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# Integrative technology and inspection planning of medical devices

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**Abstract**

Medical devices show great promise for future medicare. Due to strict legal requirements to ensure the functionality of high-risk medical devices, both manufacturing costs and quality costs contribute significantly to total production costs. Thus, quality costs have to be taken into consideration during the stage of technology planning. Due to the high variety of potential interactions between individual component properties as well as between component properties and manufacturing processes, the analysis of the influence of the manufacturing history on an efficient design of inspection processes is extremely complex. Furthermore, the effects of test strategies and quality costs on the planning of manufacturing process sequences can not be modeled to date. As a consequence, manufacturing and testing processes are designed separately and thus a high cost reduction potential remains untapped.

In this paper an approach for an integrative technology and inspection planning is presented. At first, existing approaches with regard to technology and inspection planning are reviewed. Afterwards, a model to depict the manufacturing history including alternative inspection processes will be introduced. On the basis of this descriptive model a mathematical model to determine the expected production costs of alternative technology and test sequences will be developed. Thus, the complex causalities between technology planning, manufacturing history and inspection planning are systematically explained by analytical models enabling a cost-effective, integrative technology and inspection planning.



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*Keywords:* Manufacturing Technologies; New Product Development; Technology Planning; Quality Control and Inspection

## 1. Introduction and Motivation

For modern societies the medical industry occupies a central position. Medical technology enables decisive contributions to improved patient care, better quality of life particularly in old age and thus offers great potential for the health care of the future [1]. Moreover, the worldwide demand for medical technology products shows a rising trend. The turnover of the German medical technology for example has increased by 36.7 % from 2006 to 2012 [2]. Significant determinants of the rising demand are the population growth in developing countries, a positive income development in populous emerging markets and demographic changes in industrial countries [2].

The manufacture of medical products is subject to strict regulatory requirements, see [3]. The required ensuring of the functionality implies an inspection of all safety-relevant components. High quality costs resulting from the inspection processes lead to a sharp rise in manufacturing costs. Ehrlenspiel estimated the proportion of quality costs to production costs in Germany to 5-25 %, but emphasizes that the ratio can be much higher for certain components [4]. The quality control in production and the related costs are an integral part of the manufacture of medical devices. Each inspection leads to higher costs. However, the omission of an inspection carries the risk of producing scrap and rework resulting in increasing error costs. Thus, for a cost-optimized production the consideration of quality costs in addition to the production costs has to be integrated in early phases into the framework of production planning forming an integrative approach for manufacturing and inspection process design [5]. Furthermore, time consuming iterations can be avoided following an integrative approach. Delays in product development can be reduced significantly [4,6]. Thus, by means of an integrative approach the time-to-market can be shortened contributing to a successful production ramp-up [7].



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However, due to the high variety of potential interactions between individual component characteristics and between component characteristics and production processes, the definition of a cost-effective production process and inspection sequence is extremely complex. As a result, the production and testing processes are regarded separately in the current state of research. Thus, a high cost and time reduction potential remains untapped.

## 2. State of the Art

The state of the art focuses on approaches that deal with technology planning and inspection planning to enable a cost-efficient production. Existing approaches of the fields “Technology Planning” and “Inspection Planning” are analyzed regarding their ability to support a cost efficient production planning process of medical devices.

### *2.1. Technology Planning*

The fundamental task of technology planning is to determine technologies concerning type and time frame to produce a certain product. Müller and Moryson understand technology planning as an integrated process of product development according to VDI 2221 and production planning in accordance with REFA [8,9]. By means of the parallelization of conventionally sequentially conducted steps, a fast and economic development is enabled [10].

The scientific literature in the field of technology planning focuses on approaches to design and evaluate alternative production sequences. Fallböhmer developed a methodology to design alternative technology chains [11]. The evaluation is based on the capabilities of the technologies to produce the part characteristics. Trommer focused on the evaluation of alternative production sequences introducing a methodology to prioritize technological alternatives taking into account various evaluation criteria [12]. More recent approaches detail the evaluation of production sequences considering the production environment or changes in the production program [13-15] or intensify the focus on technological dependencies of production processes [16-19]. However, all these approaches neglect the influence of inspection processes in the design of production process sequences. Neither the demand for quality assuring inspection processes in dependence of the selected production processes nor the accompanied costs are taken into consideration.

### *2.2. Inspection Planning*

The objective of inspection planning is the planning of quality control for the various production steps of a product [20]. Here, the term quality control is to be understood as "determining the extent to which products and activities meet the quality demands placed on them" [21]. The inspection planning defines various testing processes and activities in the entire production process from receipt of goods through production and assembly to delivery of the product [21,22].

Similar to the field of technology planning also the state of the art in the field of inspection planning shows approaches for a cost-effective design of inspection processes. Crostack et al. present an approach for an optimized inspection planning taking into account the inspection method, scope of inspection as well as location and time of inspection [23,24]. Krappig and Schmitt focused on the selection of measuring devices and elaborated a methodology to identify the most appropriate measuring system for a defined inspection task [25]. An approach to monitor the quality across a defined process chain is presented by Wuest et al. [26,27] However, research activities in this field assume the production process as predefined. An integrative design of the production and inspection processes enabling an optimized adjustment of production and inspection processes already in the planning phase is not presented.

### *2.3. Summary*

The state of the art shows that in both fields technology planning as well as inspection planning approaches exist to design and to evaluate production or inspection processes taking into account technological and economic criteria. However, the approaches and models only focus on aspects of either production or inspection planning. A joint consideration of technology and inspection planning does not take place. In consequence, a new approach is needed, which enables an integrative design and evaluation of technology and inspection alternatives.

## 3. Terminology and approach

The integrative understanding of production and inspection demands a joint consideration of both technology and inspection. Therefore the term “production process and inspection sequence” will be introduced to describe the entirety of production process sequences including inspection steps between certain production processes. A production process sequence describes a sequence of directly value adding, resource related production processes. [12]

This paper focuses on the economic evaluation of alternative production process and inspection sequences. Therefore, in a first step alternative production process and inspection sequences have to be identified. Since an optimal definition of inspection steps depends on the influence of the production processes on the manufactured part, an approach is presented that allows a deduction of alternative production process and inspection sequences on the basis of the manufacturing history. In this paper it is assumed, that a first production process sequence alternative is present already. However, the definition of inspection processes within the production sequence is not defined yet. In a next step, alternative production process and inspection sequences are evaluated with reference to their cost effectiveness. In order to determine the expected costs of a production process and inspection sequence a mathematical model is introduced.