



Role description

Job title	Transparency Officer
Job family	Core
Job sub-family	Science and regulation
Entry grade	FGIV
Role summary	Responsible for the assessment of commercially confidential information (CCI) and anonymisation of personal data in accordance with Regulation (EC) No 1049/2001 and EMA's Policy 0043, Policy 0070 or any other transparency measures as necessary. Responsible for identifying transparency provisions in new EU legislation and/or transparency initiatives and designing a plan for efficient and timely implementation to ensure compliance and enhance openness and collaboration across EU regulatory frameworks.
Standard role duties & responsibilities	The duties of the role are performed under the supervision, including guidance and support, of temporary staff. Assess commercially confidential information (CCI) and protected personal data (PPD) / anonymisation methodology in the context of document-/data-sharing with stakeholders; Peer review of other document managers' assessments of CCI and anonymisation of personal data within set deadlines; Analyse new EU legislation to identify transparency requirements for EMA; participation in the design of implementation plan(s), taking into account digital needs, feasibility assessment(s) and alignment with other EU transparency initiatives to ensure EMA meets its transparency obligations. Provide guidance/scientific input to help with identifying and locating documents/data when required; Assess CCI and anonymisation of personal data when EMA is consulted as a third party; Identify issues and escalate them as required;



	Draft, review and/or develop internal and external procedural guidance documents; Respond to 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, the Transparency Officer will: Liaise with internal and external stakeholders in the context of the assessment of CCI and anonymisation of personal data and/or with regards to project work.
Essential requirements	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, other life sciences or related area, legal or international affairs 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, transparency, life sciences, scientific or related area. Skills & knowledge

Nice to have Education Experience Skills & knowledge Certificates	Certificates n/a
	Education n/a
	Experience In regulatory affairs of medicinal products and/or medical, pharmaceutical, or life sciences field; In working as part of a multinational team.
	Skills & knowledge Knowledge of regulatory affairs; Knowledge of the 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	Regulatory frameworks & strategy	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

