Abstract

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The basic research problem of the dissertation is the methodology of risk management diagnosis in the medical products manufacturing. The main research issue is the scope and degree of specificity of implementing the existing standards of risk management as well as detailed questions dealing with the specification of medical products risk, and the application of standards and the scope of their use in medical products risk; what research method can be employed in the identification and the medical products risk evaluation. What results can be achieved by the implementing of the diagnostic method.
The aim of the dissertation is the identification, analysis and evaluation dealing with standards norms in the medical products risk management in the whole product life cycle. It is a methodological, theoretical as well as practical problem. The empirical part of the dissertation is based on the case study methods.
In Chapter I the concept assumptions of risk management have been presented, which show the detailed definitions and risk typology as well as the theoretical concept of risk; terms, typology, measurement and evaluation methods of risk. Chapter II deals with the presentation of medical products risk definitions as well as the introduction of the terms, origin of the medical products risk management and the presentation of the typology of employed approach in risk management and measurements and methods of detailed risk evaluation. Chapter III gives a detailed presentation of the assumptions of the diagnostic methods in the medical products risk management. The chapter also presents the review of the diagnostic methods of the management systems, chosen methods, potential problems with diagnosis as well as recommendations of preparation of diagnostic methods in medical products risk management. Chapter IV handles the stages of the methods of diagnosis in risk management in the medical products manufacturing. The chapter also presents the identification of risk in the product life cycle, the characteristic of product risk management as well the criteria choice and the evaluation method of risk management in the product life cycle. Chapter V deals with the choice of the research method employed in the research paper, definitions and the use of case study in the research. The selected method of presentation is also in the broad spectrum of qualitative research with the research paradigms taken in account. Chapter VI is the empirical part of the paper, the practical implementation of the case study with the employment of the method of diagnostics of risk management in the medical products manufacturing. The detailed description of tools used in the research has been provided; the method used has been justified as well as the choice of cases to conduct the research. The schedule and the stages of the research have been presented according to which the case study has been conducted. The employment of the method of case study in the presented dissertation allows answering the question dealing with the scope and degree of specificity of the employment of the existing standards in the risk management of medical products manufacturing.