EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Role description

Job title	Clinical Data Publication Officer
Job family	Core
Job sub-family	Scientific Communication
Entry grade	FGIV
Role summary	Responsible for assessing the commercially confidential information (CCI) and the anonymisation proposed by the marketing authorisation holders/applicants in the context of Clinical data publication and other transparency measures as necessary.
Standard role duties & responsibilities	The duties of the role are performed under the supervision, including guidance and support, of temporary staff. Assess the Commercially Confidential Information (CCI) and anonymisation proposed by marketing authorisation holders/applicant in the context of clinical data publication; Peer review of other CDP managers' assessments of MAH's/Applicant's proposed redactions and anonymisation within set deadlines defined by the CDP process; Support with checking documents to be published in the scope of clinical data publication; Identify issues and escalate them to the team lead or Head of Department; Prepare and/or develop internal and external procedural guidance documents and provide training as required; 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;

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	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 Clinical Data Publication Officer will: Liaise directly with MAHs/Applicants in the context of the assessing proposed CCI and anonymisation; Advise team members whenever needed and especially in complex situations; Liaise with international regulatory authorities, competent authorities/partners.
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* Law, medicine, pharmacy or other life sciences or related area. **Experience** Up to 3 years of full time relevant professional experience; Up to 3 years of professional experience in the field of law, medicine, pharmacy, clinical 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 the anonymisation of personal data; Knowledge of the clinical development of medicinal products. **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