



Medicines & Healthcare products Regulatory Agency



Role Description

Job Title	Pharmaceutical Assessor (Healthcare Quality and Access)
Pay Grade	SEO, progressing to G7 on completion of training and accreditation Exceptional candidates with significant post graduate work experience will be considered for recruitment at the higher G7 grade.
Location	Canary Wharf, London
Hours	37 per week (excluding lunch break)
Reports to	Head of Team in Population Health

The Medicines and Healthcare products Regulatory Agency enhance and improve the health of millions of people every day through the effective regulation of medicines and medical devices, underpinned by science and research.

About the Group and Function

The objective of the Healthcare Quality and Access Group is to drive quality and critically appraise benefits and risks to inform robust decisions on healthcare access including accelerated access pathways. It will do this by bringing together a fusion of our capabilities across both medicines and medical devices to enable licensing and market access, as well as ensuring compliance with regulations and standards.

Role Purpose

Reporting to one of the Heads of Team in Population Health, Pharmaceutical Assessors assess the quality aspects (including bioequivalence, when needed) of both initial and variation marketing authorisation applications or medicinal products and take decisions on their suitability for approval.

The role encompasses a broad range of activities from assessing an application for a new active substance, a novel dosage form, or a generic medicine, to providing scientific advice to companies around pharmaceutical/regulatory issues for development of new drug products. A comprehensive training programme is in place to support and develop suitable candidates new to this role.

Key responsibilities and results areas

Leadership and management

- Develop to provide ad hoc advice to colleagues in the Division or Agency
- Extend and deepen skills and knowledge in relevant scientific or professional areas

Service delivery

- Carry out the assessment of data provided in dossiers for initial and variation marketing authorisation applications for chemical products, making appropriate recommendations and decisions in line with the protection of public health.

- Manage own workload working in conjunction with support staff and other assessors to meet agency deadlines
- Prepare and present objective risk-based assessments or other scientific papers to expert advisory bodies

Service improvement

- Contribute to assessment policy and practice and proactively identify where such contributions would be beneficial
- Contribute to divisional procedures and proactively identify where such contributions would be beneficial

Quality and Assurance

- Promptly update agency, group or team and work management databases to reflect the progress of own work
- Display a high level of attention to detail to ensure up to date accurate data and documents are held on internal databases.
- Use own and agency resources in line with agency and divisional strategy to meet targets

General

- Develop good working relationships and communicate effectively with colleagues and other internal and external stakeholders
- Participate in other ad-hoc tasks/projects as requested by the Manager

The job description is not intended to be exhaustive and it is likely that duties may be altered from time to time in the light of changing circumstances and after consultation with the postholder.

Person Specification

Important Candidate information:

The Civil Service recently launched a new recruitment framework called [Success Profiles](#), which has replaced the *Civil Service Competency Framework*.

Success Profiles are made up of 5 elements: **Ability**, **Behaviours**, **Experience**, **Technical**, **Strengths** but it is unlikely that you will be assessed against all 5.

Behaviours, **Experience** and **Technical** elements will be assessed through your application form, in the first instance.

Success Profile	Criteria	Method of assessment: A-Application, T-Test, I-Interview, P- Presentation
Behaviour	<ul style="list-style-type: none"> • Delivering at Pace: Flexibility to adapt to changing priorities and take responsibility for achieving a successful outcome. • Communicating and Influencing: Excellent written and verbal communication skills. • Managing a Quality Service: Ability to handle high throughput of work commensurate with experience and knowledge to meet required deadlines. 	A, I
Experience	<ul style="list-style-type: none"> • Experience within the pharmaceutical industry, hospital pharmacy or academia in at least one of the following: regulatory affairs; research and development; 	A, I

	manufacture or quality control of medicinal products.	
Technical	<ul style="list-style-type: none"> Up to date specialist level of knowledge in one or more relevant scientific areas or broader knowledge across the range of scientific activities in relation to the pharmaceutical development, manufacture, and quality control of medicinal products. Working knowledge of relevant legislation and procedures applicable to the licensing of human medicinal products. Hold a degree in pharmacy, pharmaceutical sciences or chemistry, with relevant postgraduate experience or PhD equivalent 	A, I, T
Strengths	<ul style="list-style-type: none"> Relationship Builder: You quickly establish mutual respect and trust, building long lasting relationships with others. Team Player: You work well as part of a team and strive to ensure the team pulls together and is effective. Problem Solver: Keen attention to detail, a proven ability to apply critical thinking to complex and/or ill-defined problems. 	I

The Civil Service Code

These core values support good government and ensure the achievement of the highest possible standards in all that the Civil Service does. You can find out more about our values, standards of behaviour and rights and responsibilities in [The Civil Service Code](#).

The code is reflected in the Agency and Civil Service values, which state:

Agency Values

- We focus outwards on patients and public
- We work together with respect.
- We take responsibility and are accountable

Civil Service Values

Integrity	<ul style="list-style-type: none"> Putting the obligations of public service above your own personal interests
Honesty	<ul style="list-style-type: none"> Being truthful and open
Objectivity	<ul style="list-style-type: none"> Basing your advice and decisions on rigorous analysis of the evidence
Impartiality	<ul style="list-style-type: none"> Acting solely according to the merits of the case and serving equally well governments of different political persuasions