HTF ASSOCIATES LTD

Supply Chain Process Specialists

Product Recall Dummy Run

It is a requirement of holding a Wholesale Dealer's Licence (WL) from the Medicines and Healthcare products Regulatory Agency (MHRA) that you have a product Recall procedure. This will cover how you handle events that may result in a product being recalled and how you would go about this, including responsibilities and out of hours contacts for emergencies.

It is an expectation from the MHRA that a WL holder, if they have not had an actual recall in the last 12 months, will test their recall procedure at least annually. This usually takes the form of an office based "dummy run" based on one of the company's products.

The dummy run should start with the in initial receipt of information and then proceed through:

- **Initial evaluation of the data and discussion as to whether it is a recall**
- **Contact with manufacturing Qualified Person (QP) and Responsible Person (RP)**
- **Contact with the MHRA**
- **Decision to recall and classification of recall**
- **Initiation of physical recall**
- **Communication to relevant people**
- **Monitoring during recall**
- **Conclusion of recall and close off**

Every case will have its different nuances and the dummy run will test if the procedure in place is adequate.

An output of the dummy run should be a list of actions to improve the process, and rectification of any omissions or errors.

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

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