



# Medicines & Healthcare products Regulatory Agency



## Role Description

<b>Job Title</b>	Clinical Pharmacology Assessor
<b>Pay Grade</b>	Grade 7
<b>Location</b>	London, Canary Wharf
<b>Hours</b>	37 per week
<b>Reports to</b>	Head of Statistical and Clinical Pharmacology team

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

The Quality, Safety and Access group is responsible for the quality, safety and efficacy evaluation of all applications for medicinal products to be authorised for use in the UK.

## Role Purpose

As part of the evaluation of data submitted to support an application for a product license it is important to assess the clinical pharmacology & regulatory aspects of the application and this will be the main focus of the role. Reporting to the Clinical Pharmacology team leader in the Statistics and Clinical Pharmacology team, the successful applicant will use their expertise to review Marketing Authorisation Applications and advise on good drug development, interacting with medical colleagues, multi-disciplinary advisory committees and company representatives as required.

## Key responsibilities and results areas

Your scientific and professional expertise in clinical pharmacology will be important in this multi-faceted role where you will gain exposure to development programmes across the full spectrum of clinical indications. You will join 3 other Clinical Pharmacology Assessors in the Statistics and Clinical Pharmacology Team.

You will be responsible for the following:

- Carry out the assessment of clinical pharmacology data provided in marketing authorisation initial and variation applications, making appropriate recommendations and decisions in line with the protection of public health.
- Manage own workload working in conjunction with service coordinators and other assessors to meet Agency deadlines
- Prepare and present objective assessments or other scientific papers to expert advisory bodies
- 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

The job description is not intended to be exhaustive and it is likely that duties may be altered from time to time in the light of changing circumstances and after consultation with the postholder.

## 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"><li>• <b>Communicating and Influencing:</b> Excellent written and verbal communication skills. Ability to write authoritative reports and convey information through effective verbal communication and presentational skills appropriate to the target audience.</li><li>• <b>Delivering at Pace:</b> Ability to work under pressure to tight timelines and to prioritise work.</li><li>• <b>Working Together:</b> Evidence of effective interpersonal skills in a range of situations.</li></ul>
Assessment	Application Form, Interview.

Element	Experience
Criteria	<ul style="list-style-type: none"><li>• Work experience in one or more relevant scientific areas.</li></ul>
Assessment	Application Form, Interview.

Element	Technical
Criteria	<ul style="list-style-type: none"><li>• Degree in a relevant pharmaceutical science. The first degree or higher qualification must demonstrate a thorough understanding of pharmacokinetic theory.</li><li>• IT skills appropriate for an information-based organisation and a fast-paced working environment.</li></ul>
Assessment	Application Form, 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

- We focus outwards on patients and public
- We work together with respect.
- We take responsibility and are accountable

### 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>