BRITISH INTERNATIONAL FREIGHT ASSOCIATION

An Introduction to Shipping Medicines and Vaccines

With the development of COVID-19 vaccines globally, it is imperative that the distribution of the same is managed efficiently and within already established guidelines.

The guidelines for the manufacture, handling and distribution of vaccines are regulated by the Medicines and Healthcare products Regulatory Agency (MHRA). MHRA carries out inspections to check if manufacturing and distribution sites comply with Good Manufacturing Process (GMP) and Good Distribution Practice (GDP) before issuing authorisation.

Any logistics company that either stores or transports medicines and related products will be governed by these regulations. Given the expected volumes of vaccines required, the freight forwarders who are not yet regulated but considering this business should prepare for MHRA authorisation.

GDP requires that medicines be obtained from the licensed supply chain and are consistently stored, transported and handled under suitable conditions, as required by the Marketing Authority or product specification.

Subject to the product Members are storing/moving they may need to demonstrate the ability to store and move products under temperature control.

GDP guidelines currently fall under those of the European Commission and are unlikely to change following EU Exit. The full guidelines can be found at the following link to the Official Journal of the European Union – Good Distribution Practice of medicinal products for human use:

https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2013:343:0001:0014:EN:PDF

Compliance with GDP ensures that:

- medicines in the supply chain are authorised in accordance with European Union (EU) legislation.
- medicines are always stored in the correct conditions, including during transportation.
- contamination by or of other products is avoided.
- an adequate turnover of stored medicines takes place.
- the right products reach the right addressee within a satisfactory period.

The distributor should also put in place a tracing system to enable identification of faulty products and an effective recall procedure.

Detail for set up, handling and management

The whole process for the actual handling and distribution can be viewed under the World Health Organisation document “WHO good distribution practices for pharmaceutical products”, which goes into detail for each individual function/responsibility:

https://www.gmp-compliance.org/files/guidemgr/GDP_TRS957Annex5.pdf

How does an MHRA inspection work?

1. INFORMATION

For all members who seek MHRA authorisation, it is important that the management and all staff members of the business units concerned are informed about the nature and scope of the initial application including business processes. When known, the dates of the initial and subsequent inspections should be advised.

2. TEAM FORMATION

For the next step, various teams should be formed (the size of the teams depends on the size of the company / site to be inspected). The core team, usually led by the quality assurance unit or directly by the Responsible Person for GDP (RP), manages the preparations and prioritises tasks, coordinates the contact persons and reports directly to senior management.

3. GAP ANALYSIS

While preparing for the inspection, all facilities, equipment, systems and documents are analysed for possible deficiencies. The quality assurance RP should support the facilities and areas concerned. Need for improvement should be identified and, if possible, derived measures should be taken. If the elimination is not possible before the inspection is due, the problem should be described, and an action plan should be developed. This way, it can be proven to the authority that the deficiency has already been identified and addressed.

4. PREPARATION OF DOCUMENTS

The following documents and summaries should always be prepared and supplied during an inspection:

- organisation overview and chart,
- job descriptions,
- training documentation,
- important SOPs (e.g. on personal hygiene, deviation management, compliance and recall handling, handling of returns, change control, etc.),
- layout plans and overviews (also for technical equipment such as temperature controlling and monitoring systems),
- list of products,
- validation and qualification documents
- summary of non-compliances, complaints and recalls,
- process of handling suspected counterfeits.

5. DETAILED PLANNING

Depending on the business size, the following functions as described by the MHRA need to be determined:

- Inspection management: main contact person for the inspector, co-ordinates the inspection (usually the RP or a representative of the quality assurance unit);
- Experts: Subject Matter Experts (SME) representing each area are prepared to answer questions on the issue in question.
- For large companies / inspections:
  - An Inspection Coordinator: who coordinates the enquiries, appoints experts and supervises all documents;
  - The Scribe: who records the progress of the inspection, writes down questions and enquiries of the inspectors and documents their processing;
  - The Runner: who delivers enquiries from the inspection room to the coordination room.

6. TRAINING

Another important component is the training of all persons involved in an inspection. All persons involved should be specifically trained as referenced in “The Green Guide” for their tasks.

7. BEGINNING OF INSPECTION

To avoid surprises, the duration, scope and agenda of the planned inspection should be addressed at its beginning. A short presentation by senior management of not more than 10 slides introducing the company and the site does not only save time, but also supplies the inspector with important information and a possibility to make a positive first impression. The applicable safety and hygiene regulations may also be addressed here.

Finally, applicants must be aware that the approval process takes approximately 90 days (under normal circumstances).

Reference Points

MHRA

https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency

Within this website particular attention is drawn to the key reference guide referred to as “The Green Guide”

GOOD DISTRIBUTION PRACTICE (GDP)

https://www.gov.uk/guidance/good-manufacturing-practice-and-good-distribution-practice

THE GREEN GUIDE

Further information on The Green Guide can be found at https://www.pharmpress.com/product/9780857112866/green