

Digitalization of the Pharmaceuticals Production Process

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We have described the main problems in the production of a specific medicinal product at one of the leading pharmaceutical enterprises in the Russian Federation. Using the model for describing the business processes of the As is organization, the process of production and validation of medicinal products (MP) was detailed. Based on the developed schemes and surveys of the main stakeholders (owner, performers) of the processes, nine key problems in the production process of a specific MP were identified. They lead to product defects. Also, to determine the root causes of production problems, all identified problems were analyzed using the Lean production tool 5 whys. As the analysis showed, the reasons for the defects were very different from the original version and were caused by other factors. In this way, the most common causes of all key problems in the production process of a specific MP were identified. The identified problems were ranked, followed by the development of corrective measures to eliminate them.

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