"Laboratory Information Management System" Information Technology for Production Quality Assurance of Enterprise

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Abstract – **The paper analyzes how to integrate a holistic approach to the process of GMP regulation and parameter estimation of production and laboratory testing in order to improve the use of information technology in the process of ensuring the quality of products.**

Keywords – information technology; business processes; Business Activity Monitoring; GMP; info-communication network.

I. INTRODUCTION

Signing the agreement on associated membership of Ukraine in the European Union (EU) and even more in this regard, integration into the global market space necessitate adaptation (harmonization) of Ukrainian national standardization system to the accepted globally rules and regulations in the field of quality assurance and product safety standards, conformity assessment and mutual recognition of test results etc. It is logical to assume that the way of solving such problems can be prompt international practice and, in particular, the experience of the development of legislation in the EU.

The process of harmonization of legislative provisions and requirements for production, quality and distribution of products in order to eliminate technical barriers to trade and industrial development is not only in Europe but also in other regions of the world. One of the main conditions for production and trade in these markets and the markets of other foreign countries is to ensure quality in the first place through the implementation of the principles and rules of good manufacturing practice (Good manufacturing practice – GMP) [1].

II. DESCRIPTION GMP STANDARD

GMP Standard is a system of rules, regulations and guidelines in relation to production of:

- drugs;
- medical devices;
- diagnostic purpose products;
- food products;
- nutritional supplements;
- active ingredients.

In contrast to quality control procedures by examining random samples of products, which determines the suitability for use only within these samples (and, possibly, the parties made in the near future for this party time), GMP standard reflects a holistic approach and regulates and evaluates the actual parameters of the production and laboratory testing.

This holistic approach consists of the following:

- GMP is part of a comprehensive concept of quality assurance, the components of which are closely interlinked;
- all the elements of the quality assurance including guidelines on GMP, must have an appropriate legal basis; in market economies they were introduced by law;
- GMP is not a dogma, it is a developing system; There are guidelines on GMP specific for different markets, regions, states and transnational companies, but there are minimum requirements set out in the Guide on GMP, who are required to comply with all manufacturers;
- compliance of the GMP regulations is both an internal affair of the producer and the question of national importance and, therefore should be subject of regular businesses like self-control and inspection by the authorized competent state bodies;
- compliance with GMP regulations is a key element of the system of certification of medicines for international trade.

III. IMPLEMENTATION AND ANALYSIS

The approach to the concept of quality assurance and management in terms of informatization (information technology) is based on the principle of decomposition of the production process (in accordance with a holistic approach GMP).

The main stages of decomposition of production processes can be represented as:

- documentation of existing activities;
- construction of accounting system;
- building a system of analysis of production processes;
- system of control and development of production processes;
- activities to improve production processes.

To achieve the objectives of information one should be guided by Annex 11 GMP [2]: “Computerised Systems”.

As it is known [3], one of the main problems in the construction of the Quality Management System (QC - Quality Control) and the proper operation of the System of Quality Assurance (QA - Quality Assurance) of the enterprise is to comply with the requirements of international standards GLP (Good Laboratory Practice) and ISO 9000.

In terms of quality management at the present stage of development of information technologies and one of the main tools for ensuring the activities of the Standards GLP (Good Laboratory Practice) and ISO 9000 is the introduction of LIMS - Laboratory Information Management System (Laboratory Information Management System).

LIMS is a class of dedicated hardware and software systems, aimed at the automation of the analytical laboratory. Systems in this class are not just for the rapid provision of information on the quality of the laboratory, but also for management by business process control and quality management.

LIMS is an important element of IT-infrastructure of the modern enterprise which is mentioned in the Annex 11 GMP. Annex 11 is a consistent step in the development of GMP taking into account the proactive use of risk management.

The key provision of Annex 11 is that all used computer applications must be validated, and IT-infrastructure's operability is necessary to have qualified confirmation. In regulatory practice introduced a direct requirement of necessity conducting the qualification of IT-infrastructure, i.e. software and hardware, which ensure the functioning of basic computer applications. Matter how efficiently and conveniently the IT infrastructure was organized depends the successful progress of all business processes of the enterprise.

IT-infrastructure consists of the following units (Fig. 1):

- computers (user workstations);
- server (dedicated servers that perform various tasks);
- software for servers and workstations;
- office equipment (printers, copiers, fax machines, scanners);
- data network, telephone network;
- active network and telecommunications equipment (routers, switches, telephone exchanges).

The computerized system includes a number of components of hardware and software, which together perform certain functions. 11th GMP Annex applies to all forms of computerized systems, which are used in the enterprise in the regulation of GMP. This applies to spreadsheets (e.g., Excel, Visual Basic), and proprietary databases.

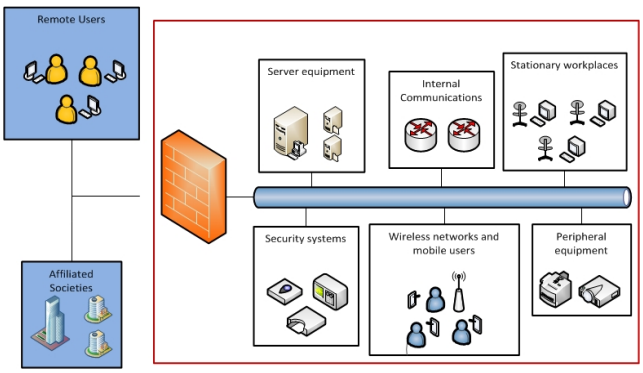

Fig. 1. Structural diagram of IT-infrastructure of the enterprise

Technology provider in the field of computer engineering, biomedical and telecommunications is considered to be a professional society IEEE (Institute of Electrical and Electronics Engineers), which includes more than 350 000 people from more than 150 countries. IEEE produces 30% of the world's published literature in electrical engineering and computer topics. In this connection it is appropriate to refer to the Guide to GAMP (Good Automated Manufacturing Practice) [4], published by the ISPE (International Society for Pharmaceutical Engineering) and aimed at assisting providers of computerized systems to provide them with adequate functionality and documented in accordance with the requirements of GMP.

GMP Annex 11 declares the principle of "do not harm", namely: «Replacing manual operations by a computerized system should not lead to decrease product quality, a process control and quality assurance of the achieved level. A computerized system should not increase the cumulative risk for the operating process». It is obvious that the claimed principle is a kind of "reinsurance" - because, in essence, the use of a computerized system has greatly improved controllability of the process and the level of quality assurance, as virtually eliminating the human factor, and thus the risks of human error. There is another side, eliminating of some risks can involuntarily significantly enhance status of others. That is why the new text of the 11th GMP Annex focuses on the risk management.

Risk management should be carried out throughout the entire period of use of a computerized system [5]. All decisions about the volume of validation, and the degree of effort on manage the accuracy of the data should be based on justified and documentary confirmed risk assessment of such system.

11th GMP Annex suggests that risk management will be applied when assessing the criticality of certain components, assessing its impact on product quality and safety, the reliability of the collecting data. Developing User Requirements Specification (User Requirements Specifications - URS, see. GAMP), the formation of operating instructions for staff, security system and measures to ensure the smooth operation should take into account the documented results of a risk assessment.

Implementation of a risk management program for the computerized system involves the identification of all its possible failure, human error, data loss, etc., assess the probability of their occurrence and the degree of severity, based on the possible consequences for the consumer. And, accordingly, the implementation of a complex of measures aimed at the elimination of all significant risks.

The solution of many key objectives of risk management will be determined by detalization and quality of LIMS database formation, including those as a basis for applying statistical methods of risk assessment. LIMS database can be used as an information basis of adaptation (harmonization) of the national Ukrainian (informative) standardization system to the accepted at the global level rules and regulations in the field of product quality and safety, standardization, conformity assessment and mutual recognition of test results etc.

Structure of the Annex 11 GMP [2] also clearly demonstrates the need for interaction the structural elements with constantly updated LIMS database. Each element of the structure not only uses the database but delivers the new (or updated) data (Fig. 2).

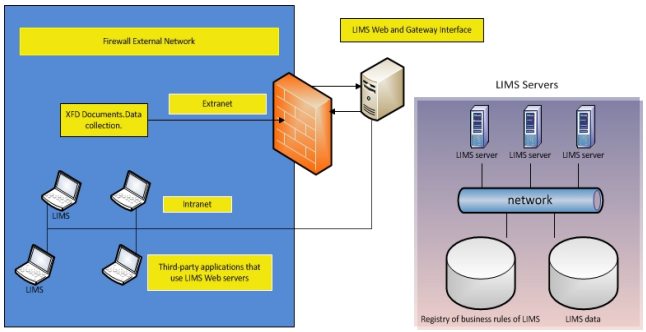

Fig. 2. Topological diagram of LIMS enterprise

Great value to the quality system has authorization. LIMS ability to maintain a system of electronic signatures is an undoubted advantage of it. This helps to fulfill one of the key provisions of the quality system - the traceability requirement, which in the LIMS can be done up to a single record.

Today it is impossible to imagine an activity of successful, developing company without the effective use of IT-technologies. Computerized systems used in the production is not only an indicator of compliance with the principles of GMP, but also factor in the competitiveness of businesses.

Quality assurance has economic consequences for producers and buyers. In particular, the introduction and application of GMP requires the use of significant financial resources, which will inevitably affect the price of products. However, the world has accumulated a lot of experience, proving the economic benefits associated with the use of quality systems.

IV. CONCLUSION

GMP's holistic approach to regulation and assessment of parameters of production and laboratory testing may be methodological basis for harmonization of Ukrainian standardization system in the world and is an important factor in ensuring the quality of products;

GMP is a part of quality assurance which ensures that products are constantly produced and controlled according to quality standards;

Information technology can be regarded as a modern tool for achieving of product quality by the concept of GMP and the integration of these standards with the process of quality management of production of the enterprise;

In terms of quality management at the present stage of development of information technologies and one of the main tools for ensuring the activities of the Standards GLP (Good Laboratory Practice) and ISO-9000 is the introduction of LIMS (Laboratory Information Management System);

LIMS allows automation of one of the most important components of the manufacturing process - quality assurance and quality control - QA / QC;

Modern LIMS allows to create (operate, modify) the databases, the number of studies subsequently can be carry out based on it, that have not only scientific but also practical value;

New information technologies, changing demands and growing awareness of the importance of the integration of standards with the process of production quality management makes integration even more important for improvement, harmonization and practical application.

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