



## Role description

<b>Job title</b>	Translational Sciences Specialist
<b>Job family</b>	Core
<b>Job sub-family</b>	Science & Regulation
<b>Entry grade</b>	AD06
<b>Role summary</b>	<p>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.</p>
<b>Standard role duties &amp; responsibilities</b>	<p>Perform duties reserved only for the Temporary Agent contractual category.</p> <p>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;</p> <p>Actively contribute to scientific advice and protocol assistance in pre-submission processes, including pre-submission meetings and SAWP discussions;</p> <p>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;</p> <p>Identify new and re-occurring topics/issues requiring further guidance or official position of committees/WPs; Act as EMA topic leader as required;</p> <p>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;</p> <p>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;</p> <p>Provide scientific training within the Agency and the network, as required;</p> <p>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;</p>



	<p>Identify new and re-occurring topics/issues requiring further guidance or official position of committees/WPs;</p> <p>Engage in related regulatory science initiatives, as requested.</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 with the reporting officer upon assuming duties.</p>
<p><b>Managing resources</b></p>	<p>Plan most daily work details within given priorities. May have a direct supervision of one or more people performing related work. Work may include a degree of planning and coordination, including small projects.</p>
<p><b>Communication and professional contacts</b></p>	<p>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.</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>In particular, a Translational Sciences Specialist, will:</p> <p>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.</p>
<p><b>Essential requirements</b> Education Experience Skills &amp; knowledge Certificates</p>	<p><b>Education</b></p> <p>A level of education which corresponds to completed university studies of at least three years attested by a diploma;</p> <p><i>Field of study</i></p> <p>Medical sciences or related subject, biomedical sciences and or translational sciences.</p> <p><b>Experience</b></p> <p>3 years from the time when a university degree was awarded on completion of a minimum of three years of study;</p>

Work experience 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 and be able to critically assess such studies and their implications for public health.

**Certificates**

n/a

**Nice to have**

Education  
Experience  
Skills & knowledge  
Certificates

**Education**

MSc in science related to medicine.

**Experience**

n/a


**Skills & Knowledge**

n/a

**Certificates**

n/a

Category	Competency	Proficiency level
<b>Role competencies</b>	n/a	n/a
	Pharmaceutical quality	Intermediate
<b>Sub-family competencies</b>	Regulatory frameworks & strategy	Intermediate
	Scientific evidence management	Intermediate
	Scientific product lifecycle and procedure management	Intermediate
	Applied knowledge	Intermediate
<b>Grade competencies</b>	Analysing and problem solving	Intermediate
	Adaptability and agility	Intermediate
	Prioritising and organising	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	Intermediate