

Role of the Qualified Person

The functions of a Qualified Person as set out in the Statutory Instruments cited previously are as follows:

- to ensure that each batch of the medicinal product to which the licence relates has been manufactured or assembled and checked in compliance with the provisions of the laws in force in that Member State and Regulations made thereunder, and in accordance of the provisions of the licence and the provisions of the product licence which relates to the product
- for medicinal products manufactured outside the European Union, the Qualified Person must ensure that each imported batch has undergone in the importing Member State a full qualitative analysis, a quantitative analysis of at least all the active constituents and all the other tests or checks necessary to ensure the quality of proprietary medicinal products in accordance with the requirements of the marketing authorisation (although it should be recognised that there are exemptions to this requirement: batches of medicinal products which have undergone such controls in a Member State shall be exempt from the above controls if they are distributed into other Member States under condition that they are accompanied by the control reports signed by the Qualified Person)
- in the case of medicinal products imported from a third country, where appropriate arrangements have been made by the Community with the exporting country to ensure that the manufacturer of the medicinal product applies standards of good manufacturing practice at least equivalent to those laid down by the Community and to ensure that the controls referred above have been carried out in the exporting country, the Qualified Person may be relieved of responsibility for carrying out those controls
- to certify in a register, or other record appropriate for the purpose, whether each production batch of the medicinal product to which the authorisation relates satisfies the requirements above and to ensure that such register or other record is regularly maintained, in particular that the appropriate entries in such register or record are made as soon as practicable after each such batch has been manufactured. In addition to manufacturing, the above applies when a Qualified Person acts for the holder of a wholesale dealer's licence concerning imported medicinal products

The role of the Qualified Person is of importance within the industry and this should be reflected in the calibre of applicant appointed to such a position. It is the opinion of the professional body concerned that every member included in the Register meets the statutory requirements to become a Qualified Person. However, it is up to individual companies to satisfy themselves of the suitability of any individual applicant for a particular post. The MHRA/VMD is responsible for determining who can be named as a Qualified Person in a Manufacturer's Licence.