Medicines Authority
Positions of Documentation Officer (Pharmaceutical Technology)
(Jobsplus Permit: 191/2015, Vacancy Number: 292680)

1. The Medicines Authority invites applications for positions of Documentation Officer (Pharmaceutical Technology) within the Authority.

2. **Terms and Conditions**
2.1. The selected candidate will be employed as a Professional Officer Grade D, on a three years definite contract with the Authority, according to its Collective Agreement.

2.2. The position of Documentation Officer (Pharmaceutical Technology) is subject to a probationary period of twelve (12) months.

3. **Salary pegged to the position**

The salary attached to the position of Documentation Officer (Pharmaceutical Technology) in 2017 is that of €18,222 per annum, rising by annual increments up to a maximum established by the Collective Agreement.

4. **Duties**

The Documentation Officer (Pharmaceutical Technology) will work as part of a multi-disciplinary team and will participate in different regulatory, administrative duties as required and shall be required to give professional service.

Key responsibilities may include the following:

- Technical review of data submitted in support of applications for different procedures for medicinal products and pharmaceutical activities, in accordance with established procedures.

- Participation in and implementation of pharmacovigilance procedures.

- Monitoring the quality and safety of authorized medicinal products through a sampling and quality defect post-marketing surveillance programme.

- Participation in inspections of pharmaceutical activities in Malta and also abroad.

- Technical liaison with, and advice to, applicants and professional colleagues in order to facilitate the review process.

- Ensuring knowledge of state-of-the-art technologies through ongoing training, professional education and review of the published literature.

- Enforcement related to licensing of medicinal products and of pharmaceutical activities.

- Participation or contribution in the enforcement of regulations governing medicinal products.

- Participation in Operating Units of the Medicines Authority and execution of professional duties in such a manner so as to contribute to the efficiency and effectiveness of the Medicines Authority.

- Offering secretariat and participation at technical and administrative meetings.

- Provision of expert regulatory and procedural advice and support.

- Ensure compliance with the protocol of the Medicines Authority and regulatory requirements.
- Monitoring and implementation of legislation, guidelines and standard operating procedures.

- Participation in other ongoing projects as required.

- Liaison with, and providing advice to, Committees established to provide guidance or overview the assessment process.

- Participation in other functions such as review of Advertising and Promotional Material, as well as other boards or committees as required.

- To observe, promote and ensure the effectiveness and efficiency of the quality management system

- To continuously improve the performance of the organisation and promote communication and liaison between different sections of the organisation.

- Keeping up to date with knowledge required for the work assigned.

- Being responsible to continuously self-monitor and improve their scientific capabilities.

- Being able to use and operate any software package or procedure provided by management.

- Promoting and maintaining good professional and ethical working relationship with colleagues at the Unit and stakeholders.

- Contribute to the preparation of technical and administrative reports as required.

- Performance of duties pertaining to other staff and deputising according to the exigencies of the services.

- Management reserves the right to require the services of the Pharmaceutical Scientific Executive in the different relevant units according to the exigencies of the Authority.

- Representing Medicines Authority at meetings, seminars, conferences and other fora, both locally as well as abroad.

- Any other duties as may be required by The Employer.

5. **Eligibility requirements**

5.1 By the closing time and date of this call for applications, applicants must be:
(i) (a) citizens of Malta; or
(b) citizens of other Member States of the European Union who are entitled to equal treatment to Maltese citizens in matters of employment by virtue of EU legislation and treaty provisions dealing with the free movement of workers; or
(c) citizens of any other country who are entitled to equal treatment to Maltese citizens in matters related to employment by virtue of the application to that country of EU legislation and treaty provisions dealing with the free movement of workers; or
(d) any other persons who are entitled to equal treatment to Maltese citizens in matters related to employment in terms of the law or the above-mentioned EU legislation and treaty provisions, on account of their family relationship with persons mentioned in paragraph (a), (b) or (c); or
(e) third country nationals who have been granted long-term resident status in Malta under regulation 4 of the "Status of Long-Term Residents (Third Country Nationals) Regulations, 2006" or who have been granted a residence permit under regulation 18(3) thereof, together with family members of such third country nationals who have been granted a residence permit under the "Family Reunification Regulations, 2007".
The advice of the Citizenship and Expatriates Department should be sought as necessary in the interpretation of the above provisions.

The appointment of candidates referred to at (b), (c), (d) and (e) above would necessitate the issue of an employment licence in so far as this is required by the Immigration Act and subsidiary legislation. The Employment and Training Corporation should be consulted as necessary on this issue.

(ii) Proficiency in English Language;

(iii) Bachelor of Science in Pharmaceutical Technology or equivalent at MQF Level 6.

Qualifications at a level higher than that specified above will be accepted for eligibility purposes, provided they meet subject requirements.

Moreover, candidates who have not yet formally obtained any of the above-mentioned qualifications will still be considered, provided that they submit evidence that they have

been approved for the award of the qualifications in question by the first quarter of the year 2018.

Applicants with experience in regulatory affairs will be preferred.

5.2 Prospective applicants should note the requirement to produce MQRIC recognition statements in respect of their qualifications from MQRIC, or other designated authorities, as applicable, as per provisions applicable to this call for applications. (http://www.pahro.gov.mt/file.aspxf=799).

6. **Submission of supporting documentation**
6.1 Qualifications and experience claimed must be supported by certificates and/or testimonials, copies of which should be attached to the application. Scanned copies sent electronically are acceptable.

6.2 Original certificates and/or testimonials are to be invariably produced for verification at the interview.

7. **Selection procedure**

Eligible applicants will be assessed by a Selection Board to determine their suitability for the position.

8. **Submission of applications**

Applications, together with a curriculum vitae showing qualifications and experience, are to be submitted to **hr.medicinesauthority@gov.mt** by not later than Monday 6th February 2017 noon.