



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

4 September 2015
EMA/466737/2015
Administration

EMA/AD/385: Risk Management Specialist, Human Medicines Evaluation Division (AD8)

The Agency is seeking to recruit a senior scientific officer motivated to contribute to public health protection by taking a key role in the area of proactive risk management of medicinal products.

The successful candidate will perform a wide range of tasks, including provision of high level scientific support in the areas of risk management, post authorisation safety planning and measuring the impact of risk minimisation activities. In particular, the successful candidate will contribute to the strategic development of the risk management framework including underlying guidance and provide oversight of the consistency in applying these principles in medicines evaluation activities. He or she will be required to promote these standards internally and externally, and participate in interactions with stakeholders (e.g. EU medicines regulatory network, pharmaceutical companies, international regulators, etc.).

The Agency offers a five-year renewable contract. The monthly basic salary will be approximately € 6,350, equivalent to € 4,789 net. In addition to this basic salary, the jobholder may be entitled to various allowances, in particular expatriation allowance and family allowances, including education allowance for dependent children. The London weighting (currently 50.7%) will be added to the salary to compensate the cost of living and the effect of the exchange rate EUR/GBP. The Agency also provides a pension scheme and world-wide health insurance.

Specific objectives of the jobholder:

Reporting to the Head of Office of a therapeutic area office in the Scientific and Regulatory Management Department, the jobholder will be responsible for the following tasks:

- Providing scientific input on Risk Management Plans (RMP) and related aspects during pre-submission as well as pre- and post-authorisation evaluation activities;
- Contribution to the continuous improvement of the framework for safety risk management including guidelines (Good Pharmacovigilance Practices modules) and provide strategic input into their future development;
- Ensure consistency in the application of risk management principles in the context of medicines evaluation across products and across therapeutic areas, including development and maintenance of relevant metrics;



- Perform duties of a risk management specialist for an assigned product portfolio, including review of Rapporteurs' pre-and post-authorisation RMP assessments, scientific and regulatory science contribution to selected Periodic Safety Update Report (PSUR) assessments, referral procedures and Post-authorisation safety studies (PASS) protocols and results.

Elements that will be taken into account in determining candidates to be invited for test/interview:

- Extensive experience in risk management or pharmacoepidemiology obtained either through previous work at a regulatory authority, in academia or in the pharmaceutical industry;
- Extensive experience in pharmacovigilance activities related to risk management as well as benefit-risk assessment and decision-making;
- Proven track record of effective cross-functional collaboration, resulting in appropriate consideration of safety data in the context of risk management planning.

Experience and knowledge in the following areas will also form part of the written/oral assessment:

- Deep understanding of EU pharmacovigilance and risk management guidelines and procedures;
- Experience of publishing original research in pharmacovigilance/epidemiology;
- Experience in the preparation or assessment of risk management plans;
- Experience in working in a multicultural environment;
- Excellent written and oral communication skills;
- Ability to network and interact effectively with colleagues and work as part of a team;
- Excellent organisational skills.

Essential requirements for admission to the selection procedure:

1. A university degree in life sciences, medicine, pharmacology or pharmacy that must have been obtained by the closing date.
2. At least nine years' professional experience after the degree above, including competence and experience in the field of the above mentioned areas and duties.
3. An excellent command of English and a thorough knowledge of another official language of the European Union to the extent necessary for the performance of duties. (For any promotion/reclassification in the future, knowledge of a third EU language would be required)

For essential requirements 1 and 2 above it will be necessary to provide documentary proof of each one at the interview stage.

The Agency:

The European Medicines Agency is a decentralised body of the European Union based in London. Its core responsibility is the protection and promotion of public and animal health through the evaluation and supervision of medicines.

Candidates that are successful in the written test and interview are placed on a reserve list, which may also be used to fill other similar posts at the same grade.

This announcement is governed by the General terms and conditions for selection procedures for Temporary Agents, attached to this publication.

Deadline for submission of application forms is 4 October 2015 at midnight.

General conditions - recruitment for the European Medicines Agency as a Temporary Agent (Administrator, Assistant or Secretary and Clerk)

These general conditions apply to internal and external selection procedures.

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1. The European Medicines Agency

The European Medicines Agency is responsible for co-ordinating the evaluation and supervision of medicinal products for human and veterinary use in the European Union (see European Parliament and Council Regulation (EC) No 726/2004 of 31 March 2004, Official Journal of the European Union No L 136/1 of 30 April 2004). The Agency was established in January 1995. It has many close contacts with the European Commission, all EU Member States, EEA-EFTA countries and many other groups in government and the private sector.

Further information on the Agency and its activities is readily accessible through the Internet; our web address is <http://www.ema.europa.eu>.

2. General principles for selection procedures for Temporary Agents

- The place of employment is London.
- Candidates must be nationals of a Member State of the European Union, Iceland, Norway or Liechtenstein, on condition that they have full rights as a citizen.
- Candidates must have fulfilled any obligations imposed on them by laws concerning military service and meet the character requirements for the duties involved.
- For each selection procedure candidates must follow the application procedure as instructed below.
- Applications have to be submitted electronically using the form available on the Agency website.
- All material to be placed on candidates' files must be submitted afresh: reference may not be made to earlier applications. No material contained in candidates' files will be returned. All the questions on the application form must be completed in full.
- Selected candidates will be included on a reserve list and, depending on the availability of Temporary Agent posts and the budgetary situation, may be offered a five-year renewable Temporary Agent contract in accordance with the Conditions of employment of other servants of the European Union (*Official Journal of the European Communities No L 56 of 4 March 1968*).¹

3. Application Procedure

There are two stages in the application procedure:

1. Online registration
2. Submission of a full application

¹ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1962R0031:20140101:EN:PDF>

3.1. Stage 1 Online registration

At the first stage candidates must submit their application electronically using the application form available in English on the Agency website. Translations of the application form are only available for reference purposes in the other official languages. All parts of the form must be completed in full.

Please note that due to the large numbers of applications we receive, when reaching the deadline for submission of applications, the system may have problems to process the large amounts of data. We therefore advise applicants to send in their application well ahead of the deadline. Applications that reach EMA after the deadline will not be admitted to the selection procedure.

3.1.1. Eligibility check before submission of the application form

Candidates should assess carefully and check before submitting their application form whether they fulfil all the conditions for admission laid down in the publication notice, particularly in terms of professional qualifications and relevant professional experience stated in the selection procedure announcement. Candidates who do not fulfil all the conditions will be excluded from the selection procedure. Application forms or requests for changes to application forms submitted after the deadline for applications are not permitted.

3.2. Stage 2 Submission of a full application (only for candidates invited to interview)

At the second stage, should the candidate be invited for interview, in order for the application to be considered complete, candidates must bring with them on the day of the interview photocopies of all the supporting documents (educational qualifications, i.e. diplomas, certificates and written proof of all the professional working experience stated in the candidate's application form, i.e. letters from the employer stating dates and nature of employment, full or part time employment, paid or unpaid employment) needed to prove that they satisfy all conditions for admission. All documentary evidence of professional experience must indicate start and end dates for previous positions and the start date and continuity for the current position held. On the day of the interview the candidate must sign his/her application form and by signing the form the candidate certifies on his/her honour that the information provided is complete and accurate.

The address indicated on the form will be used as the location for travel for candidates invited to interview.

Your application will not be accepted unless all the documentary evidence is provided and the application form has been signed on the day of the interview, if so invited. Candidates who have not submitted all the documents specified by the date of the interview will be disqualified.

3.2.1. Eligibility check for candidates invited to the interview

Education, certificates and diplomas

Candidates must provide photocopies of certificates or diplomas to show that they have completed studies of the level required by the notice of the selection procedure. The first degree/diploma obtained

by the candidate giving access to the recruitment category and being relevant to the notice in the selection procedure is counted for admission to the selection procedure.

In the case of specialist or further training, candidates must specify whether the course was full-time or part-time, which subjects were covered and the official length of the course.

Only diplomas issued by EU Member State authorities and diplomas recognised as equivalent by the relevant EU Member State bodies are accepted. If the main studies took place outside the European Union, the candidate's qualification must have been recognised by a body delegated officially for the purpose by one of the European Union Member States (such as a national Ministry of Education) and a document attesting so must be submitted with the application by the closing date. This will enable the Selection Committee to accurately assess the level of the qualifications.

Professional experience

Paid professional experience connected with the Agency's areas of activities shall be taken into account if it is on a paid basis (including study grants or internship grants). Therefore, PhDs may be counted as professional experience if the candidates received a study grant or salary during the time of the PhD. The maximum duration counted for a PhD is three years provided that the PhD has been successfully concluded by the closing date for applications of the selection procedure.

Part-time work will be calculated on a pro-rata basis, i.e. 6 months worked part time on a 50% basis will be counted as 3 months worked.

Voluntary work will only be taken into consideration if it is paid. Voluntary work must be comparable to full-time work, both in terms of number of hours worked and duration.

Military service and equivalent civilian service shall be regarded as professional experience.

Professional experience is counted only from the time the candidate obtained the certificate or diploma required for admission to the selection procedure. Where additional periods of training and study are accompanied by periods of professional activity, only the latter shall be considered as professional experience. Overlapping periods of working experience and training are only counted once.

Documents to be provided by the candidate

Candidates must provide supporting documents confirming the *length and nature* of their experience. If, for reasons of confidentiality, a candidate is unable to provide the necessary statement for their current employment, he/she must provide photocopies of the contract, the letter of recruitment and /or the first pay slip and the candidate must in any event provide a copy of the latest pay slip.

Free-lance or self-employed candidates must provide either a practicing certificate (or equivalent), or a copy of the entry in the relevant trade register, or any other official document (for example a tax document) showing clearly the length of the relevant professional experience.

Linguistic requirements

As part of the assessment for a Temporary Agent contract, evidence must be provided of a good command of English as the main working language of the Agency and a satisfactory knowledge of one of the official languages of the European Union. The official languages are: Bulgarian, Croatian, Czech, Danish, Dutch, English, Estonian, Finnish, French, German, Greek, Hungarian, Irish, Italian, Latvian, Lithuanian, Maltese, Polish, Portuguese, Romanian, Slovak, Slovene, Spanish and Swedish.

On the day of the interview, candidates may wish to have their third, fourth etc. language stated in their application form tested in an oral assessment. Candidates may obtain additional points for good and excellent command of the language which will count towards the final assessment score.

Promotion/Reclassification

Recruited candidates are required to demonstrate before their first reclassification the ability to work in a third official European Union language.

Equal opportunities

The Agency applies a policy of equal opportunities and accepts applications without distinction on grounds of sex, race, colour, ethnic or social origin, genetic characteristics, language, religious, political or other convictions or opinions, belonging to a national minority, financial situation, birth, disability, age, sexual orientation, marital status or family situation.

4. Guidance for candidates

When applying for a vacant position at the Agency, please

- use the application form and email address for submission of the application form;
- check the essential criteria stated in the vacancy announcement (i.e. professional qualification required, work experience required if applicable and knowledge of at least 2 official EU languages). Candidates who do not fulfil these criteria will be excluded from the selection procedure;
- provide clear details of your professional qualification and work experience in your application form;
- do not leave your application until the last minute. Due to the large numbers of applications we receive, when reaching the deadline for submission of applications, the system may have problems to process the large amounts of data;
- compile certificates/letters from employers that state your work experience listed in your application form;
- make yourself available for written test and interview and bear in mind that in order to ensure fairness to all candidates the test and interview schedules cannot be adapted to specific individual preferences;
- make sure that we have your updated contact details throughout the whole procedure and that you can be contacted by phone and email.

When you are invited for a test/an interview, please

- book your travel as soon as you receive the invitation letter to the test or the interview. EMA will only reimburse economy class tickets and such flights may not be available if you wait until the last minute;
- bring all supporting documents that state the length and nature of your education and professional experience with you.

5. Selection Procedure

5.1. Selection Committee – general principles

A Selection Committee is set up for the selection procedure. It consists of members designated by the Appointing Authority, i.e. the Executive Director. The Staff Committee nominates one member of the selection panel. The principle of confidentiality is enshrined in Article 6 of Annex III to the Staff Regulations, which states that the proceedings of the Selection Committee must be secret. It works in two ways: first, it imposes obligations to ensure equal treatment for candidates; and second, it seeks to protect the Selection Committee to ensure that its decisions are totally impartial.

The Selection Committee adheres strictly to the conditions of admission laid down in the publication notice when deciding whether or not candidates are to be admitted. Candidates admitted to a previous selection procedure will not automatically be eligible. **Candidates are strictly forbidden to make any contact with the members of the Selection Committee, either directly or indirectly. Any infringement of this rule will lead to disqualification from the selection procedure.**

Queries should be addressed to recruitment@ema.europa.eu.

Candidates should not encourage third parties to contact the Selection Committee on their behalf. Any infringement of this rule may lead to disqualification of the candidate.

Should the Selection Committee discover at any stage in the procedure that the candidate does not meet one or more of the general or special conditions for admission to the selection procedure or that the information on the application form does not correspond with the supporting documents, the candidate will be disqualified.

The Selection Committee decides on those candidates who are admitted to the selection procedure in accordance with the requirements as specified in the publication notice. The applications of the candidates admitted to the selection procedure are reviewed and the Selection Committee decides on those candidates who are invited to attend the test/the interview.

The Selection Committee decides on the need for interviewees to undergo one or more written tests related to the nature of the duties in order to facilitate the selection process. The Selection Committee may decide to make the test eliminatory and only the candidates that passed the test or a limited number who passed or are above a certain threshold will be invited for the interview. Following the interviews, which are conducted by the Selection Committee, the Selection Committee decides which candidates will be placed on the list reserve list.

5.2. Selection of candidates to be invited for a test/an interview

As a first step in the selection process, only candidates who fulfil the essential criteria as stated in the vacancy announcement will be admitted to the selection procedure.

Secondly, to determine candidates to be invited for a written test/an interview, a further selection will be made in line with the 'elements that will be taken into account in determining candidates to be invited for test/interview' as stated in the vacancy announcement resulting in a shortlist of candidates. The Selection Committee decides that the candidates will undergo one or more written tests depending on the nature and requirements of the position.

The Selection Committee may decide to make the test eliminatory and only the candidates that passed the test or a limited number who passed or are above a certain threshold will be invited for the interview. Shortlisted candidates will be informed if the test is eliminatory.

5.3. Interviews

The Selection Committee may decide to hold the interviews either at the Agency or remotely via Adobe Connect. Candidates will receive detailed instructions in advance of the interview.

5.4. Confidentiality

Selection procedures are strictly confidential. Candidates' personal data will be treated with strict confidentiality. Candidates are only provided with information regarding their application and outcome of their test and interview. Names of other candidates or the ranking of candidates on the reserve list are not disclosed.

5.5. Length of the Selection Procedure

The selection procedure can take up to 12 months from the date on which the position is first advertised to the reserve list of successful candidates being drawn.

6. Reserve list and recruitment

6.1. Outcome of the selection procedure

Each candidate will be informed by email/letter whether or not he/she has been placed on the reserve list. Candidates should note that inclusion on the reserve list does not guarantee appointment.

The recruitment procedure is as follows: as and when a post will be available and in addition when funds become available, candidates on the reserve list will be considered and the reserve list will be drawn on to fill vacancies. Candidates on the valid reserve list may also be considered for a different post within the same grade if the job specification and the nature of the role is similar.

If a letter of intention is issued, the candidate must undergo a compulsory medical examination to establish that he/she meets the standard of physical fitness necessary to perform the duties involved and the candidate must provide original or certified copies of all relevant documents.

6.2. Reserve list extension and expiry

Reserve lists generally remain valid until the end of the year following the year in which the list has been drawn up and may be extended. Reserve list extensions are published annually in January on the EMA website under ema.europa.eu/careers. Candidates will not be notified of reserve list extensions and are requested to consult the EMA external web page.

6.3. Conflict of interest

EMA staff members are not permitted to hold or seek to acquire during their employment at the Agency direct financial interests in a pharmaceutical company or own a current patent for a medicinal product. All such direct interests must be disposed of prior to the start of employment. Before recruiting a temporary agent, EMA will examine whether the candidate has any personal interest such as to impair his independence or any other conflict of interest. The candidate, using a specific form, will be required to inform EMA of any actual or potential conflict of interest. In such cases, EMA will take this into account in a duly reasoned opinion and take mitigating actions as appropriate e.g. consideration which tasks are assigned to the new staff member. Upon starting employment, EMA staff will be required to make a public declaration of interests again.

6.4. External activities during employment at the Agency

Staff who wish to engage in an external activity during employment (e.g. as University lecturer) have to be granted permission by the Executive Director before engaging in the chosen activity.

6.5. Occupation upon leaving employment at the Agency

Upon leaving employment with EMA, staff are required to notify the Agency during a period of two years after departure if they intend to take up paid or unpaid work with another employer, in order to determine whether or not there is a conflict of interest for the Agency.

6.6. Remuneration and benefits

It should be noted that the retirement age for staff is:

- either automatically at the age of 66 years;
- or, at the staff member's own request on the last day of the month in respect of which the request was submitted where the staff member has reached pensionable age or where he is between 58 and pensionable age and satisfies, as specified in the Conditions of Employment of Other Servants, the requirements for immediate payment of a pension.

6.7. Probation period

Successful candidates who are recruited undergo an initial probation period of 6 months.

6.8. Pay and welfare benefits

The pay of staff members consists of a basic salary supplemented with various allowances, including family allowances.

Basic Salary: there is a basic salary scale for each grade, divided into 5 steps. Staff members progress automatically to the next step every two years until they reach the top of the scale for that grade.

Allowances: In addition to their basic salary, staff members may be entitled to various allowances, in particular an expatriation or foreign residence allowance, and family allowances, including household allowance, dependent child allowance, pre-school allowance and an education allowance.

Under certain circumstances, in particular where staff members are obliged to change their place of residence in order to take up employment, the Agency may also reimburse various expenses incurred on recruitment, notably removal expenses.

6.9. EU Tax

The salaries of staff members are subject to a EU income tax deducted at source. They are exempt from national tax on salary and are members of the EU social security and pension schemes.

6.10. Remuneration

For further information about remuneration and welfare benefits, please consult our recruitment policy available on the external website under ema.europa.eu, home/about/careers.

7. Data Protection

The purpose of processing of the data you submit is to manage your application(s) in view of a possible pre-selection and recruitment at the Agency. The information candidates provide in their application form is collected for the purpose of the selection procedure.

The Agency does not make public the names of successful candidates on reserve lists. However, for the purposes of recruitment and related planning purposes, members of the Agency management may have access to reserve lists and in specific cases, to the application form of a candidate (without supporting documents, which are kept in confidence by the personnel department). Application files are kept for five years from the establishment date of the reserve list after which time they are destroyed.

The personal information we request from you will be processed in line with Regulation (EC) N° 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the EU institutions and bodies and on the free movement of such data.

In line with the Agency's archiving policy, all selection procedure records (paper and electronic files) are destroyed five years after the expiry date of the reserve list.

8. Appeal Procedures

A candidate who feels that a mistake has been made regarding eligibility may ask to have his/her application reconsidered by sending, within 20 calendar days of the date postmarked on the letter of notification, a request for review, quoting the number of the selection procedure concerned to the Chairman of the Selection Committee at the following address: European Medicines Agency, 30 Churchill Place, Canary Wharf, London E14 5EU, United Kingdom.

The Selection Committee will reconsider the application and notify the candidate of its decision within 45 calendar days of receipt of the letter.

If a candidate considers that he/she has been adversely affected by a particular decision, he/she can lodge a complaint under Article 90(2) of the Staff Regulations of Officials of the European Communities

and Conditions of employment of other servants of the European Communities, at the following address:

Executive Director
European Medicines Agency
30 Churchill Place
Canary Wharf
London E14 5EU
United Kingdom

The complaint must be lodged within 3 months. The time limit for initiating this type of procedure (see Staff Regulations as modified by Council Regulation No 723/2004 of 22 March 2004 published in the Official Journal of the European Union L 124 of 27 April 2004 – <http://europa.eu/eur-lex>) starts to run from the time the candidate is notified of the act adversely affecting him/her.

You can submit a judicial appeal under Article 270 of the Treaty on the Functioning of the EU (ex Art. 236 TEC) and Article 91 of the Staff Regulations of Officials of the European Communities to the:

European Union Civil Service Tribunal
Boulevard Konrad Adenauer
Luxembourg 2925

Please note that the appointing authority does not have the power to amend the decisions of a Selection Committee. The Civil Service Tribunal has consistently held that the wide discretion enjoyed by Selection Committees is not subject to review by the Civil Service Tribunal unless rules which govern the proceedings of Selection Committees have clearly been infringed.

For details of how to submit an appeal, please consult the website of the European Union Civil Service Tribunal: http://curia.europa.eu/en/instit/txtodcfr/index_tfp.htm.

It is also possible to complain to the European Ombudsman pursuant to Article 195(1) of the Treaty establishing the European Community and in accordance with the conditions laid down in the Decision of the European Parliament of 9 March 1994 on the Staff Regulations and the general conditions governing the performance of the Ombudsman's duties, published in Official Journal of the European Union L 113 of 4 May 1994:

European Ombudsman
1 Avenue du Président Robert Schuman
CS 30403
67001 Strasbourg Cedex
France
<http://www.ombudsman.europa.eu>

Please note that complaints made to the Ombudsman have no suspensive effect on the period laid down in Articles 90(2) and 91 of the Staff Regulations for lodging, respectively, a complaint or an appeal with the European Union Civil Service Tribunal under Article 270 of the Treaty on the Functioning of the EU (ex Art. 236 TEC).

Please note also that, under Article 2(4) of the general conditions governing the performance of the Ombudsman's duties, any complaint lodged with the Ombudsman must be preceded by the appropriate administrative approaches to the institutions and bodies concerned. Thus, before contacting the Ombudsman, candidates must have submitted a complaint/an appeal to EMA and received a negative reply by EMA.