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| **Job Description – Responsible Person** |
| Job Holder Signature: | Manager Signature: |
| Date Signed: | Date Signed: |

**Description**

To ensure that BAP Pharma is compliant with MHRA guidelines concerning medicines & Home Office guidelines for Controlled Drugs.

The Responsible Person (RP) is responsible for safeguarding product users against potential hazards arising from poor distribution practices and to be knowledgeable of UK and EU legislation as outlined in the Job Requirements.

**Responsibilities**

* To check ALL goods received are not counterfeit medicines, by looking for evidence of tampering or anything suspicious. Check product description, quantities, expiry dates, batch numbers are accurately recorded and match POs.
* Checks to be carried out by using pre-prepared template on clipboard per product arrival.
* To ensure goods that have been delivered by bona fide suppliers are to a high standard.
* To ensure goods that are damaged are returned to the supplier or destroyed by the appropriate contracted company
* To check that goods supplied damaged by BAP to clients are destroyed responsibly by client before issuing a credit note as described in SOP procedures.
* For cold chain products ensure goods have been maintained at 2-8°C by checking temp traces and storing them in the RP database, clearly labelled.
* To become familiar with BAP eQMS system and keeping it updated
* Lead QMR meetings with QP
* Advice BMs on all aspects of QA policies
* Liaise with Germany and US
* Be a mentor to US QA officer
* Be completely familiar with BAPs stock control system Orderwise and ensure goods are booked in accurately.
* Ensure that the conditions of the wholesale dealer’s license are met, and the guidelines of Good Distribution Practice are complied with.
* To print off stock report on a weekly basis from Orderwise ensuring the accuracy of the report and keeping the MD informed.
* To anticipate goods arrival by printing weekly orders on the system keeping the MD informed of any deviations.
* Check that Warehouse and Cold Room temps are kept between the parameters on a daily basis Cold Room 2-8°C, Warehouse 8-25°C.
* Ensure that SOPs are up to date and reviewed on a regular basis.
* To add any SOPs as relevant.
* Liaise with the MHRA and Home office as and when necessary. To be present for any visits by the MHRA and/or Home Office.
* Liaise with QP for goods arriving from outside the EU.
* Check that the temp probes are serviced and calibrated annually and records kept.
* To train all staff ensuring they understand the SOPs.
* Keep a record and store supplier’s WDL.
* To understand the workings of various shippers, e.g. Credos and Sherpa’s so that if there is a temp excursion a rational explanation can be given to the client.
* To keep an accurate record on the RP database of all temp traces.
* To ensure that the activities of the company are properly reflected in the Wholesale Dealer’s Licence.
* To ensure that the provisions of the Wholesale Dealer’s Licence are observed.
* To ensure that the operations do not compromise the quality of medicines.
* To ensure that an effective quality system is implemented and maintained.
* To ensure that adequate records are maintained for a period of 5 years.
* To ensure that all personnel are trained to carry out their respective duties.
* To ensure full and prompt cooperation with marketing authorisation holders in the event of recalls.
* To oversee audit of the quality system and to carry out independent audits. (Experience in hosting supplier/ client audits and regulatory audits such as MHRA).
* To ensure that appropriate standards of GDP are maintained.
* To ensure Technical Agreements are in place and maintained between suppliers and clients. (Experience in creating TA’s)
* To carry out risk assessments on business/ GDP critical areas (Experience in conducting risk assessments)
* To carry out validation exercises on new processes, equipment and changes. (Experience in process and basic equipment validation e.g. FMD System)

**Job Requirements**

* Knowledge of The Medicines Act 1968.
* Knowledge of Eudralex, The Rules Governing Medicinal Products in the European Union, Volume 4 Good Manufacturing Practice, Medicinal Products for Human and Veterinary Use.
* Good Understanding of the Wholesale Dealer’s Licence.
* Knowledge of, The Human Medicines Regulations ( UK SI 2012 1916).
* Understanding of Directive 2001/83/EC as amended, of the Community Code relating to medicinal products for human use.
* Understanding of, The New Guidelines for Good Distribution Practice of medicinal products for human use.
* Knowledge of Commission guidelines for GDP of medicinal products for human use (2013/C 68/01).

**Competencies**

* Attention to Detail and Thoroughness.
* Concern for Standards.
* Excellent communication skills.
* Diplomacy with MHRA, Home Office and Clients.
* Interpersonal awareness and sensitivity.
* Flexibility and Adaptability.
* Tenacity.

**Work Conditions**

* Reports directly to the Managing Director.
* From time to time overtime may be required to meet project deadlines.
* Sitting for extended periods of time.
* Ability to work under own initiative and as part of a team.