

A.G. ZHIKHAREV, P.A. BUZOV, S.I. MATORIN, A.N. ZAITSEV

SYSTEM-OBJECT SIMULATION OF A QUALITY MANAGEMENT SYSTEM

ISO 13485-2017

ISO 13485-2017.

The article deals with the problems faced by commercial organizations when passing external audits of the quality management system. The analysis of the domestic practice of certification of quality management systems, which showed that the key problem in this context is the lack of transparency of the certification procedure, which, in turn, gives rise to more significant problems in the process of economic activities of the organization. The authors propose the use of system-object simulation modeling 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 certification procedures for quality management systems. For this purpose, the work considers the interstate standard GOST ISO 13485-2017 in the form of a system-object simulation model, which can later be used as a tool for information and 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.

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

n - $L = \{l_1, l_2, \dots, l_n\},$ (2)

(n- L)

($l_i = [r_i, r_2, \dots, r_n]$)

li G L; - $l_i; r_1, r_2, \dots, r_n$ (3)

, S - « ».

- : $S = \{s_1, s_2, \dots, s_j, \dots, s_m\},$ (4)

m - (S)

(m- / -)

: $sm = [U, f, O],$ (5)

U - $sm,$

. $U = L_1 \wedge L_2 \wedge \dots \wedge L_n$ -

, L_1 -

f - $: L_1 \wedge L_2; L_1 \wedge L_2;$

$s_j,$ ()

L? - $L_1,$

: $f(L_1)L_1,$ (6)

f - () L?

L! -

() $s_j,$: (7)

= $\{o_i \mid o_i = [\dots]\}, i = 1, 2, \dots, p$

: $O = O_1 \wedge O_2 \wedge \dots \wedge O_p$ (8)

(1),

: $L = (l_1, l_2, \dots, l_n)$ (9)

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$$S = \{s_1, \dots, s_{20}\},$$

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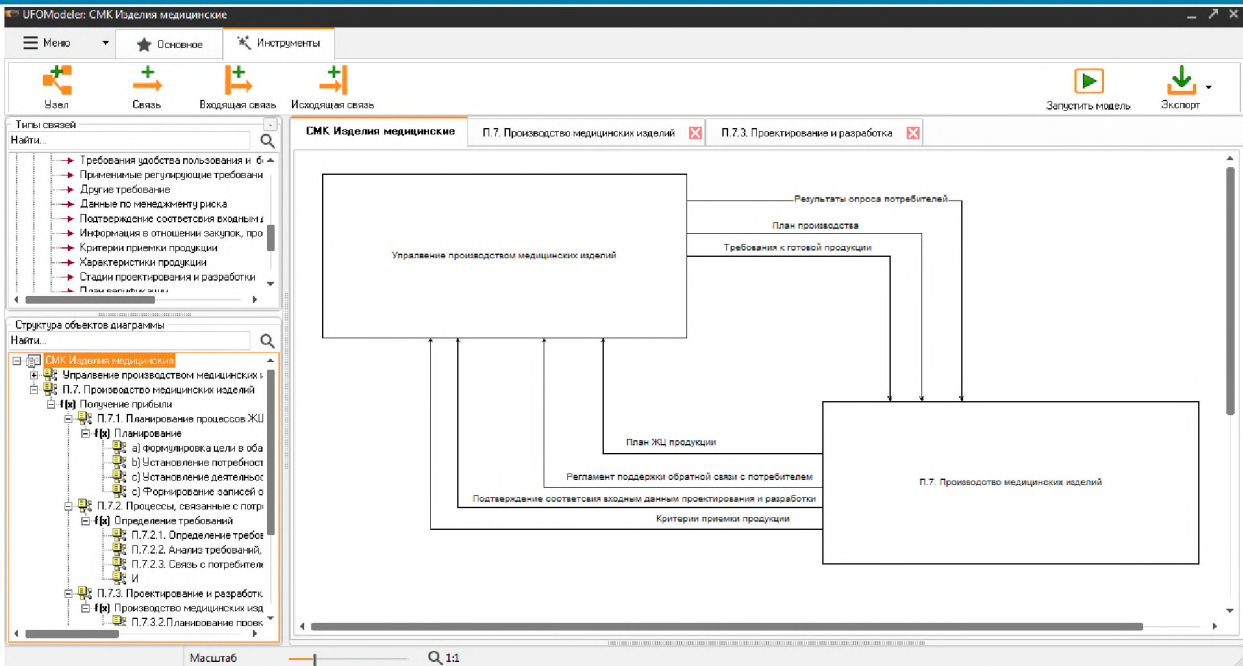
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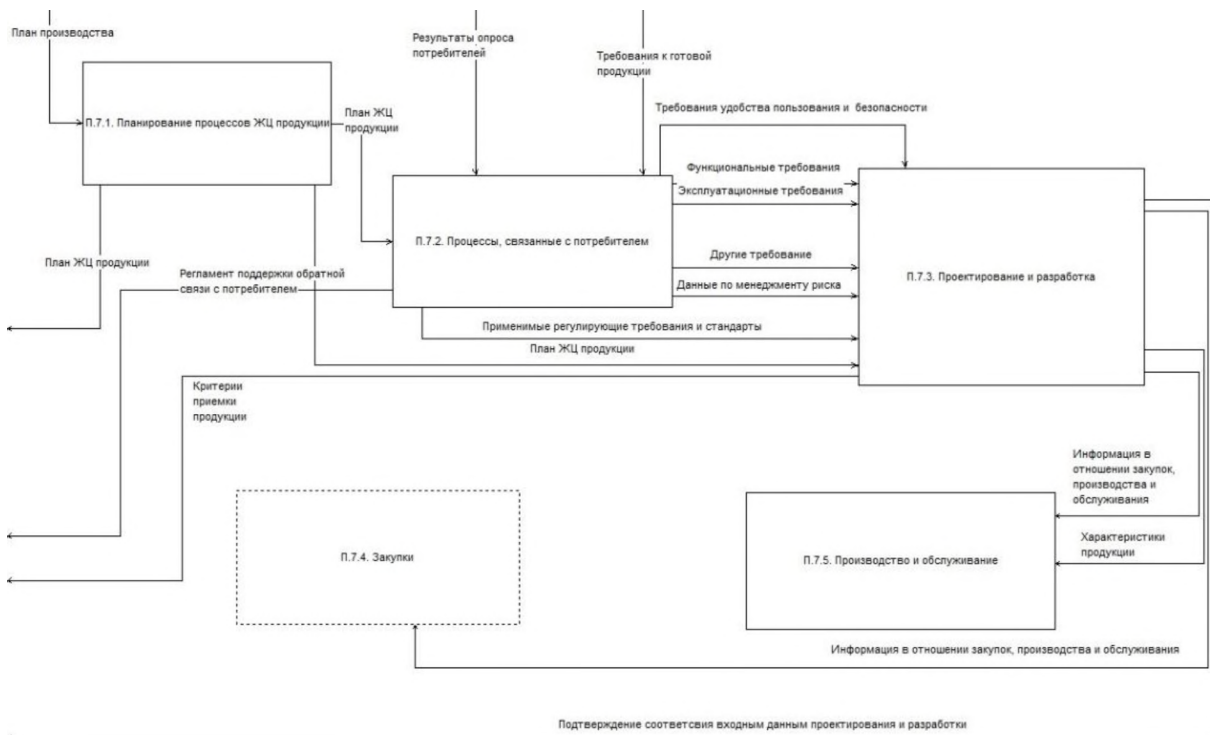
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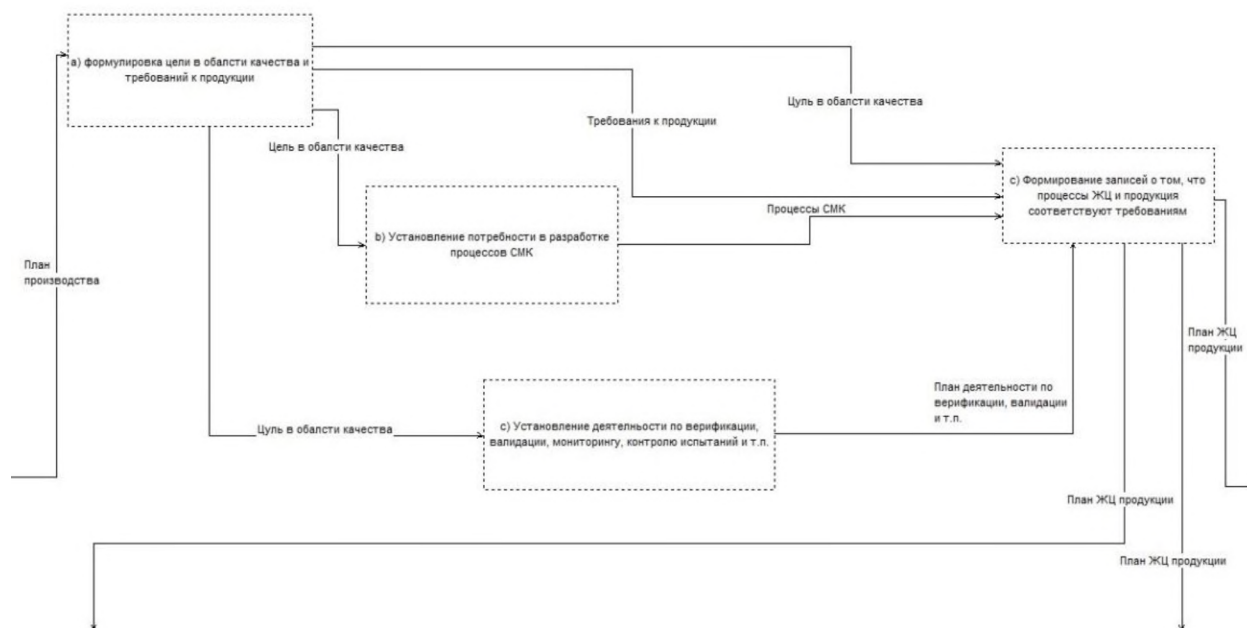
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- 1. ISO 14000: , . - 2016. -
7-1. - . 87-91. . //
- 2. . // . - 2015. - (9-2). - . 247-251.
- 3. . // . - 2017. -
- 11. - . 35.
- 4. . - 2012. - . 2. - . 79-86.
- 5. . // . - 2015. - 4. - . 95-103.
- 6. . // . - 2015. - 6(60). -
- 10. - . 91-104.
- 7. ISO 13485-2017. .
01.06.2018, .
07.06.2017.
- 8. . // XXII-
(&)» (, , 2019) 2. - C. 79-84.

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.: 89511559075
E-mail: zhikharev@bsu.edu.ru

..
.: 89103646677
E-mail: info@softconnect.ru

..
.: 89066069423
E-mail: matorin@bsu.edu.ru

..
.: 89803781139
E-mail: zaitsev_an@bsu.edu.ru