International Journal of Advanced Science and Technology
Vol. 29, No. 7, (2020), pp. 636-642

System-object modeling of quality management system of medical

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Abstract

The article discusses the problems that commercial organizations face when undergoing external audits of the quality management system. The analysis of the domestic practice of certification of quality management systems is presented, which showed that the key problem in this context is the non-transparency of the certification procedure, which, in turn, creates more significant problems in the process of the organization's economic activity. The authors propose the use of system-object simulation to improve the efficiency of the quality management system, as well as to simplify the first certification procedure. According to the authors, the system-object approach is an effective tool for systematizing and simplifying the procedures for certification of quality management systems. For this purpose, the work examines the interstate standard GOST ISO 13485-2017 in the form of a system-object simulation model, which in the future can be used as a tool for information-analytical support of the quality management system of medical devices.
Keywords: *quality management system, external audit, system-object approach, simulation, QMS standard, medical devices, GOST ISO 13485-2017.*

1. Introduction

Currently, the global economy, including the Russian one, is undergoing significant changes in the structures of production and consumption. Moreover, in many companies and organizations of the Russian Federation, the qualitative changes taking place in the world are not fully understood, and therefore underestimated. In some cases, in Russian practice there is even a complete disregard for such changes or their extreme simplification and the reduction of the entire process of implementing quality management requirements only to obtaining a certificate [1].

However, certification of a quality management system (QMS) in itself is a complex procedure for assessing QMS for compliance with stringent standards. First of all, it refers to the ISO 9001 standard, but often, in addition to it, compliance with other standards is also required, for example, ISO 13485, which are similar in the structure of requirements, but may differ in their content. Moreover, the certification system is primarily focused on the presence of a documented description of the QMS.

Today, in the practice of certification, there is a problem when the company is audited by external auditors, which is the opacity of this procedure for the company undergoing an external audit. The management of enterprises does not always understand how the auditor builds the audit process, since, at present, this is a subjective procedure carried out at the discretion of the auditor. As a result of this, even a certified QMS does not always solve problems in companies, i.e. not always improves the efficiency of the enterprise.

The aforementioned suggests that the transparency of the QMS certification procedure could provide a model for the process of conducting internal and external (third party, usually a certification body) QMS audits. Moreover, at present, there is a tendency to use imitation models in the interests of quality management.

ISSN: 2005-4238 IJAST

In the publication [2], it was shown that the simulation model of selective (single-stage, two-stage, multi-stage) product quality control provides guaranteed product quality control at various stages of production without final output quality control, thereby reducing the level of defective products, time and labor costs.

In [3], simulation modeling is used in quality management problems using the example of a specific higher educational institution. Using the Anylogic 5.0 environment, the authors, based on the simulation model "students", "teachers", and "classroom lessons", by means of repeated imitation propose to form preferred scenarios of educational institution management in terms of quality of graduates. The simulation model makes it possible to predict the consequences of changes in the values of control parameters on the quality of educational services provided.

The article [4] gives an example of the use of simulation in a multi-level product quality management system of a metallurgical enterprise. At the first level, the model monitors the technical control of products, which reduces the time of the technological process by eliminating a number of laboratory intermediate control operations, as well as develop control actions to adjust the process and reduce the percentage of rejects. At the second stage, the causes of incidents are modeled, i.e. non-compliance of the process with the established requirements, and measures are taken to prevent them, which ensures a reduction in the percentage of defects in the investigated incidents. At the third level, MI is used to solve common problems of improving the quality of products and services by improving production processes. At the fourth level, simulation models are used to actively monitor and improve the quality management processes themselves and analyze the effectiveness of the management process itself.

It should be noted that in all the examples presented, simulation of QMS processes is used as an effective, visual tool in combination with integrated management systems and databases used in enterprises.

2. Methodology

One of the modern and promising methods of simulation that has not yet been used in quality management is the system-object simulation method, based on the "Node-Function-Object" (UFO-approach) system approach and the system-object knowledge representation method (SOMPZ) [5, 6].

Consider the capabilities of system-object simulation to ensure timely assessment of the QMS compliance with the requirements of the standard and the effectiveness of the process of conducting both internal and external audits. For this, we will present the standard SMK 13485-2017 "Medical devices" in the form of a system-object simulation model [7-10]. System-object simulation model, in terms of calculus of functional nodes [11] is the following expression:

$$M=\{L,S\}, \quad (1)$$

where L is the set of streaming objects of the model (connection), having the form as:

$$L=\{l_1, l_2,... l_i,\ldots l_n\}, \quad (2)$$

where n is the number of stream objects (system connections).

Each n-th element of the set L is a special stream object (corresponding to a specific system connection), which consists of fields does not include methods and has the following form:

$$l_i=[r_1, r_2, \ldots ,r_k], \quad (3)$$

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where:

- $l_i \in L$;
- k is the number of fields of the stream object l_i;
- r_1, r_2, ..., r_n are the fields of the stream object, which are an identifier-value pair.

S is the set of nodal objects, which corresponds to many systems as UFO elements:

$$S=\{s_1, s_2,..., s_j,\ldots,s_m\}, \quad (4)$$

where m is the number of nodal objects (systems).

Each m-th element of the set S is a special nodal object (corresponding to a specific system / UFO-element), which consists of fields and a method and has the following form:

$$s_m=[U, f, O], \quad (5)$$

where:

- U – represents a set of fields for describing the interface stream objects of the node object s_m, corresponding to the set of functional connections of this system. The set U = L? ∪L !, where L? - represents a set of incoming interface stream objects corresponding to incoming system connections, L! - represents a lot of outgoing interface stream objects corresponding to outgoing system connections. Moreover: L?⊂L; L!⊂L.
- f – is a node object s_j method that describes the conversion function of incoming interface stream objects (incoming system links) L? on the way out - L !. Next, we will present the method of the nodal object in the following form:

$$f(L?)L!, \quad (6)$$

where f is the nodal object method (system function) with the domain of definition L? and the range of values L !, respectively.

- O - is a set of fields for describing the object characteristics of a node object (system) s_j, the elements of which have the following format:

$$O=\{o_i \mid o_i=[identificator, value]\}, i = 1, 2, \ldots, p \quad (7)$$

The set of fields for describing the object characteristics of the system consists of three subsets:

$$O=O?\cup O!\cup Of \quad (8)$$

3. Results and Discussion

In accordance with the formalisms presented above, we consider a system-object model of the form (1), for which the set of stream objects has the following structure:

$$L=(l_1, \ldots, l_{32},) \quad (9)$$

Elements of the set of stream objects correspond to the system connections shown in figure 1.

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Figure 1. Streaming model objects.

The set of nodal objects of the model has the following form:

$$S=\{s_1,\ldots,s_{20}\}, \quad (10)$$

Each nodal object corresponds to a system in terms of the UFO approach, as shown in figure 2.

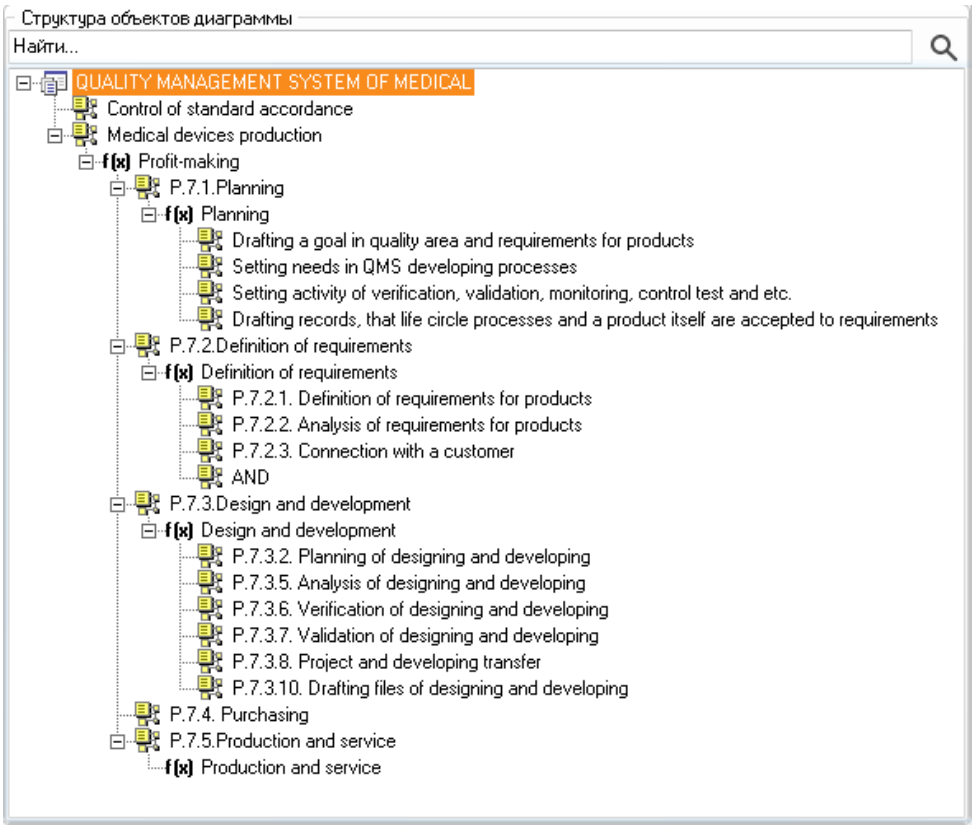

Figure 2. Nodal objects of the model.

Next, we consider the graph-analytical representation of a system-object simulation model. The context model of the QMS processes in accordance with ISO 13485-2017 is presented in figure 3.

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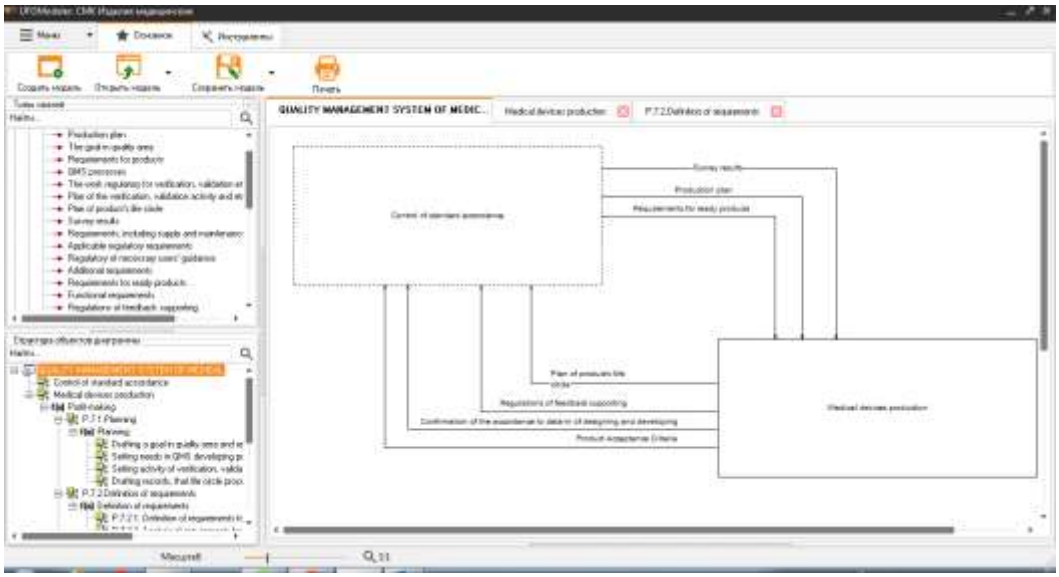

Figure 3. Contextual model of QMS processes.

As can be seen from figure 3, at the context level, the service nodal object "Management of the production of medical devices" and the subsystem "Production of medical devices", which corresponds to subclause 7 of the standard under consideration, were allocated. Picture 4 shows a model - decomposition of this subsystem:

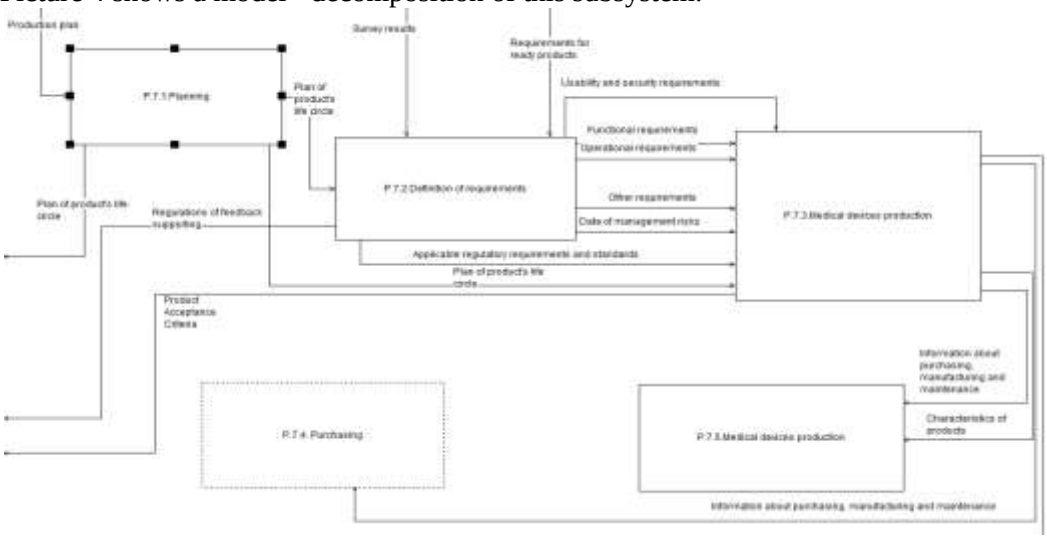

Figure 4. Model for the manufacturing process of medical devices

In accordance with the standard GOST ISO 13485-2017, the production process of medical devices includes the following processes of the product life cycle:

- Planning of product life cycle processes;
- Customer related processes;
- Design and development;
- Purchasing;
- Production and service;
- Management of equipment for monitoring and measurement.

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Let us consider in more detail the stage of planning the product life cycle, the stage diagram is presented in the figure below:

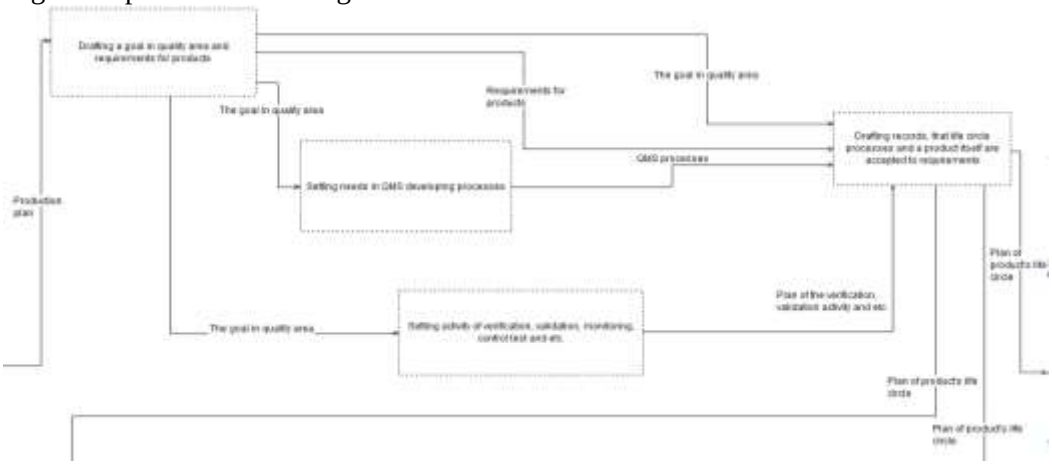

Figure 5. Stage of product life cycle process planning.

Within the framework of the subsystem shown in Figure 5, in accordance with standard 7, when planning the product life cycle processes, the organization shall establish, if appropriate:

- Quality objectives;
- The need to develop processes, documents, as well as providing resources for specific products, including infrastructure and the working environment;
- Necessary activities for verification, validation, monitoring, control and testing, processing, storage, distribution and traceability of a particular product, along with acceptance criteria;
- Records required to provide evidence that product life cycle processes and finished products are in compliance.

4. Conclusion

By the same principle, all the remaining stages of the product life cycle were presented. The developed model is clear and understandable and can be used as an effective toolkit for information and analytical support of QMS audit procedures according to standard 7. Moreover, the UFOModeler software toolkit allows you to program the logic of functioning of individual blocks of the model, which in turn opens up prospects for building a complete simulator of the QMS audit process within a specific production cycle.

Acknowledgments

The research is financially supported by the projects of the Russian Foundation for Fundamental Research No. 18-07-00355, No. 19-07-00290 and No. 19-07-00111.

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ISSN: 2005-4238 IJAST