Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Role Description

Job Title	Head of Combination Products
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. For children's health, it aims to incorporate adequate, paediatric-specific measures in the overall drug development plan of innovative drugs. 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 teams evaluating combination products working with the other teams in the Innovative Medicines group. The post holder will provide guidance and direction to the operational units in the HQA Group driving the critical appraisal of benefits & risks of combination products and medicines for children.

The post holder will also provide leadership and drive the critical appraisal of drug development plans specific for children based on considerations on benefits & risks of medicines in these areas. The post holder will complement and work with the Heads of Biological Medicines and New Active Substance teams 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 lead three multidisciplinary teams, oversee authorisation of medicinal products in combination with other medicinal products and devices, oversee activities that would lead to authorisation of products in paediatric population, collaborating with colleagues across the Healthcare Quality and Access and Safety & Scientific Research & Innovation Groups. A key aspect of this role is to ensure appropriate evaluation of combination products in compliance with regulations and aligned with the overall agency objectives.

The post holder will provide strategic and operational support to the respective teams evaluating a variety of innovative medicines for children but with a clear focus on areas of patients' unmet needs and UK strategic innovation priorities such as rare diseases

Key responsibilities and results areas

- Provide advice and guidance to the team of multidisciplinary assessors, to achieve successful delivery of operational and Agency objectives focussed on patients and public.

- Manage workload and allocation within the team, working in conjunction with Biological Products, and New Active Substance Products, and work collaboratively with teams in the Population Health and the business support teams as needed.

- Ensure that sound assessment decisions are made across the teams to protect public health including the provision of timely and appropriate scientific and regulatory advice to companies and other stakeholders and to promote innovation.

- Maintain oversight of all scientific and regulatory issues for Combination Products including those for children as relevant, ensuring smooth operation of procedural and business processes associated with the authorisation of these products.

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

- Contribute to the wider regulatory and strategic initiatives that promote and influence development of medicines for children, supporting the new active substances teams, ILAP and clinical trials unit, through agency policies.

- Work with colleagues and stakeholders to manage projects and implement changes to legislation, the UK paediatric and rare diseases strategy, information processing and work systems as necessary.

- Manage the multidisciplinary team, including the training and development of individual staff and the team as a whole and manage staff performance and contribute to the wider management of Innovative Medicines Function, motivating and developing teams to ensure delivery of targets and objectives.

- Ensure objective assessments or other scientific papers are presented to expert advisory bodies with recommendations which take account of the views of both healthcare professionals and patients in line with agency policies.

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. • Keen attention to detail with proven ability to apply critical thinking to complex problems for patient benefit and public health.	**Application and Interview**

	• Evidence of leadership and effective line management skills with excellent written and verbal communication skills. • Handle throughput of work of the team to meet the agency objectives.	
Technical	• Degree in pharmacy, medicine or science with registration with the corresponding royal college or council or eligible to be registered through equivalent registration in another EC country, when applicable. • Knowledge and experience in the development or authorisation of combination products, and medicines plus devices, , including knowledge of paediatric medicine and knowledge of relevant regulations. • Knowledge of relevant national and procedures applicable to the licensing of human medicinal products, Paediatric Investigation Plans (PIPs) and European legislation where applicable.	**Application and Interview**
Strengths	• **Inclusive** - Actively encourage and provide opportunities for others to share ideas and contributions. • **Decisive** - Make sound decisions including those which are difficult and involve conflicting considerations. • **Influencer** - Influence others, articulating the rationale to gain their agreement. • **Enabler** - Have a positive, proactive approach with a 'can do' attitude.	**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