ZESZYT NAUKOWY
Wyższa Szkoła Zarządzania i Bankowości w Krakowie

Piotr Wojciechowski Ph.D.
The School of Banking and Management
piwojcie@wszib.edu.pl

MEDICAL DEVICE QUALITY MANAGEMENT

Introduction

The system of modern health care, which is based on specialist knowledge, uses increasingly more extensively various kinds of medical devices. One cannot imagine present-day medicine without numerous simple and complex devices that are used in diagnosis, prevention, monitoring, forecasting, treatment and alleviation of illnesses, activities related to injuries and disabilities, replacement or modification of anatomical structures, physiological states or illnesses as well as in other similar areas of application. A comprehensive definition of a medical devices is given in the UE Medical Device Regulation (MDR)[1]. Patients have contact with medical devices even during short appointments at GPs where they are examined with a stethoscope, a throat spatula or a sphygmomanometer to measure blood pressure. More specialist examinations, therapeutic, dental and several other operations may involve the use of an ECG apparatus, of syringes and needles in intravenous and intramuscular injections, etc. Hospitals have several thousand various devices, from simple ones to highly complex surgical systems, including the ones based on robotic technology systems, computer tomography devices and surgical lasers. Medical devices are commonly used in domestic conditions. They are meant to be used by laypersons[2] i.e. persons without adequate experience and qualifications. In Poland, medical service quality was first regulated in 1991 when several related issues were indicated, including the methods of medical device acquisition and application[3].

The manufacturers of medical devices, particularly the managing staff, are responsible for meeting a number of legal requirements related to the production and selling of these devices. The requirements are fairly complex. It is necessary to adapt to the changing market conditions, including new medical technologies. The essence of medical device quality management is to meet two basic assumptions:

a) medical devices must be safe for the patient and the user,

[1] Regulation (EU) of the European Parliament and of the Council 2017/745 on medical devices.
[2] The term was introduced by the MDR regulation 2017/745.
[3] K. Garbacz, D. Guziak, *Znaczenie jakości w usługach medycznych w zarządzaniu szpitalem*, Studia i Prace Wydziału Nauk Ekonomicznych i Zarządzania No. 28, Wyd. Nauk. Uniw. Szczecińskiego, Szczecin 2012, p. 45.

b) medical devices must achieve the intended clinical benefits.

The entire supervisory system is based on two interdependent pillars:

a) a system management that complies with the EN ISO 13485 standard or legal requirements,
b) a medical device conformity assessment system leading to CE marking.

The aim of the paper is to make aware people responsible for managing organizations that the issues of medical devices concern not only medical staff but also people without medical education. It is necessary to have basic knowledge in this field in order to make decision at the management level in accordance with legal requirements.

1. What to start with?

This simple question is frequently asked in companies without any experience in the area of medical device production. At the beginning it is necessary to check whether a given product is subject to legal regulations for medical products. This is because there is a danger that a product may be considered a medical device even if does not meet the criteria for the definition of a medical product and in fact it is not a medical device or that a product that is a medical device may be considered as non-medical, which may be a breach of the rules of the conformity assessment system. In the case of a medical device the criteria that are included in its definition must be met. Thus, the following three cases are possible:

1. The device does not meet the criteria in the definition of a medical device. Sometimes, manufacturers tend to qualify their products as medical. The idea is to increase company image and customers' trust to the product. However, one should bear in mind that any pseudo-medical product will be rejected by a registration entity which does not accept such qualification and subsequently will not register the device. When there is no evidence for a clinical value of a given product, it cannot be replaced by the whim of company owners. Obviously, there is always the possibility that a new technology has been developed and there is no scientific evidence to support it. In such cases a clinical trial is conducted whose objective is to prove the effectiveness and safety of the device. Clinical trials are usually associated with research on new drugs or vaccines but they are also performed for medical devices.
2. The device is intended for medical use but it is not qualified in this way by its producer. This is caused by the fact that the implementation of a medical device and its system supervision generate substantial costs and involve the need to meet numerous formal

requirements. However, it should be kept in mind that there are products that should be qualified as medical devices and this path of assessment path must not be ignored.

3. Dual-use products. They may be used as medical devices but also in other areas, for example in cosmetology. A typical example of such products are nose pears, latex gloves, some types of lighting fixtures and many other. In such cases the manufacturer decides on their use, is obliged to inform potential users and prevent unauthorized use of non-medical devices in medical activities.

Unfortunately, the conformity assessment system does not provide for all possible cases, which leads sometimes to an excessive overregulation of requirements for very simple devices. The laryngological spatula is a good example. Spatulas are used by doctors in simple one-time activity. A similar product, which may be more dangerous than spatulas are ice cream sticks. As a non-medical product they have to meet only a few simple safety criteria although their use involves a higher risk of being bitten by children and the contact of the stick with the mucosa may be much longer than in the case of a spatula. However, only for spatulas it is required to provide evidence of biocompatibility, a fairly comprehensive technical documentation, to implement the monitoring of the postproduction experience, to conduct the registration process and several more. Many more similar examples can be given. Thus, although the producers of medical devices see the absurd of the situation, they have to follow legal regulations and any dispute becomes pointless.

After the medical device is identified, its classification must be conducted. There are four classes of medical devices: I, IIa, IIb and III. This stage is significant as the device classification determines a further course of action. Different classes have different requirements. Class I devices are low-risk devices and, consequently, the regulation simplifies somehow the method of conformity assessment. Class III devices are crucial to life functions, e.g. the devices correcting heart defects (artificial heart valves). The requirements are critical in such cases. To ensure correct classification, regulation 2017/745 includes an annex with 22 classification rules. A given device should be assigned to a rule where it fits best. The understanding of the rules described there is significant, especially when more than one rule can be assigned to a device under analysis.

Further work should be developed in two areas. One area concerns the development of an effective quality management system that will include at least the aspects listed in Art.10, item 9 of the regulation. The other area is related to the medical device itself. The work includes designing the device, the development of technical documentation, verification of the

conformity with the requirements and certification in the case of Class IIa, IIb and III devices. For Class I devices, manufacturer's self-assessment path is provided unless the device has measurement functions or is a sterile device. Then a certification body should be involved but only for the assessment of these aspects.

2. Objectives and methods of the systematic quality management in medical device manufacturing

Quality management system for medical device manufacturers should fully support all company processes that ensure a comprehensive supervision of every stage of medical device life cycle. The difference between the concept of quality assurance and quality management is of crucial importance. Quality management is a comprehensive approach to the issue of quality where the success depends on company organization and the determination of strategic and operational targets. Quality assurance is limited to the basic aspects that are related directly to the production and the supervision of the medical device. Obviously, quality management system includes quality assurance. This regards operational areas where main processes are carried out.

The main objective of the quality systems is to ensure medical device exploitation safety. In recent years, the system has been directed towards a proactive acquisition of feedback from the market. Thus, the development of monitoring procedures of postproduction experience became necessary. They cover a lot of information from the market that concern emerging problems, nonconformities, defects, the impact of devices on patients and any events, including serious medical incidents. All serious medical incidents are subject to official reporting and external correcting actions. The monitoring process should consider situations that took place in similar devices of other manufacturers. Thus, a scheduled monitoring is necessary of descriptive databases, e.g. of the security messages of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products[4]. In many cases, it may be necessary to identify the number of devices launched on the market, the types of users and applications and several other important clinical data. The manufacturers should have a system of scientific data storage and its updating. These actions and several similar ones are conducted at the border of the quality system and the medical device. It must be ensured that no relevant information is omitted and the technical documentation is kept updated.

[4] http://urpl.gov.pl/pl/wyroby-medyczne/komunikaty-bezpiecze%C5%84stwa (accessed: 18.05.2021).

The quality management system also includes the assurance of supervision of the production conditions, infrastructure and staff qualifications. Work environment varies and depends, among other factors, on the production profile. On the one hand, some simple products such as bandages are manufactured and on the other devices are produced that have complex measurement functions or ones that have to be produced in sterile conditions. Some products may contain human or animal tissues. All these factors have to be thoroughly considered so that no element is ignored as it may have an impact on the further functioning of the quality system. The system analyzes whether the goals are achieved and what changes should be introduced. Even the best work environment will not meet the expectations if human factors fail. Therefore, supervision over the staff should consider continuous improvement of heir qualifications, competence, skills, work culture and understanding of activities they perform. The lack of knowledge may lead to diminishing the importance of the established rules and taking shortcuts. The manufacturing of medical devices requires the need to comply with strict technological procedures. Despite the fact that the standard does not specify precisely what documents should the manufacturer dispose of, it can be assumed that they should include all the ones that will reduce the risk of errors. Operations that are accomplished in compliance with the established procedures, specifications or instructions have a key significance in the repeatability of the manufacturing processes and the compliance to technical documentation. Employees do not use a complete technical documentation as it contains all the information regarding the conformity assessment of the medical device which in many cases exceeds their needs. Consequently, instructions are prepared that refer to particular working activities at a given workplace.

Every business activity is subject to specific types of errors. They are systematically referred to as nonconformities. Obviously, it is important to prevent their emergence but it is impossible to eliminate them completely. This is the reason why EN ISO 13485 standard provides for preventive and corrective actions. They concern situations when a particular nonconformity has not emerged yet but there is a high probability that it will appear, which means that without any preventive measures the nonconformity is going to occur. Thus, the objective is to prevent the occurrence of nonconformity while corrective actions are taken when nonconformity has already occurred. It is crucial that the scheduled correction actions should concern the causes of a particular nonconformity and not just the nonconformity itself. In the case of medical devices this element of the quality system is particularly important. Nonconformities in the system may not neccesarily concern directly the device itself but several indirect process nonconformities may affect the medical device quality. An example of such a

case is the lack of adequate supervision over the storage of outdated documents. As long the problem concerns the accounting records for example, there is no risk in terms of the device safety. However, such a problem may indicate the possibility of improper supervision in the area of production documents and the use of outdated documentation is already at a high level of significance.

The application of a certified quality management system based on the ISO 13485 standard increases significantly the level of supervision over all steps of medical device manufacturing. The ISO 13485 standard includes also a number of requirements that are adapted to the specifics of medical devices, including the rules regarding the sterility of medical devices with the consideration of their quality and manufacturing standards[5]. Although it is possible in the case of Class I devices to apply simplified quality management, e.g. in line with the ISO 9001 standard and the requirements provided by MDR 2017/745, it seems reasonable to implement a complete system based on the EN ISO 13485 standard.

3. Medical device conformity assessment

The implementation of the system rules of supervision at every stage of medical device manufacturing and selling is a crucial element of the obligatory conformity assessment system within which the compliance with the essential requirements of the medical device regulation is confirmed. However, this is only a part of the necessary actions. Device conformity involves several other activities that are reflected in the technical documentation of the device. Harmonized standards are significant already at the stage of the medical device design. Their implementation results in technical effects which include product safety, reduced risk, the application of the best practices in a particular area, the demonstration and documentation of product features and a number of other important or desired effects[6].

Regulation (EU) 2017/745 describes precisely in Annexes II and III the required content of the medical device technical documentation. Proper development of each section requires significant commitment, referring to standards and guidelines as well as the trial results that were conducted for a particular device. There is a vast range of medical devices and their configurations. Manufacturers have numerous questions that are not answered directly in legal

[5] P. Dulski, *Jakość wyrobów medycznych w ramach normy europejskiej ISO 13485:2003*, Acta Bio_Optica Informatica Medica 4/2008, Vol. 14, p. 298.
[6] Z. Niechoda (translator), *Świat zbudowany na normach. Podręcznik dla studentów szkół wyższych*, Danish Standards Foundation, Nordhavn 2015, p. 36.

acts or technical standards. Some aspects need interpretation. These are given for example in Medical Devices Documents MEDDEV). Meddev guidance[7] is the basic one. There is also a working group within the Medical Device Coordination Group (MDCG)[8] whose task is to explain several issues concerning the new MDR.

A preliminary review of the references to legal and standard documents as well as guidelines well illustrates the complexity of the issues that every manager responsible for supervising the production of medical devices must consider. Obviously, this broad approach to the issue of guidelines does not mean that all doubts will be cleared[9]. Thus, current ad hoc solutions must be subject to further evaluation. Such parts of technical documentation as the medical device clinical assessment, risk analysis, effectiveness analysis or software validation (if applied) should be reviewed in terms of up-to-date data. The identification of all new or altered factors may result in the necessity to introduce changes or additions in user manuals.

Depending on the classification of the medical device, the conformity assessment may require a cooperation with a certifying body which on the basis of investigation is competent to state either the conformity or the non-conformity and the resulting need for alterations and additions. The body, after the analysis of the documentation and the device manufacturing processes, issues a conformity certificate when the analysis results are positive. However, the certificate does not replace the manufacturer's declaration of conformity nor does it remove the responsibility for the device. The company management staff should take this into consideration.

Conclusions

The article does not present all issues regarding medical device quality management. Manufacturers frequently employ external consultants to help them with conducting proper conformity assessment. This attitude may be reasonable on the condition that consultant's work is only complementary and it does not replace company's activities. The counselling process should focus on the understanding of the requirements that concern medical devices and the quality management system. New requirements that are introduced by MDR 2017/745 impose a number of obligations related to ongoing supervision. This is the reason why it is necessary

[7] https://ec.europa.eu/health/sites/default/files/md_sector/docs/md_guidance_meddevs.pdf (acccessed: 18.05.2021).
[8] https://ec.europa.eu/health/md_dialogue/mdcg_working_groups_pl (accessed 18.05.2021).
[9] M. Koperny (et al.), *Wytyczne oceny technologii medycznych. Wyroby medyczne ,* Przegląd aktualnego stanu wiedzy i rozwiązań, Agencja Oceny Technologii Medycznych i Taryfikacji, Warszawa 2019, p. 60.

to take over full responsibility for any activities that are not related only to the initial period after the implementation of the system principles and the development of technical documentation. This includes every subsequent medical device's life stage and consequently, the consulting activities should regard the support of company's operating principles.

Medical devices may cause several risks to patients and users. Great significance should be attached to the supervision over them, which is reflected by a steady increase of requirements. Moreover, the legal responsibility of manufacturers is rather high. Therefore, every effort should be made to adapt as much as possible all company's processes in order to effectively supervise the production and provision of safe and effective medical devices to their users.

Bibliography

[1] Dulski P., *Jakość wyrobów medycznych w ramach normy europejskiej ISO 13485:2003*, Acta Bio_Optica Informatica Medica 4/2008, Vol. 14.

[2] Garbacz K., Guziak D., *Znaczenie jakości w usługach medycznych w zarządzaniu szpitalem*, Studia i Prace Wydziału Nauk Ekonomicznych i Zarządzania nr 28, Wyd. Nauk. Uniw. Szczecińskiego, Szczecin 2012.

[3] Koperny M. (et al.), *Wytyczne oceny technologii medycznych. Wyroby medyczne (Medical Devices),* Przegląd aktualnego stanu wiedzy i rozwiązań, Agencja Oceny Technologii Medycznych i Taryfikacji, Warszawa 2019.

[4] Niechoda Z. (translator), *Świat zbudowany na normach. Podręcznik dla studentów szkół wyższych*, Danish Standards Foundation, Nordhavn 2015.

[5] Regulation (EU) of the European Parliament and of the Council 2017/745 on medical devices.

[6] https://ec.europa.eu/health/md_dialogue/mdcg_working_groups_pl.

[7] https://ec.europa.eu/health/sites/default/files/md_sector/docs/md_guidance_meddevs.pdf.

[8] http://urpl.gov.pl/pl/wyroby-medyczne/komunikaty-bezpiecze%C5%84stwa.

Abstract

Medical device quality management is a crucial part of economy. Legal regulations impose a number of obligations on manufacturers and the management staff without medical education should be aware of them. Medical device manufacturers should implement a quality management system and meet the requirements of the conformity assessment system. The

involvement of certification bodies or the use of external consultancy does not release companies from responsibility for medical devices. Thus, the understanding of all requirements and their implementation is necessary in companies that are involved in manufacturing and selling medical devices.

Key words

Medical devices, quality, conformity, effectiveness, safety.