



Role Description

Job Title	Quality Assessor (HQA)
Pay Grade	Grade 6
Location	London, Canary Wharf
Hours	37
Reports to	Team or Function Manager

Purpose of Role:

Reporting to the Team or Function Manager in Population Health or Innovative Medicines, Senior Assessors are required to assess the pharmaceutical quality & regulatory aspects of product licensing initial and variation applications and other procedures including those with new or complex issues. Senior Assessors will also make a more advanced contribution to the Function and Agency through wider activities associated with this work.

Key Responsibilities:

1. Assessment of Applications

- Carry out the assessment of pharmaceutical quality data provided in marketing authorisation initial and variation applications and other procedures including those with new, wide-ranging or complex issues 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 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 expert advisory bodies
- Take a lead in providing 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, specifically to promote efficient development without compromising the evidence base for regulatory decision making.

2. Sharing Knowledge and Development of Self and Colleagues

- Mentors or coaches other staff to enhance their knowledge and contribution
- Provides ad hoc advice to colleagues in the division or Agency
- 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 and proactively identify where such contributions would be beneficial



- Make individual contributions to representational or professional activities inside or outside the Agency

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 local 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	Behaviours
Criteria	<ul style="list-style-type: none"> • Evidence of highly effective interpersonal skills in a range of situations. • Highly developed written and verbal communication skills used in a range of circumstances and appropriate to the target audience to make proactive contributions to internal and external issues and disseminate knowledge within the Agency and outside as appropriate. • Flexibility to adapt to changing priorities and ways of working taking responsibility for achieving a successful outcome
Assessment	Application, Interview

Element	Experience
Criteria	<ul style="list-style-type: none"> • Experience of working as an accredited pharmaceutical/quality assessor having demonstrated a consistently high level of performance in that role and proven ability to handle a high throughput commensurate with experience and knowledge to meet required timelines. • Proven ability to work largely independently and effectively to evaluate and provide



	<p>insight into the most 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.</p> <ul style="list-style-type: none"> • Evidence of an up to date specialist level of knowledge in one or more relevant scientific areas or broader knowledge across the range of scientific activities. • 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.
Assessment	Application, Interview

Element	Technical
Criteria	<ul style="list-style-type: none"> • Honours Degree a relevant specialist subject. • Detailed working knowledge and experience of all relevant national and European regulations and procedures applicable to the relevant area. • IT skills appropriate for an information-based organisation and a fast-paced working environment.
Assessment	Application, Interview

Element	Strengths
Criteria	<ul style="list-style-type: none"> • Ability to write authoritative reports and convey information through effective verbal communication and presentational skills appropriate to the target audience. . • Ability to identify the main issues and implications in complex problems considering relevant stakeholder requirements to take a clear and considered approach to situations when making decisions.
Assessment	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

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