EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Role description

Job title	Scientific Officer
Job family	Core
Job sub-family	Science & Regulation
Entry grade	FGIV
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	The duties of the role are performed under the supervision, including guidance and support, of temporary staff. 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.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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	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. 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 Officer 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**

	Up to 3 years of full time professional relevant experience; 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; Scientific writing skills; Proficient in English language; Proficient in MS Office suite; Knowledge and understanding of the EU pharmaceutical legislation. **Certificates** n/a
Nice to have Education Experience Skills & knowledge Certificates	**Education** Masters in a relevant field of study (Medicine or Life sciences); *Field of Study* Scientific background relevant to perform the role. **Experience** In regulatory affairs on EU-wide or national procedures or other work on the regulation of medicines; In information analysis and reporting on scientific/regulatory matters; Clinical experience in a therapeutic field; In working for a multinational organisation and managing multiple international stakeholders; Nonclinical experience in a Good Laboratory Practice (GLP) laboratory. **Skills & Knowledge** Understanding of medicines regulation. **Certificates** Evaluation of medicines; Regulatory affairs.

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