# VALIDATION AS IMPORTANT ASPECT OF GUARANTEEING OF QUALITY OF LABORATORY ANALYSIS

N. S. Mazur, V. E. Dobrova, S. V. Misyurova, V. V. Propisnova, I. A. Otrishko
The National University of Pharmacy, Kharkiv, Ukraine
dobrova_vika@mail.ru

Nowdays only a small number among hundreds of Ukrainian laboratories actually meets the requirements of ISO/IEC 17025:2005, based on the approaches to quality assurance contained in the standard ISO 9001:2000. ISO Standard ISO/IEC 17025:2006 defines a set of general requirements for the competence of laboratories to form a system of mutual confidence in the results of their work. Therefore, the immediate task is to research, develop and implement quality assurance procedures in laboratories of clinical diagnostics by means of the validation work.

The main object of evaluation are methods by which measurements are certain parameters in the laboratory, and in order to guarantee reliable and accurate analysis is a procedure of validation of laboratory methods.

In the absence of laboratory services in medical institutions of our country experience of quality control of laboratory diagnostics based on the application of the principles of a specialized laboratory medicine standard of ISO 15189-2009 «Medical Laboratories. Particular requirements for quality and competence». Specialists of national laboratories have many questions regarding the quality assurance of laboratory measurements.

**The purpose of the study** is to explore the aspects of quality assurance in the laboratory of clinical diagnostics of CDC of National University of Pharmacy through the validation of assessment date of hematological methods. Identify the features, approaches and requirements to assess validity (validation) of laboratory methods and key points of uncertainty.

In this work we used analytical, statistical and biological methods.

**Results.** In DSTU ISO/IEC 17025:2006 was given the following definition: «validation (assessment date) techniques – research and confirmation by providing objective evidence that the particular requirements for a specific target using executed». That is, the method must be appropriately rated investigated and evaluated characteristics measurement results by this method. If the estimated characteristics

meet your requirement methods, the method is considered to be validated in the laboratory, it can be used to test biological samples.

Validation of methods in the laboratory should be conducted under conditions of specificity: using calibrated working equipment which operated properly; staff involved in the validation have the necessary competence; facilities meet the requirements for monitoring environmental conditions and facilities.

Validational set of characteristics that should be determined, depending on the method, the type of product or object test/measurement, and biological test systems, which will be conducted the study. For certain techniques can be defined such validational properties: resistance to external influences (robasnist), selectivity/specificity of the method, accuracy, reproducibility, repeatability (convergence), sensitivity to the effects of the parameters of the sample/the object test. Set of characteristics and methodological approaches to their definition depends on each specific technique, but the presence/absence of each characteristic must be justified in executing appropriate validated documents (validation scenarios and protocols).

A good practice is to review the information contained in the published literature that relates to the method. This allows you to evaluate the overall effectiveness of a test/calibration and to determine any possible limitations or weaknesses. The presence of links to such information helps to reinforce the validation done by the same laboratory.

Validation of the method should be conducted prior to the application of the method/test. It is important to remember that when you make any changes in the content of the method, the laboratory must evaluate it (conduct validation) and documentally impact these changes. If necessary, you need to create a new (re-) validation to check and demonstrate the compliance changes.

**Conclusions.** Evaluation of intralaboratory convergence and reproducibility of a number of hematological methods in the laboratory of clinical diagnostics of CDC of National University of Pharmacy showed good resistance of methods for the studied parameters; measurement accuracy is proved in laboratory throughout the range of measurements. Accordingly, the values obtained for the studied parameters can be considered accurate and reliable.