Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Role Description

Job Title	Head of New Active Substances
Pay Grade	SCS1
Location	
Hours	
Reports to	Deputy Director, Innovative Medicines

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

The post holder is part of the Innovative Medicines senior leadership team providing operational management support to the respective teams evaluating new chemical entities across various therapy areas and will provide guidance, direction to two operational units driving the critical appraisal of benefits and risks of new chemical entities. The post holder will complement and work with the Heads of Biological Medicines and Combination Medicinal Products to enable early authorisation and market access to innovative medicines and will support matrix working across these areas as well as those in the Population Health as necessary.

The post holder will oversee authorisation of new chemical medicinal products collaborating with colleagues across the Group, ensuring compliance with regulations and ensuring early access to innovative new chemical active substances aligned with the overall agency delivery plan and objectives.

Key responsibilities and results areas

- Provide leadership and management to two multidisciplinary teams, including the training and development of individual staff and the team, managing their performance and contribute to the wider management of the Innovative Medicines Function, motivating and developing teams to ensure delivery of targets and objectives focussed on patients and public.

- Ensure the quality of assessment decisions made across the teams to protect public health.

- Maintain oversight of all scientific and regulatory issues for New Active Substance products ensuring the smooth operation of procedural and business processes associated with the work on authorisation of these products.

- Manage workload and allocation within the team, working in conjunction with Biological Products, Combination Products and establish collaborative work with teams in the Population Health and the business support teams as needed.

- Contribute to Agency policy through the development and communication of authorisation responsibilities for New Active Substance Products dealing with issues proactively.

- Collaborate with other Agency employees and stakeholders to manage projects and implement changes to legislation, information processing and work systems as necessary.

The post holder will be required to create a sense of purpose for colleagues through highlighting connections between our work and the impact on patients and the public. Inspire colleagues to be fully engaged in their work. Deliver difficult or complex messages with decisiveness, clarity and sensitivity, being persuasive when required. Promote diversity, inclusion and equality of opportunity, respecting difference and external experience. Ensure team members are accountable: Empowered to make decisions, innovate and challenge without being blamed. Be self-aware and role-model continuous self-learning and development.

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 the 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** - Confidence to work in a pressurised, high demand environment, delivering results while maintaining high standards. • **Working Together** - Flexibility to adapt to changing priorities and take responsibility for achieving a successful outcome. • **Communicating & Influencing** – explain complex issues in a way that is easy to understand and brings others with you. • **Leadership** - motivating and developing both individuals and teams to ensure delivery of targets and objectives.	Application and Interview
Experience	• Previous experience in one or more of team management, regulatory affairs, research and development, and quality control of medicinal products within academia, the pharmaceutical industry or hospital pharmacy. • Evidence of leadership and effective line management with excellent interpersonal communication skills. • Keen attention to detail with proven ability to apply critical thinking to complex problems for patient benefit. • Handle throughput of work of the team to meet the agency objectives.	Application and Interview
Technical	• Degree in pharmacy, medicine or science with registration with the corresponding royal college or council and eligible to be registered through equivalent registration in another EC country, when applicable. • Detailed knowledge and experience in the development or authorisation of new medicinal products and variations, including knowledge of relevant regulations. • Knowledge of relevant national and procedures applicable to the licensing of human medicinal products and European legislation where applicable.	Application and Interview
Strengths	• **Enabler** - have a positive, proactive approach with a 'can do' attitude. • **Decisive** - make sound decisions including those which are difficult and involve conflicting considerations. • **Influencer** - you influence others, articulating the rationale to gain their agreement. • **Challenger** – you bring a fresh perspective and appreciate other's views.	Application and Interview

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