Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Role Description

Job Title	Non-clinical Assessor
Pay Grade	G6
Location	Canary Wharf, London
Hours	37 per week
Reports to	Head of Non-clinical Team

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 portfolio 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.

The Innovative Medicines function delivers a risk appropriate critical appraisal of quality, safety and efficacy of innovative medicinal products, determining whether a product's benefits outweighs the risks. It aims to accelerate their route to market to drive earlier patient access. Through this function the Agency will be seen as a leader in facilitating early access to safe and innovative medicines attracting the life sciences sector and contributing to a positive patient experience and to the improvement of public health outcomes

Role Purpose

Reporting to the Head of Non-clinical Team, Non-clinical Assessors assess the pre-clinical aspects of clinical trial and marketing authorisation applications for medicinal products and take decisions on their suitability for approval.

This role encompasses the evaluation of a range of new chemical and biological products, including new active substances, at different stages of development. The reports written and recommendations made will be highly influential in initiating trials of new medicines and taking these through clinical development and/or allowing new medicines to be made widely available to patients.

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 clinical trial authorisation and marketing authorisation applications for chemical and biological products making appropriate recommendations and decisions in line with the protection of public health.
- Involvement in the Innovative Licensing and Access Pathway (ILAP) and provision of scientific advice on the non-clinical aspects of drug development.
- Manage own workload working in conjunction with service coordinators and other assessors to meet agency deadlines
- Prepare and present objective 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, divisional or team, 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 Unit Manager

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

Agency Values

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

Person Specification

Important Candidate information:

The Civil Service use a recruitment framework called *Success Profiles*. 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	• **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	• Substantial experience in at least one of the following; toxicology or non-clinical regulatory affairs within the pharmaceutical industry, governmental departments or academia.	**A, I**
Technical	• 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 non-clinical development of human medicinal products. • Working knowledge of relevant legislation and procedures applicable to the licensing of human medicinal products. • Degree in toxicology or other appropriate life science with a minimum of three years relevant postgraduate experience or PhD equivalent	**A, I, P**
Strengths	• **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's values, which state that we will strive to be:

Civil Service Values	
Integrity	• Putting the obligations of public service above your own personal interests
Honesty	• Being truthful and open
Objectivity	• Basing your advice and decisions on rigorous analysis of the evidence
Impartiality	• Acting solely according to the merits of the case and serving equally well governments of different political persuasions