



# Medicines & Healthcare products Regulatory Agency



## Role Description

<b>Job Title</b>	Head of Biological Products
<b>Pay Grade</b>	SCS1
<b>Location</b>	
<b>Hours</b>	
<b>Reports to</b>	Deputy Director, Innovative medicines

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 Innovative Medicines function delivers a risk appropriate critical appraisal of quality, safety and efficacy of innovative medicinal products, determining whether a product's benefits outweighs the risks. It aims to accelerate their route to market to drive earlier patient access. Through this function the Agency will be seen as a leader in facilitating early access to safe and innovative medicines attracting the life sciences sector and contributing to a positive patient experience and to the improvement of public health outcomes

## Role Purpose

Reporting to the Deputy Director, the post holder is part of the Innovative Medicines senior leadership team providing operational management support to the teams evaluating biological and advanced therapy medicinal products working with other senior leaders enabling authorisation and market access to innovative medicines.

The post holder will lead licensing of biological and advanced therapy products with responsibility for successful implementation of Human Medicines Regulation, the review of Advanced Therapy Medicinal Products regulation including oversight of development of new vaccines. The post holder will provide guidance and direction to two operational teams in the HQA Group driving the critical appraisal of benefits & risks of new biological and biosimilar products.

A key aspect of this role is to ensure early access to innovative new medicines aligned with the overall agency delivery plan and objectives. The role requires a positive, proactive individual with a 'can do' approach.

## Key responsibilities and results areas

- Provide advice and guidance to the multidisciplinary teams to achieve successful delivery of operational and Agency objectives focussed on patients and public.
- Ensure the quality of assessment decisions made across the teams to protect public health.
- Maintain oversight of all scientific and regulatory issues relating to Biological Products, ensuring smooth operation of procedural and business process associated with the work on authorisation of biological medicines and advanced therapy products.

Manage workload and allocation within the team, working in conjunction with Combination Products and New Active Substance Products, and work collaboratively with teams in the Population Health and the business support teams as needed.

- Contribute to Agency policy through the development and communication of authorisation responsibilities for vaccines, biologic and advanced therapy products dealing with issues proactively.
- Collaborate with other Agency employees and stakeholders to manage projects implementing changes to legislation, information processing and work systems as necessary.
- 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.

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

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## 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
<b>Behaviour</b>	<ul style="list-style-type: none"> <li>• <b>Delivering at Pace</b> - Confidence to work in a pressurised, high demand environment, delivering results while maintaining high standards.</li> <li>• <b>Working Together</b> - Flexibility to adapt to changing priorities and take responsibility for achieving a successful outcome.</li> <li>• <b>Communicating &amp; Influencing</b> – explain complex issues in a way that is easy to understand and brings others with you.</li> <li>• <b>Leadership</b> - motivating and developing both individuals and teams to ensure delivery of targets and objectives.</li> </ul>	<b>Application and Interview</b>
<b>Experience</b>	<ul style="list-style-type: none"> <li>• Previous experience in drug development or regulation of medicinal products and evidence of analysis of complex information and sound judgement in decision making.</li> <li>• Detailed knowledge and experience in the development of biological medicines and advanced therapy medicinal products.</li> <li>• Evidence of leadership and effective line management skills with excellent written and verbal communication skills with proven ability to apply critical thinking to complex problems for patient benefit.</li> </ul>	<b>Application and Interview</b>
<b>Technical</b>	<ul style="list-style-type: none"> <li>• Degree in medicine, pharmacy, 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 or equivalent experience.</li> <li>• Thorough knowledge of relevant national regulation and procedures applicable in the above areas and European legislation where applicable.</li> </ul>	<b>Application and Interview</b>
<b>Strengths</b>	<ul style="list-style-type: none"> <li>• <b>Decisive</b> - make sound decisions including those which are difficult and involve conflicting considerations.</li> <li>• <b>Influencer</b> - You influence others, articulating the rationale to gain their agreement.</li> <li>• <b>Challenger</b> - You see other people's views and can appreciate there are many different angles to consider.</li> <li>• <b>Inclusive</b> - You actively encourage and provide opportunities for others to share ideas and contributions.</li> </ul>	<b>Application and Interview</b>

## 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

<b>Integrity</b>	<ul style="list-style-type: none"><li>• Putting the obligations of public service above your own personal interests</li></ul>
<b>Honesty</b>	<ul style="list-style-type: none"><li>• Being truthful and open</li></ul>
<b>Objectivity</b>	<ul style="list-style-type: none"><li>• Basing your advice and decisions on rigorous analysis of the evidence</li></ul>
<b>Impartiality</b>	<ul style="list-style-type: none"><li>• Acting solely according to the merits of the case and serving equally well governments of different political persuasions</li></ul>