



Role description

Job title	Access to Documents Officer
Job family	Core
Job sub-family	Scientific communication
Entry grade	FGIV
Role summary	Responsible for the assessment of commercially confidential information (CCI) and protected personal data (PPD) in the context of a request of access to documents in accordance with Regulation (EC) No 1049/2001 and EMA's Policy 0043 on access to documents.
Standard role duties & responsibilities	The duties of the role are performed under the supervision, including guidance and support, of temporary staff. Assess third party's proposals for commercially confidential information (CCI) and protected personal data (PPD) in the context of a request of access to documents in accordance with Regulation (EC) No 1049/2001 and EMA's Policy 0043 on access to documents; Identify CCI and PPD, in the absence of a response from third party or in case of re-release; Peer review (after the probation period) of other ATD document managers' assessments of third parties' proposed redaction within set deadlines; Support with identifying and locating documents when required and ensure these meet the requester's requirements; Assess CCI and PPD when EMA is consulted as a third party (after the probation period) in the context of an ATD request received by partner organisations; Identify issues and escalate them as requested; Participate and/or develop internal and external procedural guidance documents; Answer Requests for Information (RFIs) when applicable in line with the Agency's practice.



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	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, an Access to Documents Officer, will: Liaise with third parties; In the context of the assessment of proposed redaction(s) or clarification of the request to access documents.
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; <i>Field of study</i> Medicine, pharmacy or other life sciences, or related area. Experience Up to 3 years of full time relevant professional experience. Up to at least 3 years of professional experience in the field of medicine, pharmacy, research, pharmaceuticals, biotechnology, regulatory affairs, life sciences, scientific or related area. Skills & knowledge Knowledge of regulatory affairs. Certificates

	n/a
Nice to have Education Experience Skills & knowledge Certificates	Education n/a Experience In regulatory affairs of medicinal products and/or medical, pharmaceutical, or life sciences field and/or law; In working as part of a multinational team. Skills & knowledge Knowledge of regulatory affairs; Knowledge of the clinical development of medicinal products; Knowledge of the anonymisation of personal data. Certificates n/a

Category	Competency	Proficiency level
Role competencies	n/a	n/a
	n/a	n/a
Sub-family competencies	Corporate communication	Basic
	Scientific communication	Basic
	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