

Role of the Responsible Person (RP)

If you have a Wholesale Dealer's Licence (WL) from the Medicines and Healthcare products Regulatory Agency (MHRA) you will have a nominated Responsible Person (RP) named on your licence.

The RP is responsible for ensuring that the conditions of the WL are met and that the guidelines on Good Distribution Practice (GDP)* are complied with. If the RP does not adequately carry out their duties the licensing authority may consider the suspension of the licence, withdrawal of acceptance of the RP on that licence and their acceptability on other licences.

The RP does not have to be an employee of the licence holder but must be at his disposal. A direct reporting line to the Managing Director is necessary. If not an employee a written contract which specifies their responsibilities, duties and authority must be in place. The RP does not need to be a pharmacist, but must have several years

experience in pharmaceutical storage and distribution as well as a working knowledge of GDP and the products under the licence.

The RP will regularly review and monitor all areas relevant to GDP such as accuracy of records, compliance with established Standard Operating Procedures (SOPs), the quality of handling and storage equipment and facilities, temperature monitoring and other relevant areas. Where the licence covers a number of sites the RP should cover all these sites. It is possible to have a nominated deputy in order to do this, and the MHRA encourage the addition of a deputy RP on the licence where the situation justifies this.

HTF Associates sister company GDP Pharma Services Ltd specialises in the supply of high quality contract RPs and can match the right person to your situation.

*As defined in "Rules & Guidance for Pharmaceutical Manufacturers and Distributors 2007"

HTF Associates specialises in the Supply Chain operation in the Pharma Industry. This includes outsourced supply chain management, obtaining a Wholesaler Dealer's Licence (WL) from the MHRA, selecting pre-wholesalers and advice on all aspects of Supply Chain Management in the pharmaceutical industry.

For further information and help on this topic contact HTF Associates at enquiry@htfassociates.co.uk