EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Role description

Job title	Scientific Specialist
Job family	Core
Job sub-family	Science & Regulation
Entry grade	AD06
Role summary	Provide scientific, regulatory or procedural input and oversight relating to the safety, efficacy and quality aspects of human or veterinary medicines.
Standard role duties & responsibilities	Perform duties reserved only for the Temporary Agent contractual category. Provide scientific coordination and regulatory and/or procedural support in relation to the any of the following areas: Development, evaluation and surveillance of medicinal products for human or veterinary use and of Maximum Residue Limits for substances for veterinary use; Referrals and related procedures for medicinal products for human or veterinary use; Management of requests for scientific advice, protocol assistance, parallel scientific advice with other decision makers (e.g. FDA or HTA bodies), as well as qualifications; Preparing the summary report and supporting the coordination of the initial assessment for orphan medicine designation, paediatric investigation plans or limited markets classifications; The delivery of high-quality product information through assessment of invented names, product information and its translations, mock-ups and specimens, and provision of advice and training on product information guideline principles; Apply EU pharmaceutical legislation to the operations of the Agency as required; Lead to the development of regulatory and/or procedural guidance documents and provide training as required; Coordinate and supervise the operation of Scientific Committee meetings, Working Parties, Working Groups, Advisory/Expert Groups, etc and related activities; Respond to the requests for information received by the EMA in the scientific field.

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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	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.
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. In particular, a Scientific Specialist will: Liaise with internal and external stakeholders and interested parties, internal and external subject experts; Coordinate, support, lead effective communication and relations; Daily internal communication and interaction related to the management of the procedures with other colleagues across the Agency and the extended product team members; Prepare and contribute to the preparation of communication documents for allocated procedures; Contribute to the preparation of Scientific Committee meetings, Working Parties, Working Groups, Advisory/Expert Groups, including providing scientific support as applicable.
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; *Field of study* Life Science (e.g. biology, chemistry, biochemistry, pharmacy).

	Experience 3 years from the time when a university degree was awarded on completion of a minimum of three years of study; Experience in either a competent authority in the field of medicines regulation, the pharmaceutical industry or in a healthcare / academic setting should have been obtained in: In the scientific, regulatory, or procedural aspects of the research, development, authorisation, productions or supervision of human or veterinary medicines In working with medicinal products containing medical devices and associated regulatory framework; **Skills & Knowledge** Organisational skills; Communication skills; Critical review and drafting of scientific and regulatory documents for expert and lay audiences; Presenting scientific, or regulatory matters at a high level (including experts); Proficient in English language; Proficient in MS Office suite; Knowledge and understanding of the EU pharmaceutical legislation and the regulatory framework for pharmaceutical products in the EU; Knowledge of the typical issues in quality, non-clinical, or clinical development in one or more therapeutic areas; Knowledge of general methodology for quality, non-clinical, or clinical development; Knowledge of at least one area relevant for quality, non-clinical, or clinical development of medicines. **Certificates** n/a
Nice to have Education Experience Skills & knowledge Certificates	**Education** Masters in a relevant field of study (Medicine or Life sciences); Master's degree in regulatory science and/or affairs. *Field of study* Scientific background relevant to perform the role. **Experience** In information analysis and reporting on scientific/regulatory matters; Clinical experience in a therapeutic field;

	Pharmaceutical development experience; With medicines assessment at a National Competent Authority; Regulatory scientists/product manager experience; Non-clinical experience; Experience in the preparation and/or review of any part of an application dossier; Experience in working with stakeholders (industry and national/international authorities). **Skills & Knowledge** Understanding of medicines regulation. **Certificates** n/a

Category	Competency	Proficiency level
Role competencies	Developing and applying innovative practices	Intermediate
	Pharmaceutical quality	Intermediate
Sub-family competencies	Regulatory frameworks & strategy	Intermediate
	Scientific evidence management	Intermediate
	Scientific product lifecycle and procedure management	Intermediate
	Applied knowledge	Intermediate
Grade competencies	Adaptability and agility	Intermediate
	Analysing and problem solving	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