



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Role description

Job title	Scientific Senior Specialist
Job family	Core
Job sub-family	Science & Regulation
Entry grade	AD08
Role summary	Provides scientific, regulatory or procedural input and oversight relating to the safety, efficacy and quality aspects of human or veterinary medicines.
Standard role duties & responsibilities	<p>Perform duties reserved only for the Temporary Agent contractual category.</p> <p>Provide scientific coordination and regulatory and/or procedural support in relation to the any of the following areas:</p> <p>Development, evaluation and surveillance of medicinal products for human or veterinary use and of Maximum Residue Limits for substances for veterinary use;</p> <p>Referrals and related procedures for medicinal products for human or veterinary use;</p> <p>Management of requests for scientific advice, protocol assistance, parallel scientific advice with other decision makers (e.g. FDA or HTA bodies), as well as qualifications;</p> <p>Preparing the summary report and supporting the coordination of the initial assessment for orphan medicine designation, paediatric investigation plans or limited markets classifications;</p> <p>The delivery of high-quality product information through assessment of invented names, product information and its translations, mock-ups and specimens, and provision of advice and training on product information guideline principles;</p> <p>Apply EU pharmaceutical legislation to the operations of the Agency as required.</p> <p>Lead the development of regulatory and/or procedural guidance documents and provide training as required;</p> <p>Coordinate and supervise the operation of Scientific Committee meetings, Working Parties, Working Groups, Advisory/Expert Groups, etc and related activities;</p> <p>Respond to the requests for information received by the EMA in the scientific field;</p> <p>Provide scientific input to developers of medicines addressing a public health urgency and to the Emergency Task Force.</p>



Specific role duties & responsibilities	<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 with the reporting officer upon assuming duties.</p>
Managing resources	<p>Control daily work priorities and has influence on overall daily work priorities of the organisational unit, team /project or programme. Involved in the direction, planning, coordination and review of the work of others within the same function. Some degree of external coordination is required.</p> <p>In particular, a Scientific Senior Specialist will:</p> <p>Coordinate input from internal and external subject experts;</p> <p>Train, mentor and supervise junior staff members, interims and trainees;</p> <p>Support management on appraisal, objective setting, development and recruitment;</p> <p>Monitor and manage the workload of supervised colleagues and reporting to the line manager any anticipated bottlenecks.</p>
Communication and professional contacts	<p>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.</p> <p>Complex partnership at a higher functional level both inside and/or outside of the Org. Structure/ Agency. Contacts requiring negotiation and persuasion to reach a defined objective/goal between various parties with mixed interests. Normally a partnership would be connected also to the Agency's core business or a programme/project.</p> <p>In particular, a Scientific Senior Specialist will:</p> <p>Liaise with internal and external stakeholders and interested parties as required. Coordinate, support, lead effective communication and relations;</p> <p>Daily internal communication and interaction related to the management of the procedures with other colleagues across the Agency and the extended product team members;</p> <p>Prepare and contribute to the preparation of communication documents for allocated procedures;</p> <p>Contribute to the preparation of Scientific Committee meetings, Working Parties, Working Groups, Advisory/Expert Groups, etc providing scientific support as applicable.</p>
Essential requirements Education Experience Skills & knowledge Certificates	Education <p>A level of education which corresponds to completed university studies attested by a diploma when the normal period of university education is four years or more, or a</p>

level of education which corresponds to completed university studies attested by a diploma and appropriate professional experience of at least one year when the normal period of university education is at least three years.

Field of study

Life Science (e.g. biology, chemistry, biochemistry, pharmacy, background etc.)

Experience

9 years from the time when a university degree was awarded on completion of a minimum of four years of study;

Experience in either a competent authority in the field of medicines regulation, the pharmaceutical industry or in a healthcare / academic setting should have been obtained in:

In the scientific, regulatory, or procedural aspects of the research, development, authorisation, productions or supervision of human or veterinary medicines;

In working with medicinal products containing medical devices and associated regulatory framework.

Skills & Knowledge

Organisational skills;

Communication skills;

Critical review and drafting of scientific and regulatory documents for expert and lay audiences;

Proficient in English language;

Proficient in MS Office suite;

Knowledge and understanding of the EU pharmaceutical legislation and the regulatory framework for pharmaceutical products in the EU, including ICH guidelines relevant to the role;

Knowledge and understanding of current legislation and guidance in the area of expertise and ability to interpret those and advise on their application;

Presenting scientific, or regulatory matters at a high level (eg to experts);

Knowledge of the typical issues in quality, non-clinical, or clinical development in one or more therapeutic areas;

Knowledge of general methodology for quality, non-clinical, or clinical development;

Knowledge of trends and innovative developments in the area of pharmaceutical manufacturing and bordering legislation (e.g. medical devices);

Knowledge of analytical methods and research skills.

Certificates

n/a

Nice to have Education Experience Skills & knowledge Certificates	Education PhD and/or Specialization in a relevant field of study (Medicine or Life science disciplines) Master's degree in regulatory science and or affairs <i>Field of Study</i> Scientific background relevant to perform the role;
	Experience In information analysis and reporting on scientific/ regulatory matters; In researching, analysing and presenting scientific data including scientific writing; In working for a regulatory body, clinic or medical organisation, academic institution or similar, in the area of medicines development; Knowledge of legal, regulatory and procedural aspects of EU Medicines Regulatory framework.
	Skills & Knowledge Understanding of medicines regulation.
	Certificates n/a

Category	Competency	Proficiency level
Role competencies	Pharmaceutical quality	Intermediate
	Influencing and persuading	Advanced
	Prioritising and organising	Advanced
Sub-family competencies	Regulatory frameworks & strategy	Advanced
	Scientific evidence management	Intermediate
	Scientific product lifecycle and procedure management	Intermediate
	Applied knowledge management	Advanced
Grade competencies	Adaptability and agility	Intermediate
	Coping with pressures and setbacks	Advanced
	Analysing and problem solving	Advanced
Core competencies	Ethics and integrity	Intermediate

	Team collaboration	Advanced
	Customer centricity	Advanced
	Results orientation	Advanced
	Communication	Advanced
	Cross-cultural sensitivity	Advanced
	Continuous learning and self-development	Intermediate