



## Role Description

<b>Job Title</b>	<b>Medical Assessor in the Innovative Medicines group in Healthcare Quality and Access</b>
<b>Pay Grade</b>	Grade SCS1 (Salary in accordance with CDF pay scales)
<b>Location</b>	London, Canary Wharf
<b>Hours</b>	37 (Job share and part-time work available)
<b>Reports to</b>	Head of Combination products

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.

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.

### Purpose of Role:

Reporting to the Head of Combination products in Innovative Medicines, the medical assessor is required to assess the clinical and regulatory aspects of marketing authorisation applications for products in **Psychiatry, neuromuscular diseases and/or neurodevelopmental disorders** including those with new or complex issues for adult and paediatric patients. Commensurate with seniority and experience, the assessor will be contributing to the Agency's wider innovation activities and ensuring that safe and effective medicinal products continue to become available to UK patients promptly. They will analyse evidence from a range of sources as well as take into account stakeholders and patients' views through more complex assessments and wider activities associated with this work.

The post holder will be expected to work in mainly in the area of new active substances, combination products, but also collaborate across the Innovative Medicines teams and establish medicines, using matrix functioning principles to evaluate applications of other product types, where appropriate.

### Key Responsibilities:

#### 1. Assessment of Applications

- Carry out the assessment of clinical data provided in marketing authorisation initial and variation applications, applications made through EAMs (early access to medicine scheme and ILAP (innovative licensing and access pathway) including those with new, wide-ranging or complex issues making appropriate recommendations and decisions aligned to the protection of public health.
- Manage own workload working in conjunction with other assessors to meet agreed timelines responding to public health demands



- Prepare present and discuss objective assessments or other scientific papers at expert advisory groups, e.g., Commission on Human Medicines as needed
- Take a lead in providing reliable, timely and appropriate scientific and regulatory advice to companies 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, specifically to promote efficient development without compromising the evidence base for regulatory decision making.

## 2. Sharing Knowledge and Development of Self and Colleagues

- Commensurate with experience, mentor or coach other staff to enhance their knowledge and contribution
- Provide advice to colleagues in the division or Agency as needed
- Continues to extend and deepen skills and knowledge in relevant scientific or professional areas

## 3. Contribution to Policy and Procedures

- Contribute to and influence assessment policy and practice, –and proactively identify where such contributions would be beneficial
- Contribute to and influence divisional procedures
- Make individual contributions to representational or professional activities inside or outside the Agency
- Support and develop interactions with international regulators, both for assessments and regulatory science

## 4. Communication with Stakeholders

- Develop good working relationships with colleagues and with internal and external stakeholders
- Deal effectively with official correspondence to agreed timelines

## 5. Management and Use of Resources

- Use own and Agency resources in line with Agency and divisional strategy to meet targets
- Provide support when required to assist other Functions and Agency teams

### 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	Experience
Criteria	<ul style="list-style-type: none"> <li>• Evidence of an up to date specialist level knowledge in one or more following relevant scientific areas:-               <ul style="list-style-type: none"> <li>○ Psychiatry</li> </ul> </li> </ul>



	<ul style="list-style-type: none"> <li>○ Neurodevelopmental disorders</li> <li>○ Neuromuscular diseases</li> <li>○ Paediatric neuropsychiatric conditions</li> </ul> <ul style="list-style-type: none"> <li>● Proven ability to work largely independently and effectively to evaluate complex assessments including those with new or wide-ranging issues under pressure, using evidence from a number of sources to make appropriate recommendations or decisions in line with the protection of public health.</li> <li>● Excellent verbal and written presentation skills appropriate to the target audience including evidence of communication with patients and other members of the public.</li> <li>● Excellent interpersonal skills to facilitate team-working/team-leading, consulting and co-operating with colleagues from different disciplines and with variable degrees of expertise.</li> </ul>
<b>Assessment</b>	Application, Interview.

<b>Element</b>	<b>Technical</b>
<b>Criteria</b>	<ul style="list-style-type: none"> <li>● Degree in Medicine and with a relevant postgraduate qualification within specialist area. Registered to practice clinical medicine.</li> <li>● Detailed knowledge of relevant national applicable to the relevant area and/or ability to acquire such knowledge quickly</li> </ul>
<b>Assessment</b>	Application, Interview.

<b>Element</b>	<b>Behaviours</b> The actions and activities that people do which result in effective performance in a job.
<b>Criteria</b>	<p><b>Managing a Quality Service</b></p> <ul style="list-style-type: none"> <li>● 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.</li> <li>● Maintain own levels of performance in challenging circumstances and encourage others to do the same.</li> </ul>



	<p><b>Deliver at Pace</b></p> <ul style="list-style-type: none"> <li>Evidence of flexibility to adapt to changing priorities and take responsibility for achieving a successful outcome.</li> </ul> <p><b>Communication and Influencing</b></p> <ul style="list-style-type: none"> <li>Communicate with others in a clear, honest and enthusiastic way in order to explain complex issues and to build trust.</li> </ul>
<b>Assessment</b>	Application, Interview.

Element	Strengths
<b>Criteria</b>	<ul style="list-style-type: none"> <li><b>Responsible:</b> You take ownership for your decisions and hold yourself accountable for what you have promised to deliver.</li> <li><b>Decisive:</b> Ability to identify the main issues and implications in complex problems considering relevant stakeholder requirements when making decisions.</li> </ul>
<b>Assessment</b>	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	
<ul style="list-style-type: none"> <li>Innovative</li> <li>Proactive</li> <li>Impartial</li> </ul>	<ul style="list-style-type: none"> <li>Evidence-based</li> <li>Open</li> <li>Trustworthy</li> </ul>



Medicines & Healthcare products  
Regulatory Agency



Please be advised your line manager will be required to endorse your completed application form, therefore we recommend you allow your line manager 3 working days to complete the relevant request to ensure you can submit your application on time. Unfortunately, the HR Department will be unable to extend the closing date unless there are extenuating circumstances.