MINISTRY OF HEALTH OF UKRAINE
BOGOMOLETS NATIONAL MEDICAL UNIVERCITY
DEPARTMENT OF THE ORGANIZATION AND ECONOMICS OF PHARMACY

GENERALIZATION OF TERMS OF GOOD PRACTICES IN PHARMACY

(guidelines)

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LIST OF SYMBOLS

API – active pharmaceutical ingredient

ASMF – active substance master file

ADR – adverse drug reaction

CPP – critical process parameter

CQA – critical quality attribute

DNF – drug master file

GDP – good distribution practice

GLP – good laboratory practice

GMP – good manufacturing practice

GPP – good pharmacy practice

GRP – good regulatory practice

GSP – good storage practice

GVP – good pharmacovigilance practices

HTA – health technology assessment

INN – international non-proprietary name

LOS – length of stay

OTC – nonprescription, over-the-counter drug

PSURs – periodic safety update reports

SOP – standard operating procedure

VMP – validation master plan

INTRODUCTION

Good practices in pharmacy are the defining basis of the quality assurance system for medicines. Good practice standards are requirements set by health regulators and cover all stages of the life cycle of a drug, from his development, laboratory and clinical research, production, quality control to the sale of drugs to the patients. The creation of an effective quality assurance system at all stages of drug circulation is based on the principles and rules of good practice (GXP). GXP is a general term used to denote effective quality standards in many areas, including pharmaceuticals, where "x" is a symbol to denote a specific quality guideline.

The effectiveness of the implementation of good GXP practices depends entirely on the quality of the standard operating procedures (SOPs) developed by the pharmaceutical (pharmacy) institution.

Such terms have clear definitions, as a rule, are characterized by legal content, so their misinterpretation can negatively affect the quality of drugs or the provision of pharmaceutical care and services in general. This obliges pharmacists to use in their activities only terms that accurately reflect the meaning of a particular concept of organizational and production processes.

To achieve this goal, we have formulated the following tasks: to identify the subject area of all relevant GXP practices; make an exhaustive list of key terms; work out the classification of terms in alphabetical order. At present, the pharmaceutical terminology given in the guidelines on good practice is not presented in the form of an ordered system. In this regard, our guidelines are relevant and useful for professionals. The guidelines present more than 150 special terms, which are listed in alphabetical order in English and are the most commonly used in good practice guidelines.

The presented publication is recommended for students who study in medical university whit specialization "Pharmacy, Industrial Pharmacy", teachers, scientists, graduate students, interns and specialists working in the quality assurance system of drugs.

Adverse Reaction (Adverse Drug Reaction, ADR) – a response to a medicine which is noxious and unintended and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease or for the restoration, correction or modification of physiological function.

Antigen – any of various foreign substances such as bacteria, viruses, endotoxins, exotoxins, foreign proteins, pollen, and vaccines, whose entry into an organism induces an immune response (antibody production, lymphokine production, or both) directed specifically against that molecule.

API (Active Pharmaceutical Ingredient) – any substance or mixture of substances intended to be used in the manufacture of a drug (medicinal) product and that when used in the production of a drug becomes an active ingredient of the drug product.

Audit – a systematic examination to substantiate whether activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.

Change Control – change control is a procedure that ensures changes are implemented in a controlled and coordinated manner.

Classified Area – an area in which the environment is of specified particulate and microbial quality. Grade A – the local zone for high risk operations.

Clean area (clean room) – an area (or room) with defined environmental control of particulate and microbial contamination, constructed and used in such a way as to reduce the introduction, generation and retention of contaminants within the area.

Clean Room – a room in which the concentration of airborne particles is controlled to meet a specified airborne particulate Cleanliness Class.

Clean Zone – a defined space in which the concentration of airborne particles and microorganisms are controlled to meet specific Cleanliness Class levels.

Clinical Trial (Clinical Study) – any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and

excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy.

Contamination – the undesired introduction of impurities of a chemical or microbiological nature, or of foreign matter, into or onto a raw material, intermediate, or API during production, sampling, packaging or repackaging, storage or transport.

Control – to manage the conditions of an operation to maintain compliance with established criteria.

Controlled study or controlled trial – clinical testing in which one group of subjects is used as a standard of comparison to determine the usefulness of a new medical approach.

Controlled Environment – any area in an aseptic process system for which airborne particulate and microorganism levels are controlled to specific levels, appropriate to the activities conducted within that environment.

Critical Area – area where sterilized products or containers/closures are exposed to the environment (i.e. aseptic preparation and filling).

Critical process steps – process steps that must be controlled within established operating ranges to ensure that the API or intermediate will meet specifications for quality and purity.

Distribution (Pharmaceutical distribution) – the division and movement of pharmaceutical products from the premises of the manufacturer of such products, or another central point, to the end user thereof, or to an intermediate point by means of various transport methods, via various storage and/or health establishments.

Distribution Actors – persons or entities involved in the supply, delivery and logistics management of medicines (e.g. wholesalers, importers).

Dosage forms (also called unit doses) – are pharmaceutical drug products in the form in which they are marketed for use, with a specific mixture of active ingredients and inactive components (excipients), in a particular configuration (such as a capsule shell, for example), and apportioned into a particular dose.

Double-blind study – a scientific study in which neither the subject (patients) nor the investigators (treating physicians) know who is receiving the experimental

treatment and who is receiving a placebo (a control or "sugar pill").

Drug – chemical substance that produces a change in body function.

Drug distribution – passage of a drug from the blood to the tissues and organs of the body.

Drug master file (DMF) – providing data on a processing facility, drug substance, packaging material or excipient confidentially to controlled organization.

Drug product – a finished dosage form, for example, a tablet, capsule or solution, that contains an active pharmaceutical ingredient, generally, but not necessarily, in association with inactive ingredients.

Drug substance – the unformulated drug substance that may subsequently be formulated with excipients to produce the dosage form.

Drug Utilization Research – research on marketing, distribution, prescription, and use of medicines in a society, with special emphasis on the resulting medical, social and economic consequences.

Environmental Monitoring Program – documented program, implemented through standard operating procedures, that describes in detail the procedures and methods used for monitoring particulates as well as microorganisms in controlled environments (air, surface, personnel gear).

Expiry/expiration date – the date (usually placed on the containers/labels of an API) designating the time during which the API is expected to remain within established shelf-life specifications if stored under defined conditions and alter which it should not be used.

Full-line Wholesale (full-line wholesaling, full-liner) – all activities consisting of the purchase and sale, warehousing, order preparation and delivery / distribution of the full assortment of medicines (in range and depth) on a defined market.

Generic drug – the equivalent drugs that are available from multiple manufacturers.

Generic name – nonproprietary name of a drug.

Good Clinical Practice (GCP) – a standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials

that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

Good Distribution Practice (GDP) – good distribution practices are that part of quality assurance that ensure that the quality of a pharmaceutical products is maintained through adequate control throughout the numerous activities which occur during the distribution process.

Good Laboratory Practice (GLP) – is a quality system for research laboratories and organizations to ensure the uniformity, consistency, reliability, reproducibility, quality, and integrity of products in development for human or animal health.

Good Manufacturing Practice (GMP) – that part of quality assurance which ensures that pharmaceutical products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization.

Good Pharmacy Practice (GPP) – guidelines are based on the pharmaceutical care given by pharmacists. The guidelines recommend that national standards are set for: the promotion of health, the supply of medicines, medical devices, patient self-care and improving prescribing and medicine use by pharmacists' activities.

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

Good Regulatory Practices (GRP) – are defined as internationally recognized processes, systems, tools and methods to improve the quality of regulations and ensure that regulatory outcomes are effective, transparent, inclusive and sustained.

Good Storage Practices (GSP) – are that part of quality assurance that ensures that the quality of pharmaceutical products is maintained by means of adequate control throughout the storage thereof.

Health Technology Assessment (HTA) – is the application of scientific knowledge in health care and prevention.

High-risk Procedures – generic procedures involving the preparation and administration of products (e.g. medicines) that have been identified by risk assessment as most likely to pose a significant risk to patients.

Hospital Pharmacists – health care professionals who provide services to patients and health care professionals in hospitals.

Hospital Pharmacy – is the health care service, which comprises the art, practice, and profession of choosing, preparing, storing, compounding, and dispensing pharmaceuticals and medical devices, advising health care professionals and patients on their safe, effective and efficient use.

Hospital Pharmacy Specialist – a pharmacist who has completed an additional training program after completing the pharmacist degree in order to gain more specific and in-depth knowledge about hospital pharmacy.

In-process controls – testing and activities performed during production to monitor and, if necessary, adjust the process.

In-process material – any material manufactured, blended, or derived by chemical reaction that is produced for, and used in, the preparation of an API.

Installation Qualification – establishing confidence that process equipment and ancillary systems are capable of consistently operating within established limits and tolerances.

Installation Qualification (IQ) – the documented verification that the facilities, systems and equipment, as installed or modified, comply with the approved design and the manufacturer's recommendations.

International Non-proprietary Name (INN, Generic Name) – the shortened scientific name based on the active ingredient.

International Non-proprietary Name Prescribing (INN Prescribing) – requirements for prescribers (e.g. physicians) to prescribe medicines by its INN, i.e. the active ingredient name instead of the brand name. INN prescribing may be allowed (indicative INN prescribing) or required (mandatory/obligatory INN prescribing).

Internet Pharmacy (Online Pharmacy) – umbrella term for retailers of prescription-only medicines (POM) and Over-the- Counter (OTC= medicines who sell their products via the World Wide Web.

Labeling – printed materials that accompany a prescription drug when shipped in interstate commerce.

Laxative – a substance that promotes bowel movements.

Laxatives – laxatives (purgatives, aperients) are foods, compounds and/or drugs that facilitate or increase bowel movements.

LD50 – lethal dose 50, or dose that will kill 50 percent of the laboratory animals tested.

Leachable – leachables are chemical entities, both organic and inorganic, that migrate from components of a container closure system or device into a drug product over the course of its shelf-life.

Length of Stay (LOS) – the number of days an individual stay in a hospital or in-patient facility.

Lethal dose – the dose of a chemical or biological preparation (a bacterial exotoxin or a suspension of bacteria) that is likely to cause death.

Lifecycle Management – the practice of brand-name manufacturers seeking to further extend the market exclusivity periods for their medicines to maintain revenue streams.

Ligand – an agent with a strong affinity to a metal ion.

Line Clearance – line clearance includes a careful examination of the area and equipment before batch to batch or product to product change over to avoid cross contamination.

Linearity – the linearity of an analytical procedure is its ability (within a given range) to obtain test results which are directly proportional to the concentration (amount) of analyte in the sample.

Line-item Budgeting – a general term used to describe a relatively unsystematic budgetary chart of accounts.

Lipoprotein – a molecule that contains a protein and a lipid (fat).

List Price – the prices that purchasers display as the prices at which they are prepared to sell their products and/or regulated by legislation.

Loading dose – initial drug dose administered to rapidly achieve therapeutic drug concentrations.

Local anesthetic – drug that reduces response to pain by affecting nerve

conduction. The action can be limited to an area of the body according to the site of administration.

Long Term Care Beds in Hospital – hospital beds accommodating patients requiring long term care due to chronic impairments and a reduced degree of independence in activities of daily living.

Long Term Care Beds in Nursing and Residential Care Facilities – beds, dedicated to long term nursing care or used for palliative care, for people requiring ongoing health and nursing care due to chronic impairments and a reduced degree of independence in activities of daily living (ADL).

Long term testing – stability studies under the recommended storage condition for the re-test period or shelf life proposed (or approved) for labelling.

Lot – a batch, or a specific identified portion of a batch having uniform character and quality within specified limits.

Lot number (control number, or batch number) – any distinctive combination of letters, numbers, or symbols, or any combination of them, from which the complete history of the manufacture, processing, packing, holding, and distribution of a batch or lot of an API or other material can be determined.

Medical Device – is any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application.

Medical Services – services provided by a health care system to a population.

Nonprescription, over-the-counter (OTC) drug – drug that can be purchased without the services of a physician.

Oral administration – route of drug administration by way of the mouth through swallowing.

Orange Guide – "Orange guide" is published by MHRA. "Orange guide" contains the requirements of Good Manufacturing Practice (It contains EU guidance on good manufacturing and good distribution practice along with relevant information on EU and UK legislation).

Order – in the context of hospitals: Statement in the patient's permanent medical record describing actions, including medication administration, that an authorized individual wish to be undertaken during a hospital visit.

Original Product (Originator, Original Medicine) – the first version of a medicine, developed and patented by an originator pharmaceutical company which has exclusive rights to marketing the product in the European Union for 20 years.

Over the counter drugs (OTC) – a drug product that is safe and effective for use without a prescription.

Over-the-counter (OTC) medicine (Over-the-counter Product, Non-Prescription Medicines (NPM)) – medicines which may be dispensed without a prescription.

Patent – is a set of exclusive rights granted by a state (national government) to an inventor or their assignee for a limited period of time in exchange for public disclosure of its invention

Periodic safety update reports (PSURs) – are pharmacovigilance documents intended to provide an evaluation of the risk-benefit balance of a medicinal product for submission by marketing authorization holders at defined time points during the post-authorization phase.

Pharmaceutical – referring to pharmacy or medical drugs; any therapeutic product used in medicine.

Pharmaceutical Equivalence – medicines are pharmaceutically equivalent if they contain the same amount of the same active substance(s) in the same dosage forms that meet the same or comparable standards.

Pharmaceutical Promotion – includes all kind of information and promotion activities to consumers, doctors or pharmacists that provide incentives with the aim of influence prescription, dispensing, sales or consumption of pharmaceuticals.

Pharmaceutical Service – all services rendered by pharmaceutical staff to support the provision of pharmaceutical care.

Pharmaceutical System – comprises the following elements: regulatory (marketing authorization, market surveillance, vigilance), pricing, funding &

reimbursement, supply chain/distribution and consumption of medicines.

Pharmacists – persons who have completed studies in pharmacy at university level (granted by adequate diploma) and who are licensed to practice pharmacy.

Pharmacopoeia – pharmacopoeia is a book or encyclopedia of Drugs Standards, their formulas, Methods for making medicinal preparations and other related information's which is published under the jurisdiction of government body.

Pharmacovigilance – is the process and science of monitoring the safety of medicines and taking action to reduce risks and increase benefits from medicines.

Pharmacy Chain (Pharmacy Group) – a group of different pharmacies belonging to the same owner which may or may not be a pharmacist.

Phase I clinical trials – small studies involving healthy volunteers to assess drug tolerability (safety), metabolism, structure-activity relationships, and mechanism of action in humans.

Phase II clinical trials – tests designed to determine, under controlled conditions, whether or not a drug has therapeutic benefit (efficacy) with individuals having the target disease (patients) and document eventual short-term side effects (adverse reactions) and risks associated with the drug.

Phase III clinical trials – larger studies to gain confirmatory efficacy and safety data in a broad base of patients.

Phase IV human testing or post-marketing surveillance – tests conducted after marketing to obtain additional data regarding product safety and efficacy over the life of a drug.

Placebo – a product which stimulates the marketable product but has no active ingredient present.

Qualification – the action of proving that any equipment or process works correctly and consistently and produces the expected results. Qualification is part of, but not limited to, a validation process, i.e., installation qualification (1Q), operation qualification (OQ), and performance qualification (PQ).

Quality – the degree to which a set of inherent properties of a product, system, or process fulfils requirements.

Quality Assurance (QA) – the sum total of the organized activities performed with the intent to ensure that all APIs are of the quality required for their intended use.

Quality Assurance (QA) – the sum total of the organized arrangements made with the object of ensuring that all APIs are of the quality required for their intended use and that quality systems are maintained.

Quality Control – covers all measures taken, including the setting of specifications, sampling, testing and analytical clearance, to ensure that starting materials, intermediates, packaging materials and finished pharmaceutical products conform with established specifications for identity, strength, purity and other characteristics.

Quality System – an appropriate infrastructure, encompassing the organizational structure, procedures, processes and resources, and systematic actions necessary to ensure adequate confidence that a product (or services) will satisfy given requirements for quality.

Single-blind study – a study in which one party (either the patient or investigator) is unaware of what medication the patient is taking.

State of control – a condition in which the set of controls consistently provides assurance of continued process performance and product quality.

Sterile – free of any viable organisms (Absence of life).

Storage – the storing of pharmaceutical products up to the point of use.

Synergistic – complementary or additive.

Therapeutic effect – desired drug effect to alleviate some condition or symptom of disease.

Therapeutic Group – group of medicines according to their indications of use.

Validation – establishing documented evidence that provides a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specifications and quality attributes. For computer systems: The assurance, through testing, that hardware or software produces specified and predictable output for any given input.

Validation Master Plan (VMP) – a document providing information on the

company's validation work programme. It should define details of and timescales for the validation work to be performed. Responsibilities relating to the plan should be stated.

Validation protocol – a written plan stating how validation will be conducted and defining acceptance criteria. For example, the protocol for a manufacturing process identifies processing equipment, critical process parameters/operating ranges, product characteristics, sampling, test data to be collected, number of validation runs, and acceptable test results.

CONCLUTIONS

1. The conducted generalization and streamlining of basic terms of good practices in pharmacy indicates the urgent need to standardize pharmaceutical terms that are often used by professionals, in particular in good pharmacy practice. At present, the pharmaceutical terminology given in the guidelines in good practice is not presented in the form of an orderly system.

2. Due to the different presentation of individual terms in good practice guidelines, it is appropriate to unify the terminology to prevent different interpretations in the process of implementing GxP, the effectiveness of which depends on the professional development of the SOP.

3. The creation of SOP is a complex and responsible process that requires developers not only professional mastery of the content of operating procedures, but also a deep knowledge of special pharmaceutical terminology, especially the basic terms established by domestic law.

4. The proposed classification of terms is important both for the educational process of future professionals and for practical pharmacy in general, especially in the context of Ukraine's integration into the European Union.

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