

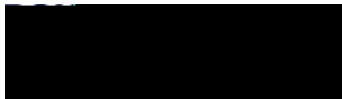
Section 1: Updated Study Guide

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
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The QP study guide advises that applicant must have had at least one/two¹ 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.

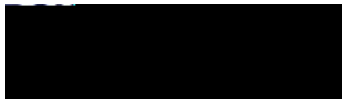
Applicants should also review the qualification of their experience with their sponsor prior to making their application.

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 activities 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?

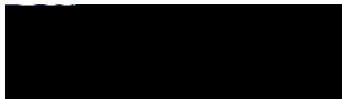
No. Even if this is your 2nd application, you will be treated as a new applicant and therefore you will need to use the new application forms and make sure your next application reflects the new Study Guide.

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

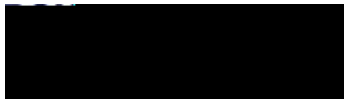


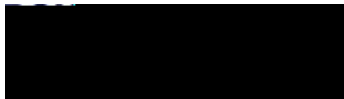
Which products and processes are eligible as my area of expertise?

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

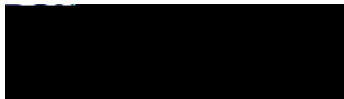






Do you assess members from outside the UK?

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).



Contact details for QP applications and enquiries