EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

# Role description

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| **Job title** | Translational Sciences Officer |
| **Job family** | Core |
| **Job sub-family** | Science & Regulation |
| **Entry grade** | FGIV |
| **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** | The duties of the role are performed under the supervision, including guidance and support, of temporary staff.<br><br>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;<br><br>Actively contribute to scientific advice and protocol assistance in pre-submission processes, including pre-submission meetings and SAWP discussions;<br><br>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;<br><br>Identify new and re-occurring topics/issues requiring further guidance or official position of committees/WPs; Act as EMA topic leader as required;<br><br>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;<br><br>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;<br><br>Provide scientific training within the Agency and the network, as required; |

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| | 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;<br><br>Identify new and re-occurring topics/issues requiring further guidance or official position of committees/WPs;<br><br>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:<br><br>activities of the organisational entity within which the job holder carries out those tasks;<br><br>the set of annual performance and development objectives, which are established together with the reporting officer;<br><br>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** | No management or supervision of resources. |
| **Communication and professional contacts** | 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.<br><br>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.<br><br>In particular, a Translational Sciences Officer will:<br><br>Represent the Agency in ERA (GMO and non-GMO), N-C 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**<br>Education<br>Experience<br>Skills & knowledge<br>Certificates | **Education**<br><br>A level of education which corresponds to completed university studies of at least three years attested by a diploma;<br><br>*Field of study*<br><br>Medical sciences or related subject, biomedical sciences and or translational sciences.<br><br>**Experience** |

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| | Up to 3 years of full time professional relevant experience;<br><br>Work experience with aspects of translational sciences as applied in pharmaceutical industry, the regulatory network, or academia.<br><br>**Skills & Knowledge**<br><br>Thorough knowledge and understanding of translational sciences.<br><br>**Certificates**<br><br>n/a |
| **Nice to have**<br>Education<br>Experience<br>Skills & knowledge<br>Certificates | **Education**<br><br>MSc in science related to medicine.<br><br>**Experience**<br><br>n/a<br><br>**Skills & Knowledge**<br><br>n/a<br><br>**Certificates**<br><br>n/a |

| Category | Competency | Proficiency level |
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| **Role competencies** | n/a | n/a |
| | Pharmaceutical quality | Intermediate |
| **Sub-family competencies** | Regulatory frameworks & strategy | Intermediate |
| | Scientific evidence management | Basic |
| | Scientific product lifecycle and procedure management | Basic |
| | Applied knowledge | Intermediate |
| **Grade competencies** | Adaptability and agility | Intermediate |
| | Coping with pressures and setbacks | Intermediate |
| | Analysing and problem solving | Intermediate |

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| **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 | Basic |