Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Role Description

Job Title	Senior Benefit Risk Evaluation Assessor: Benefit Risk II
Pay Grade	SEO
Location	London Canary Wharf with flexible working option OR Designated homeworking
Hours	37 hours per week excluding lunch breaks
Reports to	Head of [Therapeutic Group] Benefit Risk II

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 signals and developing effective and measurable risk mitigation measures
• 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

Role Purpose

The core purpose of this role is to provide a robust benefit risk assessment of potential safety signals using data from a range of sources and technical, scientific, clinical and regulatory knowledge and/or practical experience.

Benefit Risk Evaluation assessors are responsible for engaging with a range of stakeholders including patients and the public to make timely and robust benefit-risk assessments and recommend safety actions and risk mitigations that are outcome focused.

Benefit Risk Evaluation assessors are flexible according to business needs and work across therapeutic teams and the wider agency and the health and social care system to respond promptly to potential safety issue and protect patient safety. All benefit risk roles require working flexibly to perform and contribute to benefit risk assessments across all medical products as required.

Safety and Surveillance: Benefit Risk Evaluation

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
Neuro Psychiatric Conditions, Cognition and Mental Health	Gastrointestinal System, Nutrition, Endocrine and Fertility

Key responsibilities and results areas

- Conduct robust benefit risk assessments in relation to emerging safety signals utilising a range of data sources
- Be proactive in engaging with all stakeholders including patients and the public, health care professionals and manufacturers to complete benefit risk evaluation assessments
- Recommend timely and proportionate regulatory actions to enhance benefit and mitigate potential residual patient safety risks; this may include the development of impactful safety messages
- Work in a matrix way to conduct benefit risk assessments, and as required assess clinical investigation applications and Exceptional Use Authorisations to set deadlines
- Keep accurate records of benefit risk assessments and decisions as required
- Contribute to and lead projects across the product life cycle to ensure compliance with regulations and contribute to assessing the impact of regulatory decisions on protecting patients and ensuring public health

General

- Contribute to external committees and groups as appropriate to raise standards in devices safety
- Be committed to continuous development to acquire and maintain knowledge and skills

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	**Communicating and influencing -** Communicate in a straightforward, honest and engaging manner, choosing appropriate styles to maximise understanding and impact. Ensure communication has a clear purpose and takes into account people's individual needs. Share information as appropriate and check understanding.	A,I
Behaviour	**Making Effective Decisions -** Display confidence when making difficult decisions, even if they prove to be unpopular. Consult with others to ensure the potential impacts on end users have been considered. Gain a clear understanding of customer's needs and expectations. Act to prevent problems and provide solutions.	A,I
Experience	Proven understanding of risk management principles to reduce harm (direct or indirect). Technical knowledge and/or practical experience of a range of medical products	A,I
Experience	Proven experience of managing complex projects to agreed milestones, managing conflicting priorities and the work of others	A,I

Technical	• Degree or equivalent qualification in a health care or related discipline (such as biological sciences, engineering, medical physics or equivalent and/or healthcare qualification) ○ And/or • Previous relevant experience such as healthcare, medical device manufacturing or regulatory environment.	A,I
Strengths	• **Analytical -** You seek and analyse information to inform decisions based on the best available evidence. • **Adaptable -** You can adapt to variations in work or environment and your effectiveness isn't impacted by change. You are flexible and versatile and act as an advocate for change. • **Networker -** You proactively create and maintain positive, professional and trusting working relationships with a wide range of people within and outside the organisation. You identify connections and reach out to bring people together.	I

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