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HARMONIZATION OF QUALITY SYSTEMS OECD GLP AND NATIONAL STATE STANDART ISO/IEC 17025 IN UKRAINE

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ABSTRACT. *The article deals with the features of quality systems OECD GLP and National State Standard ISO/IEC 17025. The necessity of harmonization and compatibility of data of different quality systems within one organization is reasoned in this work. A risk management system aimed at identifying, analysing and reducing probability of an unfavourable result and minimizing possible losses were considered.*

Key Words: *OECD GLP, ISO/IEC 17025, risk management, harmonization of quality systems.*

Introduction. A distinctive feature of the current stage of development of research activities in Ukraine is focus on harmonizing the functional interaction of generally accepted international requirements of quality management systems during conducting chemical safety assessment studies. An important place in this harmonization is taken by the implementation into practice of research organizations, where domestic regulatory requirements already exist (ISO/IEC 17025: General requirements for the competence of testing and calibration laboratories), principles of Good Laboratory Practice (OECD GLP).

OECD GLP principles is a quality system of management controls for research laboratories and organizations to ensure the uniformity, consistency, reliability, reproducibility, quality, and integrity of various chemicals in non-clinical studies.

ISO/IEC 17025 is a technical competence and management system standard developed specifically for testing and calibration laboratories. ISO/IEC 17025 is applied to a broad range of laboratories, including non-clinical laboratories.

The same processes proceeded in different research departments of the same organization are often duplicated during conducting the study and preparation of documentation. Sometimes “duplication” leads to misunderstanding or inconsistency of interpretations of the same processes from the point of view of different quality systems. Therefore, providing harmonization and compatibility of various quality systems is an urgent task, the solution of which will allow to avoid ambiguity and reducing the quantity of documents aimed at providing and adherence of research processes in the laboratory, and will improve its quality.

The purpose of the study was to introduce unified approaches of OECD GLP and ISO/IEC 17025 quality systems in safety assessment of chemicals.

Materials and Methods. Expert-analytical review of OECD GLP and ISO/IEC 17025 regulatory documents has been conducted.

Results and Conclusions. Quality system ISO/IEC 17025 is implemented in various research organizations which allow to obtain technically reasonable testing results. GLP accreditation is required in order to compare the quality of study results in order to mutually recognize data between research organizations of different countries. State enterprise «L.I. Medved's Research Centre of Preventive Toxicology, Food and Chemical Safety, Ministry of Health» (Research Centre) has implemented two quality systems: OECD GLP and National State Standard ISO/IEC 17025. Research Centre has a Quality Control Department which entities audits and supports quality of all procedures involved in studies in accordance with this two quality systems (fig. 1).

Research Centre conducts non-clinical (toxicological) and field studies in accordance with the requirements of GLP (accreditation certificate of the Slovak National Accreditation Service (SNAS) № G-042) and physico-chemical, medico-biological, microbiological, ELISE tests are conducting in accordance with the require-

Fig. 1. Quality Control Department of L.I. Medved's Research Centre of Preventive Toxicology, Food and Chemical Safety, Ministry of Health of Ukraine

ments of National State Standard ISO/IEC 17025 (accreditation certificate of the National Accreditation Agency of Ukraine № 2H375).

The requirements of these quality systems include the organization of the processes and conditions under which the Research Centre carries out the planning, conducting studies provides their quality and integrity, and also carries out risk analysis (risk management). The principles and standards of GLP and National State Standard ISO/IEC 17025, which are already harmonized in the Research Centre, include requirements for resources (personnel, reagents, equipment and laboratory conditions, services, metrological traceability), processes (sampling, studies protocols, technical records, control of data, reporting of results), as well as requirements for the management system.

In respect of the publication of the new version of quality standards National State Standard ISO/IEC 17025 of 2017, the harmonization and implementation of Risk management during studies and testing in the Research Centre has acquired considerable importance. The implementation of harmonization allows to identify the types of risks (critical risk, acceptable risk, tolerable risk) that have the greatest impact on the course of the conducted studies, as well as the activities of the organization in general. After identifying the types of risks, the degree of their criticality should be determined and a decision regarding the necessary actions to eliminate or reduce it (determination of risk acceptance) is made. Determination of risk acceptance is carried out in order to reduce the probability of an unfavourable result and to minimize potential losses (the probability or impact of unfortunate events) (fig. 2).

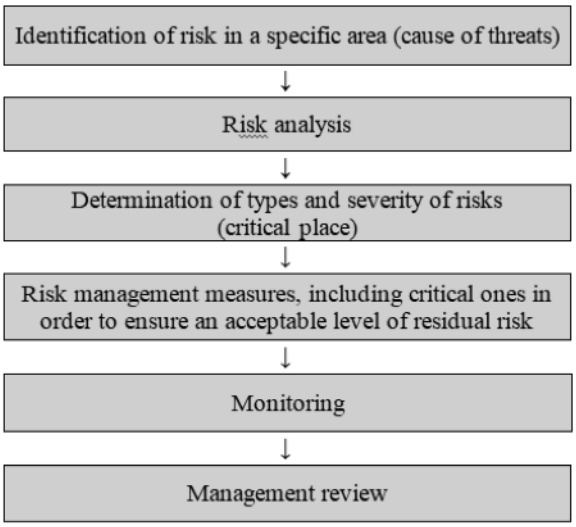

Fig. 2. Risk management system

As it can be seen from fig. 2, during the studies and testing, sources of risk, objects or subjects of its impact are identified, scenarios of hazardous events that can affect the quality of the data are analysed. Possible consequences resulting from its occurrence are also analysed. Next, an action plan for managing residual critical risks is drawn up. It includes information on possible terms, necessary resources and ways of its elimination or reduction. After that, the monitoring is carried out by authorized personnel and the analysis of the effectiveness of these activities is carried out by the leaderships.

The Research Centre has developed an universal algorithm, which contains all the abovementioned information regarding possible risks during the studies and ways of its prevention or minimizing. As an example, table 1 contains the results of risk identification in the one-generation reproduction toxicity study (OECD guideline 415).

The Research Centre considers the risks associated with laboratory activities in order to:

– prevent or reduce the undesirable effects of various factors and possible failures in laboratory activities;

– increase the amount of opportunities for achieving the objectives;

– ensure high-quality work of units.

Table 1

Ways of prevention or minimizing threats in the one-generation reproduction toxicity study (OECD guideline 415)

Title of the process: The procedure for determining functional parameters in male rats				
Risk identification	Type of the risk	Potential reason of risk occurrence	Method of reaction to the risk	Ways of prevention or minimizing risk
Euthanasia time of experimental male rats	Critical	Staying of animal in the CO_2 chamber after euthanasia too long time, which leads to excessive heat loss of the examined organs	Euthanasia time is controlled by the responsible personnel	Periodical procedure control by the quality control manager
Reuse of slides for smears preparation	Critical	Absence of slides for smears preparation utilization after the end of the study	Slides for smears preparation utilization after the end of the study is controlled by the responsible personnel	Periodical procedure control by the quality control manager
Determining the fact of mating of experimental animals	Acceptable	Determination of sperm presence in a vaginal smear during the metestrus period	Further monitoring of the estrous cycle by the responsible personnel	Observation for the same time of smears preparation by the responsible personnel. Periodical procedure control by the quality control manager
Staining of smears with Methylene blue	Tolerable	Overload of smears staining time	Smears staining time is controlled by the responsible personnel	Periodical procedure control by the quality control manager

Thus, the harmonization of international requirements into a single system in the Research Centre ensures the accuracy of the obtained data, and eliminates the occurrence of «duplication» of documentation during conduction of studies and testing.

Conclusions

1. Studies in State enterprise «L.I. Medved's Research Centre of Preventive Toxicology, Food and Chemical Safety, Ministry of Health, Ukraine» are conducted in accordance with the harmonized principles and standards of OECD GLP and National State Standard ISO/IEC 17025, which increase the level of its quality.
2. The harmonization of the two quality systems OECD GLP and National State Standard ISO/IEC 17025 is presented as a single unit, reflecting the requirements of these standards.
3. The risk management system is the basis for improving the effectiveness of the management system, and preventing the negative impact of various factors on studies and testing.

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ГАРМОНІЗАЦІЯ СИСТЕМ ЯКОСТІ OECD GLP І ДСТУ ISO/IEC 17025 В УКРАЇНІ

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***РЕЗЮМЕ**. У статті описані особливості систем якостей OECD GLP і ДСТУ ISO/IEC 17025, обґрунтовано необхідність проведення гармонізації та сумісності даних систем якостей в умовах однієї організації. Розглянуто систему управління ризиками, спрямованої на ідентифікацію, аналіз та зниження ймовірності виникнення несприятливого результату і мінімізацію можливих втрат.*
***Ключові слова:** OECD GLP, ISO/IEC 17025, ризик менеджмент, гармонізація систем якості.*

ГАРМОНИЗАЦИЯ СИСТЕМ КАЧЕСТВА OECD GLP И ДСТУ ISO/IEC 17025 В УКРАИНЕ

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***РЕЗЮМЕ.** В статье описаны особенности систем качеств OECD GLP и ДСТУ ISO/IEC 17025, обоснована необходимость гармонизации и совместимости данных систем качеств в условиях одной организации. Рассмотрена система управления рисками, направленная на идентификацию, анализ и снижение вероятности возникновения неблагоприятного результата и минимизацию возможных потерь.*
***Ключевые слова:** OECD GLP, ISO/IEC 17025, риск менеджмент, гармонизация систем качества.*

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