Section 1: Updated Study Guide

The Medicines Legislation relating to the QP changed because of the UK leaving the EU. Can you advise what the QP applicant is expected to know?

The candidate is expected to know the legislation surrounding the UK withdrawal from the EU (Brexit) as it impacts the Qualified Person. Specifically:

- The licensing structure in the UK and the requirements for national licences;
- The application of EU directives in Northern Ireland and the role of the NH7-vfr t x he (
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The QP study guide advises that applicant must have had at least one/two[1] years relevant practical experience in one or more Quality Assurance activities in premises Authorised for the Manufacture of medicinal products. It is important for applicants to demonstrate direct qualifying practical experience of Quality Assurance within an Authorised Manufacturing facility. It should be noted that site visits do not qualify for practical experience in the candidates preferred dosage form stated on the application form.

It is recommended that applicants critically review their experience to ensure this meets the requirements described in the HMR 2012 and VMR 2013.

Applicants should also review the qualification of their experience with their sponsor prior to making their application.

Qualifying experience gained only in specific Quality Assurance roles (e.g. auditing or project management) is unlikely to provide sufficient practical experience to prepare the applicant fully for their interview scenario questions, and therefore the qualifying time in these roles may need to be extended and/or additional wider QA experience may be required.

Where roles have responsibilities split between licenced and unlicenced facilities, the qualifying experience can only count as contributing where it is related to completing Quality Assurance activitie Td[t)-9.6 (iv

I have submitted my form but now left that company. Do I need to resubmit my application form?

I failed my interview before the registration process had been implemented and plan on re-submitting my application. Can I submit my application against the old version of the Study Guide?

No. Even if this is your 2nd application, you will be treated as a new applicant and therefore you will need to use the new application forms and make sure your next application reflects the new Study Guide.

Section 3: QP Application

Who should be my sponsor for my QP application?

Please refer to the 'Guidance Notes for Applicants and Sponsors'.

You need the support of a sponsor, who must be a member of one of the Joint Professional Bodies

Which products and processes are eligible as my area of expertise?

Any, as long as you have a minimum of two years' appropriate experience under a full manufacturer's authorisation (Human Medicines Regulation 2012). This is reduced to one year if the applicant is a qualified pharmacist.

Can I apply for QP eligibility if I only have experience in API manufacture or research and development, or under a Specials Licence?

The relevant practical experience must be gained in a facility that holds a full manufacturer's authorisation. As most API (bulk drug) and R & D do not usually require a manufacturer's


ROYAL SOCIETY
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Do you assess members from outside the UK?

If you are not intending to act as a QP in the UK and intend to seek nomination as a QP on a Manufacturer's Authorisation issued by another EU Member State, you may wish first to contact the competent authority for that state (refer to the European Medicines Agency).

If you have already been named as a QP on a Manufacturer's Authorisation in another Member State and intend to seek nomination as a QP in the UK, you should not apply to the JPB. The holder of the Manufacturer's Authorisation should apply to the competent authority in the UK (MHRA or VMD) to add you to the authorisation as a QP.

I am eligible to act as a QP under the transitional provisions of the Clinical Trials Directive 2001/20/EC or the Traditional Herbal Medicinal Products Directive (2004/24/EC, amending 2001/83/EC). Can I apply for an entry on the Register?

If you have been accepted by the MHRA under transitional arrangements to act as a QP for traditional herbal medicinal products and have been named as a QP on an appropriate manufacturer's authorisation, you can apply for a certificate and an entry in the Register (Category E applications). Certification by a professional body is not essential in these circumstances, but you are nevertheless eligible for certification and are advised, in any event, to retain details of the licence(s) on which you are named.

If you have the relevant practical experience under these manufacturer's authorisations, you are eligible to apply under Category A. Please refer to the Guidance Notes.

Update Dec 2017: The MHRA has issued information for Transitional IMP QPs (named as a QP in a valid application for a manufacturing authorisation for IMPs made prior to 1st May 2006 under the Medicines for Human Use (Clinical Trials) Regulations 2004). Further information can be found on the MHRA website here: https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency

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Contact details for QP applications and enquiries