies, stability)	5.1
	5.2
	5.3

f. Knowledge of non-clinical development (<i>e.g., in vitro/in vivo models, alternative approaches such as organoids, immunogenicity, biodistribution, case studies</i>)	6.1
	6.2
	6.3
NOTE: For Thematic Area 2 (RNA-based Therapeutics), training proposals must address all GENERAL learning objectives and at least one of the SPECIFIC ones (points “e” and “f”).	
g. Optional/additional learning objectives [please list any additional learning objective below and describe related contents in the column at side]	7.1