Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Role Description

Job Title	Medical Assessor - Benefit Risk Evaluation, Oncology, Haematology & Thrombotic Diseases
Pay Grade	SCS1
Location	Canary Wharf, London
Hours	42 hours per week (including meal breaks)
Reports to	Head of Oncology, Haematology & Thrombotic Diseases

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 new Safety and Surveillance Group brings together into a single integrated structure devices and medicines safety expertise with enforcement capabilities. These functions will be supported by our data and evidence generating capabilities complementing our signal generating capabilities produced via the new Safety Connect System.

Medicines and devices have traditionally been regulated separately largely driven by different regulatory processes and ways of working. As science and technology drives increasing understanding of disease, it is also opening new opportunities for treatments with both functions. Product profiles are changing, becoming ever more complex and the boundaries between functions are blurring. These changes provide a unique opportunity to bring functional capabilities together to better address the regulatory challenges of the future. Against this background and the drive to improve treatment availability for patients, safety remains at the heart of our decision making. As such the core objective of the Safety & Surveillance Group is to protect the public from risks associated with medicines and medical devices by:

- Ensuring a world class, comprehensive vigilance system that can promptly detect and monitor signals across the product life cycle
- Evaluating the benefit risk of medicines and devices for which signals or other safety concerns emerge and developing effective and measurable risk mitigation measures
- Ensuring patients and other stakeholders are involved in the regulatory processes and appropriate messages are issued for patients and stakeholders following regulatory decisions
- Deploying innovative interventions to reduce the criminal threat
- Exploiting data and embracing new technologies to develop the evidence to support our actions and understand their impact

The Benefit Risk groups I and II within Safety and Surveillance comprise 10 teams covering the following the therapeutic areas:

Benefit Risk I	Benefit Risk II
Oncology, Haematology, Thrombotic disease	Musculoskeletal, Trauma and Cosmetic
Immunology, Biocompatibility and Non-Clinical	Respiratory, Imaging and Critical Care
Vaccines, Infectious Diseases and Diagnostics	Cardiovascular and Fluid Management
Senses, Movement and Pain	Metabolic and Renal Systems
Neuropsychiatric Disorders, Cognition and Mental Health	Gastrointestinal System, Nutrition, Endocrine and Fertility

Role Purpose

The Agency is facing a rapidly evolving external environment involving increasingly complex products and utilisation of these products across an ever more diverse health system.

Reporting to the Head of Oncology, Haematology and thrombotic disease, a Medical Assessor is required to assessment of a wide range of data, contributing to the Agency's wider PV activities and ensuring that safe and effective medicines and medical devices continue to be available to UK patients. They will analyse evidence from a range of sources as well as take into account stakeholders and patients' views to monitor the benefit: risk balance of medicinal products and devices in clinical use. The post holder will undertake effective matrix working as appropriate across the Benefit-Risk Evaluation functions, the wider Safety and Surveillance Group and Agency life-cycle Groups. The post holder will ensure that scientific, technical, and clinical benefit-risk assessment of potential safety issues takes place promptly and contributes to sound regulatory decisions regarding safety of medicines and performance of devices.

Key responsibilities and results areas

In this key role you will

- evaluate the benefit: risk balance of medicinal products and medical devices in response to new data and make evidence-based recommendations for action to minimise risk and maximise benefit.
- develop regulatory expertise on risk management systems, supporting the agency's objective of safely bringing innovative products to patients as rapidly as possible.
- provide scientific advice and conduct assessments of risk management plans in support of new applications for innovative products
- present and discuss your scientific assessments with clinical and scientific expert advisory groups
- take actions to reduce newly identified risks associated with medicines and medical devices, ensuring timely and effective communications to healthcare professionals and patients.
- develop communications for the public, senior officials or ministers as required.
- maintain good working relationships with colleagues and with internal and external stakeholders
- develop in depth knowledge of relevant Regulations and regulatory procedures
- extend skills and knowledge in relevant scientific or professional areas to maintain an influential role

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

Person Specification

Important Candidate information:

The Civil Service recently launched a new recruitment framework called *Success Profiles*, which has replaced the *Civil Service Competency Framework.*

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.

Element	**Behaviours** The actions and activities that people do which result in effective performance in a job.
Criteria	**Managing a Quality Service** • Evidence of ability to work in a pressurised, target driven environment, delivering results on time within a range of deadlines maintaining high standards of quality. • Maintain own levels of performance in challenging circumstances and encourage others to do the same. **Deliver at Pace** • Evidence of flexibility to adapt to changing priorities and take responsibility for achieving a successful outcome. **Communication and Influencing** • Communicate with others internal and external to the agency in a clear, honest and enthusiastic way in order to explain complex issues and to build trust.
Assessment	Application, Interview,

Element	**Experience** The knowledge or mastery of an activity or subject gained through involvement in or exposure to it.
Criteria	• Excellent written communication skills, including the ability to write authoritative reports. Excellent verbal and presentation skills • Excellent interpersonal skills to facilitate team-working/team-leading, consulting and co-operating with colleagues from different disciplines and with variable degrees of expertise. • Experience of analysing clinical/scientific information from a range of sources including case reports, clinical trials and observational studies, making sound

	judgements for recommendations to protect patient safety and public health.
Assessment	Application, Interview,

Element	**Technical** The demonstration of specific professional skills, knowledge or qualifications.
Criteria	• Medically qualified and registered to practice with the General Medical Council. • Clinical, academic or pharmaceutical medicine experience, including evidence of an up-to-date specialist level of knowledge and evidence of analysis of data and preparation of reports, scientific publications or reviews or manuscripts for regulatory submissions.
Assessment	Application, Interview,

Element	**Strengths** The things we do regularly, do well and that motivate us.
Criteria	• **Decisive:** You use your judgement and take a considered approach to situations and tasks when making decisions. • **Responsible:** You take ownership for your decisions and hold yourself accountable for what you have promised to deliver.
Assessment	Application, 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:

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

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