*Kompetentnost' / Competency (Russia)* 7/2021
ISSN 1993-8780. DOI: 10.24412/1993-8780-2021-7-26-30

# Medical Device Manufacturing Enterprise: Difficulties of Implementing an Integrated Management System

**R.N. Ismailova**[1], FSBEI HE Kazan National Research Technological University (FSBEI HE KNRTU), PhD (Chem.), isma_70@mail.ru
**S.M. Goryunova**[1], FSBEI HE KNRTU, PhD (Chem.), svetlanagoryunova@yandex.ru

[1] Associate Professor of Department, Kazan, Republic of Tatarstan, Russia

**Citation:** Ismailova R.N., Goryunova S.M. Medical Device Manufacturing Enterprise: Difficulties of Implementing an Integrated Management System, *Kompetentnost' / Competency (Russia)*, 2021, no. 7, pp. 26-30. DOI: 10.24412/1993-8780-2021-7-26-30

**key words**

integrated management system, medical device suppliers, standard, product life cycle

In the article we have outlined the problems of implementing an integrated management system (IMS) at an enterprise that produces medical devices. The use of classical integrated systems for such enterprises has shown their inefficiency. Therefore, for the development and implementation of IMS, there is a problem with the choice of a standard that would help an enterprise to reach a new level, increasing its competitiveness and the number of consumers of manufactured products. For the enterprise under consideration, this standard was GOST ISO 13485–2017 Medical devices. Quality management systems. Requirements for regulatory purposes.
The analysis of the enterprise's life cycle of products showed that not all stages of the life cycle are documented procedures, and some duplicate each other. Optimization of the existing workflow has made it possible to reduce the time for obtaining information to perform various types of work, as a result, to reduce the cost of producing high-quality products.

## References

1. Svitkin M.Z. Prakticheskie aspekty sozdaniya ISM [Practical aspects of creating IMS], *Metody menedzhmenta kachestva*, 2007, no. 5, 14 P.
2. Merkushova N.I. Integrirovannye sistemy menedzhmenta: predposylki sozdaniya na rossiyskikh predpriyatiyakh [Integrated management systems: prerequisites for creation at Russian enterprises], *Molodoy uchenyy*, 2013, no. 12, pp. 327–331.
3. Martsynkovskiy D.A. Upravlenie riskami v sovremennykh sistemakh menedzhmenta [Risk management in modern management systems], Moscow, *Russkiy Registr*, 2010, 246 P.
4. Goryunova S.M. Problemy vnedreniya standarta ISO 13485:2003 na otechestvennom predpriyatii [Problems of implementation of the ISO 13485:2003 standard at a domestic enterprise], *Vestnik Kazanskogo tekhnologicheskogo universiteta*, 2014, no. 4, pp. 3–4.
5. GOST ISO 13485–2017 Medical devices. Quality management systems. Requirements for regulatory purposes, Moscow, *Standartinform*, 2018, 42 P.