EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Role description

Job title	Regulatory Affairs Officer
Job family	Core
Job sub-family	Science & Regulation
Entry grade	FGIV
Role summary	Provide regulatory intelligence and advice to European Medicines Agency staff, Scientific Committees, National Competent Authorities and Industry, on the development, evaluation and surveillance of medicinal products in compliance with Union legislation.
Standard role duties & responsibilities	The duties of the role are performed under the supervision, including guidance and support, of temporary staff. Responsible for providing regulatory advice across the activities of the Division, ensuring consistency across the Agency for regulatory topics; Involvement in complex procedures, consultations with EMA Legal Department and provision of risk-based regulatory checks of documents before the transmission to the Applicant/MAH/EC (e.g. negative validation, negative opinion, opinion recommending granting marketing authorisations under exceptional circumstances, re-examination) to facilitate compliance with Union legislation/procedures/guidelines; Develop general and specific regulatory and procedural guidance to Agency's staff, the Agency's scientific committees, working parties/satellite groups and interested parties; Escalate matters of significance for information or action to the Head of Service/Head of Department, in particular those with significant reputational, policy, compliance or resource implications; Take responsibility, as delegated, mainly as scientific/content lead or subject matter expert, including scientific quality assurance, for procedures and topics within the Service relating to product life-cycle management and regulatory affairs.
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;

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	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	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 Regulatory Affairs Officer will: Liaise with internal and external stakeholders as required. Coordinate, support, lead effective communication and relations.
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 three years of proven full-time professional relevant experience; Experience in either a competent authority in the field of medicines regulation, the pharmaceutical industry or in a healthcare / consultancy setting should have been obtained in: the scientific, regulatory, or procedural aspects of the research, development, authorisation, productions or supervision of human or veterinary medicines. **Skills & Knowledge** Scientific writing skills; Proficient in English language; Proficient in MS Office suite; Knowledge and understanding of the EU pharmaceutical legislation. **Certificates** Regulatory affairs; Evaluation of medicines.

Nice to have Education Experience Skills & knowledge Certificates	**Education** Master's degree in regulatory science and or affairs. **Experience** As a Regulatory Affairs professional on EU-wide procedures or national procedures or other work on the regulation of medicines; Experience in either a competent authority in the field of medicines regulation, the pharmaceutical industry or in a healthcare /consultancy setting; In working for a multinational organisation and managing multiple international stakeholders. **Skills & Knowledge** n/a **Certificates** n/a

Category	Competency	Proficiency level
Role competencies	n/a	n/a
	n/a	n/a
Sub-family competencies	Regulatory frameworks & strategy	Intermediate
	Applied knowledge	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