



Role description

Job title	SME Officer
Job family	Corporate Functions & Administration
Job sub-family	Engagement, Communication, International and Institutional Affairs
Entry grade	FGIV
Role summary	Provide financial and administrative assistance to Regulation (EC) No. 2049/2005 and the coordination of related activities in line with the strategic agenda of the Agency.
Standard role duties & responsibilities	<p>The duties of the role are performed under the supervision, including guidance and support, of temporary staff.</p> <p>Review small and medium-sized enterprise (SME) status applications according to standard operating procedures;</p> <p>Provide regulatory, administrative and procedural assistance to SMEs;</p> <p>Plan the organisation of workshops and training events for SMEs;</p> <p>Plan the organisation of internal and external meetings with stakeholders;</p> <p>Supervise the provision of translations of product information for marketing authorisations applications by SMEs;</p> <p>Prepare documents, manuals and other relevant communication tools (e.g. newsletters, targeted mailings, user guide);</p> <p>Support the Agency activities related to the 'Publication and access to clinical-trial data' policy (Policy 70) and the provision of a redaction tool software licence, the pharmacovigilance fee regulation 658/2014 and stakeholders' engagement;</p> <p>Monitor and report SME activities in relevant systems, databases and governance documents;</p> <p>Support the implementation and delivery of the Agency and the European medicines regulatory network strategies relating to Regulatory Science and Innovation;</p>



	<p>Identify and address future challenges from innovative scientific developments by contributing to the operation of the Regulatory Science Observatory across the Agency;</p> <p>Forecast and analyse trends in science and technology, upcoming products and their impact on EMA's work by contributing to a systematic horizon scanning capability.</p>
<p>Role Specific Duties & Responsibilities</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 upon with the reporting officer upon assuming duties.</p>
<p>Managing resources</p>	<p>No management or supervision of resources.</p>
<p>Communication and professional contacts</p>	<p>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.</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, an SME Officer will:</p> <p>Collaborate with Commission Directorates/European Agencies and European Institutions in related areas of activity;</p> <p>Represent the Agency in external meetings and public conferences;</p> <p>Collaborate with International institutions in related activities.</p>
<p>Essential requirements Education Experience Skills & knowledge Certificates</p>	<p>Education</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>Life Sciences (e.g. biology, biochemistry, chemistry, pharmacy, medicine).</p> <p>Experience</p> <p>Up to 3 years of full time relevant professional experience;</p>

In either a competent authority in the field of medicines regulation, the pharmaceutical industry or in a healthcare/academic setting obtained on scientific, regulatory or procedural aspects of research, development, authorisation, manufacturing or supervision of human or veterinary medicines;

In preparing and updating of SOPs/WINs, templates and other quality management systems documents and guidance.

Skills & Knowledge

Organisational skills;

Attention to details;

Knowledge of the legal and regulatory framework for medicinal products in the EU;

Knowledge of commonly used IT tools and systems, including teleworking tools and meeting organisers.

Certificates

n/a

Nice to have

Education
Experience
Skills & knowledge
Certificates

Education

Master’s degree or course in regulatory affairs.

Experience

In analysing and reporting on scientific/regulatory matters;

In preparing, reviewing or assessing a regulatory application dossier;

In dealing with internal and external stakeholders (industry and national/international authorities);

In working in an international organisation.

Skills & Knowledge

Understanding of pharmaceutical, (non)clinical, pharmacovigilance regulatory requirements in pre- and post-authorisation;

Understanding of EU SME definition;

Understanding of EMA roles and responsibilities, and activities of the Committees.

Certificates

Certificates corresponding to the aforementioned requirements.

Category	Competency	Proficiency level
Role competencies	Continuous improvement	Basic
	Regulatory frameworks & strategy	Intermediate
Sub-family competencies	Understanding business context	Intermediate

	Corporate communication	Basic
	Applied knowledge	Intermediate
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