



Medicines & Healthcare products Regulatory Agency

Role Description

Job Title	Benefit Risk Evaluation Assessor: Musculoskeletal, Trauma and Cosmetic (TAU6)
Pay Grade	G7
Location	10SC, Canary Warf or home working
Hours	37 hours or part-time/flexible
Reports to	Head of Musculoskeletal, Trauma and Cosmetic (Benefit Risk Evaluation 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

To assess benefit risk evaluations within the specialist therapeutic area, provide input into the development of the Benefit Risk Evaluation Group within Safety and Surveillance, working in a matrix way across therapeutic groups and the wider agency as required to ensure patient safety is at the centre of all we do.

Safety and Surveillance: Benefit Risk Evaluation

Benefit Risk I	Benefit Risk II
Oncology, Haematology, Thrombotic disease (TAU1)	Non-Inflammatory Musculoskeletal and Trauma (TAU6)
Allergy, immune system and Inflammatory Disorders (TAU2)	Respiratory, Imaging and Critical Care (TAU7)
Vaccines and Infectious Diseases (TAU3)	Cardiovascular and Fluid Management (TAU8)
Skin, Senses, Movement and Pain (TAU4)	Metabolic and Renal Systems (TAU9)
Psychiatric Disorders, Cognition, Mental Health and CNS (TAU5)	Gastrointestinal System, Nutrition, Endocrine and Fertility (TAU10)

Key responsibilities and results areas

- Actively participate in meetings and work programmes to assess safety signals involving medical devices and medicines
- Working across benefit risk evaluation teams evaluate the benefit and risks of a full range of medical products as required on new and emerging safety signals and/or new and emerging data/evidence and make recommendations for actions to protect patients
- Ensure patient experience informs benefit risk decisions by identifying and providing opportunities for patient involvement in benefit risk evaluations
- Be the lead benefit risk evaluation assessor for safety on Expert Advisory groups and/or short life working groups as appropriate to support effective benefit risk evaluations of potential safety issues
- Lead/contribute safety expertise to national and international committees and fora to set and improve standards for medical products
- Lead and develop cross portfolio projects identifying and deploying resources and mentoring more junior staff as required to achieve agency patient safety goals

General

- As appropriate, lead on the development of accurate and informative Ministerial submissions, Parliamentary Questions, Enquiries, Freedom of Information requests and press enquiries, relating to benefit/risk evaluations sometimes to tight deadlines.
- Ensure timely responses to queries from Private Office and Press Office.

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	<p>Making Effective Decisions - Encourage both innovative suggestions and challenge from others, to inform decision making. Analyse and accurately interpret data from various sources to support decisions. Find the best option by identifying positives, negatives, risks and implications. Present reasonable conclusions from a wide range of complex and sometimes incomplete evidence.</p> <ul style="list-style-type: none"> • 	A,I
Behaviour	<p>Seeing the Big Picture - Ensure plans and activities in your area of work reflect wider strategic priorities and communicate effectively with senior leaders to influence future strategies.</p> <ul style="list-style-type: none"> • Develop and deliver critical improvements and improved ways of working across benefit risk evaluation, safety and surveillance and the wider Agency 	A,I
Experience	<ul style="list-style-type: none"> • In depth knowledge and/or experience of relevant regulations and procedures applicable to medicines and medical devices and sharing knowledge to improve the capability of the various benefit risk evaluation groups and the wider safety and surveillance function • Experience of critically analysing complex clinical/scientific/technical information from a number of sources under pressure and making appropriate recommendations or 	A,I

	<p>decisions to protect patient safety/public health even when the evidence is not clear</p> <ul style="list-style-type: none"> • Writing authoritative reports • Experience in delivering presentations desirable 	
Experience	<ul style="list-style-type: none"> • Experience of working regulatory, healthcare, safety and making recommendations to protect patients • Influencing others to take safety seriously 	A,I
Technical	<ul style="list-style-type: none"> • Degree/postgraduate qualification in a relevant discipline e.g. health, science, regulation or equivalent experience 	A,I
Technical	<ul style="list-style-type: none"> • Technical and regulatory knowledge based on previous experience and the ability to acquire new technical knowledge and skills • 	A,I
Strengths	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.	I
Strengths	Team Player - You work well as part of a team and strive to ensure the team pulls together and is effective.	
Strengths	Mediator - You provide stability and cohesion within teams, finding common ground and purpose. You enjoy collaborating with others to drive forward a shared goal.	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	<ul style="list-style-type: none"> • Putting the obligations of public service above your own personal interests
Honesty	<ul style="list-style-type: none"> • Being truthful and open
Objectivity	<ul style="list-style-type: none"> • Basing your advice and decisions on rigorous analysis of the evidence
Impartiality	<ul style="list-style-type: none"> • Acting solely according to the merits of the case and serving equally well governments of different political persuasions