Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Role Description

Job Title	Head of Special Populations
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 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.

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 patient population. This includes special populations such unlicensed imports, the high-volume work on generic medicines, complementary products as well as parallel imports. It enables wider access to these important medicines as alternative or complimentary to innovative medicines and by making more medicines available in the self-medication arena where it is safe to do so and 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, to ensure lower risk assessment transferred to and managed by that function will continue to receive sufficient regulatory and scientific support from appropriate expertise within the team.

Role Purpose

Reporting to the Deputy Director, the post holder is part of the Population Health senior leadership management team providing strategic and operational support to the respective teams evaluating a variety of medicines aimed at special populations with a focus on special populations with unmet needs as well as supporting widening access to medicines by reclassifying product to over-the-counter

supply where it is safe to do so. The post holder will complement and work with the Heads of Established Medicines and Repurposed Medicines to enable early authorisation and market access and will support matrix working across these areas as well as those in the Innovative Medicines group.

The post holder will lead two multidisciplinary teams and oversee activities that would lead to authorisation of products for special populations collaborating with colleagues across the Healthcare Quality and Access Group, ensuring appropriate evaluation in compliance with regulations and aligned with the overall agency objectives.

Key responsibilities and results areas

- Provide advice and guidance to the team to achieve a successful delivery of operational and Agency objectives focussed on patient and public.
- Manage the multidisciplinary team, including staff performance and the training and development of individual staff.
- Contribute to the wider management of Population Health Function, motivating teams to ensure delivery of targets and objectives focussed on patients and public.
- Influence the wider regulatory and strategic initiatives that promote and influence development of Medicines for special populations and the reclassification of medicines.
- Ensure that assessment decisions made within the unit are sound, in particular those with new, wide ranging or complex issues and those having broader implications for national or international policy or public health and that scientific papers are presented to expert advisory bodies including recommendations which take account of the views of both healthcare professionals and patients in line with agency policies. Resolve challenges making appropriate recommendations and decisions in line with the protection of public health.
- Maintain oversight of all scientific and regulatory issues for the team's scope of work, ensuring the smooth operation of procedural and business processes associated with the team's work.
- Manage workload and allocation within the team, working in conjunction with other teams within Population Health and work collaboratively with teams in the Innovative Medicines group and Authorisation Lifecycle group as needed.
- Work with colleagues and stakeholders to manage projects and implement changes to legislation, information processing and work systems as necessary.
- Take a lead in providing sound, timely and appropriate scientific and regulatory advice relating to companies at meetings and in writing reflecting contemporary regulatory guidance and relevant regulatory decisions. Advice should be given in line with protection of public health and to promote innovation.

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	**Application and Interview**

	objectives supporting the division and the relevant deputy director.	
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. • Detailed knowledge and experience in the development and authorisation of medicines, including an understanding of applications for the reclassification of medicines. • An appreciation of the nature and range of special populations and of how regulation of medicines can help to meet their needs • 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