Federal State Budgetary Educational Institution of Higher Education "Volgograd State Medical University" of the Ministry of Health of the Russian Federation

Department of Management and Economics of Pharmacy, Medical and Pharmaceutical Commodity Science

The quality of medical equipment and pharmaceutical products, quality indicators. Types of regulatory documentation. From standardization and certification of medical and pharmaceutical products.

Lecture № 3

Discipline: medical and pharmaceutical commodity science

3 course, 5 semester

Volgograd -2022

LECTURE PLAN

1. Introduction.
2. Quality , the definition of the concept. The quality of medical and pharmaceutical products. Comprehensive quality assessment.
3. Groups of quality indicators.
4. Quality indicators of medicines and medical devices.
5. The role of standards in preserving the use value and quality of goods.
6. Types of regulatory and technical documentation.
7. Types of ND used for medicines and medicinal products.
8. Quality assurance in the field of drug circulation.
9. Standardization. General provisions.
10. C standardization system for medical and pharmaceutical products.
11. Certification. General provisions. Certification of medical and pharmaceutical products.

“Quality is the degree to which the totality of the inherent characteristics of an object meets the requirements.”

(standard GOST R ISO 9000-201 5)

“Product quality is a set of properties and characteristics objectively inherent in a product, the level or variant of which is formed when a product is created in order to meet existing needs” (*Ogvozdin V. Yu.* “Quality Management. Fundamentals of Theory and Practice”: Textbook, 6th edition, M., Publishing House “Delo i Service”, 2009, 304 p.).

Science already has a concept that means the ability of a product or service to meet the requirements (meet the needs):

In economics, this concept is called the term *utility* (eng. *utility*)

McConnell Campbell R., Brew Stanley L. Economics : Principles, problems and politics: In 2 volumes / Per. from English. — M.: Respublika, 1992. 2nd ed. T. 2 .;

in political economy this concept is called *use value* , which is also defined as *utility*

Economic Encyclopedia. Political economy: In 3 volumes - M .: Sov. encyclopedia, 1972-1979.;

in Webster's Encyclopedic Dictionary, a quality suitable for application is also defined as *utility* . (Merriam-Webster, Use)

In other words , **the ability of the quality of an object to satisfy needs is called not quality, but utility . This concept expresses not the properties of things in themselves, but the relationship of people to these properties.**

A clear example of the concept of "usefulness" can be our attitude to drugs, each of which, having its own quality (properties and characteristics), can be useful to one and useless or, moreover, harmful to another.

In connection with the definitions of quality and usefulness accepted in science, the relationship between these concepts can be expressed by the following formula:

utility = quality + satisfaction of needs .

The object (subject) of commodity science, along with the product, is a single use value, which is characterized in commodity science by the category of quality.

The quality (quality) of goods is a set of consumer properties of goods that determine their ability to satisfy certain needs in accordance with their purpose .

A property of a product is understood as its objective feature, which manifests itself during production, operation or consumption.

DEFINITION OF THE CONCEPT "QUALITY OF A DRUG"

The quality of a medicinal product is a set of properties that give the medicinal product the ability to satisfy consumers in accordance with its intended use and meet the requirements established by law and regulatory documents.

“The quality of a medicinal product is the compliance of a medicinal product with the requirements of a pharmacopoeial article or, in the absence of a regulatory documentation or a regulatory document.”

(FZ RF No. 61 of 12.04.2010

"On the Circulation of Medicines", in the current edition)

The product of labor , created in the production process, **before implementation has only a potential quality that** turns into a real one in the process of **consumption** , that is, when the product begins to participate in the satisfaction of specific social needs.

Quality requirements can be

- **consumer** ,
- **the organization itself** (internal standards of the manufacturer),
- **“interested parties”** (for example, the state).

Quality, like use value, has two sides:

- technical (tangible)

- economic (socio-economic) .

The modern regulated formulation ***of quality reflects its technical side, which is directly dependent on the level of development of technology and production technology.***

The technical aspect of quality is the object of research in commodity science.

The economic side is important in shaping the quality of goods:

Without taking into account costs, there may be a contradiction between the technical improvement of products and the economic effect of its use .

It is impossible to increase quality indefinitely by excessively increasing production costs, but, on the other hand, it is also impossible to reduce the cost of production due to an unacceptable decrease in its quality.

CONCLUSION: the highest utility is the product that fully satisfies social needs with minimal labor costs.

Comprehensive quality assessment. Qualimetry.

Quality can be assessed or quantified.

Qualimetry is a scientific discipline that studies the methodology and problems of a comprehensive, quantitative assessment of the quality of objects of any nature.

Qualimetry is an area of practical and scientific activity related to the development of theoretical foundations and methods for measuring and quantifying quality.

Qualimetry is an integral part of **qualitology** - the science of quality .

The object of qualimetry is the study of the principles and methods of quality assessment. **Subject** - a set of properties of objects and processes that make up the quality, with which a person contacts in his practical activities.

QUALITY INDICATORS OF MEDICAL GOODS(1)

Goods quality indicator - this is a quantitative characteristic in relation to specific conditions of production and consumption, regulated by regulatory documentation.

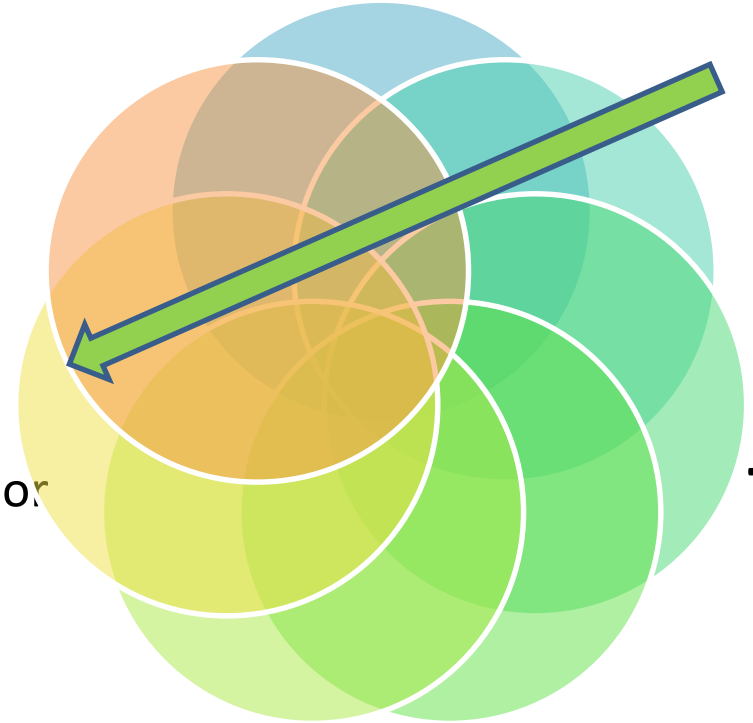
- meaning

(indicator value

is the result of a quality or

quantitative

measure indicator) .



Each indicator has:

- name (the name of the indicator serves as a characteristic of the quality of the goods),

SIGNS OF CLASSIFICATION OF QUALITY INDICATORS IN COMMODITY

In commodity science, quality indicators are classified according to the following criteria:
- the number of characterized properties (single and complex);
- purpose (defining and integral);
- way of expression (in physical units and points);
- determination method (organoleptic, instrumental, sociological, expert);
- areas of application (product units, sets of units of homogeneous products, sets of units of heterogeneous products);
- stages of definition (at the design stage, at the production stage, at the consumption stage).

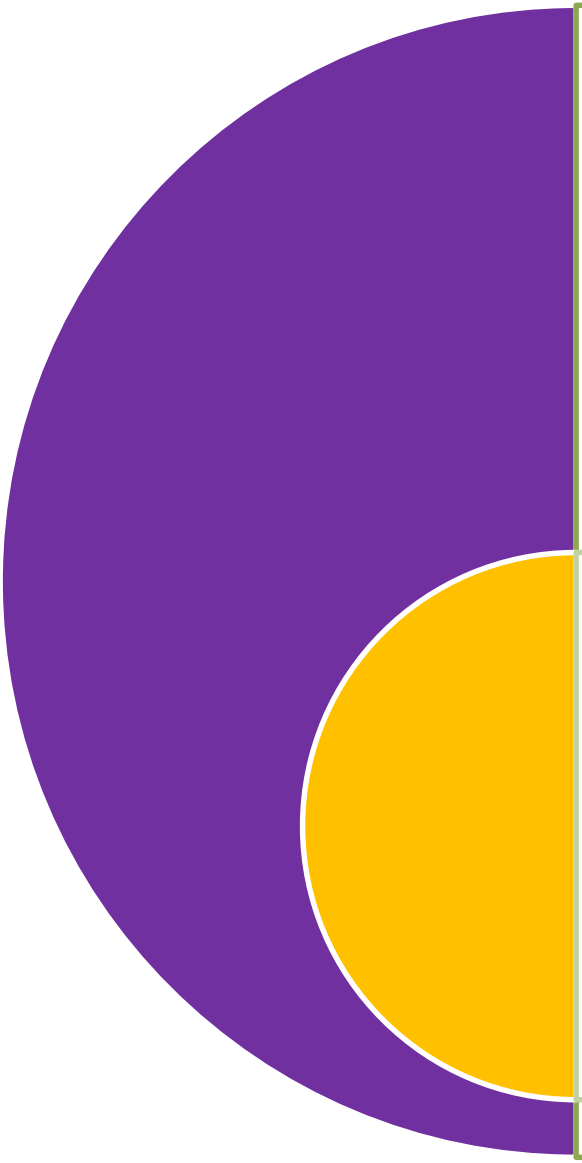
Quality indicators by name are divided into groups depending on:

characterizing properties
-single
- complex

destination
-basic
-defining

Unit indicators are indicators designed to express simple properties of goods (color, shape, acidity, integrity).

MAIN QUALITY CRITERIA



The choice of the nomenclature of product quality indicators is regulated *by state standards.*

The set of indicators consists of single indicators designed to express simple properties of the product.

MAIN QUALITY CRITERIA FOR MEDICINES

Drug safety - characteristics of medicines based on a comparative analysis of their effectiveness and assessment of the risk of harm to health.

Bioavailability of drugs reflects the content of a free substance in the blood plasma after a certain period of time after its administration relative to the initial dose of the drug.

The effectiveness of medicines - characterization of the degree of positive effect of drugs on the course of the disease.

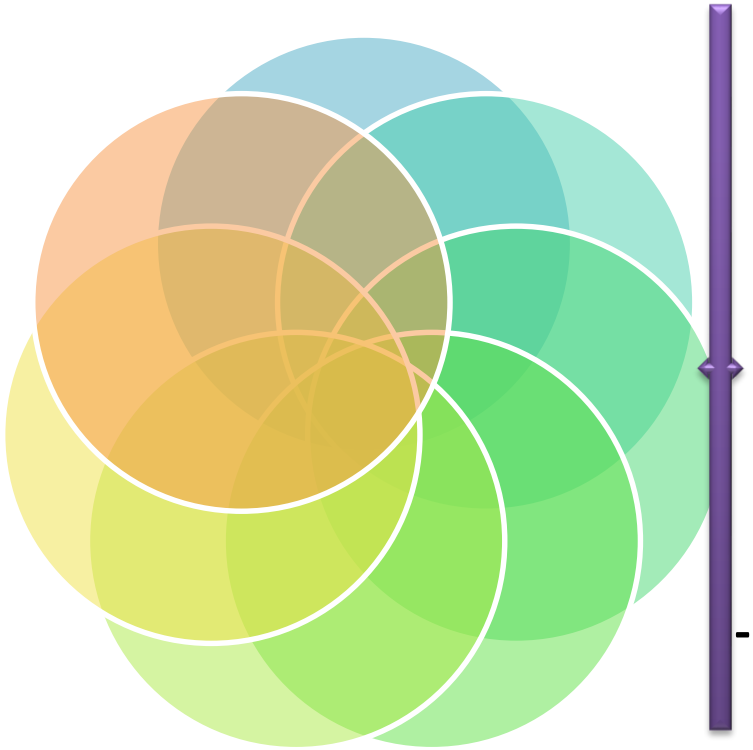
QUALITY INDICATORS OF MEDICAL PRODUCTS

IMPORTANT: each type of product has its own individual quality indicators .

EXAMPLE: the quality of dressings is determined by such **single indicators as hygroscopicity, capillarity, neutral reaction of water extract** , etc.

These indicators are set by industry methods. Their evaluation is the task of qualimetry.

For all medical equipment , the following groups of single quality indicators are distinguished:



- appointment,

- reliability

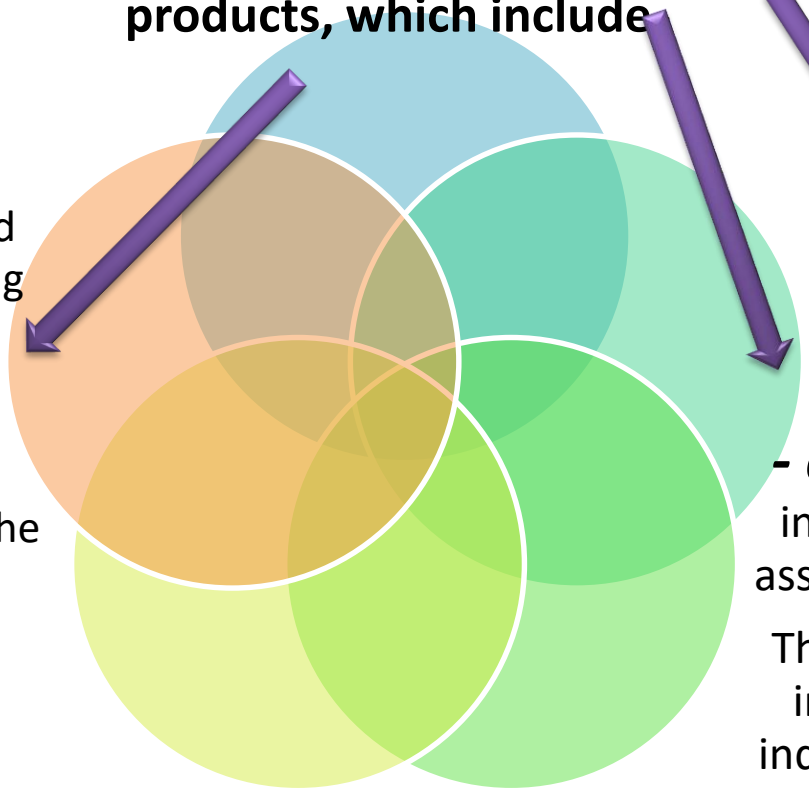
- durability,

- manufacturability, etc.

INDICATORS FOR ASSESSING THE QUALITY OF MEDICAL PRODUCTS

In addition to single indicators, a whole group of indicators is used to assess the quality of medical products, which include

- integral quality indicators are expressed through the corresponding sum of economic and technical indicators (for example, the overall beneficial effect from the use of a medical device, the total costs of its creation and operation).

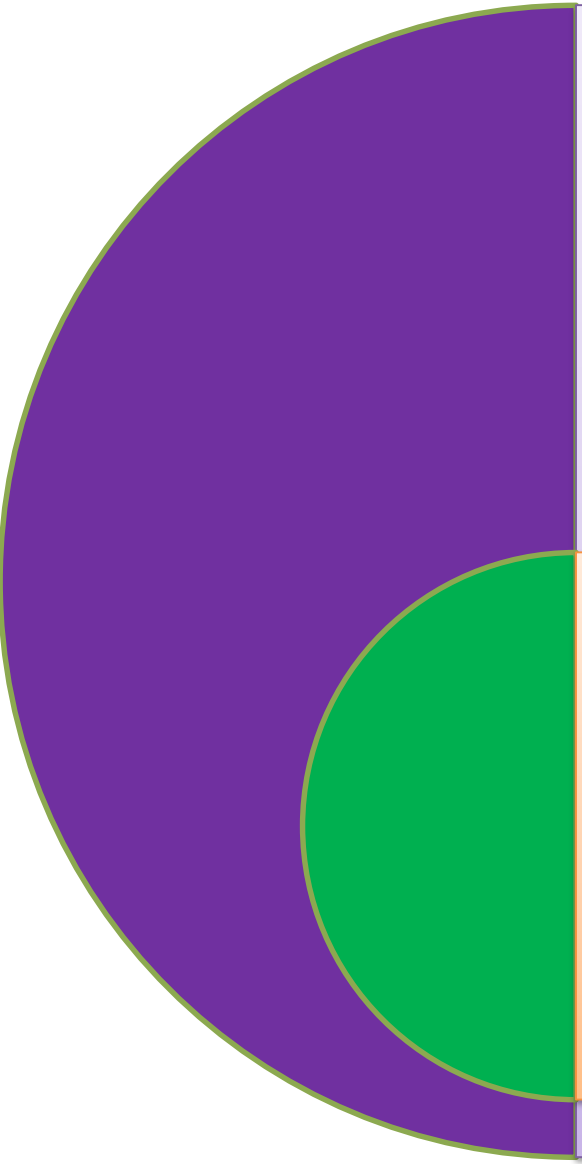


-complex indicators - indicators designed to express the complex properties of goods;

- defining indicators - indicators that are crucial in assessing the quality of goods.

These in commodity analysis include many organoleptic indicators - appearance, color, taste, smell, as well as the state of aggregation of drugs ;

QUALITY CRITERIA: QUALITATIVE FEATURES AND QUANTITATIVE CHARACTERISTICS



In quality management, qualitative characteristics are of great importance (material color, product shape, the presence or absence of a certain coating on the surface of the part, etc.).

Quantitatively, the characteristics based on the assessment of qualitative features are expressed in points or in the form of two mutually exclusive (alternative) options (for example, compliance or non-compliance of the geometric parameters of the product with the requirements of technical documentation).

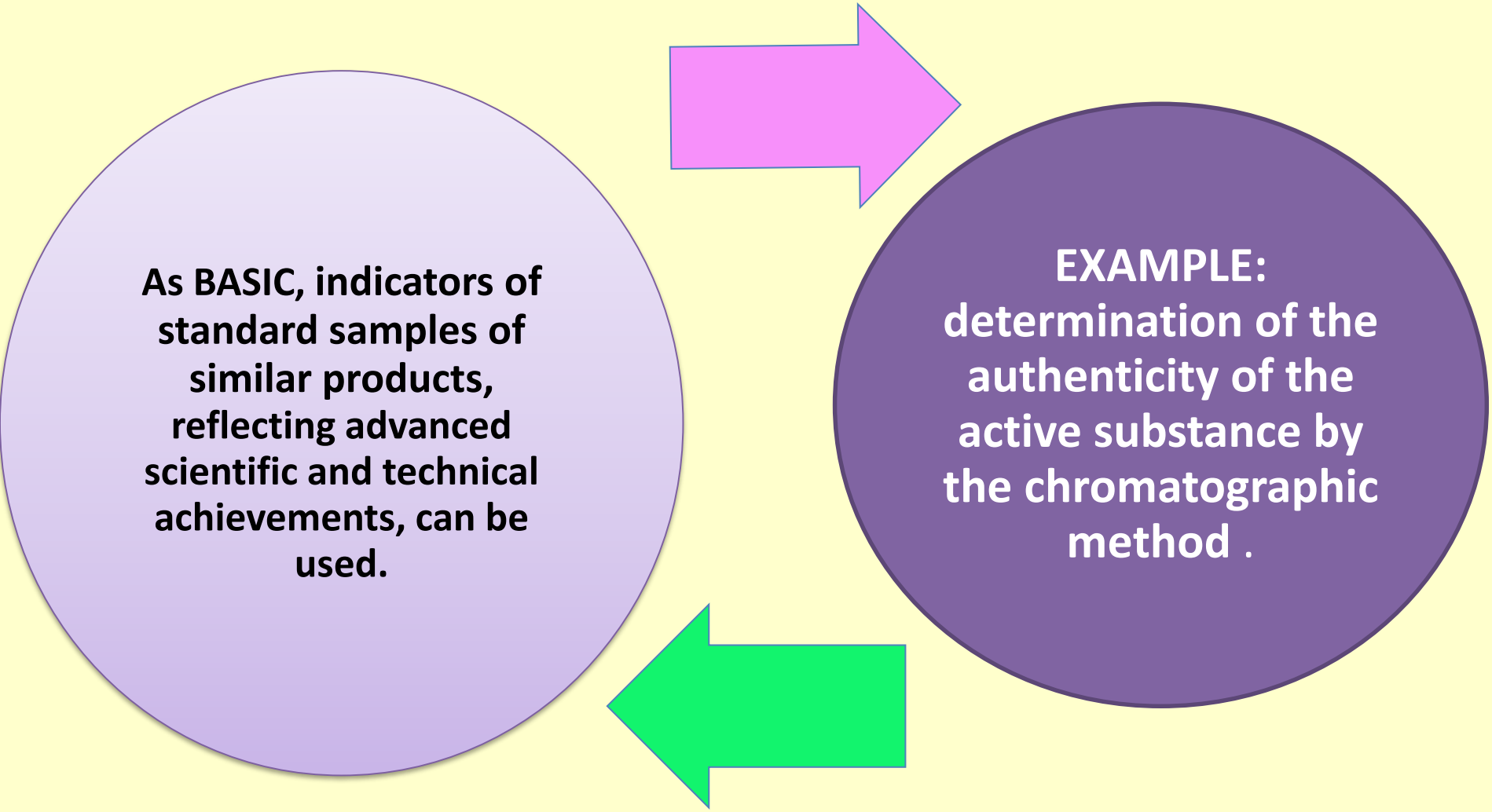
To characterize the quality of medical equipment and technology, they often use

-basic,

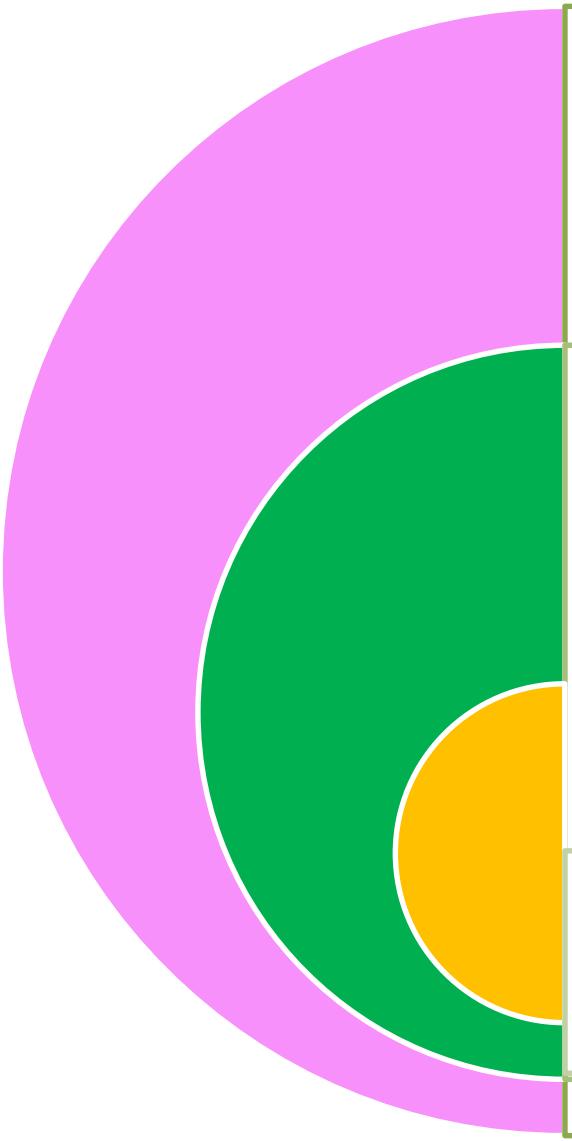
-relative,

-optimal values of the product quality index.

Quality Score Baseline



Quality Score Baseline



The relative values of the quality index are defined as the ratio of the indicators of a real sample to the base indicators and are expressed in fractions of a unit or percentage.

With optimal values of the quality index achieve either the maximum effect from the operation or consumption of products at a given cost for its creation and operation (consumption), or a given effect at the lowest cost, or the greatest effect-to-cost ratio.

To determine the **actual values of quality indicators, a number of methods are used: measuring, registration, calculation, organoleptic, sociological.**

Methods for assessing quality and methods for obtaining quality indicators

Method	How to get information
Measuring	With the help of measuring and control tools
Registration	Registration and counting of certain events
Estimated	Modeling and forecasting
Organoleptic	Use of the human senses
Sociological	Collection and processing of opinions of actual or potential consumers

QUALITY ASSESSMENT

Assessment of the level of product quality serves as the basis for developing the necessary decisions in the quality management system. In general, this assessment consists of the following steps :

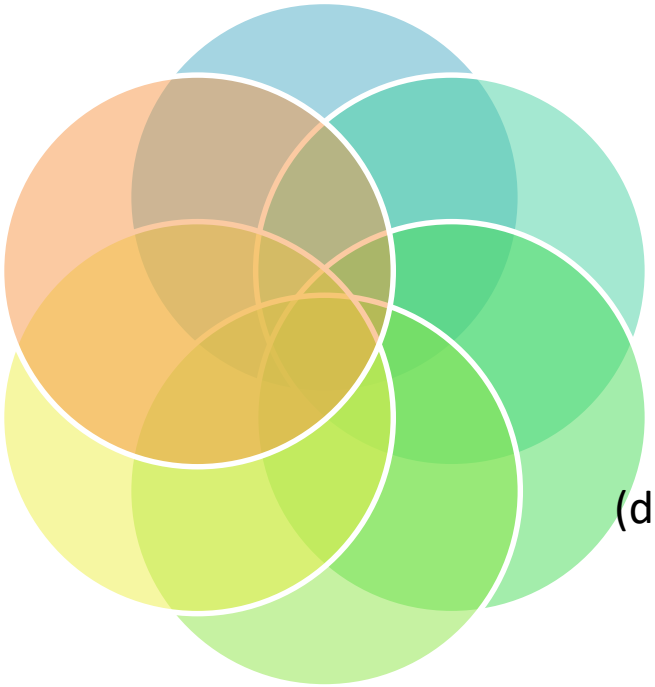
STAGE 1 . Selection of the nomenclature of quality indicators and justification of its necessity and sufficiency;

STAGE 2. Selection (development) of methods for determining the values of quality indicators of the evaluated products;

STAGE 3 . Determination of the actual values of quality indicators and their comparison with the base ones;

STAGE 4. Deciding on the level of product quality and measures aimed at improving it.

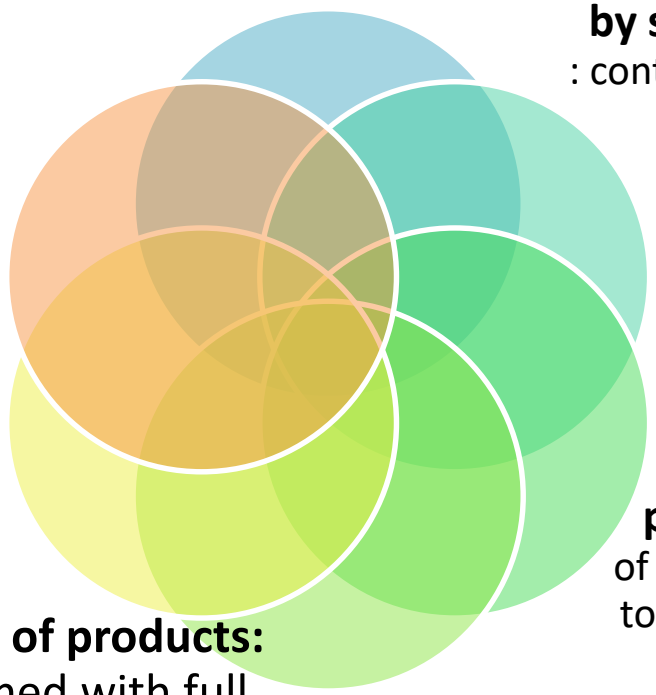
A product that meets all the established quality requirements is called good. It does not contain defects, but may have acceptable deviations in quality indicators or parameters.



FORMS AND METHODS OF PRODUCT QUALITY CONTROL (1)

Groups of various forms and methods of quality control (form an effective quality assurance system for medical products):

at the place of execution: stationary control performed at stationary control points; sliding control performed directly at the workplace;



by stages of the product life cycle : control of the design of new products; control of production and sales of products; control of operation and consumption of products;

by stages of the production process : incoming quality control of materials, semi-finished products, tools and fixtures before the start of production; intermediate control performed during the technological process; final acceptance control carried out over blanks, parts, assembly units, finished products;

by the degree of coverage of products: complete control, performed with full coverage of the presented products; selective control, carried out not over the entire mass of products, but only selectively;

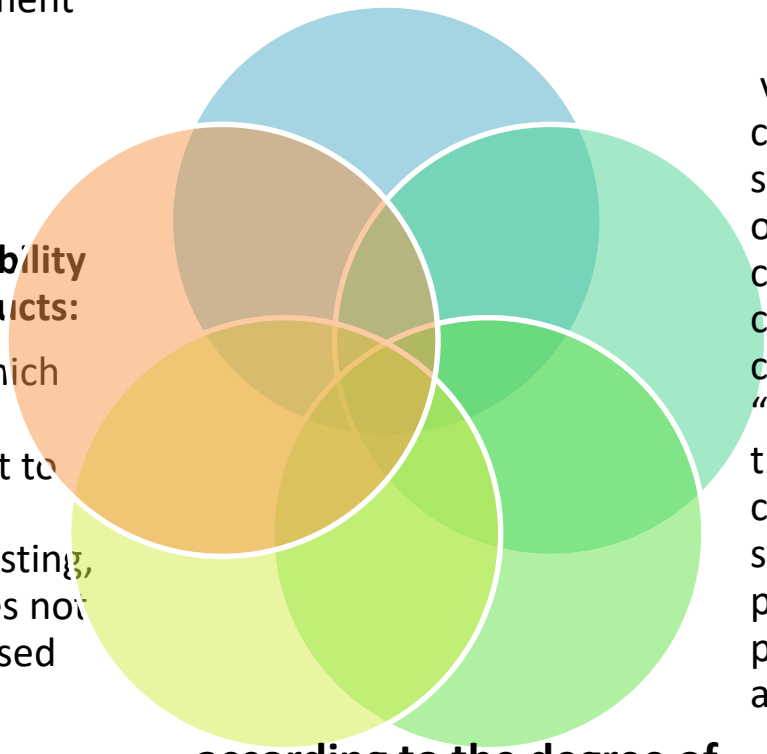
FORMS AND METHODS OF PRODUCT QUALITY CONTROL (2)

by execution time: continuous and periodic;

by performers: self-control, control of masters, department of technical control (QCD), inspection control.

on organizational forms of detection and prevention of marriage:

volatile control performed by the controller arbitrarily, without a schedule, with a systematic bypass of the jobs assigned to him; ring control, performed by the controller when bypassing a certain number of workplaces "along the ring" in accordance with the hourly schedule; statistical control, which is a form of periodic selective control; current preventive control performed to prevent defects at the beginning and in the manufacturing process ;

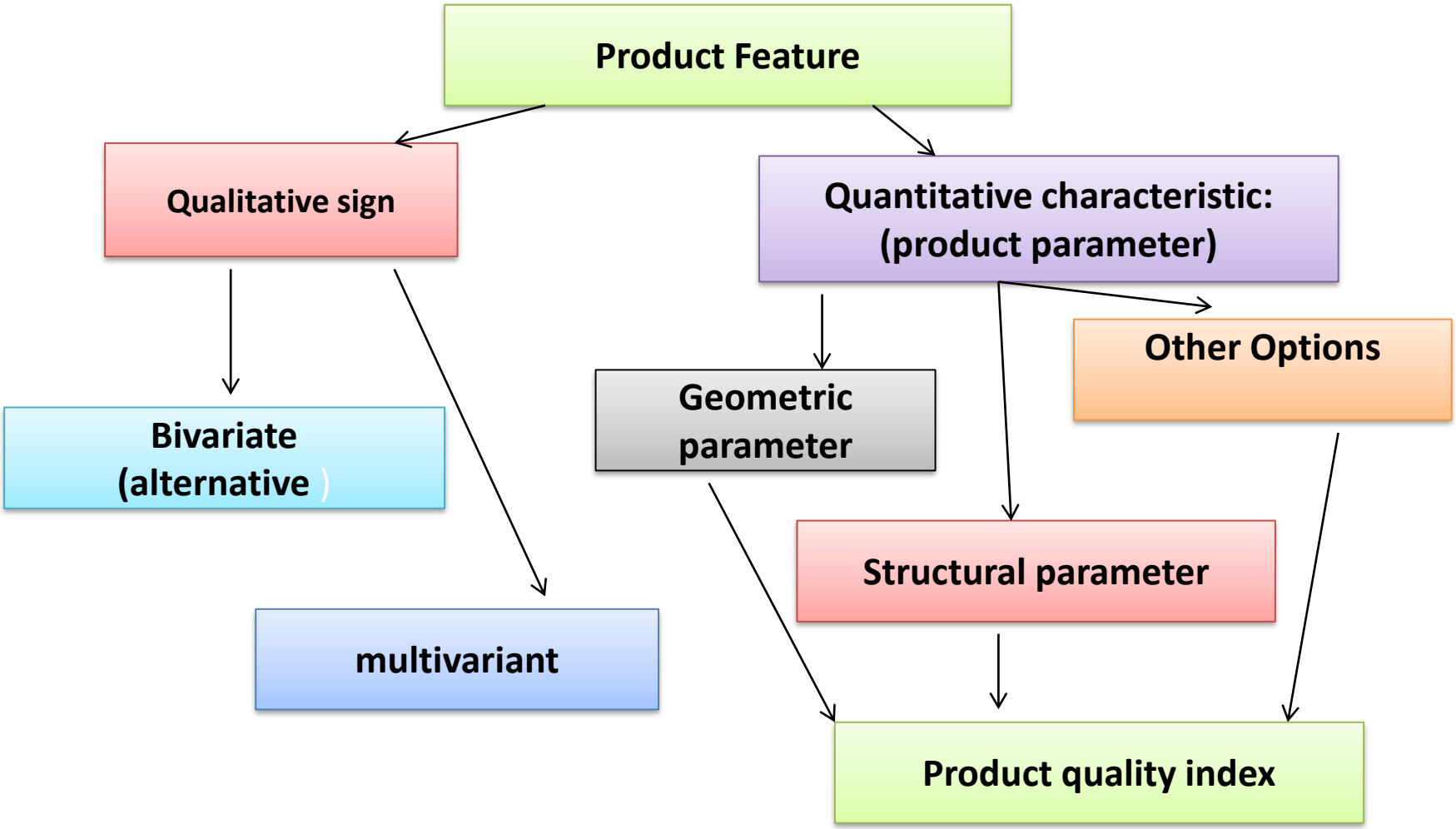


on the impact on the possibility of subsequent use of products:

destructive control, after which the used sample loses its properties and is not subject to further use for its intended purpose; non-destructive testing, after which the product does not lose its quality and can be used for its intended purpose;

according to the degree of mechanization: manual, mechanized, automated, automatic control;

Relationship between the concepts of "feature", "parameter" and "quality indicator" of products



STANDARDS

The quality of the goods is regulated by the standard.

Standard (from the English standard - norm, sample) - an official state or regulatory document of an industry, enterprise, firm that establishes the necessary quality characteristics, requirements that a given type of product or product must satisfy.

Regulatory document: A document that establishes rules, general principles, or characteristics relating to various activities or their results . (*GOST 1.1-2002. INTERSTATE STANDARD Interstate standardization system. Terms and definitions)*

Standard: ***A normative*** **document,** ***which is*** **developed by consensus,** ***adopted by a*** **recognized body** ***at the appropriate level , and establishes*** **for general and repeated use rules, general principles or characteristics regarding various activities or their results, and which aims to achieve an optimal degree of streamlining in a certain area.** (*GOST 1.1-2002. INTERSTATE STANDARD Interstate standardization system. Terms and definitions*

NOTE Standards should be based on the generalized results of science, technology and practical experience and aimed at achieving the optimum benefit to society.

Стандарт – это нормативно-технический документ по стандартизации, устанавливающий комплекс правил, норм, требований к объекту стандартизации и утвержденный компетентным органом.

Государственные стандарты РФ	Международные стандарты ИСО 9000
	

Categories of standards

International Standard: A standard adopted by an international standardization organization and available to a wide range of *users.*

1. International standards include **ISO standards, IEC standards and ISO/IEC standards, which are joint publications of ISO and IEC.**

2. In international standardization, along **with standards ,** ISO guides **(ISO Guide) , ISO / IEC** guides **(ISO / IEC Guide), ISO** technical reports , denoted by the index **[prefix] ISO / TO (ISO / TR),** international standardized profiles , indicated by the index [prefix] **ISO/IEC ISP (ISO/IEC ISP),** assessments of technology areas indicated by the index [prefix] ISO/OTN (ISO/TTA), ISO recommendations indicated by the index [prefix] ISO/R (ISO/R) , ISO specifications , denoted by the suffix [prefix] ISO/TS [ISO/TS], public ISO specifications , denoted by the suffix [prefix] ISO/OTS [ISO/PAS], industry technical agreements , denoted by the suffix [prefix] ISO/OTS [ISO/ITA].

Categories of standards

Regional standard: A standard adopted by a regional standardization organization and available to a wide range of *users.*
NOTE An example of a regional standard is the European standard designated by the suffix [prefix] EH [EN].

Interstate standard: A regional standard adopted by the Eurasian Council for Standardization, Metrology and Certification and available to a wide range of users.

National Standard: A standard adopted by a national standards body and made available to a wide range of *users.*

The national standards include the following categories of RF standards:

The State Standard of the Russian Federation (GOST R or GOST) is adopted by the Federal Agency for Technical Regulation and Metrology. It is compiled for organizational, methodological and general technical facilities, products, works and services of intersectoral and nationwide significance, therefore it is mandatory for all enterprises, organizations and institutions of Russian, republican and local subordination in all sectors of the national economy of Russia;

Industry standard (OST) - adopted by the state government body within its competence. It is mandatory for all enterprises and organizations of other industries that use or consume the products of this industry. Such standards are established for raw materials, semi-finished products used in this industry, as well as for certain types of consumer goods. Industry standards are approved by the ministry (department), which is the leader in the production of these products .

Enterprise Standard (STP) - adopted by the enterprise. It reflects the peculiarities of the technological process of obtaining goods inherent in each enterprise and contains a list of quality indicators that must not be lower than the requirements of GOST or OST for similar products.

Standard of the scientific and technical association (STO) - adopted by the scientific and technical, engineering society or other public association .

Types of standards depending on the object and aspect of standardization

Depending on the object and aspect of standardization, as well as the content of the established requirements, the following types of standards are developed:

- product standards;
- standards for the processes (work) of production, operation, storage, transportation, sale and disposal of products;
- service standards;
- fundamental standards (organizational-methodical and general technical);
- standards for terms and definitions;
- standards for control methods (tests, measurements, analysis).

- **State standard of Russia (GOST R)** - this is a type of standard that is being developed for products, works and services, the needs for which are **of an intersectoral nature; approved by the State Standard of Russia.**
- **Enterprise standard (STP)** - is developed in the absence of GOST R for the object of standardization.
- **Specifications (TS)** - this is the NTD that establishes the technical requirements that products must meet.
- **The quality standard for medicinal products** is a **regulatory document (RD)** containing **a list of standardized indicators and methods for drug quality control, approved by the Ministry of Health of the Russian Federation.**

PRODUCT STANDARDS

Product standards establish for groups of homogeneous products or for specific products the requirements and methods for their control in terms of safety, basic consumer properties, as well as requirements for the conditions and rules for operation, transportation, storage, use and disposal.

Characteristics of types of NTD

- ***A product standard*** *is* a normative technical document that ***establishes the requirements*** that a product or group of products must satisfy in order to ***ensure its suitability for its intended purpose.***

Main types of standards:

- ***State standard of Russia (GOST R or GOST)*** - This is a type of standard that is developed for products, works and services, the needs for which are of an intersectoral nature.

Its designation:

index registration number year of approval

Characteristics of NTD types (2)

❖ **Industry standard (OST)** - a type of standard developed in the absence of GOST R or, if it is necessary to establish requirements that *expand those established by GOST R.*

- It is established for additional technical requirements and group characteristics necessary for the manufacture and supply of drugs (terms, designations, acceptance rules, labeling, packaging, storage, transportation, etc.);
- Approved by the Ministry of Health of the Russian Federation and the medical industry.

Its designation:

OST 42-0002-16,

❖ **OST** - index,
❖ **42** - symbol of the ministry or department,
❖ **0002** - registration number in the department for the introduction of new drugs,
❖ **16** - year of approval.

Characteristics of NTD types (3)

- **Enterprise standard (STP) - is** developed in the **absence of GOST R or OST** for the object of standardization.

Its designation:

STP 424-11,

where

STP - index,

424 - registration number,

11 is the year of approval.

Characteristics of NTD types (3)

- **Specifications (TS)** *is* a normative and technical document that establishes the technical requirements that a product, process or service must satisfy.
- - They can be a standard or part of a standard.
- - Specifications are developed for one specific product, material or substance, or for several specific products, materials, substances, etc. (group TU).
- - The requirements established by the technical specifications *should not contradict the mandatory requirements of state (interstate) standards that apply to these products.*

Quality control of finished medical products and dietary supplements is carried out in accordance with the specifications.

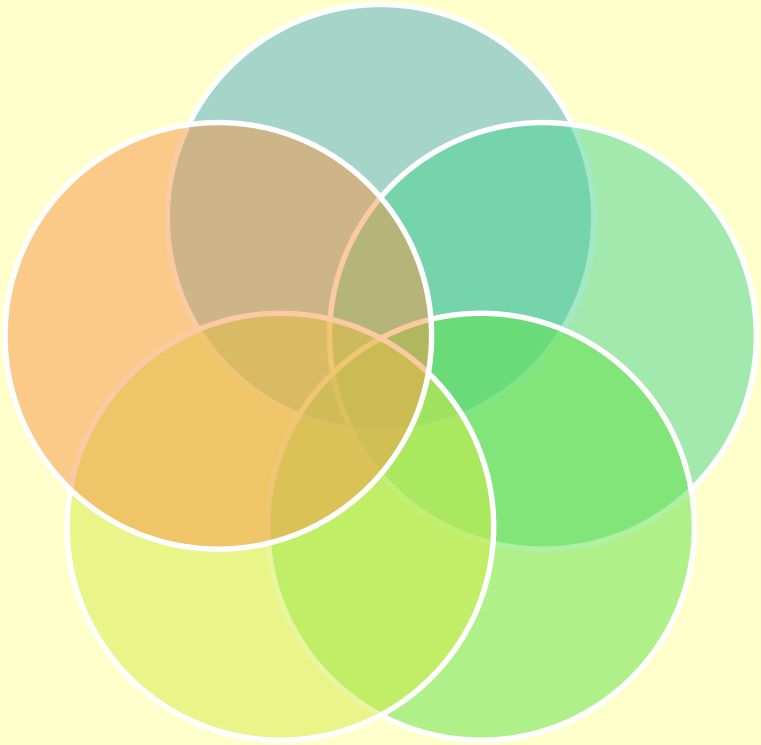
TU 64-1 323-19,

where, **TU -** index, **64** - number of the ministry and department, **323** - registration number, **19** - year of approval.

Characteristics of types of NTD for medical products

Types of NTDs used for medical products:

- operational documents.

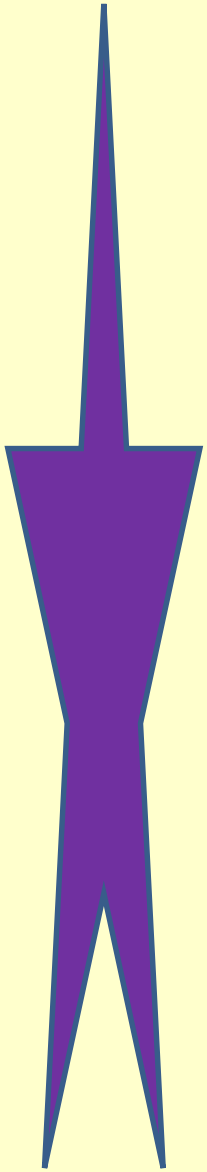


- GOST R

-THAT

-OST

The regulatory and technical documentation for PRODUCTS includes the following types of documents:



- technical conditions (TU);
- technological instruction (TI);
- technological regulations (TR);
- technological process (TP);
- safety data sheet (PB);
- label;
- formulation;
- quality passport.

OTHER TYPES OF DOCUMENTS

In addition to the NTD, there are also **operational documents** that are included in the product kit when they are released from the manufacturer.

A label is attached to simple products (product name, product designation and index, technical data, standard number or technical specifications to which the product complies, information about the acceptance of the QCD, information about the number of products in one package, release date).

OTHER TYPES OF DOCUMENTS (2)

Passports or forms are attached to complex products .

The passport indicates the main parameters and characteristics of the product, provides data similar to the information on the label, warranty obligations of enterprises, information on conservation and packaging.

If a magazine or leaflets are attached to the passport, which indicate the operation of the product and information about maintenance, then these **documents are called form** .

Where necessary, **operational documents are accompanied by a technical description and operating instructions.**

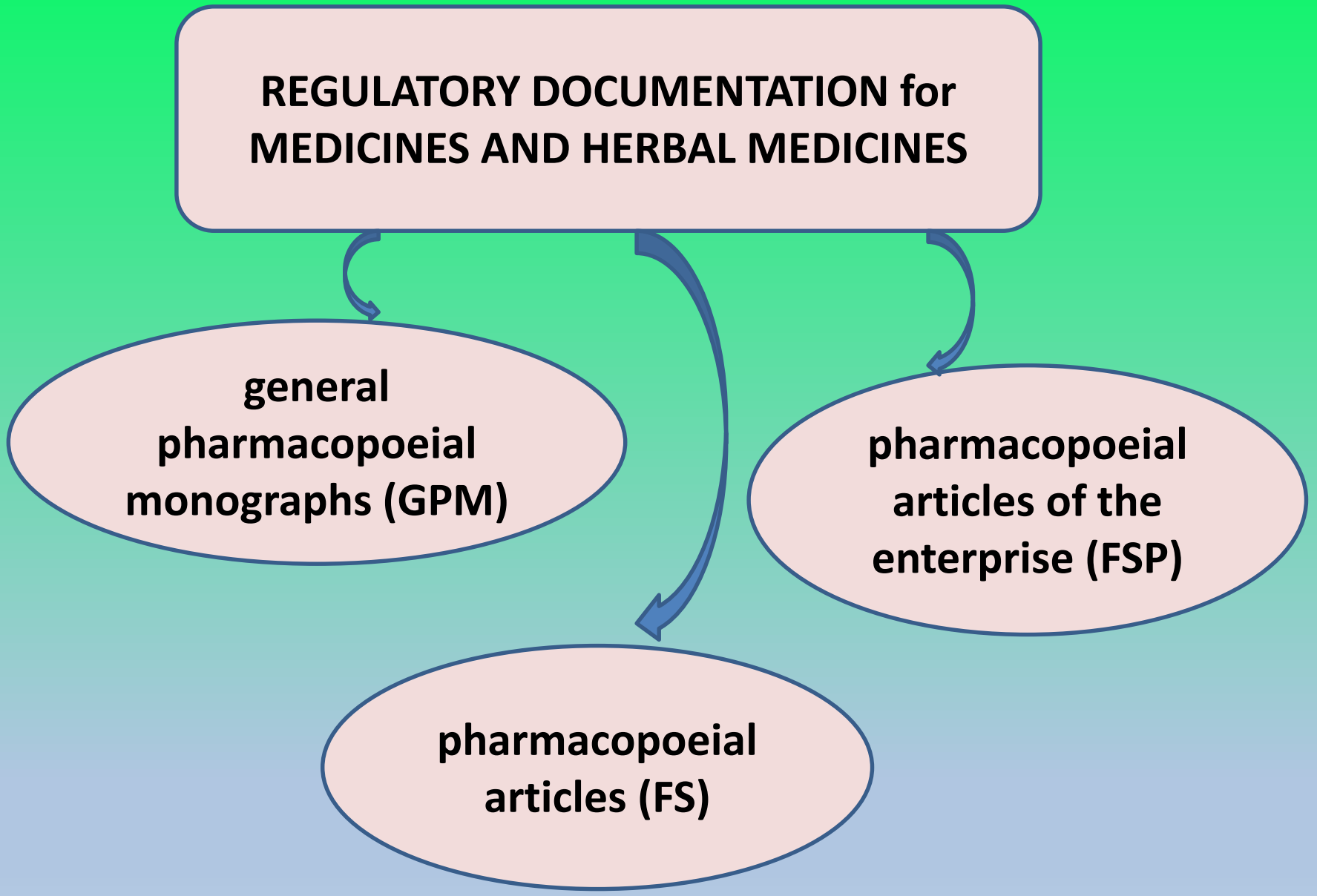
Quality standard for medicines

The drug quality standard is a ND containing a list of standardized indicators and methods for drug quality control, approved by the Ministry of Health of the Russian Federation.

Regulatory documentation for medicines

Regulatory documentation - a document containing a list of quality indicators of a medicinal product for medical use determined by the results of relevant examinations, methods for controlling its quality and established by its manufacturer. *(Federal Law No. 61 "On the Circulation of Medicines" (current edition)*

Regulatory document - a document containing a list of quality indicators and (or) quality control methods for a dosage form determined by the results of relevant examinations, descriptions of biological, biochemical, microbiological, physicochemical, physical, chemical and other methods of analysis of medicinal products for veterinary use, requirements for reagents used for this analysis, titrated solutions, indicators and established by its manufacturer. *(Federal Law No. 61 "On the Circulation of Medicines" (current edition)*


REGULATORY DOCUMENTATION for MEDICINES AND HERBAL MEDICINES
general pharmacopoeial monographs (GPM)
pharmacopoeial articles of the enterprise (FSP)
pharmacopoeial articles (FS)

Information contained in some types of NTD

FS	FSP	GOST, TU	GOST "Rules acceptance and test methods
Description	Description	Technical	Acceptance rules
Authenticity	Authenticity	requirements	Sampling and
quantitative	quantitative	Requirements	preparing them for
definition	definition	security	test
Package	Package	Acceptance rules	Methods
Marking	Marking	Test Methods	tests
Storage	transportation	Package	
Best before date	Snoring	Marking	
	Best before date	Transportation	
	Pharmacotherapeutic	Storage	
	Group	Guarantees	
		manufacturer	

Types of ND used for drugs and MPC

- ***General pharmacopoeial monograph (GPM)*** - general pharmacopoeial monograph - a document approved by the authorized federal executive body and containing a list of quality indicators and (or) quality control methods for a specific dosage form, medicinal plant materials, descriptions of biological, biochemical, microbiological, physicochemical, physical, chemical and other methods analysis of the medicinal product, as well as the requirements for the reagents used for this analysis, titrated solutions, indicators. *(Federal Law No. 61 "On the Circulation of Medicines" (current edition)*
- **Its designation:**

OFS-42-0007-19 ,

where: **OFS** - index,

42 - symbol of the ministry or department,

0007 - registration number,

19 is the year of approval.

Types of ND applicable to drugs and VP (2)

- **Pharmacopoeia article (FS)** - a document approved by the authorized federal executive body and containing a list of quality indicators and quality control methods for a medicinal product. *(Federal Law No. 61 "On the Circulation of Medicines" (current edition)*
- FS are approved for drugs that have the greatest therapeutic value, are widely included in medical practice and have high quality indicators. FS are included in the state pharmacopoeia (serial production).
- Its designation:

FS-42-00018-17,

where is **FS** -index,

42 - symbol of the ministry or department,

00018 - registration number,

17 is the year of approval.

Types of ND applicable to drugs and VP (3)

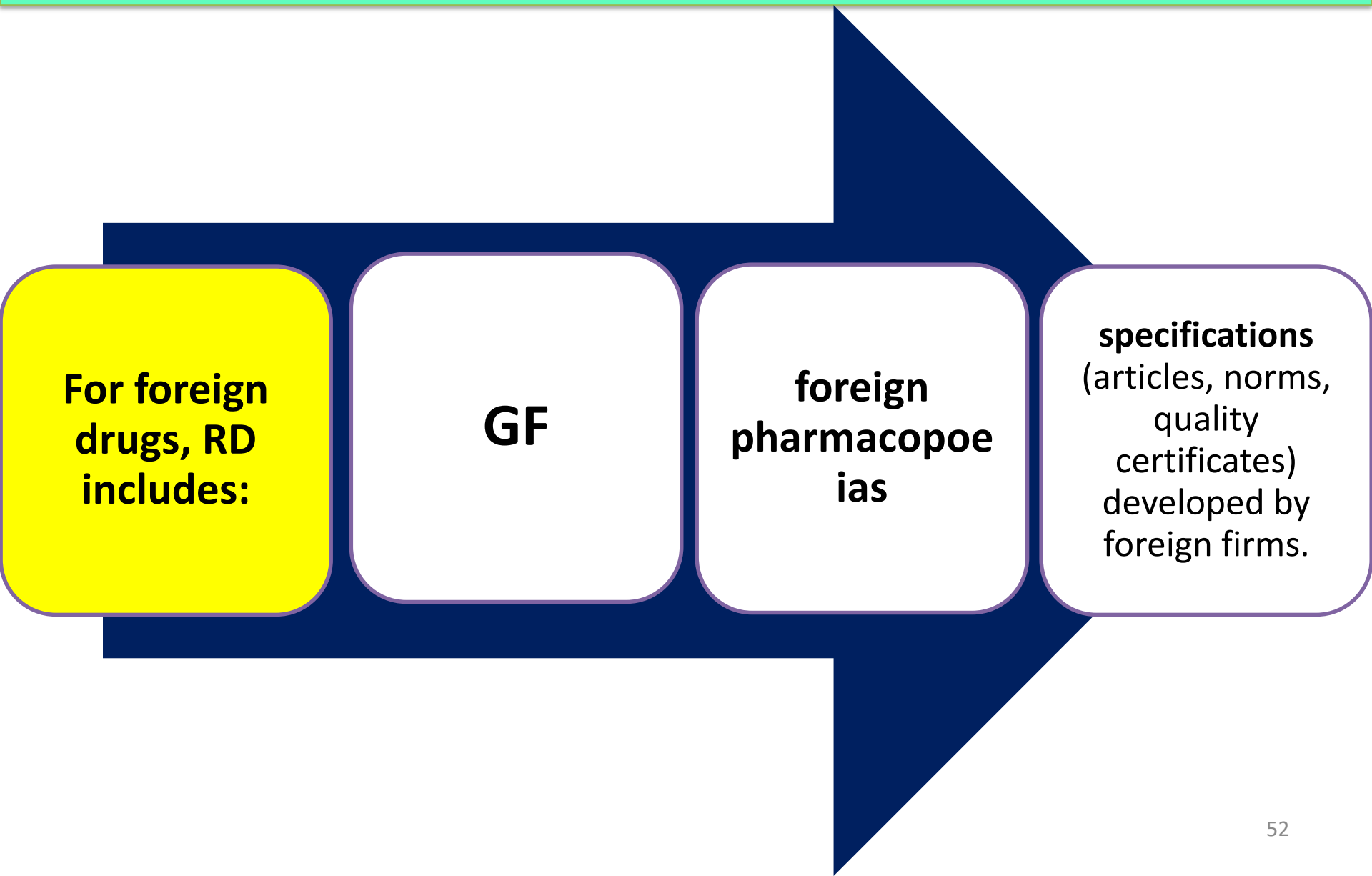
- **Pharmacopoeial article of the enterprise (FSP)** - a quality standard for drugs under a trade name, containing a list of indicators and methods for quality control of drugs produced by a particular enterprise, taking into account the specific technology of this enterprise and passed the examination and registration in the prescribed manner.

Its designation:

FSP-42-0208-00046-12,

- FSP - index,
- 42 - symbol of the ministry or department,
- 0208 - company code,
- 00046 – registration number of the standard,
- 12 - year of approval.

Types of ND for foreign medicines



PHARMACOPEIA - STATE QUALITY STANDARD

The term "Pharmacopoeia" comes from the Greek words pharmakon - medicine and poieo - I do, and is translated into Russian as a guide to the preparation of medicines.

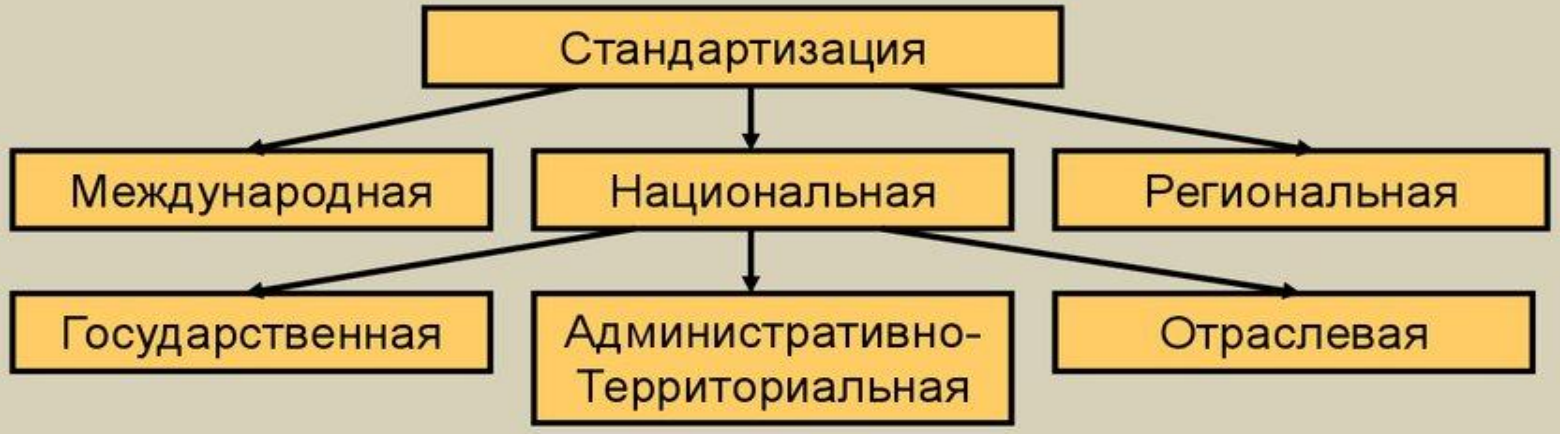
The State Pharmacopoeia (SP) is a collection of state drug quality standards that has a legislative nature.

Currently, the GF XIU edition is in force.

Standardization

Standardization - the activity of establishing rules and characteristics for the purpose of their voluntary reuse, aimed at achieving order in the areas of production and circulation of products and increasing the competitiveness of products, works or services.

Уровни стандартизации



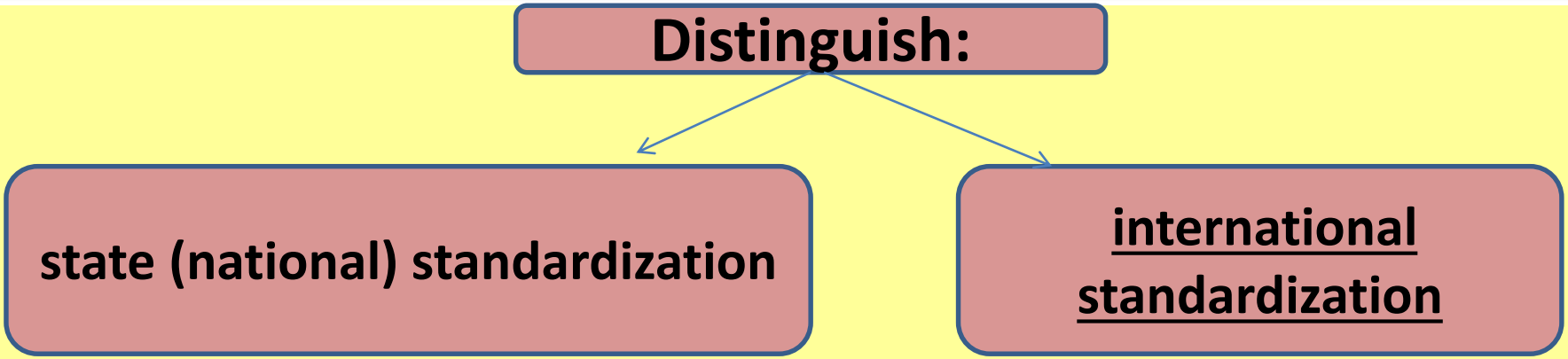
Международная стандартизация – участие в стандартизации открыто для соответствующих органов любой страны.

Региональная стандартизация – деятельность открыта только для соответствующих органов государств одного географического, политического или экономического региона мира.

Национальная стандартизация – стандартизация в одном конкретном государстве (при этом может осуществляться на разных уровнях: на государственном, отраслевом уровне, в том или ином секторе экономики, на уровне ассоциаций, производственных фирм, предприятий и учреждений).

Административно-территориальная стандартизация – стандартизация, которая проводится в административно-территориальной единице (области, крае и т.п.)

Standardization. General provisions



State standardization is a form of development and implementation of standardization, carried out under the guidance of state bodies according to unified state standardization plans .

International standardization is carried out by special international organizations or a group of states in order to facilitate mutual trade, scientific, technical and cultural ties.

International standardization

ISO (International standard Organization) is an authoritative international organization engaged in the development of international standards

ISO 9000, ISO 9001 series standards

quality assurance package

ISO 14000 series standards

package of documents on environmental management

The generality and universality of the ISO 9000, 9001 standards lies in the fact that the Quality Assurance models are not developed for any specific area - they are intended to be applied in all areas and for all countries.

The purpose of the state standardization system

In Russia operates **state standardization system (SSS)** , **uniting and streamlining work on standardization throughout the country, at all levels of production and management based on a set of state standards.**

The main goal of the State Standardization System is **to promote the proportional development of all branches of the state with the help of standards that establish indicators, norms and requirements that correspond to the advanced level of domestic and foreign science, technology and production.**

Goals and objectives of standardization

Establishment of requirements for the quality of finished products based on the standardization of its qualitative characteristics, as well as the characteristics of raw materials, materials, semi-finished products and components

Development and establishment of a unified system of indicators of product quality, methods and means of control and testing , as well as the required level of reliability of products, taking into account their purpose and operating conditions

Establishment of norms, requirements and methods in the field of design and production in order to ensure optimal quality and eliminate the irrational variety of types, brands and sizes of products.

Goals and objectives of standardization (continued)

Development of unification of industrial products, increasing the level of interchangeability , efficiency of operation and repair of products

Ensuring the unity and reliability of measurements , the creation of state standards of units of physical quantities

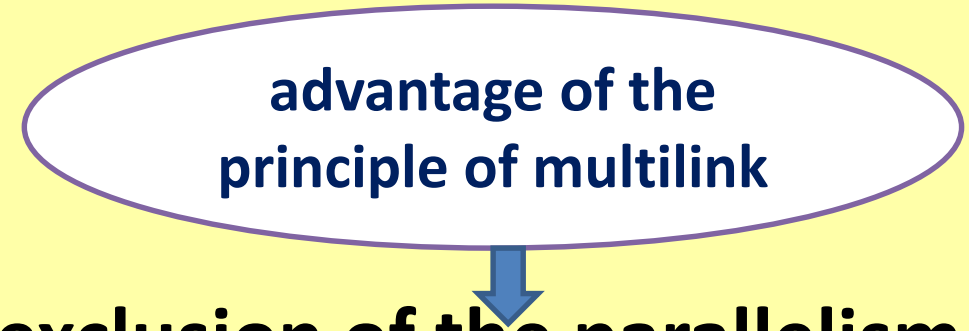
Establishment of unified documentation systems

Establishment of systems of standards in the field of ensuring labor safety, environmental protection and improving the use of natural resources

Standardization principles

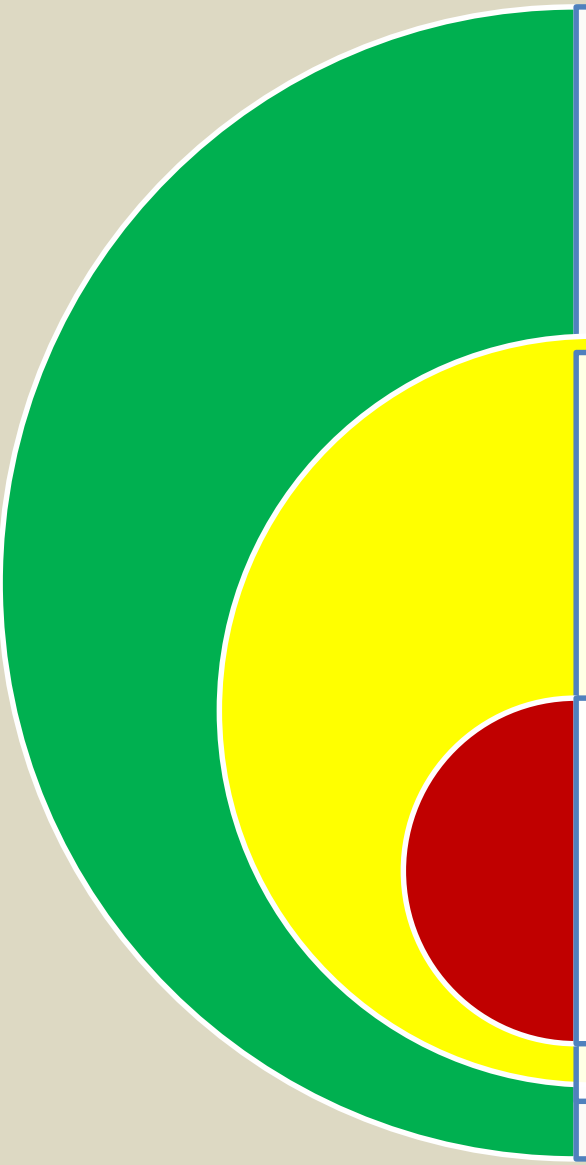
- ***complexity,***
- ***multi-layered and multi-linked ,***
- ***economical use of material resources,***
- ***use of progressive technologies.***
- An example of the implementation **of the principle of comprehensive standardization** is the standardization of medicines
- (***Standards and pharmacopoeia articles introduce increased requirements for the quality of raw materials, for the quality of equipment, devices that control the technological process of production, packaging, labeling, conditions for transportation and storage, etc.)***

- **The principle of multi-stage and multi-link** implies the stability and specificity of the objects of standardization at each level.
- Standards at different levels (state, sectoral, republican, enterprise standards) **are interconnected and represent links in the same chain.**



complete exclusion of the parallelism of standards, since state standards have their own objects, and republican and industry standards have their own.

The principle of economical use of material resources



The principle of economical use of material resources

- consists **in the standardization of materials used in the manufacture of certain products,** and contributes to the streamlining of the logistics of the enterprise.

For the first time, such a principle was widely applied during the Great Patriotic War, when standardization faced the task of maximizing the use of available material resources.

The principle of using advanced technologies

- - when **developing a product standard, the most progressive and efficient method** of manufacturing a product is used.
- In the case of developing a standard **for a production method** , a standard is created **for the most progressive method.**

STANDARDIZATION METHODS. UNIFICATION

- ***Unification***

- Practical work on standardization is carried out by various methods, the choice of which depends on specific tasks. These methods include:

unification *(lat. uni* - one, *facere* - do)

- ***— establishing uniformity, bringing to a single form (documents, parts, equipment, spare parts, etc.).***
- - **the most common and effective method of standardization;**
- - consists in a rational reduction in the number of types, types and sizes of products of the same functional purpose and is aimed at reducing the number of product varieties by combining them, changing the design.

STANDARDIZATION METHODS. SIMPLIFICATION.

Simplification

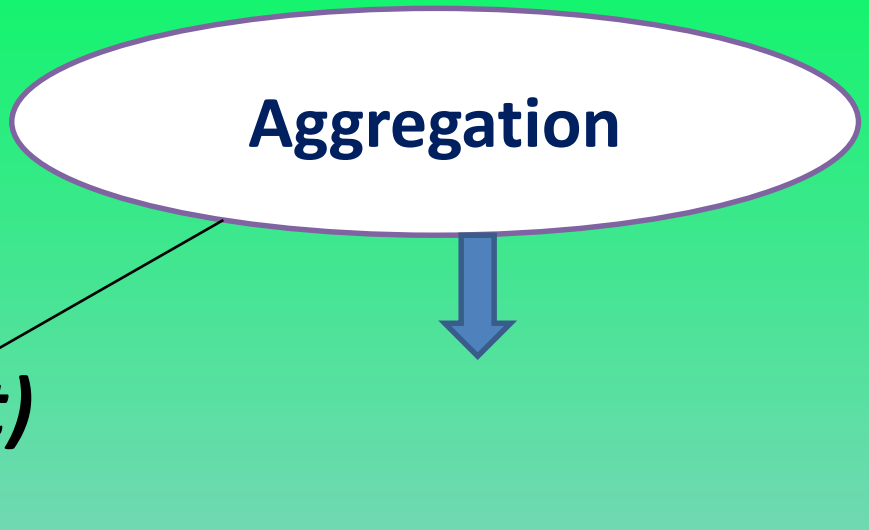
- - a form of standardization **, which consists** in **simply reducing the number of brands of semi-finished products, components** , etc. used in the development of a product or in its production. up to a quantity that is **technically and economically feasible, sufficient to produce products with the required quality indicators** .
- Being the simplest form and the initial stage of more complex forms of standardization **, simplification turns out to be economically beneficial, as it leads to simplification of production** , facilitates logistics, warehousing, and reporting.

STANDARDIZATION METHODS. TYPING

Typing

- - ***giving standard forms, using typical processes, techniques, and solution methods common to many objects.***
- **It consists in the development and establishment of standard design and technological solutions** that contain common characteristics for a number of products or processes and **can reduce the time spent on product design and development** .

STANDARDIZATION METHODS. AGGREGATION



(enlargement)

- - consists in the creation of medical devices and equipment **by arranging (assembling) them from a limited number of standard or unified parts** . This method makes it possible to use in the production of products unified and mastered in the production of parts and assemblies.

- **The basis** of the State Standardization System of the Russian Federation is **the Fund of laws, by-laws, normative documents on standardization.**
- **The Fund presents a four - level system:**

Technical legislation - the legal basis of the GSS

State standards, all-Russian classifiers of technical and economic information

Industry standards and standards of scientific, technical and engineering societies

Enterprise Standards and Specifications

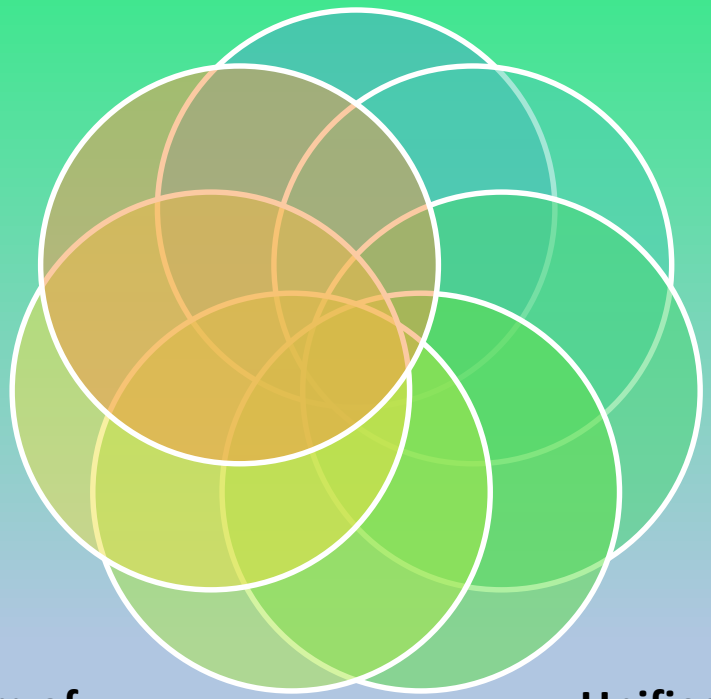
Unified state systems of standards

Such systems include:

State System for Ensuring the Uniformity of Measurements (GSI),

State Standardization System (SSS),

Unified system of classification and coding of technical and economic information
,



Unified system for design documentation (ESKD),

Unified system of technological documentation (ESTD),

Unified system of technological preparation of production (ESTPP),

QUALITY ASSURANCE IN THE SPHERE OF MEDICINES CIRCULATION

Pharmaceutical products, like other groups of goods, go through various stages of the life cycle (quality loops). Product quality is planned and shaped in the production area (during the design or planning process, as well as in the production or implementation process) and is subject to changes in the consumer (during operation).

The requirements of each stage are reflected in the respective good practice guides.

In most countries **, good practice standards are requirements set by healthcare organizations during the development, research, production and distribution of medicines .**

Good practice guidelines set quality standards at various stages of the drug life cycle.

All good practices are links in the same chain, since each practice occupies its own segment of the product life cycle.

GOOD PRACTICES

***Good Laboratory Practice (Good Laboratory Practice - GLP)* - a** set of rules for planning, performing, controlling, evaluating and documenting laboratory studies that are part of the preclinical study of medicinal products and ensure the quality, accuracy and completeness of the data obtained.

Good Clinical Practice (Good Clinical Practice - GCP) - a set of rules for planning, performing, evaluating and documenting clinical trials of medicinal products, compliance with which ensures the accuracy of the data obtained, the protection of the rights of persons participating in the trials, and the confidentiality of data about these persons.

Good manufacturing practice* (*Good Manufacturing Practice - GMP) - a set of rules for the organization of production and quality control, which are part of the quality assurance system. Compliance with the requirements of good manufacturing practice ensures the stable production of medicines in accordance with the requirements of regulatory and technical documentation and quality control in accordance with analytical regulatory documentation.

GOOD PRACTICES (2)

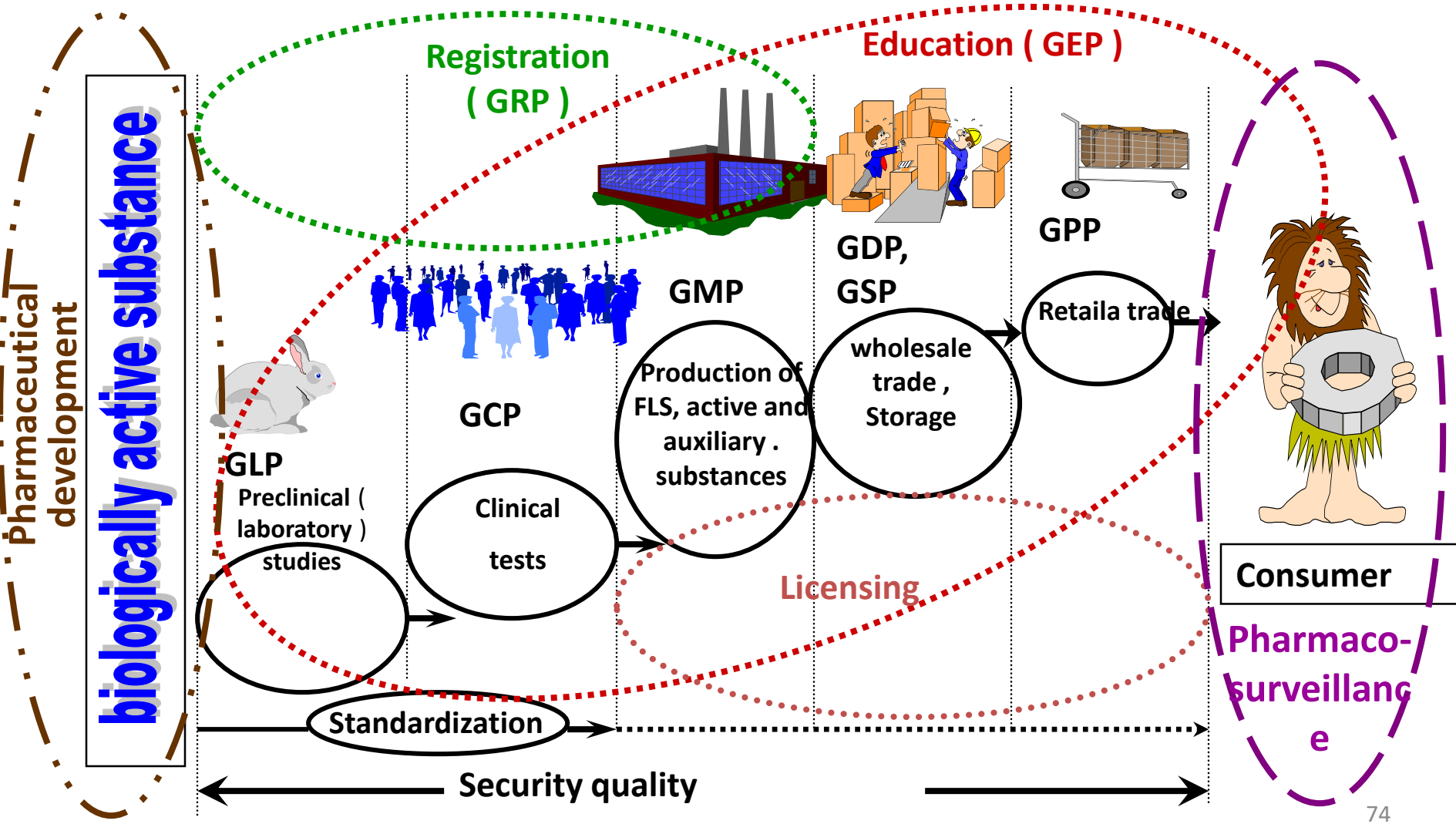
Good Practice for the Storage of Pharmaceutical Products (Guide to Good Storage practice for Pharmaceuticals - GSP) - special measures necessary for the proper storage and transportation of pharmaceutical products. These measures can be adapted, if necessary, to a specific situation, provided that all quality standards are met.

Good Distribution Practices (Good distribution Practice - GDP) - a set of rules and requirements for distribution, compliance with which ensures the quality of medicines in the process of managing and organizing their wholesale distribution at all its stages.

Good Pharmacy Practice (Good Pharmaceutical Practice - GPP) - activities related to the supply, storage and use of medicines and medical products, carried out in pharmacies, medical institutions and at home.

Good Practice for National Drug Control Laboratories (Good practices for National Pharmaceutical control Laboratories - GPCL / WHO) is a set of criteria for the work of a drug control laboratory that provides the basis for the correct assessment of results and conclusions about the compliance of the quality of drugs with the requirements of specifications.

Elements ensure quality medicinal funds based _ principles “proper practitioner”



Certification

Certification is a form of implementation by the certification body of confirmation of compliance of objects with the requirements of technical regulations, the provisions of standards or the terms of contracts.

Goals of certification

The main goal of certification is to **protect the rights and interests of consumers , to conduct a unified state policy in the field of providing the population.**

The system of certification of medical devices **is aimed at achieving the following goals:**

- **assistance to consumers in the competent choice of products;**
- **promoting exports and increasing the competitiveness of products;**
- **consumer protection from an unscrupulous manufacturer;**
- **safety control for the environment, life, health;**
- **confirmation of product quality indicators.**

PROCEDURE FOR CERTIFICATION OF PRODUCTS

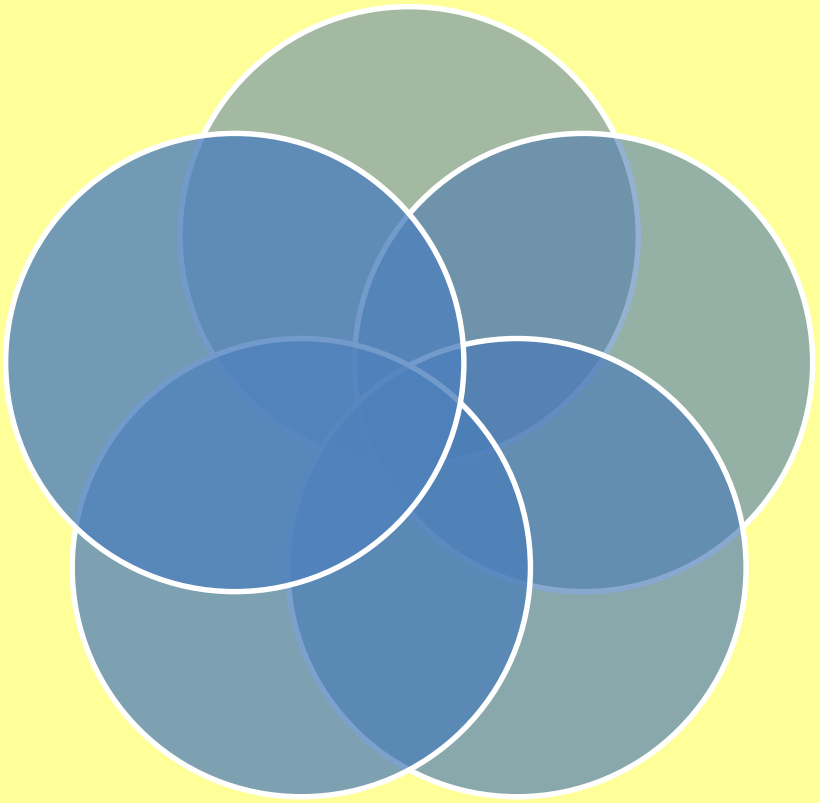
Product certification is carried out in the following order:

- filing an application for certification;
- consideration and adoption of a decision on the application;
- selection, identification of samples and their testing;
- verification of production (if provided by the certification scheme);
- analysis of the obtained results, decision making;
- the possibility of issuing a certificate;
- issuance of a certificate of conformity;
- inspection control over certified products in accordance with the certification scheme.

CONFIRMATION METHODS

The **methods of proof** are:

- consideration of the application-declaration (with attached documents).



- trial;

- verification of production (used when an analysis of the technological process is necessary to assess the quality);

- inspection control (provided for in most schemes, it is carried out after the issuance of a certificate);

Declaration of Conformity

Declaration of conformity - a form of confirmation of product compliance with the requirements of technical regulations.

The Declaration of Conformity is an alternative system for confirming product quality by a seller or manufacturer .

Declaration of conformity of goods differs little from the mandatory certification procedure . The only **significant difference is that when declaring, it is the applicant who is responsible for the completeness and truthfulness of the specified information on the declared goods.**

Mandatory confirmation is carried out in the form of acceptance of a declaration of conformity and mandatory certification.

During certification, confirmation of conformity is carried out by an independent party - the certification body, and when declaring, confirmation of conformity is carried out by the manufacturer or supplier.

A declaration of conformity is **a document in which a manufacturer, seller or performer certifies that the product supplied, sold by him or the service provided (hereinafter referred to as the product) meets the requirements for mandatory certification or service.**

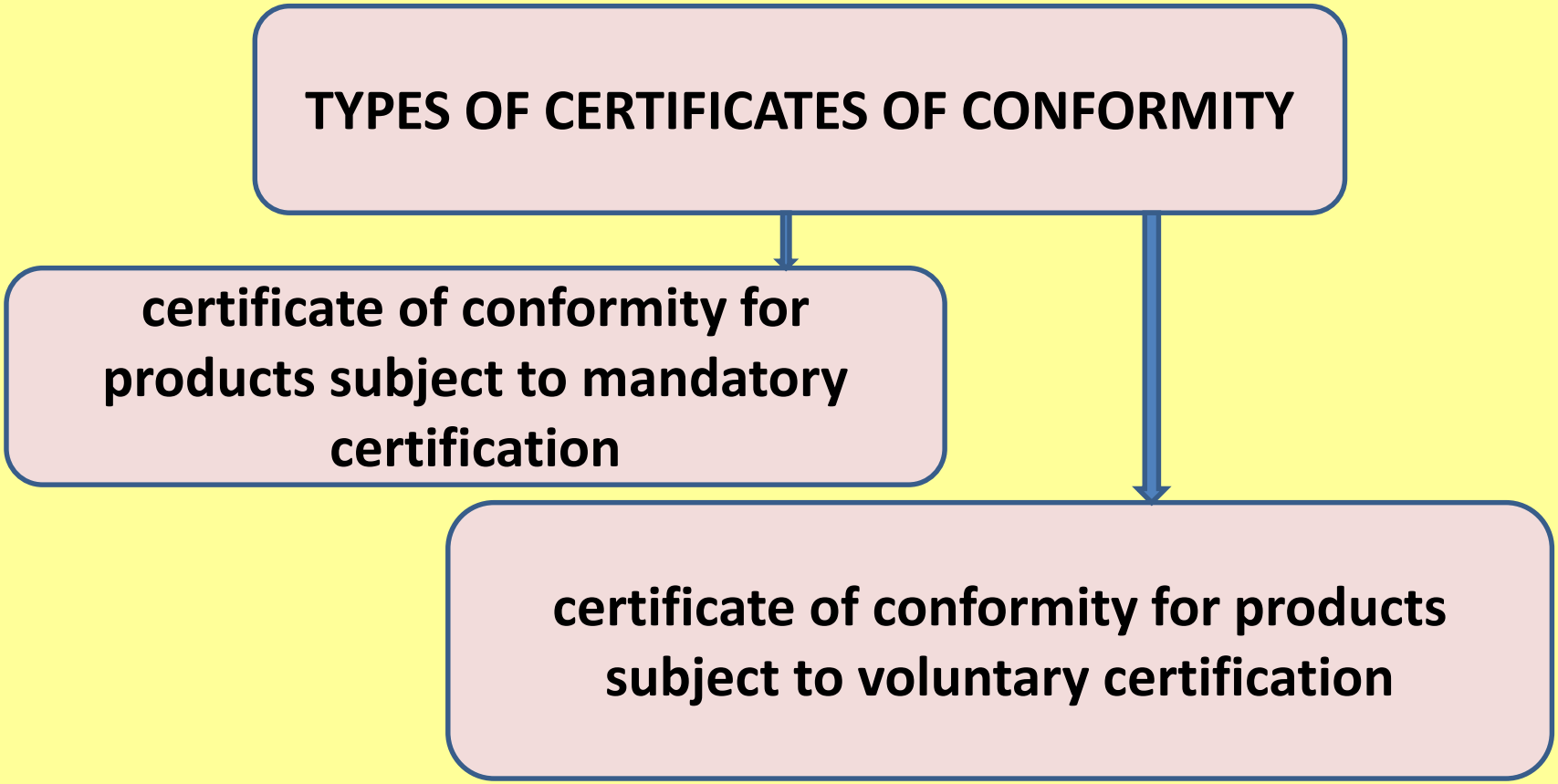
The declaration of conformity and the certificate of conformity have equal legal force and are valid throughout the territory of the Russian Federation in respect of each unit of products put into circulation in the territory of the Russian Federation **during the validity of the declaration of conformity or the certificate of conformity, during the shelf life or service life of the products** established by in accordance with the legislation of the Russian Federation.

The emerging trend in Russia to reduce the list of products subject to mandatory certification will contribute to **the expansion of voluntary certification, which is a market tool to combat counterfeit products.**

Certificates of conformity for a particular **product** are issued **by certification bodies** that have the appropriate **accreditation** - permission to issue certificates of conformity, based on the documents submitted by them for products, the main of which is **the test report.**

- **Test reports are issued by an accredited testing laboratory after testing appropriately selected product samples.**
- **A test report is a document containing test results.**
- **NB!**
- **the certificate of conformity must be accompanied by a test report from an accredited testing laboratory**
- There **are two signatures on the bottom of the certificate itself:**
- - head of the certification body;
- - an expert on this product, which, like the research laboratory and certification body, has a narrow scope of accreditation.

- **The certificate of conformity (quality certificate, safety certificate, customs certificate)** is **a document confirming that the product meets the quality and safety requirements established for this product by the current standards and regulations .**



CERTIFICATION OF MEDICAL DEVICES

Before selling medical devices, it is necessary to assess their compliance with current legal requirements. Permits guarantee the high quality of products, because the life and health of patients depends on it.

Certification of medical devices is a verification procedure carried out by authorized bodies (centers) at the request of manufacturers or importers of goods.

Certification and declaration of medical devices

In order to confirm the conformity of the goods to a certain level of quality specified in the NTD, certification and declaration of conformity are carried out.

The objects of certification are determined by **Decree of the Government of the Russian Federation of December 1, 2009 N 982 (as amended on July 4, 2020) "On approval of a single list of products subject to mandatory certification and a single list of products whose conformity is confirmed in the form of a declaration of conformity"**

Certification of medical devices

It is carried out in accordance with the Federal Law of the Russian Federation "On Certification of Products and Services".

The product certification system includes two interrelated parts :

certification of conformity of production (quality systems) - compliance with the requirements of international rules of the organization, standards is confirmed by a competent organization that has passed the appropriate accreditation;

product conformity certification - confirmation of product compliance with the requirements established in the RD.

Certification of medical equipment is carried out by the Federal Agency for Technical Regulation and Metrology, certification bodies and testing laboratories (centers).

Certification tests are subjected to MT that have passed acceptance and acceptance tests and registration.

The assessment of product conformity with the established requirements is carried out by an expert of the certification body after analyzing the test reports (issued by testing laboratories), assessing production, certifying production and studying other documents on product compliance.

Based on the expert opinion, the certification body decides to issue a certificate, draws up and registers it.

The validity period of the certificate for MT is established by the relevant technical regulations.

A record of the certification carried out indicating the number and date of issue of the certificate is made in the technical and shipping documentation.

Equipment subject to mandatory certification

Products used in medicine are usually classified depending on the magnitude of the potential hazard:

Class 1 (low risk) - microscopes, medical scales;

class 2a (medium risk) - laboratory equipment;

2b class (increased degree of risk) - defibrillators, cardioanalyzers ;

Grade 3 (high risk) - endoprostheses.

The following products are subject to mandatory quality and safety checks:

- Medical equipment;
- surgical implants;
- therapeutic and diagnostic devices;
- medical kits;
- control and measuring equipment;
- materials used in surgery;
- medical instruments;
- dental materials;
- prosthetic and orthopedic goods;
- polymer medical products.

Enterprises that decide to engage in the manufacture and sale of medical products are **required to issue permits. The same rule applies to companies organizing import deliveries to the territory of Russia.**

The list of required documents may include:

declaration GOST R (according to the requirements of RF PP No. 982) - is developed during the conformity assessment of diagnostic gloves, masks, instruments, paper products, dressings, furniture, dental materials, tubes, catheters, lenses;

registration certificate of Roszdravnadzor (according to the rules of the RF GD No. 1416) - issued for all medical products (including medicines) and is unlimited;

certificate of approval of the types of measuring instruments (SUTSI) - must be obtained for measuring instruments (tonometers, cardiographs, scales).

Declaration GOST R

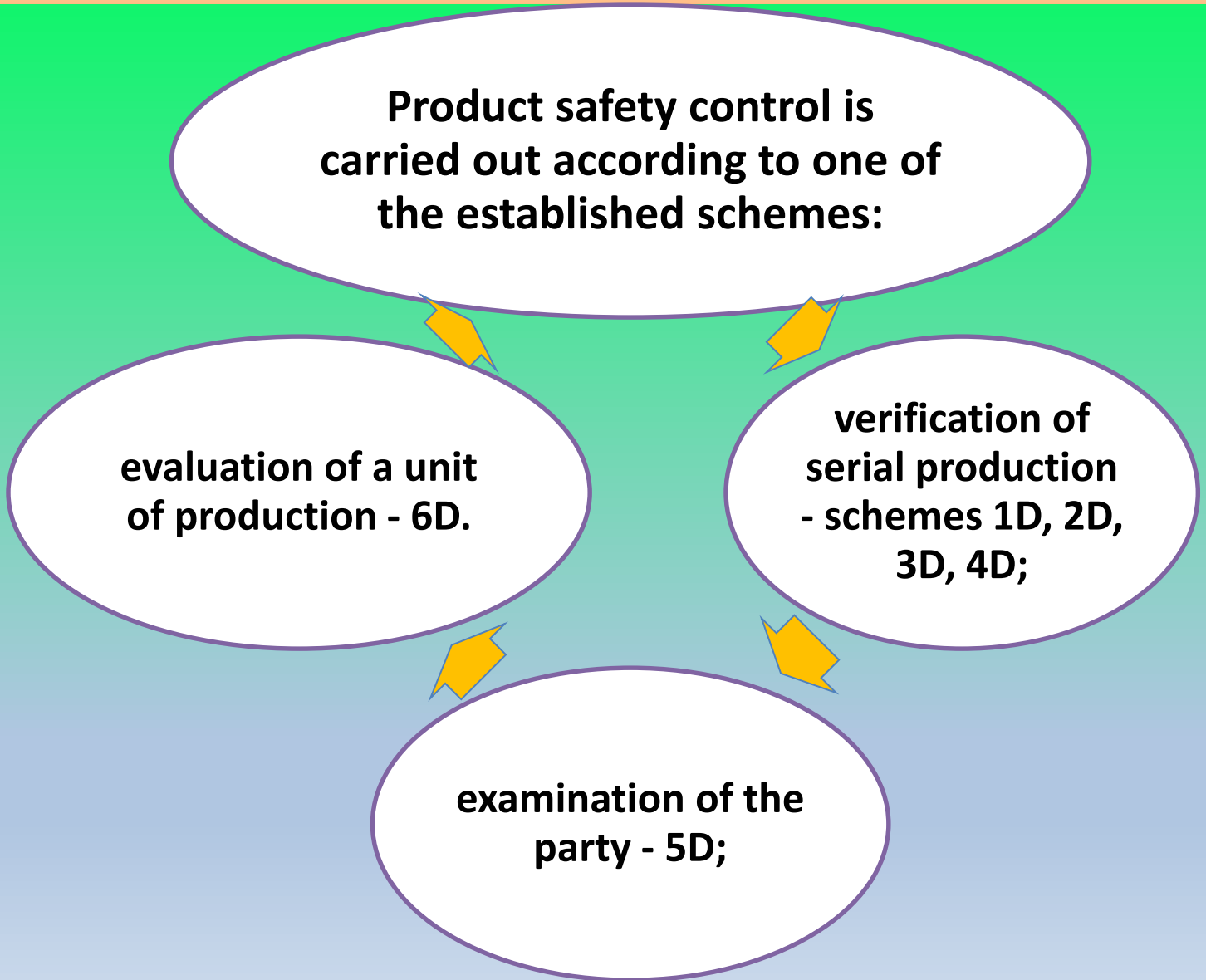
The document is legally valid in Russia for three years from the date of registration. Before issuing the declaration, a unique number is assigned, which is entered in the unified register of the FSA. This is the main indicator of the authenticity of the permission and its legitimacy.

Conformity assessment is carried out in specialized laboratories and is a check of the quality and safety of the goods, as well as an analysis of the registration and technical information of the entrepreneur.

The declaration is drawn up on a simple white sheet of A4 format, contains important data about the product and its manufacturer (applicant).

Only resident companies of the Russian Federation can apply to an authorized center for registration of a document, foreign enterprises need an official representative from our country.

Declaration schemes



Why is a voluntary quality assessment needed?

A voluntary certificate is an important competitive advantage for doing business. It testifies to the compliance of products with the requirements of national standards, which the entrepreneur can choose independently.

For example, these could be:

GOST ISO 13485-2017 Medical products. Quality management systems. Requirements for regulatory purposes;

GOST 31508-2012 Medical products. Classification depending on the potential risk of use. General requirements.

Voluntary evaluation will allow winning government tenders and making large deliveries to medical institutions that have strict requirements for products.

Stages of issuing a certificate

- contacting a reliable center that issues only legitimate documentation;
- filling out an application for the provision of services and transferring the necessary documentation;
- product identification and selection of a suitable scheme;
- signing an agreement between the parties and paying an advance;
- study of the data provided by the experts of the center;
- selection of samples for testing and examination;

Stages of issuing a certificate

preparation of protocols;

registration of the finished document in the FSA register and sending to the client (on condition that the studies have confirmed the compliance of the products with the current standards).

Further, the goods are marked with the sign of conformity "PCT". Now the entrepreneur can carry out the turnover of products throughout Russia legally.

TECHNICAL REGULATION WITHIN THE EAEU, THE CUSTOMS UNION

DECISION No. 1510 of November 26, 2019 ON THE PROCEDURE FOR INTRODUCING MEDICINES FOR MEDICAL USE IN CIVIL CIRCULATION

In accordance with Article 52.1 of the Federal Law "On the Circulation of Medicines", the Government of the Russian Federation decides:

1. Approve the attached:

Rules for the submission of documents and information on medicinal products for medical use introduced into civil circulation;

Rules for issuing a test report on the compliance of the first three batches or batches of a medicinal product for medical use (with the exception of an immunobiological medicinal product), first produced in the Russian Federation or imported into the Russian Federation for the first time, with the quality indicators provided for by regulatory documentation;

Rules for issuing permission to put into civil circulation a series or batch of an immunobiological medicinal product, issuing a conclusion on the compliance of a series or batch of an immunobiological medicinal product with the requirements established during its state registration;

Rules for making a decision to terminate the civil circulation of a series or batch of a medicinal product for medical use.

REGULATION No. 1510 of November 26, 2019 ON THE PROCEDURE FOR PUTTING MEDICINES FOR MEDICAL USE IN CIVIL CIRCULATION (3)

This ordinance entered into force on November 29, 2019.

THANK YOU FOR ATTENTION!