Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Role Description

Job Title	Head of Established Medicines
Pay Grade	SCS1
Location	
Hours	
Reports to	Deputy Director, 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 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 Population Health function delivers a risk appropriate critical appraisal of quality, safety and efficacy of healthcare products that are critical to the NHS and wider population. This includes special populations such as paediatrics, our work on self-medication and unlicensed imports, the high-volume work on generic medicines, complimentary products as well as parallel imports. It enables wider access to these important medicines as alternative or complimentary to innovative medicines, reduces costs to the healthcare system, delivering positive patient benefits.

This function aims to realise efficiencies to focus on more complex products, getting the most value from highly skilled Agency resource. There will be a symbiotic relationship between this function and Innovative Medicines to ensure we retain our deep technical knowledge and offer development opportunities to also work on newer innovative medicines through matrix working and/or rotation of staff.

This function will also work closely with colleagues in the Authorisation Lifecycle function to ensure lower risk variations transferred and managed by that function will continue to receive sufficient regulatory and scientific support from appropriate expertise within the Population Health function.

Role Purpose

The post holder is part of the Population Health senior leadership management team providing operational support to the respective teams dealing with a variety of generic medicines across therapy areas who will provide leadership and drive the critical appraisal of benefits & risks of generic and complimentary medicinal products. The post holder will complement and work with Heads of Repurposed Medicines and Special Population teams to enable early authorisation and market access

and will support matrix working across these areas as well as those in the Innovative Medicines functions.

The post holder will lead two multidisciplinary teams, oversee authorisation of generic and complimentary medicinal products as well as other products including unlicensed medicines and the import notification system, collaborating with colleagues across the Healthcare Quality and Access Group. A key aspect of this role is to ensure appropriate evaluation of generic and complimentary medicines in compliance with regulations and aligned with the overall agency 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.

- Contribute to the wider regulations influencing development of generic and complimentary medicines, as well as the development and communication of authorisation responsibilities for these medicines and deal with issues proactively. Identify contributions that are beneficial.

- Policy, regulatory strategy and operational delivery lead for unlicensed medicines, including cannabis based medicinal products and the import notification system.

- Ensure the quality of assessment decisions made across the teams to protect public health and monitor and promote the quality of product licensing data and documents in line with Agency and operational procedures.

- Maintain oversight of all scientific and regulatory issues for the team's scope of work on generic and complimentary medicines, ensuring the smooth operation of procedural and business processes.

- Manage workload and allocation within the team, working in conjunction with teams in the Population health portfolio, and work collaboratively with teams in Innovative Medicines group and the business support teams as needed.

- Collaborate with other Agency employees 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 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. • 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 supporting the division and the relevant deputy director	**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 generic and complimentary medicines with	**Application and Interview**

	knowledge of development of innovative medicines, including knowledge of relevant regulations. • Knowledge of relevant national and procedures applicable to the licensing of human medicinal products and European legislation where applicable.	
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