COMPLAINTS ANALYSIS IN THE FIELD OF MEDICAL DEVICES PRODUCTION INDUSTRY

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ABSTRACT: This paper addresses the context of complaints in medical products, analyzing their role in ensuring quality, safety and regulatory compliance throughout the life cycle of medical devices. In the medical industry, the concept of customer goes beyond the commercial dimension, including direct customers, end users and regulatory authorities, whose requirements decisively influence the design, manufacture and use of products. The ISO 9001:2015 and ISO 13485:2016 standards form the basis of quality management systems applicable in this field, promoting customer focus, risk management and process control of medical products. In particularly, ISO 13485 emphasizes regulatory compliance and patient safety, treating complaints as critical sources of information for identifying nonconformities and preventing incidents. For this purpose, the paper presents the main categories of complaints encountered in the medical device industry, namely complaints about quality, functionality, safety, reliability, durability, after-sales service, and defective components. Their characteristics, potential impact on patient safety, and the need to assess the risk associated with each complaint are analyzed. It also highlights the role of structured processes for investigation, root cause determination, and implementation of corrective and preventive actions (CAPA).

KEY WORDS: Quality Management System, Occupational Health, Medical Device, Customer Claims, Risk Management.

1. INTRODUCTION

The medical device industry is characterized by a high level of regulation, technologi-cal complexity, and direct responsibility for patient safety. In this context, the concept of "customer" takes on a broader meaning, including not only the commercial entities involved in the purchase of products, but also end users, patients, and regulatory authorities. Properly understanding their requirements and integrating them into the design, manufacturing, and after-sales processes, it is a central element of quality management systems applicable in the medical field.

The international standards ISO 9001 and ISO 13485 provide the necessary framework for quality, risk, and compliance management, playing an essential role in preventing non-conformities and managing complaints. Quality complaints are an important indicator of medical device performance and a critical tool for continuous improvement, ensuring safety, and maintaining regulatory compliance.

This paper analyzes the context of complaints in the medical device industry, highlighting the link between customer requirements, risk

management, and quality management systems. It presents the main types of complaints, their impact on safety, and the importance of managing them systematically throughout the entire life cycle of the medical device.

2. CUSTOMER'S CONCEPT SPECIFIC TO DEVELOPMENT, MANUFACTURING AND MEDICAL DEVICES PRODUCTION

In the medical industry, the concept of "customer" refers not only to the end buyer, but to all structures that influence or use the medical product. Therefore, the term "customer" in the medical industry is divided into several types, namely:

- Direct customers, which are hospitals, clinics, laboratories, distributors or integrators of medical equipment, or public or private healthcare institutions. In the case of direct customers, they are directly responsible for procurement, implementation, and maintenance [1].
- The end customer is represented by doctors, nurses, medical technicians, and, last but not least, patients. In their case, their needs influence the ergonomics, safety, performance, and ease of use of the medical device.
- The regulatory customer is represented by the competent authorities (notified bod-ies, national authorities). Although not a commercial customer, it defines the mandatory requirements that must be treated as customer requirements.

The concept of the customer in the development, manufacture [2] and medical devices production it is central to the quality management system according to ISO 9001 and ISO 13485 standards. Therefore, due to the major challenges facing the medical industry and the continuous change it is undergoing in terms of quality, safe-ty, and efficiency of operations, ISO 9001 and ISO 13845 standards have become essential tools for healthcare organizations, providing a regulated framework for quality and risk management.

ISO 9001 focuses on general quality management, representing continuous improvement and customer satisfaction, while ISO 13845 is specialized for medical devices, setting strict requirements for quality management systems, ensuring that products are safe and effective for users.

ISO 9001 is the international standard for quality management systems developed by the International Organization for Standardization (ISO). This standard provides a set of principles that help organizations ensure the effectiveness of their processes and deliver both services and products that meet customer and applicable regulatory requirements.

According to the requirements of ISO 9001:2015, implementing a quality management system offers organizations multiple benefits, such as:

- The ability to consistently deliver quality and compliant products and services. This benefit allows the organization to ensure that both its products and services consistently meet customer requirements, as well as applicable legal requirements and regulations.
- Increased customer satisfaction: by consistently delivering compliant products and services, the organization creates various opportunities to improve customer relationships, which contributes to increased customer satisfaction.
- Identifying and managing risks and opportunities: it allows the organization to consider relevant risks and opportunities, taking into account its context and strategic objectives.
- Demonstrating compliance: it ensures that the implementation of the system enables the organization to demonstrate compliance with the specific requirements of the standard, which can bring competitive advantages.

The key principles of the customer concept in the manufacture of medical devices, according to the two standards, are: understanding customer requirements, translating customer requirements into product requirements, and the customer as a benchmark for quality.

Understanding customer requirements refers to explicit requirements (technical specifications, performance) [3] and implicit

requirements (safety, reliability, legal compliance) [4].

Translating customer requirements into product requirements involves transform-ing customer requirements into functional requirements, safety requirements, perfor-mance requirements, testing and validation requirements.

The quality of a medical device is determined by its consistent ability to meet cus-tomer requirements, ensure patient safety through effectiveness and reliability, and comply with regulatory standards, all supported by a robust Quality Management System (QMS) such as ISO 13485.

ISO 13485:2016 is the internationally recognized standard for quality management systems (QMS) applicable to the medical device industry. It sets out requirements for the design, manufacture, distribution, installation, and maintenance of medical devices, as well as related services. The standard is intended to ensure the safety, quality, and compliance of medical devices with legal requirements and international regulations.

ISO 13485 focuses primarily on ensuring the quality and safety of medical devices by implementing a management system that ensures compliance with applicable regulations for medical devices, demonstrates the organization's ability to provide medical devices that meet customer and authority requirements, and minimizes the risks associated with products and manufacturing processes [5].

3. THE ROLE OF CUSTOMER FEEDBACK IN THE MEDICAL DEVICE DEVELOPMENT PROCESS

Customer feedback plays a necessary role in the product development process throughout its entire life cycle, both in the initiation phase (design phase), where information related to design input is presented, the production phase through com-plaints and non-conformities, and the post-sales phase through vigilance regarding possible defects or non-conformities that arise during the use of the devices during the warranty period.

This contributes to continuous product improvement, risk prevention, and in-creased satisfaction and confidence.

In addition to providing feedback, the customer also plays an important role in risk management. Therefore, in the medical industry, customer requirements are closely linked to risk management in order to protect the patient, minimize clinical risks, and ensure the safe and predictable use of the product. At the same time, the customer is equally responsible as both a beneficiary and a vulnerable party in the product use process, which is why safety takes precedence over cost or commercial performance.

The correct application of the customer concept results in safe and effective medi-cal devices, proper compliance with regulations, fewer complaints and incidents, an enhanced reputation for the manufacturer, and sustainable market access.

As a result of the standards presented above, the incorrect functionality of medical devices manufactured as a result of production processes and failure to comply cor-rectly and accurately with customer requirements subsequently leads to various types of complaints, such as: quality complaints, functionality complaints, safety com-plaints, reliability/durability complaints, after-sales service complaints, or complaints about defective components. durability complaints, after-sales service complaints, or complaints about defective components.

Quality complaints in the medical industry represent any documented report or feedback provided by the customer, end user, or competent authority that signals a potential or actual non-compliance of a device or its associated service with the re-quirements specified by the customer, the applicable regulations according to stand-ards, or the expected performance.

The essential characteristics of quality complaints concern: manufacturing defects, malfunctioning or performance below specifications, patient/user safety issues, labeling errors, instructions for use or packaging, incorrect delivery or incomplete documentation, or non-conformities arising

from normal use of the product. According to the context regulated by ISO 13485 or the competent authority FDA, each complaint must be officially recorded, risk assessed, systematically investigated, fully documented, and closed with corrective/preventive actions if necessary.

Functionality complaints in the medical industry indicate that the medical device does not function according to customer specifications or its intended use under normal and correct conditions of use. These defects may occur even if the product is aesthetically or physically adequate but does not fulfill the technical role for which it was designed. Some common complaints where the medical product does not meet the optimal parameters required for the technical role for which it was created are: the device does not start or stops uncontrollably, incorrect, unstable, or non-compliant results, lack of response to commands, intermittent functionality, software errors or system crashes, unstable calibration or loss of settings, performance below stated limits, incompatibility with other specified equipment.

These complaints are considered critical because they can affect patient safety, the effectiveness of medical care, and clinical decisions based on device results.

Similar to quality complaints, functionality complaints have an eight-step process for closure [6], [7] (Figure 1).

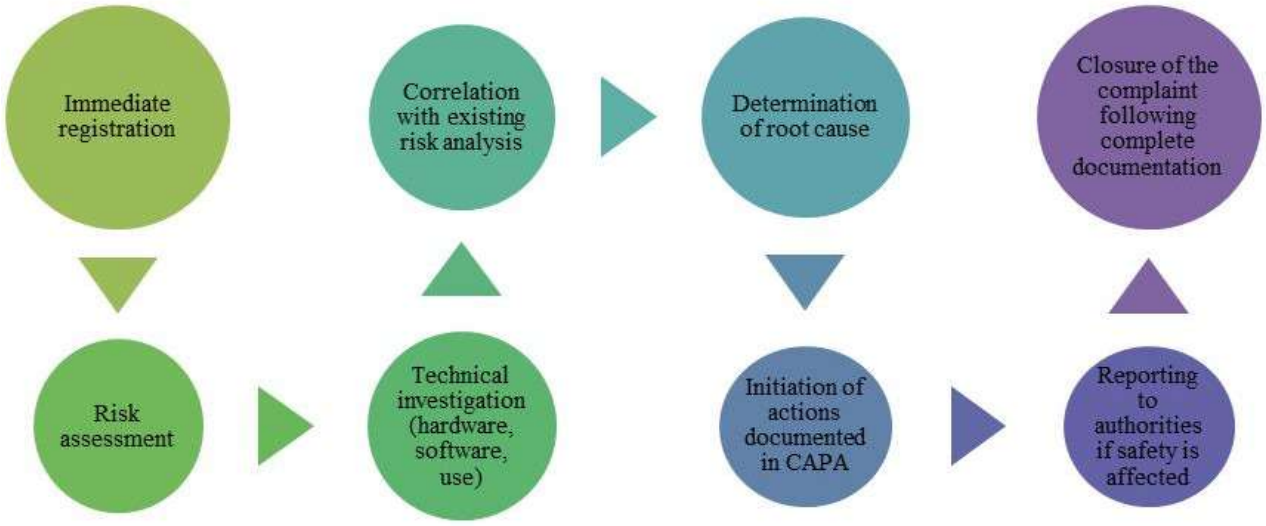

Figure 1. Complaints regarding the functionality of medical devices

Safety complaints are critical quality complaints that signal situations in which the medical device poses or may pose a major risk to patient health or safety, regardless of whether or not it has caused actual harm. This type of complaint is a top priority because it can lead to a major incident or event that could endanger the life or integri-ty of the patient. Some common complaints in which the medical device does not meet safety criteria are: risk of electric shock, overheating or fire, defects that may cause injury to the patient, use of biologically incompatible or contaminated materi-als, lack of critical warnings on the packaging or device, deficiencies in protective mechanisms, loss of essential safety functions, or software errors with an impact on safety.

Reliability/durability complaints are quality complaints that indicate that a medical device does not maintain its specified parameters throughout its declared life cycle, under normal and compliant conditions of use, maintenance, and storage. This type of complaint indicates premature degradation of the product compared to the expectations justified by the specifications stated in the product's user documentation.

Examples of complaints of these types are highlighted in Figure 2.

After-sales service complaints are quality complaints that signal service activities, more

specifically, maintenance, installation, calibration, repair, or technical support processes related to a medical device, after its presence on the market and which present a non-conformity of the service provided with the specified requirements, internal procedures or expectations justified by the customer's technical documents. These may indirectly affect the functionality, reliability or safety of the device.

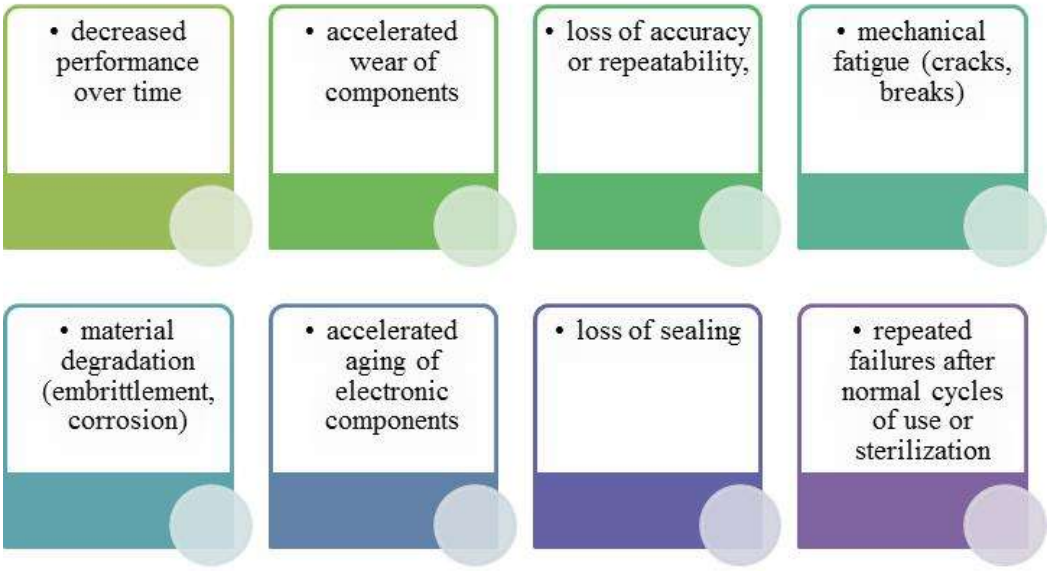

Figure 2. Types of complaints specific to medical devices

Over time, the following types of complaints have been encountered: non-compliant installation of the device, incorrect or unverified calibration, use of unau-thorized parts, incomplete or incorrect service documentation, failure to comply with service procedures, unjustified delays in critical interventions, lack of traceability of interventions, incorrect post-service software configurations.

Complaints about defective components are quality complaints that indicate that one or more components or subassemblies used in the construction of the medical device are non-compliant. They have defects or do not meet the specified technical, functional, or safety requirements, with a real or potential impact on the performance, reliability, or safety of the final product. These complaints can occur both during production and after sale. Over time, the following types of complaints have been encountered: electronic components with parameters outside tolerances, cracked, deformed, or prematurely worn mechanical parts, materials that do not comply with specifications (dimensions, composition), contaminated or degraded components, batches with systematic defects, or incompatibility between components [8].

4. CONCLUSIONS

According to the two presented standards, ISO 9001 and ISO 13485, quality com-plaints, regardless of their type, are an essential source of information for monitoring the performance and safety of medical devices throughout their life cycle. Systematic analysis of complaints allows organizations to obtain real data from the use of products in practical conditions, providing an accurate picture of how medical devices meet the requirements of customers, end users, and regulatory authorities.

Proper, documented, and traceable complaint management directly contributes to the early identification of nonconformities, design, manufacturing, or usage deficien-cies, as well as potential risks associated with patient safety. By correlating com-plaints with existing risk analyses and applying root cause determination processes, organizations can prevent problems from recurring and reduce

the likelihood of inci-dents or adverse events occurring.

At the same time, quality complaints provide valuable input for continuous im-provement processes, supporting the optimization of manufacturing processes, the validation of existing controls, and the updating of technical documentation. The implementation of corrective and preventive actions (CAPA) following the analysis of complaints ensures continued compliance with applicable standards and regulations, strengthening the confidence of customers and competent authorities.

By systematically addressing complaints, organizations in the medical industry can improve product performance, reduce clinical risks, and ensure ongoing compliance with customer and regulatory requirements.

Therefore, complaint handling should not be perceived solely as a regulatory obli-gation, but as a strategic quality management tool that supports the development of safe, reliable, and effective medical products, contributing to patient protection and sustainable growth of organizations in the medical industry.

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