



Role Description

Job Title	Expert Quality Assessor
Pay Grade	Grade SCS1 (Salary according to CDF Pay Scale)
Location	London, Canary Wharf
Hours	37
Reports to	Head of Biological 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.

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

Purpose of Role:

Reporting to the Team or function Manager, Expert Assessors are required to assess the quality related aspects of product licensing initial and variation applications including those with new or very complex issues with wide-reaching implications. Expert Assessors will also make a high profile, long term or strategic contribution to the Function and Agency through their wider activities.

Key Responsibilities:

1. Assessment of Product Licensing Submissions

- Carry out the assessment of pharmaceutical quality data provided in marketing authorisation initial and variation applications and other procedures including those with novel, very complex or sensitive issues with wide-ranging consequences making appropriate recommendations and decisions in line with the protection of public health.
- Manage own workload working in conjunction with business support and other assessors to meet International, Agency or local deadlines
- Promptly update Agency or local work management databases to reflect the progress of own work



- Prepare and present objective assessments or other scientific papers to internal and external expert advisory bodies and committees
- Take a lead in providing influential, reliable, timely and appropriate scientific and regulatory advice to companies at meetings 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.

2. Sharing Knowledge and Development of Self and Colleagues

- Mentors or coaches other staff to enhance their knowledge and contribution and take a lead in the wider sharing of knowledge to colleagues
- Provides ad hoc advice to senior managers, other parts of DHSC, other governmental departments and bodies and ministers.
- Continues to extend and deepen skills and knowledge in relevant scientific or professional areas at the highest level to maintain an influential role in National and where relevant, international decision making

3. Contribution to Policy and Procedures

- Initiate, lead or influence guidelines, procedures or policy and practice nationally and with international partners
- Anticipating where such changes are needed to minimise risks to the Agency and to benefit public health
- Effectively perform in a high-level representational role outside the Agency.

4. Communication with Stakeholders

- Maintain good working relationships with colleagues and with internal and external stakeholders
- Effectively use a network of contacts to understand and operate within the wider political and government framework
- Deal effectively with sensitive or challenging 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
- Anticipate resource needs to support initiatives or policy changes recommended

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
Criteria	<ul style="list-style-type: none"> • Evidence of highly effective interpersonal skills in a range of situations to facilitate team-working and team leading.



	<ul style="list-style-type: none"> Highly developed written and verbal communication skills used in a range of circumstances and appropriate to the target audience to proactively influence internal and external issues and disseminate information internally and externally as appropriate. Flexibility to adapt to changing or conflicting priorities and new ways of working taking responsibility for achieving a successful outcome within necessary timelines whilst maintaining effective performance under challenging circumstances
Assessment	Application

Element	Experience
Criteria	<ul style="list-style-type: none"> Experience of working as a senior or lead-senior pharmaceutical/quality assessor having demonstrated a consistently high level of performance in that role and proven ability to handle a varied and challenging workload with high throughput commensurate with experience and knowledge to meet required timelines. Proven ability to evaluate and provide insight into the most complex, novel, sensitive or evolving issues with wide-ranging consequences, under pressure, using evidence or taking input from a variety of sources to make sound recommendations or decisions in line with the protection of public health. Recognised by peers and those outside the Agency as having an expert level of knowledge and leading opinion in one or more relevant therapeutic or scientific areas which is shared to the benefit of the division Evidence of being able to effectively use knowledge and skills to develop others for example by coaching and mentoring, advising colleagues in own area of specialisation, constructively reviewing the work of others and in presentations
Assessment	Application

Element	Technical
Criteria	<ul style="list-style-type: none"> Honours Degree in pharmacy and registration with the GPhC or, for the Biologicals Unit, honours degree in a relevant specialist subject. Detailed working knowledge and experience of national and European regulations and procedures applicable to the relevant area and evidence of being able to work within the wider governmental or international environment to achieve successful outcomes. IT skills appropriate for an information-based organisation and a fast-paced working environment.



Assessment	Application, and interview if necessary
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Element	Strengths
Criteria	<ul style="list-style-type: none"> • Ability to identify the key issues, and foresee wider and longer-term implications, in complex problems considering relevant stakeholder requirements to take a clear and considered approach to situations when making decisions and judgements. • Proven ability to operate effectively in a high-level representational role and of influencing development of key regulatory guidelines, policy or systems • Proven ability to provide authoritative professional, technical or scientific leadership in the most technically difficult or evolving situations
Assessment	Application

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

- | | |
|--------------|------------------|
| • Innovative | • Evidence-based |
| • Proactive | • Open |
| • Impartial | • Trustworthy |