EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Role description

Job title	Epidemiology Specialist
Job family	Core
Job sub-family	Evidence generation
Entry grade	AD06
Role summary	Support the regulatory decision-making by identifying and using the best methods to derive evidence from healthcare and pharmacoepidemiological studies data, specifically activities relating to Real World Evidence leading to the creation of a framework that delivers access to and analysis of the multi-national real-world data that will help optimise medicinal development and decision-making.
Standard role duties & responsibilities	Perform duties reserved only for the Temporary Agent contractual category. Provide expertise for the identification, and validation and utilisation of electronic healthcare data sources, disease registries and innovative data sources in Europe to support the EMA regulatory science strategy and the regulatory decision-making; Use of epidemiology on the basis of real-world data to study populations, diseases and the performance of medicines for the assessment of the safety and performance of medicines once placed on the market; Design, conduct and coordinate pharmacoepidemiological studies on the safety and efficacy of medicinal products (with development of study protocol, statistical analyses and report writing) using in-house electronic health care databases, including (but not limited to) drug utilisation studies, studies on the effectiveness of risk minimisation measures and etiological studies; Support EMA scientific committees and working parties in methodological aspects that contribute to scientifically sound and efficient drug development; Contribute to the development of scientific guidelines on the design and analysis of pharmacoepidemiological studies; Coordinate the development of a capacity within the EU Regulatory Network to analyse independent patient data from pharmacoepidemiological studies; Develop training materials for the EU Regulatory Network on assigned subjects;

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	Advise companies developing medicines on the design of pharmacoepidemiological studies.
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 upon with the reporting officer upon assuming duties.
Managing resources	Plan most daily work details within given priorities. May have a direct supervision of one or more people performing related work. Work may include a degree of planning and coordination, including small projects.
Communication and professional contacts	Required to regularly communicate (verbally and in writing) information, which requires careful explanation and interpretation, taking into account what to communicate and how best to convey the information. Writing and creating information that is specialist, sensitive, confidential, legal and/or regulatory in nature. 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.
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* n/a **Experience** 3 years from the time when a university degree was awarded on completion of a minimum of three years of study; Proven experience in at least one of the following: designing and conducting pharmacoepidemiological studies including operational work in protocol development and data analysis, interpretation and reporting; designing or interpreting pharmacoepidemiological studies, including e.g. adaptive designs;

	managing, transforming and analysing healthcare data, with practical use of statistical software like SAS or R; developing and delivering training on data analytics and methodology for observational data; In working in a multidisciplinary team and in a multicultural environment. **Skills & knowledge** n/a **Certificates** n/a
Nice to have Education Experience Skills & knowledge Certificates	**Education** Completed PhD or master's degree in medicine, pharmacy, epidemiology, statistics, mathematics, data science, computer science or related scientific subjects. **Experience** In working in a regulatory environment related to the evaluation of medicines or interacting with regulatory agencies; In coordinating research projects; In using data analytics solutions which include artificial intelligence components and cloud technologies. **Skills & knowledge** n/a **Certificates** n/a

Category	Competency	Proficiency level
Role competencies	n/a	n/a
	n/a	n/a
Sub-family competencies	n/a	n/a
	Pharmacoepidemiology	Intermediate
	Applied knowledge management	Intermediate
Grade competencies	Adaptability and agility	Intermediate
	Analysing and problem solving	Intermediate
	Prioritising and organising	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	Intermediate