



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Role description

Job title	Senior Translational Sciences Specialist
Job Family	Core
Job Sub-Family	Science & Regulation
Entry grade	AD08
Role summary	Provide expert scientific support in translational sciences, covering one or more specific areas (e.g. non-clinical, clinical pharmacology, environmental risk assessment) across Agency activities. Provide expert scientific support to the work of Committees, Working Parties, the European Commission, and other relevant stakeholders. Engage in related regulatory science initiatives.
Standard role duties & responsibilities	Perform duties reserved only for the Temporary Agent contractual category . Provide expert scientific support in translational sciences, covering one or more specific areas (e.g. non-clinical, clinical pharmacology, environmental risk assessment) across Agency activities; Actively contribute to scientific advice and protocol assistance processes, including pre-submission meetings and SAWP discussions; Provide expert scientific support in translational sciences, covering one or more specific areas (e.g. non-clinical, clinical pharmacology, environmental risk assessment) across Agency activities; Provide advice and input into the finalisation of documents/letters/guidance in all aspects of translational sciences matters to the EMA and the EU network as requested; Identify new and re-occurring topics/issues requiring further guidance or official position of committees/WPs; Act as EMA topic leader as required; Peer-review rapporteurs' assessment reports for initial Marketing authorisation applications (MAA) and selected post-authorisation procedures (such as extension of indication and referrals) in relation to translational sciences aspects; Provide scientific secretariat to relevant WPs/DGs and committees, if appointed, in liaisons with other WPs/DGs and committees, with main input into the scientific secretariat to the relevant working parties;

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	Provide scientific training within the Agency and the network, as required; Provide input into emerging safety issues, responses to requests from the European Commission and other EU bodies, as required in the area of translational sciences; Identify new and re-occurring topics/issues requiring further guidance or official position of committees/WPs; Engage in related regulatory science initiatives, as requested.
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 with the reporting officer upon assuming duties.
Managing resources	Control daily work priorities and has influence on overall daily work priorities of the organisational unit, team /project or programme. Involved in the direction, planning, coordination and review of the work of others within the same function. Some degree of external coordination is required.
Communication and professional contacts	Required to communicate (verbally and in writing) complex/diverse conceptual ideas and/or information which may be highly detailed, technical or specialist in nature. At this level, the aim of communication is to influence and to change behaviours to comply with a defined objective. The role requires the use of an extensive range of communication techniques to respond to potentially tense, conflicting or highly competitive situations with a significant financial, legal and/or reputational impact. Complex partnership at a higher functional level both inside and/or outside of the Org. Structure/ Agency. Contacts requiring negotiation and persuasion to reach a defined objective/goal between various parties with mixed interests. Normally a partnership would be connected also to the Agency's core business or a programme/project. In particular, a Senior Translational Sciences Specialist will: Represent the Agency in ERA (GMO and non-GMO), non-clinical and clinical pharmacology issues, support the EMA contribution to the EC Green Deal, and on these topics, liaise with the veterinary medicines Division as necessary, ensuring developments and their expertise are shared across EMA and network.
Essential requirements Education Experience Skills & knowledge Certificates	Education A level of education which corresponds to completed university studies attested by a diploma when the normal period of university education is four years or more, or a level of education which corresponds to completed university studies attested by a

diploma and appropriate professional experience of at least one year when the normal period of university education is at least three years;

Field of study

Medical sciences or related subject, biomedical sciences and or translational sciences.

Experience

9 years from the time when a university degree was awarded on completion of a minimum of four years of study;

with aspects of ERA or translational sciences as applied in pharmaceutical industry, the regulatory network, or academia.

Skills & Knowledge

Thorough knowledge and understanding of translational sciences;

Able to critically assess studies and their implications for public health;

Leadership skills to implement relevant translational sciences considerations into support for, and assessment of, medicinal products coming for scientific advice or marketing authorisation.

Certificates

n/a

Nice to have

Education
Experience
Skills & knowledge
Certificates

Education

PhD in science related to medicine.

Experience

n/a

Skills & Knowledge

n/a

Certificates

n/a

Category	Competency	Proficiency level
Role competencies	n/a	n/a
	Pharmaceutical quality	Advanced
Sub-family competencies	Regulatory frameworks & strategy	Advanced
	Scientific evidence management	Advanced
	Scientific product lifecycle and procedure management	Advanced

	Applied knowledge	Advanced
Grade competencies	Analysing and problem solving	Intermediate
	Prioritising and organising	Advanced
	Influencing and persuading	Advanced
Core competencies	Ethics and integrity	Intermediate
	Team collaboration	Advanced
	Customer centricity	Advanced
	Results orientation	Advanced
	Communication	Intermediate
	Cross-cultural sensitivity	Advanced
	Continuous learning and self-development	Intermediate