PROPER CONTROL OF THE LIFE CYCLE OF MEDICAL PRODUCTS

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*Summary.* The research paper studies good practices in the pharmaceutical industry at the different stages. Good practices in the pharmaceutical industry are specific principles and regulations that establish requirements for the quality assurance system at of each stage of drug circulation. Each of them represents the system for ensuring that products are consistently produced and controlled according to quality standards.

*Key words:* good practices, Good laboratory practice, Good manufacturing practice, Good pharmacovigilance practices

The developing and implementation of effective public healthcare system model based on relevant, meaningful, robust, results and principles of careful use of resources is of great importance. State monitoring of the quality of medicine is carried out by the State Medical Service of Ukraine, which also prepares a decision (order) on the prohibition (stopping) of the production, sale, storage and use of medicinal products that do not meet the requirements defined by normative legal acts and regulatory documents, including those for which notifications have been received about unforeseeable adverse reactions and/or death of a person due to the use of a series or series of a medicinal product before the investigation of their causes.

All medicinal products are manufactured or packaged at a pharmaceutical production and there is a very strict control before the manufacture of medicines. Therefore, different types of drug control are going to be analyzed. Good practices in the pharmaceutical industry are specific principles and regulations that establish requirements for the quality assurance system at of each stage of drug circulation.

At the stage of pharmaceutical development - Good Manufacturing Practice (GMP);
At the stage of preclinical studies - Good Laboratory Practice (GLP);
At the stage of clinical trials - Good Clinical Practice (GCP);
At the state registration stage – Good Regulatory Practice (GRP);
At the industrial production stage – Good Manufacturing Practice (GMP);
At the wholesale stage – Good Distribution Practice (GDP);
At the stage of retail implementation - Good Pharmacy Practice (GPP);
At the stage of pharmacovigilance - Good pharmacovigilance practice (GVP);
At the stage of state monitoring of the quality of pharmaceuticals - Good regulatory practice (GRP).

Let’s consider some of the good practices in more detail. The question arises why there are so many principles and regulations.

**Good manufacturing practice (GMP)** is a system for ensuring that products are consistently produced and controlled according to quality standards. It is designed to minimize the risks involved in any pharmaceutical production that cannot be eliminated through testing the final product. The main risks are: unexpected contamination of products, causing damage to health or even death; incorrect labels on containers, which could mean that patients receive the wrong medicine; insufficient or too much active ingredient, resulting in ineffective treatment or adverse effects. GMP covers all aspects of production; from the starting materials, premises and equipment to the training and personal hygiene of staff. Detailed, written procedures are essential for each process that could affect the quality of the finished product. There must be systems to provide documented proof that correct procedures are consistently followed at each step in the manufacturing process - every time a product is made.

One of the fundamental purposes of the **Principles of Good Laboratory Practice (GLP)** is to ensure the quality and integrity of test data related to non-clinical safety studies. The way in which study data, supporting human, animal and environmental safety assessment, is generated, handled, reported, retained and archived has continued to evolve in line with the introduction and ongoing development of supporting technologies. However, the main purpose of the requirements of the Principles of GLP remains the same in having confidence in the quality, the integrity of the data and being able to reconstruct activities performed during the conduct of non-clinical safety studies.

The difference between GMP and GLP is their scope. Good Manufacturing Practice applies to the entire drug manufacturing process while Good Laboratory Practice applies only to the safety testing phase.

**Good Clinical Practice (GCP)** is the international ethical, scientific and practical standard to which all clinical research is conducted. Compliance with GCP ensures patients and the public that the rights, safety and well-being of people taking part in studies are protected and that research data is reliable. The protection of clinical trial subjects is consistent with the principles set out in the Declaration of Helsinki. This is a statement of ethical principles developed by the World Medical Association.

The Declaration of Helsinki adheres to such principles as: «The Declaration of Geneva of the WMA binds the physician with the words, “The health of my patient will be my first consideration,” and the International Code of Medical Ethics declares that, “A physician shall act in the patient’s best interest when providing medical care.” It is the duty of the physician to promote and safeguard the health, well-being and rights of patients, including those who are involved in medical research. The physician’s knowledge and conscience are dedicated to the fulfillment of this duty.

The primary purpose of medical research involving human subjects is to understand the causes, development and effects of diseases and improve
preventive, diagnostic and therapeutic interventions (methods, procedures and treatments). Even the best proven interventions must be evaluated continually through research for their safety, effectiveness, efficiency, accessibility and quality. While the primary purpose of medical research is to generate new knowledge, this goal can never take precedence over the rights and interests of individual research subjects.

Physicians must consider the ethical, legal and regulatory norms and standards for research involving human subjects in their own countries as well as applicable international norms and standards. No national or international ethical, legal or regulatory requirement should reduce or eliminate any of the protections for research subjects set forth in this Declaration».

Good Regulatory Practices (GRPs) are processes and tools to help improve the quality and effectiveness of SPS measures so that they protect human, animal, or plant life or health, without creating unnecessary barriers to trade. It is implied that the medicinal product undergoes state registration. For example, in Ukraine, state registration is carried out by the Ministry of Health of Ukraine. Any medicinal product can be checked on the website of the state register of medicinal products. If the drug can be found here, then it is really a medicine. And if not, then most likely it is a biologically active supplement. After registration of the drug, it is put into production. As mentioned earlier, GMP is responsible for quality production.

Good distribution practice (GDP) describes the minimum standards that a wholesale distributor must meet to ensure that the quality and integrity of medicines is maintained throughout the supply chain.

It sets out minimum standards to ensure medical device and pharmaceutical products comply with regulations. GDP applies to warehousing, storage, and transportation, and it covers everything from storing and transporting products under the right conditions. Doing so, minimizes the risk of product degradation, ensuring product integrity at the correct destination on time. Unique parts of GDP include guidance on transportation covering aspects such as temperature control, vehicle controls, and conducting risk assessments on transport routes. Guidance on brokers is also unique to GDP, i.e., guidance on those who facilitate transactions in the supply chain without ever handling the product.

Next to GDP is GPP. This is the standard for quality assessment of pharmacies and pharmacists, assessing both the professional and moral of the staff beyond the minimum legal requirements. Pharmacies that meet GPP standards operate based on principles:

- Pharmacies put the health and benefits of the community above business profits.
- Pharmacies provide all kinds of medicines necessary for treatment at the Clinic.
- Conditions for arranging and preserving medicines must be ensured to comply with regulations.
- Selling medicines must ensure the quality, all necessary information and monitor the patient's medicine use process.
- Pharmacists who manage pharmacies participating in self-treatment activities: provide and guide the use of medicine to treat symptoms of some simple diseases without a doctor's prescription.
- Prescribe the right medicine, in accordance with the patient’s pocket, to ensure that the patients use the medicine reasonably, safely and effectively.

Good pharmacovigilance practices are a set of measures drawn up to facilitate the performance of pharmacovigilance in the European Union (EU).

The World Health Organization (WHO) defines pharmacovigilance as “The science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem.”

WHO specifies that any newly developed drug must meet three critical conditions prior to approval by its respective regulatory agency: good quality; effectiveness; safety for intended purpose(s). The scope of pharmacovigilance has broadened to include interactions of medicines, abuse and misuse of medicines, counterfeit medicines, medication errors, adverse drug reactions/events, and lack of efficacy.

Medicines are not the only products considered under the purview of pharmacovigilance practice, but also: vaccines, blood products, medical devices, biologicals, herbals, traditional/complementary substances.

**Conclusion** Therefore, the production and sale of medicinal products requires proper control. Each stage of the life cycle of a medicinal product requires assessment of safety, quality and bioavailability for patients.

Good Regulatory Practices (GRPs) are processes and tools to help improve the quality and effectiveness of SPS measures so that they protect human, animal, or plant life or health, without creating unnecessary barriers to trade. Regulatory procedure for post-registration control of medicinal products means is carried out by the State Expert Center of the Ministry of Health of Ukraine and the State service of medicines.

**References:**

