



Role description

Job title	Regulatory and Digital Development Specialist
Job family	Core
Job sub-family	Regulatory and Digital Development
Entry grade	AD06
Role summary	Responsible for developing the strategy for the EU NTC, for its implementation and follow-up to deliver on EMA and the European Medicines Regulatory Network's (EMRN) strategic goals. Lead on activities of the EU NTC and the EMA Digital Academy in accordance with their roadmaps.
Standard role duties & responsibilities	Perform duties reserved only for the Temporary Agent contractual category. Coordinate and implement 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; Develop, define, execute and continuously adapt the EU Network Training Centre (EU NTC) strategy to meet evolving business and stakeholder needs; 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 needs¹; Work with relevant subject matter experts externally and internally to develop training curricula and to design, the development and delivery of high-quality learning for EU Network staff, including advising on the use of learning technology / technology enabled solutions (training delivery mechanisms); In liaison with the EU NTC TrSG and Training Champions, plan and deliver a catalogue of training courses (face-to-face/virtual/e-learning) designed to meet the EU Network needs through the learning management system (LMS); Lead the implementation of policies, standards and quality guidelines for learning design, development and delivery, carrying out related research as needed;

¹ The actual development of course content will be performed by subject matter experts and is not within the scope of this role.



	Coordinate the business support for the LMS, including data checks, consolidating query answers and FAQs, tracking implementation of agreed changes, designing processes and templates for monthly updates. This will include liaison and support with the Local Administrator network; Set up and coordinate the reporting on the delivery of training to relevant fora, in particular to the TrSG; Continuously improve the internal processes that support the EU NTC, particularly those requiring interaction with other areas of the EMA (IT, Talent Development); Lead (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; Regularly provide updates on projects / initiatives to various stakeholders / general management when applicable.
Role specific duties & responsibilities	The specific tasks of an individual job holder, linked to this role description, are further detailed, and referenced in: activities of the organisational entity within which the job holder carries out those tasks; the set of annual performance and development objectives, which are established together with the reporting officer; 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.
Managing resources	Plan most daily work details within given priorities. May have a direct supervision of one or more people (e.g. contractors) performing related work. Work may include a degree of strategic and financial planning and coordination, including projects.
Communication and professional contacts	Required to regularly communicate (verbally and in writing) information, which requires careful explanation and interpretation, taking into account what to communicate and how best to convey the information. Writing and creating information that is specialist, sensitive, confidential, legal and/or regulatory in nature. 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. Act as point of contact for the EU NTC TrSG; Act as contact person between the EU NTC and NCAs, including the Training Champions and the Local Administrator network;

Lead 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.

Lead 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

3 years from the time when a university degree was awarded on completion of a minimum of three years of study.

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

Skills & Knowledge

Strong project management, stakeholder management and engagement skills;

Excellent communication skills, both written and verbal;

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

Coordinating teams and/or resources through an assigned task or project.

Skills & Knowledge

Proven track-record of thinking strategically, analysing, and proactively responding to changing business needs and objectives, while considering implications of strategic decisions on affected stakeholders;

Knowledge of the EU regulatory framework for pharmaceuticals and EU health

policies;

Certificates

n/a

Category	Competency	Proficiency level
Role competencies	Understanding business context	Intermediate
	Stakeholder relations management	Intermediate
	Influencing and persuading	Intermediate
Sub-family competencies	Scientific communication	Intermediate
	Regulatory frameworks & strategy	Intermediate
	Applied knowledge management	Intermediate
Grade competencies	Analysing and problem solving	Intermediate
	Adaptability and agility	Intermediate
	Prioritising and organising	Intermediate
Core competencies	Ethics and integrity	Intermediate
	Team collaboration	Intermediate
	Customer centricity	Intermediate
	Results orientation	Intermediate
	Communication	Intermediate
	Cross-cultural sensitivity	Intermediate
	Continuous learning and self-development	Intermediate