Good Practice – GxP

What does GxP stand for?

GxP is an abbreviation for generic good practice, which refers to the series of laws, regulations, and guidance that govern various areas of the research, development, testing, manufacturing, and distribution of medicines.

Examples of GxP include:

- GLP – Good Laboratory Practice
- GCP – Good Clinical Practice
- GMP – Good Manufacturing Practice
- GDP – Good Distribution Practice
- GVP – Good Pharmacovigilance Practices

Why is GxP important?

Patients expect medicines to be safe, effective, and of high quality. GxP rules and guidelines ensure that all aspects of the medicines development process are conducted according to the best methods for safety, efficacy, and quality.

Good Laboratory Practice (GLP)

The purpose of Good Laboratory Practice (GLP) is to ensure that all laboratory results are reliable. This is particularly relevant during non-clinical development, when lead compounds that were identified during research are investigated. It is important that researchers have confidence in the results observed in laboratory settings before the development of the

medicine proceeds to first-in-human (Phase I) trials.

In order to ensure the reliability of laboratory results, the principles of GLP govern the planning, performance, monitoring, recording, reporting, and archiving of non-clinical studies (1). However, GLP is also relevant during the continued clinical development of the medicine.

Good Clinical Practice (GCP)

The purpose of Good Clinical Practice (GCP) is to ensure that all clinical trials in human participants adhere to ethical and scientific standards in order to protect the rights, safety, and well-being of trial participants as well as the reliability and credibility of trial results.

Since medicine development has increasing global impact, GCP is an international standard; GCP guidelines are formulated by the International Council for Harmonisation (ICH), and are also known as the ICH-GCP. The ICH-GCP intends to protect the rights and safety of trial participants in line with the principles set out in the Declaration of Helsinki. The ICH-GCP also provides for the confidentiality of any records that could identify participants of clinical trials, in accordance with the applicable regulatory requirements. ICH-GCP also ensures the quality and integrity of the data collected during clinical trials (2).

The European Medicines Agency coordinates GCP-related activity at the EU level. If a company applies for a Marketing Authorisation (MA) in the EU, it must ensure that all clinical trials included in that application adhere to the EU recognised principles of GCP, regardless of where those trials were conducted.

Good Manufacturing Practice

The purpose of Good Manufacturing Practice (GMP) is to ensure that products are consistently produced according to the appropriate quality standards (3).

The reliability of the quality of products is guaranteed by controlling the five critical parameters:

- **Manpower**

People must be competent for their job and trained accordingly.

- **Milieu (Environment)**

The environment must not have an adverse impact on the quality of the product, and access to the manufacturing zone should be restricted to authorised personnel.

- **Machines**

Any piece of equipment that is used in the manufacturing or the control of the product must be calibrated and validated in order to ensure that it will perform as expected and consistently produce reliable results.

- **Methods**

Documentation of all activities must be kept to ensure consistency. This includes Standard Operating Procedures (SOPs), manufacturing instructions, analytical methods, etc.

- **Materials**

All materials must comply with specifications and be correctly identified. The use of materials must be recorded and traceable.

Good Distribution Practice (GDP)

The purpose of Good Distribution Practice (GDP) is to guarantee that the distribution process has no negative impact on the product. There must be no alteration of the property of the medicine during distribution to retail pharmacists or patients (4).

Companies must ensure that the storage conditions of medicinal products are monitored during distribution. This is particularly critical in the case of medicines that must be stored under specific temperature or humidity conditions.

Companies must also ensure that medicines are traceable throughout the process of distribution. This is necessary in case of a recall, so that all affected products can quickly be located.

GDP is also important in order to prevent contamination by other products and to ensure that there is an adequate turnover of the product in storage.

Good Pharmacovigilance Practices (GVP)

The purpose of Good Pharmacovigilance Practices (GVP) is to ensure that continuous safety monitoring activities of a medicine take place once it has gone to market, and that all appropriate actions are taken in order to reduce the risks and increase the benefits of a medicine.

This includes the collection and description of adverse drug reactions (ADRs) throughout the medicine’s life cycle, the reporting of any ADRs to the regulatory authorities, and subsequent updates to the Summary of Product Characteristics

(SmPC) / Package Leaflet (PL) via Periodic Safety Update Reports (PSURs). Patients must be encouraged to report adverse reactions to their doctor or directly to the Marketing Authorisation Holder (MAH).

Good Documentation Practices (GDocP)

Throughout the medicines R&D process, companies must appropriately document any activity related to the medicine by following Good Documentation Practices (GDocP). GDocP is described in various Good Practice (GXP) guidelines such as GCP and GMP. They ensure documentation and record-keeping systems are adequate and controlled. This includes the control and archiving of documents and the correct use of signatures and authorisation.

Quality Assurance (QA) and Quality Control (QC)

Quality assurance refers to the process used to measure and assure the quality (of e.g. a medicine, clinical trial, procedure) and to prevent any mistake, while quality control is the process of ensuring expected standards are met or to identify mistakes. Companies must have quality assurance and control systems in place in order to ensure and monitor reproducibility, transparency, and compliance throughout all their activities.

References

1. EMA GLP https://www.ema.europa.eu/en/human-regulatory/research-development/compliance/good-laboratory-practice-compliance (4 July 2021)
2. EMA GCP https://www.ema.europa.eu/en/human-regulatory/research-development/compliance/good-clinical-practice (4 July 2021)
3. EMA GMP https://www.ema.europa.eu/en/human-regulatory/research-development/compliance/good-manufacturing-practice (4 July 2021)
4. EMA GDP https://www.ema.europa.eu/en/human-regulatory/post-authorisation/compliance/good-distribution-practice (4 July 2021)