



## Role description

<b>Job title</b>	Regulatory and Digital Development Officer
<b>Job family</b>	Core
<b>Job sub-family</b>	Regulatory and Digital Development
<b>Entry grade</b>	FGIV
<b>Role summary</b>	Responsible for the implementation of the strategy for the EU NTC, and the follow-up to deliver on EMA and the European Medicines Regulatory Network's (EMRN) strategic goals. Execute the activities of the EU NTC and the EMA Digital Academy in accordance with their roadmaps.

<b>Standard role duties &amp; responsibilities</b>	<p>The duties of the role are performed under the supervision, including guidance and support, of temporary staff;</p> <p>Execute activities relating to capability and capacity building across the European Medicines Regulatory Network (EMRN) (and its partners and stakeholders as appropriate), in the areas of regulatory, scientific, data and digital topics relevant to public and animal health in Europe;</p> <p>Contribute to the development, definition, execution and continual adaptation of the EU Network Training Centre (EU NTC) strategy to meet evolving business and stakeholder needs;</p> <p>Identify and gather learning and development needs and priorities in liaison with the EU NTC Training Steering Group (TrSG) and Training Champions through different methods (e.g. surveys), identify gaps in learning, and ensure provision of suitable interventions and development of learning curricula in line with such needs<sup>1</sup>;</p> <p>Work with relevant subject matter experts externally and internally to develop training curricula and to design the development and delivery of high-quality learning materials for EU Network staff;</p> <p>In liaison with the EU NTC TrSG and Training Champions, contribute to the planning and delivery of a planned catalogue of training courses (face-to-face/virtual/e-learning) designed to meet the EU Network needs through the learning management system (LMS);</p>
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<sup>1</sup> The actual development of course content will be performed by subject matter experts and is not within the scope of this role.



	<p>Contribute to the implementation of policies, standards and quality guidelines for learning design, development and delivery, carrying out research as needed;</p> <p>Ensure the business support for the LMS, including data management creation of FAQs, implementation of agreed changes, designing processes and templates for monthly updates. This will include liaison with the Local Administrator network;</p> <p>Prepare reporting on the delivery of training to relevant fora, in particular to the TrSG;</p> <p>Contribute to the continuous improvement of the internal processes to support the EU NTC, particularly those requiring interaction with other areas of the EMA (IT, Talent Development);</p> <p>Conduct (in liaison with relevant EMA departments and offices) work / projects to extend (EU NTC) learning to (selected) external audiences including business case development, selection of best suited engagement platform and development of governance, processes and communication channels to include such audiences in the EU NTC learning service offering. Potential audiences include non-EU Regulators and Academia;</p> <p>Regularly provide updates on projects / initiatives to various stakeholders / general management when applicable.</p>
<p><b>Role specific duties &amp; responsibilities</b></p>	<p>The specific tasks of an individual job holder, linked to this role description, are further detailed, and referenced in:</p> <p>activities of the organisational entity within which the job holder carries out those tasks;</p> <p>the set of annual performance and development objectives, which are established together with the reporting officer;</p> <p>the requirement to comply with SOPs, WINs, confidentiality undertaking and other documentation relevant to the role and its scope. These will be agreed upon with the reporting officer upon assuming duties.</p>
<p><b>Managing resources</b></p>	<p>No management or supervision of resources.</p>
<p><b>Communication and professional contacts</b></p>	<p>Required to receive and convey information, orally and/or in writing, of a non-routine nature which needs careful explanation and interpretation e.g. explaining or interpreting policies, systems, processes; dealing with matters of a sensitive nature; formulating responses to more complex enquiries; drafting news items, letters, minutes, reports or presentations.</p> <p>Regular professional contacts with others inside and/or outside the Agency on functional matters. Solicits/gives information, provides advice/guidance and should use initiative. A likely requirement is to influence others' thinking and negotiate with various parties within own job responsibilities. Normally connected to the Agency's core business or a project.</p> <p>Act as point of contact for the EU NTC TrSG;</p> <p>Act as contact person between the EU NTC and NCAs, including the Training Champions and the Local Administrator network;</p>

Contribute to assessments and negotiations with suppliers (concessions) with respect to proposals for new, externally delivered courses and follow up, together with EMA Talent Development, after evaluation of training;

Liaise with internal counterparts in EMA Talent Development with respect to training of interest to EMA staff members, issues relevant to use of the Learning Management System and development of e-learning materials; optimal use of concessions, etc.;

Prepare and implement developments for the EMA Digital Academy in liaison with the EU NTC lead and the Head of Digital Change, ensuring it meets business needs to develop capabilities in digital related topics and the expansion of the Digital Academy to the wider Network.

**Essential requirements**

Education  
Experience  
Skills & knowledge  
Certificates

**Education**

A level of education which corresponds to completed university studies of at least three years attested by a diploma.

**Experience**

Up to three years of full-time professional relevant experience.

**Skills & Knowledge**

Basic stakeholder management and engagement skills;

Good communication skills, both written and verbal;

Basic understanding and knowledge of the relevant stakeholders/partners;

**Certificates**

n/a

**Nice to have**

Education  
Experience  
Skills & knowledge  
Certificates

**Education**

A degree in Regulatory Science (health), Organisational Psychology, Human Resources Management, Business Administration, Life Sciences or a related degree is desirable.

**Experience**

Experience in designing, developing, and implementing learning and development and/or HR programmes or projects;

Experience in a competent authority in the field of medicines regulation, the pharmaceutical industry or in a healthcare / academic setting.

**Skills & Knowledge**

Good project management skills;

Knowledge of the EU regulatory framework for pharmaceuticals and EU health policies.

**Certificates**

n/a

Category	Competency	Proficiency level
<b>Role competencies</b>	Understanding business context	Basic
	Stakeholder relations management	Basic
<b>Sub-family competencies</b>	Scientific communication	Basic
	Regulatory frameworks & strategy	Basic
	Applied knowledge	Intermediate
<b>Grade competencies</b>	Adaptability and agility	Intermediate
	Coping with pressures and setbacks	Intermediate
	Analysing and problem solving	Intermediate
<b>Core competencies</b>	Ethics and integrity	Intermediate
	Team collaboration	Intermediate
	Customer centricity	Intermediate
	Results orientation	Intermediate
	Communication	Intermediate
	Cross-cultural sensitivity	Intermediate
	Continuous learning and self-development	Basic