

## Obtaining a Wholesale Dealer's Licence (WL)

Any organisation or individual purchasing or selling pharmaceutical product in the UK must have a valid Wholesale Dealer's License (WL) from the Medicines and Healthcare products Regulatory Agency (MHRA). This applies even if you are only concerned with over the counter medicines.

The standard application and inspection process with the MHRA takes approximately 3 months, but you should allow 4 months from the application date to having your license in your hand.

The MHRA will arrange to inspect all the sites named on your license – your administration site must be named even if no product is held there. The inspector will check that you have all the relevant process in place to ensure you will operate according to Good Distribution Practice (GDP). This is defined in the "Orange Guide" issued by the MHRA\* and is covered by various EU legislation.

At the heart of a company's adherence to GDP is the Quality management System (QMS), which has at its centre a good set of Standard Operating Procedures (SOPs) that define how you will operate in the GDP relevant areas. The SOPs you require will vary depending on the type products you deal in, whether you will store them yourself (or outsource), where you will purchase product from. Certain categories of products require additional process e.g. Controlled Drugs (CD), Parallel Imported or Distributed products, Cold Chain products (stored 2-8°C), "Specials", Unlicensed medicine, etc.

We have experience of all the various combinations and can draft a comprehensive set of SOPs suitable for your particular business model.

Another key aspect is effective temperature monitoring and recording of the warehouse areas, and the process around the alarms and reacting to these.

The MHRA will charge an application fee and also an inspection fee. Their current process is to return to inspect again 9 to 15 months after granting your WL – so they can check examples of your paperwork and processes for real.

\* "Rules & Guidance for Pharmaceutical Manufacturers and Distributors 2007"

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HTF Associates specialises in the Supply Chain operation in the Pharma Industry. This includes outsourced supply chain management, obtaining a Wholesaler Dealer's License (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](mailto:enquiry@htfassociates.co.uk)**