GLP Planet

GLP-planet
Session 1
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Harmonization of requirements for preclinical studies - Russia, EURASEC, OECD

ДОМ НПО ФАРМАЦИИ

Preclinical Center Quality Management System
Per aspera ad astra

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Topic	ISO 9000	GMP	GLP
Year of creation	**1947**	**1963**	**1978**
Standard focus	Quality management system and customer satisfaction. Continuous improvement effective resource management	Requirements for the organization of production and quality control of medicines for medical and veterinary use	The organizational process and the conditions under which the laboratory plans, conducts, and monitors studies. All research data is recorded and reported. Means are provided to maintain the quality and integrity of research data. Guaranteed the ability to retrospectively verify this data.
The first document in the Russian Federation	**1987**	**1974** **(before good practices)** **2000 (GMP)**	**2010**
History of the standard in the Russian Federation	**5** standard versions	**8** various types of documents (GOST, Government Decisions, Orders, etc.)	**2** consecutive GOST (GOST R 53434-2009 and GOST 33044-2014) and 1 order (№199n), duplicating each other
Quality policy	The main directions and goals of the organization in the field of quality, formally formulated and documented by top management		Not mentioned
Quality objectives	The result to be achieved. They can be strategic, tactical or operational.		Not mentioned
Quality manual	A document describing a quality management system. Not binding since 2015		Not mentioned

Additional standards were not issued sequentially!

- GOST 33647-2015 Terms and definitions
- GOST 31879-2012 Guides for compliance monitoring procedures for GLP Principles
- GOST 31880-2012 Guidance for the conduct of laboratory inspections and study audits
- GOST 31881-2012 The role and responsibilities of the study director in the application of GLP Principles
- GOST 31882-2012 Establishment and Control of Archives
- GOST 31883-2012 Quality assurance in the application of GLP principles
- GOST 31884-2012 Compliance of laboratory suppliers with GLP principles
- GOST 31886-2012 Application of the GLP principles to short term studies
- GOST 31888-2012 he role and responsibilities of the sponsor in the application of GLP principles
- GOST 31890-2012 Organization and management of multi-site studies
- GOST 31891-2012 Application of GLP principles to in vitro studies
- GOST 31900-2012 Guidance for the preparation of GLP inspection reports

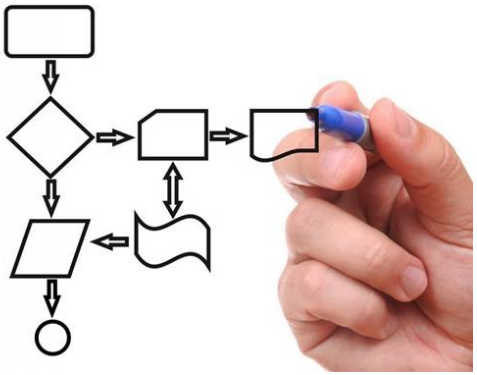
Quality management principles

1 – Customer focus

2 – Leadership

Quality management principles

3 – Staff involvment



4 – Process approach

Quality management principles

5 – Enhancement

6 – Factual decision making

Quality management principles

7 – Interaction management

COMMUNICATION OF THE PROCESS APPROACH AND RISK MANAGEMENT

Not all processes of the quality management system have the same level of risk in relation to the organization's ability to achieve its goals.

In accordance with the requirements of par. 6.1 ISO 9001:2015, the organization is responsible for applying risk-based thinking and for actions in relation to risk, including the feasibility of registering and maintaining documented information as evidence of the identification of risks by the organization

RISK
Temperature offset of laboratory animals outside recommended ranges

Guidelines / recommendations for keeping laboratory animals	Animal species/temperature maintenance, °C		
	Mice	Rats	Guinea pigs
Guide for the care and use laboratory animals	20 – 26	20 – 26	20 – 26
Guidelines on care of laboratory animals and their use for scientific purposes	19 – 23	19 – 23	16 – 23
Code of practice for the housing and care of animals bred, supplied or used for scientific purposes	20 – 24	20 – 24	15 – 21
Guidelines for accomodation and care of laboratory animals	20 – 24	20 – 24	20 – 24

Responsibilities of quality assurance staff
Eurasian Economic Commission (EEC) Council decision of 3 November 2016. N 81 " Approval of the Good Laboratory Practice Rules of the Eurasian Economic Union in the Circulation of Medicines"

The responsibilities of the staff responsible for quality assurance include:

- a) development of SOPs and their implementation in a testing laboratory, systematic verification of their compliance;
- b) conducting an inspection in order to confirm compliance of the study with these Rules, the availability of study plan and SOP for staff, as well as confirmation of the fact of their implementation during the study;
- c) verification of final reports to confirm that the methods, procedures, observations and results are presented accurately and fully reflect the raw data;
- d) written communication (report) on the results of inspections to the top management of the testing laboratory, study director, lead investigator and, if necessary, other senior employees;
- e) preparation and signing of the conclusion attached to the final report, which indicates the types of inspections, their dates, including information on the stages of the test being examined, and the date the inspection results were passed on to the test laboratory top management, study director and lead investigator. This conclusion should also contain information that the raw data are reliably reflected in the final report.

Qualification of quality assurance staff
Eurasian Economic Commission (EEC) Council decision of 3 November 2016. N 81 " Approval of the Good Laboratory Practice Rules of the Eurasian Economic Union in the Circulation of Medicines"

- Quality assurance stuff must undergo appropriate training and have the experience necessary to carry out their duties. Employees should be familiar with the research procedures, standards and systems used in the testing laboratory.
- Persons assigned to perform quality assurance functions should have an understanding of the basic principles of controlled activities. They must also have a clear understanding of these Rules.
- If the quality assurance officer does not have special knowledge or if another person's opinion is required, then expert assistance should be sought. Top management should ensure that there is a documented training program covering all aspects of the quality assurance work. Attendance at internal and external seminars and courses can be arranged. Training should be provided on communication and conflict resolution techniques. Training should be ongoing and subject to periodic review.
- The training of quality assurance personnel should be documented and their competency should be assessed. These documents must be constantly updated and maintained.

Research Center competency

- the presence of specialists with specialized education;
- availability of timely training;
- availability of publications on the topic of study;
- H-index of study director and key investigators involved.

Thanks for your attention!