

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

R.N. Ismailova¹, FSBEI HE Kazan National Research Technological University (FSBEI HE KNRTU), PhD (Chem.), isma_70@mail.ru

S.M. Goryunova¹, FSBEI HE KNRTU, PhD (Chem.), svetlanagoryunova@yandex.ru

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

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key words

integrated management system,
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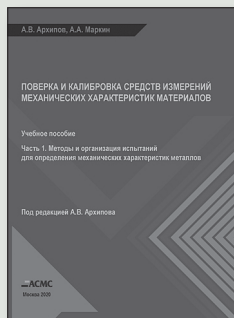
In the article we have outlined the problems of implementing an integrated management system (IMS) at an enterprise that produces medical devices. The use of classical integrated systems for such enterprises has shown their inefficiency. Therefore, for the development and implementation of IMS, there 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.

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НОВАЯ КНИГА

Архипов А.В., Маркин А.А.



Проверка и калибровка средств измерений механических характеристик материалов. Часть 1

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Техническое изделие основывается на разработке модели и на расчетах параметров изделия в соответствии с выбранной моделью. Моделирование невозможно без учета свойств материалов, из которых будет создано изделие. Рассмотрены установленные нормативно-технической документацией методы определения механических характеристик материалов, их физической основы, номенклатуры: терминология, классификация, область и особенности применения. Пособие предназначено для слушателей АСМС, повышающих квалификацию по специальности «Проверка и калибровка средств механических измерений».

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