MALTA
MEDICINES
AUTHORITY

IN009/09 Appendix 2 Version 01

GUIDELINES FOR SUBMISSION OF QP STATUS APPLICATIONS

In the European Union, for a person to be named on a Manufacturing Importation Authorisation (MIA) as a Qualified Person (QP), s/he must be approved by the Competent Authority issuing that MIA as being eligible to be named as a QP. In order to do this, the Competent Authority must be satisfied that Directive 2001/83/EC requirements (article 49) as transposed into the national legislation (Medicines Act 2003 article 38 (1e) and regulation 9 of S.L. 458.36 as amended) are fully met.

Applications for QP status are downloadable from the Malta Medicines Authority website (www.medicinesauthority.gov.mt):
https://servizz.gov.mt/en/Pages/Health-and-Community-Care/Health/Medicines/WEB180/default.aspx
which can be filled in as e- form also (https://eforms.gov.mt/pdfforms.aspx?fid=hcc042e)
When the Malta Medicines Authority receives an application for QP status, this is validated and if the application is found to be complete (including the relative fee payment of €116.47), it is assessed for the applicants' conformance with the requirements of S.L. 458.36 as amended. If there is a positive assessment the applicant will be called in for an interview in the next interview session. Interviews are usually carried out twice a year, one interview session being held generally in the first quarter and another session in last quarter of every calendar year (subject to availability of applications eligible for interview).

As from 12th April 2011, applications are being considered as being positively assessed and hence eligible for a QP interview if all the following criteria are met:

1) Applicant must either be an EU/EEA citizen (providing proof through a valid passport or identity card) or if a non EU citizen has a Maltese residence and a Maltese working permit (documents proving this must be shown) or a letter issued by a local company holding an MIA that it intends to employ the applicant as a QP;

2) Must have at least worked full time for a minimum of two years (if the course of his / her primary degree is four years) in the quality aspect of an EU/EEA/MRA Competent Authority authorised manufacturing facility producing medicinal products for human use and covering the dosage form/s for which s/he will be interviewed and eventually accepted. Applicants performing work as specified in regulation 9e(i) of SL 458.36 in a facility with a valid Manufacturing Importation Authorisation (MIA) referred to also as an importer's licence, will also be covering this requirement. The requirement of two years work experience becomes one year full time work experience if the primary degree was of 5 years duration and if the primary degree was of 6 years duration, the necessary full time work experience required is of 6 months. Applicants with a bachelor's degree followed with a master's level degree (MQF Level 7) or a doctorate degree (MQF Level 8) in a field pertaining to one of the scientific disciplines listed in regulation 9a(i) of SL 458.36 shall be considered as being consecutive for the scope of fulfillment of practical experience required in regulation 9e(ii).
3) Experience gained in a facility which is not a domestic manufacturing facility, must be in a facility with an MIA for human use if within the EU/EEA, or a facility issued with an EU GMP certificate for human use if not within the EU/EEA. Experience gained in the Quality department at a company corporate level having site/s with an MIA or EU GMP certificate shall also qualify as gained eligible experience for the scope of regulation 9e(i) and 9e(ii). Experience gained in a local manufacturing facility prior to Malta's ascension to the EU must be in a facility authorised to manufacture medicinal products for human use by the competent authority at that time;

4) Must have a primary degree, extending over a period of not less than four years, in a scientific discipline as specified in Legal Notice 381 of 2005 as amended (in either pharmacy, medicine, chemistry, pharmaceutical chemistry and technology, or biology) issued by a University (MQRIC equivalence certification for foreign

universities must be provided and a detailed transcript of the course if course is not a local pharmacy degree). Applicants with Bachelor of Science (BSc) degrees conferred by the University of Malta for BSc course intakes before October 1995 shall be deemed as being also eligible to apply. BSc degrees of applicants for course intakes from October 1995 onwards must be at least four years in duration to be eligible to apply. The Bachelor of Science in Pharmaceutical Technology or any other degree in the scientific disciplines listed in regulation 9a(i) of SL 458.36 where the course duration of study is three years shall also be deemed to apply for eligibility if followed by a Master's of Science in Pharmacy, or a similar Master's degree in a pharmaceutical science field, covering all subjects mentioned in the legislation with a minimum of two years' work experience as per regulation 9e(i) of S.L.458.36.

The pharmacy degree conferred by the University of Malta automatically covers all subjects listed in the S.L. 458.36. If the primary degree does not cover all the academic subjects mentioned in S.L.458.36, applicant must cover the remaining subjects in a masters degree or some other post graduate qualification (Post Graduate Diploma or Certificate) delivered by an entity accredited to deliver such course by the educational competent authority in that country. In case of Post Graduate Certificates these certificates must be issued after an assessment is made by the entity delivering the course. Certificates of attendance will not be accepted. All subjects must be covered by such certification. A MQRIC equivalence certificate must always be presented in case of foreign accredited educational organisations or Maltese accredited educational organisations other than the University of Malta.

5) The eligibility for QP status will be only for those dosage forms which the applicant had experience in at the time of application and of the interview, and hence for additional dosage form/s a new application has to be submitted and the above criteria have to be adhered to once again as applicable.

For any queries or clarifications please send an email on: inspectorate.adm@gov.mt