Pharmacist Roles at the MHRA

A summary of the variety of roles available for pharmacists within the MHRA:

Want to work in one of the most stimulating environments for pharmaceutical scientists, using your knowledge to help safeguard the health of everyone living in the UK? Then consider working at the MHRA. We employ over 900 people, including over 200 pharmacists, working in a wide variety of different roles. We can guarantee no two days are ever the same; the variety of our work makes it interesting, rewarding and different.

Pharmacist roles in the Licensing Division

In this area, pharmacists work in multidisciplinary teams with medical doctors, toxicologists, statisticians and other scientific and non-scientific staff. Around 90 pharmacists work as pharmaceutical assessors and a further ten hold management positions. The majority of assessors review new applications and variations to licences for products containing chemical or biological substances, in all cases the job involves evaluating data and preparing an assessment report that sets out the basis for granting or refusing an application.

The work of an assessor is very varied. Assessors in the Clinical Trials Unit review data generated during the early-late development of a product (often on a new drug substance) and help to ensure the safety of products used in clinical trials. Assessors in the Parallel Import Units assess the proposed importation of products authorised elsewhere in the European Union and proposals for the labelling and information for patients and healthcare professionals. Assessors in the Chemical and Biological Units review a very broad range of information covering manufacture, characterisation and control of the drug substance, development, scale-up and commercial manufacture of the product and data that support the shelf life and storage conditions for the product. Much of their work involves European applications for products and hence there is regular interaction with colleagues in other EU Member States. Assessors also agree specifications for the drug substance and product, review the validation of analytical methods as well as working with the applicant to agree the product literature and labelling for the product.

Pharmacist roles in post-marketing surveillance of medicines

MHRA has a strong public health role focusing on the safety aspects of medicines once they have been authorised and are in clinical use. This type of work in pharmacovigilance is about the detection and monitoring of adverse events around the use of medicines, evaluation of the risk and taking action where necessary. We use a variety of information sources ranging from Yellow Card reporting to safety information provided by companies. We are responsible for the assessment of safety variations (contraindications, side effects etc), renewal of authorisations and the assessment of patient information provided with medicines and advertising material.
We also undertake therapeutic reviews for products or classes of drug where clinical use has changed since they were first authorised and reclassification of medicines to allow wider availability where it is safe to do so. This often leads on to other initiatives such as improving the availability of medicines for children.

Pharmacists in this area use their full range of pharmaceutical knowledge with particular emphasis on safe use of medicines in practice, whether prescription or over-the-counter, with a particular focus on safe and effective use of products by patients.

Pharmacist roles in Inspectorate

There are a number of pharmacists working as inspectors. They are part of teams including chemists, biologists, microbiologists and other life science graduates as well as non scientific staff. The work of a medicines inspector is very varied and involves working with other agency departments (enforcement, licensing, and MHRA assessors) as well as with industry, trade associations and receiving authorities.

Currently there are approximately 60 inspectors of which ten are Pharmacists. The inspectorate is split into groups:

- The **Good Laboratory Practice** inspectors are responsible for assessing pre-clinical safety studies performed to support clinical trials applications or the registration of a new medicinal product. The types of studies that the GLP group monitor are very diverse and range from in-vitro studies which monitor the effect of novel compounds on DNA replication through to two year carcinogenicity tests. The GLP group are also responsible for monitoring safety studies in other industrial sectors. These include veterinary medicines, chemical substances, agrochemicals and food additives.

- The **Good Clinical Practice** team are responsible for ensuring that clinical trials are performed in accordance with EU and UK legislation. The group monitor each step in the clinical development of new medicines from phase I studies in healthy volunteers through to large phase III efficacy studies in target patient populations. During the course of a typical GCP inspection the team will interview key staff involved with the trial, review quality systems and review key documents.

- The **Good Manufacturing Practice** inspectors are responsible for monitoring the manufacture of medicinal products to ensure that companies comply with EU GMP. The GMP inspection process requires a considerable amount of international travel to countries including India, USA and China among others.

- Finally the **Good Pharmacovigilance Practice** inspectors are responsible for monitoring the safety of medicines once they have been granted a marketing authorisation and licensed for use in the UK and other European countries.

Pharmacist roles in the British Pharmacopoeia (BP)

Within this area, pharmacists work within a multidisciplinary team of scientists to produce texts for the BP and the BP (Veterinary). Pharmacists can expect a varied and challenging role within the BP Secretariat. This team is responsible for all the technical, scientific and editorial work necessary to produce the BP and involves writing, editing and proof-reading monographs as well as providing a technical “after sales service” for users around the world. The work also involves effectively communicating with experts from a variety of Expert Advisory Groups covering medicinal chemicals, biological and biotechnology-derived materials, herbal materials and aspects relating to pharmaceutical quality. There is an opportunity to represent the BP abroad, such as at the European Pharmacopoeia in Strasbourg and the WHO in Geneva.
Pharmacist Roles in the Communications Division
Pharmacists in this area help publicise the work of the agency, explaining why we have a regulator, how it works, the dangers of buying medicines over the internet, as well as highlighting the various initiatives undertaken by the agency. One of these is currently promoting YellowCard reporting by both patients and healthcare professions. This is done to various audiences such as pre-registration pharmacists, pharmacy students, RPSGB local branch meetings & patient support groups amongst others.

Pharmacist roles in the Medicines Information Team
Our medicines information team consist of pharmacists with other life scientists and support staff. The team provides support for our assessors and medicine inspectors helping them to access and analyse data from the Agency’s database of licensed medicines and other information sources. The team also offers an information service to external customers who need information which the MHRA holds but is not available elsewhere. The team deals with over 200 written enquiries every month, and supports the agency’s Central Enquiry Point answer telephone and email enquiries.

Customers from outside the agency include other government departments, doctors, pharmacists, the pharmaceutical industry and the general public. The team also has to provide technical information on UK licensed medicines to other regulatory and law enforcement agencies worldwide. The work requires a good general knowledge of medicines and communication skills but specialist knowledge on regulatory processes and medicines licensing is picked up very quickly ‘on the job’. No two days are ever the same and the variety of enquiries makes the work both interesting and rewarding.

Training available for pharmacists
Training and coaching are provided to new pharmacists to ensure that they are soon able to work independently as well as part of a team. They require the skills and knowledge (regulatory, scientific and soft skills) to make informed decisions which then contribute to the assessment of the safety of medicines on the market. Pharmacists are often required to provide guidance and scientific advice to industry and to represent the Agency at internal and external meetings.

CPD Support available for pharmacists
Working in MHRA, you have your own set of competencies for government pharmacists developed under the RPSGB’s CPD programme. Support, guidance, mentoring and coaching in this area is also available from the MHRA’s CPD Facilitator.

Office locations
Our main offices are located in Vauxhall, south London with satellite offices in Welwyn Garden City, York and Blackpool.
Expected Salary & Benefits:

Salary Policy: A performance-related pay system operates & progression is dependent on performance.

Working Week: • 36 hours excluding lunch breaks but including flexible start/finish times.
• Further flexible working arrangements may be available, depending on the type of job.

Holidays: • 30 days annual leave.
• In addition, 10½ public and civil service ‘privilege’ days at specified times of the year.

Pension: Civil Service Pension Scheme.

Other benefits: • Interest-free season ticket loan or bike loan
• On-site exercise studio at Market Towers
• Subsidised canteen serving hot and cold food
• CoreCare Employee Assistance Services and access to the Civil Service Benevolent Fund
• Variety of staff and Civil Service sports and social clubs
• Childcare vouchers

Training: On-going learning and development, including;
• Continuing professional development programmes for the large range of specialist groups;
• Coaching support;
• Mentoring programmes for certain specialist roles where on-the-job training is required.

Location: The majority of MHRA jobs are based at the Head Office in Vauxhall, London; we also have satellite offices in Welwyn Garden City, York and Blackpool.

Application and Selection: All our jobs are advertised on our web site at www.mhra.gov.uk. Sign up for our e-mail alerts in this area to be kept informed of any suitable vacancies as they come up.

Being a government organisation we cannot accept speculative CV’s.