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Ensure You Comply With The New GDP Regulations

The EU are to make their GDP (Good Distribution Practice) guidelines law on 8th September 2013.

Whether you are operating within the EU or planning to transport products there, understanding the changes to the GDP regulations, which are about to be made by the EU will help your organization comply, and will also help to safeguard your supply chain from fraudulent and possibly harmful products.

The Responsible Person should*…

- [ ] Have appropriate experience, knowledge and training in GDP.
- [ ] Possess sufficient authority, resources and responsibility to fulfil their duties.
- [ ] Fulfil their responsibilities personally and should be continuously contactable. They may delegate duties but not responsibilities.
- [ ] Carry out their duties in a way that permits the wholesale distributor to demonstrate GDP compliance and that public service obligations are met.
- [ ] Ensure the quality system is implemented and maintained.
- [ ] Focus on management of authorised activities and accuracy and quality of records.
- [ ] Ensure initial and continuous training programmes are implemented and maintained.
- [ ] Coordinate and promptly perform any medicinal product recalls.
- [ ] Ensure that relevant customer complaints are dealt with effectively.
- [ ] Ensure that suppliers and customers are approved.
- [ ] Approve any subcontracted activities that may impact on GDP.
- [ ] Ensure self-inspections are performed at appropriate, regular intervals – following a prearranged programme – and necessary corrective measures are put in place.
- [ ] Keep appropriate records of any delegated tasks.
- [ ] Decide on the final disposition of returned, rejected, recalled or falsified products.
- [ ] Approve any returns to saleable stock.
- [ ] Ensure that any additional requirements imposed on products by national law are adhered to.

* National legislation sets out specific requirements for the Responsible Person in each Member State.
Also, a written job description must exist, defining the Responsible Person's authority to take decisions related to their responsibilities.

The quality system should ensure that…

- [ ] Medicinal products are procured, held, supplied or exported in a way that is compliant with the requirements of GDP.
- [ ] Management responsibilities are clearly specified.
- [ ] Products are delivered to the right recipients within a satisfactory time period.
- [ ] Records are made contemporaneously.
- [ ] Deviations from established procedures are documented and investigated.
- [ ] Appropriate corrective and preventive actions (commonly known as CAPA) are taken to correct deviations and prevent them in line with the principles of quality risk management.

Management should review the system periodically, focussing on…

- [ ] Measurement of the achievement of the quality system against objectives.
- [ ] Assessment of performance indicators that can be used to monitor the effectiveness of processes within the quality system, such as complaints, deviations, CAPA, changes to processes; feedback on outsourced activities; self-assessment processes including risk assessments and audits; and external assessments such as inspections, findings and customer audits.
- [ ] Emerging regulations, guidance and quality issues that can impact the quality management system.
- [ ] Innovations that might enhance the quality system.
- [ ] Changes to the business environment and objectives.
- [ ] Documentation and communication of the review process and its outcomes.

The system must also cover any activities outsourced to third parties. Including…

- [ ] Assessing the suitability and competence of the Contract Acceptor to carry out the activity and checking authorisation status, if required.
- [ ] Defining the responsibilities and communication processes for the quality-related activities of the parties involved.
- [ ] Monitoring and review of the performance of the Contract Acceptor, and the identification and implementation of any required improvements on a regular basis.

The above information is adapted directly from the new guidelines.

Whitehall Training

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