



APPLICATION FOR QUALIFIED PERSON (QP) STATUS

VERSION 6

Surname _____

Name _____

Applying for eligibility as QP for the following categories: *(Tick the appropriate boxes)*

- Non-sterile solid dosage forms
 - Non-sterile liquid dosage forms
 - Sterile products If ticked please specify type of products:
 - Medicinal gases
-
- Medicinal products of human blood or tissue origin
 - Repackaging/relabelling operations only

Address for communication

Qualifications

Experience

Professional Association(s)

Current employment details

Attach a detailed curriculum vitae and proof of payment of fee to this application.

The Medicines Authority will process your personal data in accordance with the provisions of the Data Protection Act (Chapter 440 of the Laws of Malta) for the purpose of granting Qualified Person Eligibility and in the event that such an eligibility is granted to maintain it. No personal data will be divulged to third parties unless you have specifically given your consent or where disclosure is necessary to comply with a legal obligation. You may exercise the right of access to the data held about you by submitting a written request to the Authority. In the event that your personal data in our possession is inaccurate you have the right to request rectification. You also have the right to request the blocking or erasure of data where such data has been unlawfully processed.

Signature of applicant

Date

Address

Dear Mr/Ms _____,

Following your application for Qualified Person (QP) status you are invited to attend an interview on _____ in the Board Room of the Medicines Authority.

You are requested to provide the Board:

- a) details of qualifications held, dates obtained and including subjects studied
- b) current employer and position held, including a description of duties and the range of medicinal products handled
- c) previous employers and positions held relevant to the QP post (eg the production and/or quality control of medicines), with dates and the range(s) of medicinal products handled
- d) briefly how knowledge of GMP and QP duties has been achieved (eg courses, reading, work as or in association with a current QP or GMP auditor etc)
- e) police conduct

An application fee of €116.47 has to be deposited in the account below and proof of payment has to be provided prior to the interview if this was not attached to your application.

Bank account details and important notes for payment of the applicable fee are available on the authority's website:

<http://www.medicinesauthority.gov.mt/pub/Notice%20to%20stakeholders.pdf>

<http://www.medicinesauthority.gov.mt/pub/Information%20on%20cheque%20deposit%20payments.doc>

Kindly confirm your attendance by phone on _____ or by e-mail to

_____ .

Regards,

Inspectorate & Enforcement Directorate