



Medicines & Healthcare products Regulatory Agency

Role Description

Job Title	Statistical Assessor
Pay Grade	G7
Location	Canary Wharf, London
Hours	37 per week (excluding meal breaks)
Reports to	Head of Statistics 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 objective of the Healthcare Quality and Access Group 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.

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

Role Purpose

As part of the evaluation of data submitted to support an application for a product license it is important to evaluate the clinical study designs and statistical analysis methods used in the clinical studies submitted, and this will be the main focus of the role. Reporting to the Head of Statistics Team in New Active Substances, the successful applicant will use their statistical 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

- Carry out the assessment of clinical study 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) 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
- Provide reliable, timely and appropriate scientific and regulatory advice to applicants 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
- Reviewing protocols for studies planned to be run in the UK

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 The actions and activities that people do which result in effective performance in a job.
Criteria	<ul style="list-style-type: none"> • Evidence of effective interpersonal skills in a range of situations. • Excellent written and verbal communication skills. • Ability to work under pressure to tight timelines and to prioritise work.
Assessment	Application form and Interview

Element	Experience The knowledge or mastery of an activity or subject gained through involvement in or exposure to it.
Criteria	<ul style="list-style-type: none"> • Relevant work experience and knowledge relating to the design, analysis and interpretation of clinical studies.

	<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.
Assessment	Application form and Interview

Element	Technical The demonstration of specific professional skills, knowledge or qualifications.
Criteria	<ul style="list-style-type: none"> • MSc or PhD in Statistics or closely related subject or equivalent experience. • Knowledge of relevant guidelines, regulations and procedures and/or ability to acquire such knowledge quickly. • IT skills appropriate for an information-based organisation and a fast-paced working environment.
Assessment	Application for and 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:

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