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HANDLING OF MEDICAL DEVICES' CUSTOMER COMPLAINTS ON THE EXAMPLE OF COMPANIES BASED IN POLAND

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Purpose: The main purpose of this article was to identify and analyze correction activities and corrective actions, taken by medical devices' companies, as a result of a customer complaint.
Design/methodology/approach: The article presents the results of the study conducted among medical devices' companies, operating on the Polish market. These companies have implemented and certified quality management system in accordance with the requirements of ISO 13485. In addition, these companies, as part of their activities, carry out various processes related to medical devices, but performing production process was the main criteria for qualifying the company for the study. On this basis, 209 companies, meeting these criteria, have been defined. The study was conducted using a survey questionnaire, available in electronic form. As part of the survey, 90 correctly completed survey questionnaires were received, what means that the response rate of surveys reached the level of 43%.
Findings: The most important correction activities, indicated by the surveyed companies, include verification of suspicious products throughout the whole supply chain and replacement of a defective product with a new one. From the corrective actions perspective almost 70% of respondents indicated trainings of production employees. This is strongly related to the identified root causes, by these companies, as operators' errors (50% of the causes lie with such errors). Almost 50% of respondents declared the update of work instructions as a corrective action, which is also related to the high number of indications for operator trainings.
Originality/value: The article presents main activities, that are taken by the medical devices' companies in Poland to increase the safety and performance of medical devices, if an abnormality occurs. The article may be treated as an benchmark for medical devices companies once reviewing their approach to implementing corrections and corrective actions.

Keywords: Customer complaint, medical device, containment, corrective actions.

Category of the paper: Research study.

Introduction

Medical devices are key products for the provision of healthcare, both from the prevention and treatment side. Medical devices cover a wide range of products, from syringes to advanced diagnostic and surgical devices. Depending on the market, different devices may be classified as medical devices. It is assumed that there may be up to 2 million medical devices in the world (POLMED, 2022).

The medical devices industry is a very dynamically developing branch of industry, both on a global scale and in Poland. The development of the medical device market has been observed for many years, as well as the prospect of future, of at least 8 years, looks definitely promising. In 2021, the value of the global medical device market was estimated at USD 488.98 billion. In 2022, the market is projected to reach $495.46 billion and is projected to grow steadily to reach $718.92 billion in 2029. The growing market for medical devices is associated with a high demand for medical devices, and this demand is caused by many factors, such as: an aging society, the spread of chronic diseases, increasing emphasis on early diagnosis of diseases and preventive treatment. However, global turmoil, such as the global COVID-19 pandemic, is not without significance for the development of the market. It caused a decrease in the market of medical devices by 1.9% in 2020 compared to 2019 (Medical Market Research Report, 2022). On the one hand, there was a much higher demand for medical devices used to equip hospitals and the so-called temporary hospitals (e.g. medical beds), and on the other hand, there was visible decrease in demand for medical devices not related to the fight against the effects of the coronavirus. A smaller number of planned treatments and operations resulted in the cancellation or postponement of orders for medical devices for surgical, oncological or aesthetic medicine applications. Companies, belonging to the medical device industry, had to approach their activities in a very flexible way and revise them to meet current needs (Queen, 2021, pp. 247-248).

The value of the Polish medical devices market, measured by the revenues of enterprises in this sector, was estimated at PLN 17.5 billion in 2020 (POLMED, 2022). The cited value of the medical devices market in Poland is systematically growing, which can be seen basing on the comparison of this value with the value of the market from 2010, when it amounted to PLN 3.5 billion (Rutkowski, 2021). The POLMED report (2022) also specifies that in Poland there is a significant number of entities that are manufacturers, importers or distributors of medical devices, which was estimated at 5266 enterprises.

The need to develop diagnostic and treatment procedures, within the healthcare system, causes a dynamic development of the medical devices market, on a global scale, in Europe or in Poland, as mentioned above. However, this development not only brings opportunities for the development of enterprises in this industry, but also may bear the hallmarks of risk. These risks may be related to the high speed of introduction of new, innovative products on the

market, which are also designed and manufactured in a dynamic and changing environment. This, in turn, can cause defects of medical devices, that can appear at different stages of the device's life cycle, from the design phase of the device to the delivery, servicing and disposal phase of the device. The defects in question and the related irregularities in the functioning of the medical device are not limited to any type of medical device – it may concern any type of medical equipment. The consequences can be seen as a threat to the health or life of patients. Such a threat may occur in the form of infections, a longer time of conducting a medical procedure or the need to stop it while working (Wąsik, 2017).

Medical devices that do not meet their intended function (effectiveness) or are considered dangerous (device safety), in addition to local regulations on reporting medical incidents, are reported to the manufacturer (directly or indirectly) for the purpose of conducting a complaint procedure. The complaint procedure is aimed, above all, at the ongoing protection of users of medical devices and ultimately the introduction of such actions that will prevent the occurrence of a problem in the future, due to the identified root cause. Based on the above, purpose of this article is to identify and analyze corrections and corrective actions, taken by companies in the medical device industry in Poland, as a result of a complaint received regarding a medical device. One can assume than that properly planned and implemented corrections and corrective actions are an important element in ensuring the safety and effectiveness of medical devices.

2. Safety and effectiveness of medical devices

Medical devices, due to their use in the health care system, are treated as devices of particular importance. It is required that medical devices, when providing medical assistance, will be characterized by safety and effectiveness in relation to the patient and persons, performing medical procedures (Wąsik, 2017). Analyzing the historical and current European regulations in the field of medical devices, it can be concluded that the safety of medical devices means the absence of unacceptable risk when the device is used in accordance with its intended purpose, defined by the manufacturer (EU Regulation 2017/745; Feliczek, 2014). Analogous to the safety feature of a medical device, the second key parameter is the effectiveness of its functioning. In turn, performance should be understood as the ability of a device to achieve its intended use, while the product is used as defined by the manufacturer (EU Regulation 2017/745).

In order to ensure the safety and effectiveness of a medical device, laws and regulations are created and must be implemented, by companies involved in processes related to medical devices, to be able to offer such device on the market (release on the market). Requirements for companies related to medical devices, both from legislation and industry, concern not only the

technical aspects of devices, but also organizational issues of the company, such as implementation and maintenance of the quality assurance system.

Designing a medical device, producing a prototype, testing a trial series (including the implementation of clinical trials, if required) and placing the medical device on the market are only the implementation of the initial stages in the life cycle of the medical device, according to the scheme shown on figure 1.

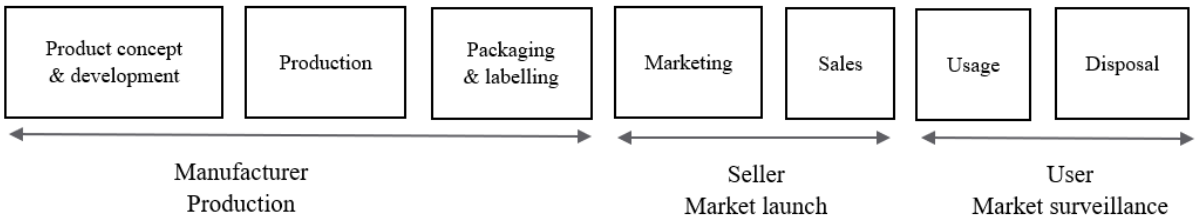

Figure 1. *Life cycle of a medical device.* Source: (Sakłak, 2016).

Market surveillance, which begins after the stage of placing a medical device on the market, occurs throughout the entire further life cycle of the device, up to its disposal, and consists in ongoing monitoring of the safety and effectiveness of the medical device (Sakłak, 2016). In the opinion of this article authors, market surveillance can be divided into two types, depending on the entity that conducts it. On the one hand, we have formal market surveillance, carried out by specialized and dedicated state administration units, and on the other hand, we have market surveillance carried out, in a natural way, by companies in the medical device industry.

An example of the first group conducting market surveillance is the American Food and Drug Administration (FDA), in the United States of America, and the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (abbreviation: URPL), which supervises the Polish market. Referring to the motto of the Polish URLP "Acting in the area of medicinal products, medical devices and biocidal products, we protect health and care about the safety of society" (URLP, 2022), periodic surveillance programs, over the medical devices market, are created. The currently available market surveillance program, from 2021, assumed the following activities of the Authority (URLP, 2022):

- collecting and analyzing information on the safety of devices,
- control of undertakings involved in processes relating to medical devices, including their subcontractors established in the territory of Poland,
- issuing administrative decisions concerning devices.

Analyzing the market surveillance program, it can be concluded that the implementation of proceedings against medical incidents (adverse events) and actions related to the safety of medical devices also plays a very important role. A medical incident will be perceived as abnormality concerning a medical device such as a malfunction, defect, deterioration of the characteristics or performance of the device, but also a abnormality in the marking or instructions. In order to fulfil the definition of a medical incident, another condition must still

be met, namely that the nonconformity in question may or could have led to the death or serious deterioration of the state of health of the patient or user of the device. In addition, this nonconformity initiates the launch, of the so-called, Field Safety Corrective Actions (FCSA). The goal of these external actions is to minimize serious deterioration of health or to minimize the risk of death (URLP, 2022). On this basis, it can be concluded that not every abnormality noticed will be a medical incident, which, in principle, is of interest to the URLP, within the framework of formal market surveillance, implementing the program of this surveillance. However, any abnormality noticed should be of interest to the relevant company, operating in the supply chain of the medical device industry.

As mentioned above, medical device companies also carry out some market surveillance, but in a less formal way. Companies involved in processes related to medical devices do not have a market surveillance program because this is not their core business. These undertakings, as part of their supervision, collect various information from the market, from those relating to the needs for the development of the product, the change of its design or functionality (as an entry into the design of new products or a change in the design of existing products) to the abnormalities of the product that have been noticed. If this non-compliance is not a medical incident, then all data, in this respect, remain with entities that are related to this abnormality (device design entity, component suppliers, device assembler, sterilization process supplier, etc.) and are not provided as part of formal market surveillance. Non-compliance with a product is usually considered as part of the company's internal complaint handling process and in accordance with the procedure adopted there. Procedures related to the handling of complaints are often based on requirements, in this respect, applicable on the market where the medical device is authorized for marketing and non-compliance has been noticed.

3. Process of handling customer complaints

According to the standard of ISO 13485:2016, which specifies requirements for quality management system, for companies in the medical device industry, a complaint is "a written, electronic or oral notice stating deficiencies related to the identity, quality, durability, reliability, usability, safety or performance of a medical device that has been exempted from the supervision of the organization, or related to a service that affects the operation of such medical devices" (ISO 13485:2016). Analyzing the mentioned definition of a medical device complaint and comparing it with the general definition of a complaint included in the ISO 9001:2015 standard, it can be concluded that it is quite detailed and wide in its scope. Taking this into account, it can be concluded that any noticed abnormality related to the medical device will be subject to complaint. The definition of a complaint, included in the ISO 13485:2016 standard, is not the only definition of a complaint within the medical device industry. Depending on the

market, the definitions of a medical device complaint may vary, sometimes even significantly. However, regardless of the definition of a medical device complaint, the most important thing is the process of dealing with complaints, including early identification whether the reported defect is really a non-compliance and endangering the health or life of the patient or user of the device[1].

The process of handling complaints is one of the processes functioning in the company, and begins with receiving information from an internal or external client. In this way, we distinguish two types of complaints, internal and external, where an external complaint is a report from outside the company about a noticed abnormality. Internal complaints, i.e. those coming from the interior of the company, should be of great importance for the organization, because defects are detected by employees who notice them themselves. The occurrence of internal complaints testifies to a well-designed and functioning internal quality control system and a high level of quality awareness of the company's employees. Complaints can also be classified due to the form of information received, i.e. official and unofficial complaints, due to the importance of the complaint (low, medium, high), as well as assuming the criteria of the subject of the complaint (component for the production of the product, semi-finished product, finished product) (Szczerba, Białecka, 2016). In the context of this article, the authors are interested in complaints received from external customers for a finished medical device, but the reason may of course be, for example, on the design side, components or production process.

After the stage of receiving information from an external customer, the next stages of the process of dealing with customer complaints, which are listed in Table 1, are implemented.

Table 1.
Phases of complaints' handling process

Phase
Receiving information from an external customer and registering a complaint
Preliminary analysis of the reported abnormality and risk analysis
Introduction of corrections (if possible)
Analysis of the samples received (if required) and confirmation of nonconformity
Root Cause Analysis
Planning corrective actions
Implementation of corrective actions and verification of their effectiveness
Closing the complaint along with communication with the customer

Source: Own study.

After receiving a report from the customer, the company makes a preliminary analysis of the reported abnormality and evaluates the level of risk associated with this abnormality. Depending on the defect, it is sometimes possible to confirm the nonconformity already on the basis of the evidence provided (e.g. photos, videos, descriptions), and thus quickly plan immediate corrections, aimed at protecting the customer on an ongoing basis against receiving defective products. Similarly, based on the information received, it is also possible to analyze

[1] A complaint is "an expression of dissatisfaction addressed to an organization related to its product or service, or the complaint handling process itself, where a response or solution is expected or required" (ISO 9001:2015).

the root cause and plan corrective actions that will eliminate the root cause of the problem, so that the defect does not occur in the future, due to this identified root cause.

However, if the information provided is insufficient, the customer is often expected to submit samples of defective products for further investigation. Only the conducted analysis leads to confirmation or rejection of nonconformity, and consequently starts or stops the further process of dealing with the complaint. One may be dealing with a defect that is revealed only under certain conditions, which cannot be verified on the basis of the preliminary information received. In this case, the company may introduce basic corrections (such as additional control in or after the production process), but the effectiveness of such actions may be limited. Therefore, it is important to be quick in cooperation between the customer and the company, in terms of providing the required information and samples, and this will additionally depend on the level of risk associated with the reported abnormality.

If the nonconformity of the product is confirmed, the company shall analyze the root cause of this nonconformity. This is one of the most important stage of the complaint handling process, because the proper identification of the root cause will determine whether corrective actions are properly planned, and thus whether the effectiveness of the complaint handling process will be achieved. Various quality management methods and techniques can be used to identify the root cause of nonconformity, such as 5 x Why, or the Ishikawa diagram or a combination thereof. The implemented corrective actions should be verified in terms of their effectiveness. Different methods of this verification are adopted, from simulating the occurrence of an error, after the implementation of corrective actions, to market surveillance consisting in observing whether customers continue to observe a given problem, within a given period. At the same time, only the confirmed effectiveness of corrective actions allows the company to resign from maintaining the introduced corrections (e.g. additional product control if such was introduced). Closing the customer complaint and appropriate communication with the customer, in this respect, carry out the last stage of the complaint handling process.

Two stages of the complaint handling process have been of particular interest in the context of the conducted research. This is the stage of corrections and the stage of corrective actions. It is these stages, that are aimed at the current and target protection of the customer against receiving nonconforming products, and thus ensure the safety and effectiveness of the product, already in the phases after the product has been released on a given market.

4. Corrections and corrective actions in the process of handling customer complaints of medical devices

4.1. Method of the study

The subject of the conducted study, regarding the type of corrections and corrective actions introduced, as a consequence of receiving a medical device's complaint, were companies in the medical device industry, operating on the Polish market. These companies have implemented and certified quality management system in accordance with the requirements of ISO 13485. In addition, these companies, as part of their activities, carry out various processes related to medical devices, but performing production process was the main criteria for qualifying the company for the study. Basing on the defined criteria, 209 companies, meeting these conditions, have been defined.

The study was conducted using a survey questionnaire, available in electronic form. As part of the survey, 90 correctly completed survey questionnaires were received, what means that the response rate of surveys reached the level of 43%.

The surveyed companies, to a large extent, also carry out other processes related to medical devices, apart from their production process. Almost 78% of companies distribute medical devices and almost 50% design medical devices. In particular, in the context of the simultaneous design and manufacture of medical devices, this is an important aspect from the point of view of implementing of corrective actions, aimed at changing the design of the device, if the root cause is in this respect. It can certainly be said that the process of changing the design of a product can be much faster, when the manufacturer of the product, at the same time, has a direct impact on its design. If the company is a so-called contract manufacturer (is responsible for the contract production process) then the process of changing the design of the product may be more complicated. At the same time, this may cause that the target corrective actions will be introduced longer, and thus corrections, temporarily securing the client, will need to last for a longer period.

Analyzing the organizational aspects of the surveyed companies, over 80% of organizations are large or medium-sized enterprises, operating in the form of a limited liability company. More than half of these companies have the advantage of foreign capital. Almost 70% of the surveyed companies, in addition to a certified quality management system according to the requirements of ISO 13485, also have an implemented and certified quality management system, according to the requirements of ISO 9001, and a quarter of these organizations also have a certified safety and environmental management system.

4.2. Identification of corrections – study results

The first area of interest, as part of the conducted study, were corrections taken as a response to the customer's complaint regarding medical device. As already indicated in this article, corrections may be introduced immediately after the receipt of a notification of abnormalities, but not in every case or not every time they will achieve the assumed effectiveness. This is particularly important in the case of non-obvious defects (e.g. related to electronic systems of medical devices). On figure 2 it is shown the distribution of responses to the question about corrections. Respondents indicated types of corrections that have been introduced in their companies.

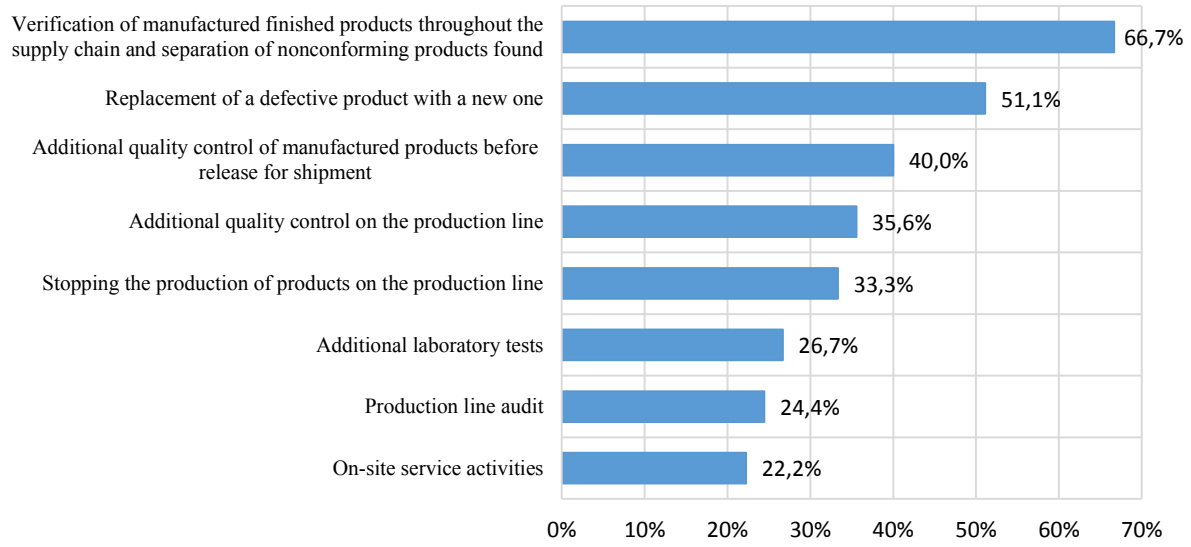

Figure 2. Corrections. Source: Own study.

Based on the answers presented on figure 1, it can be seen that almost 67% of respondents indicate a check of already manufactured products, throughout the supply chain and the separation of nonconforming products (suspicious – at this stage this is also how these products can be defined). The entire supply chain can mean for a company:

- stock levels of finished products within the organization itself or in external warehouses under the supervision of the company,
- medical devices in transport,
- medical devices in the customer's warehouse.

Regarding medical devices at the customer's site, such devices may also be on his production line if the device undergoes additional processes (e.g. sterilization). The task of the company, that received the complaint, as part of corrective action, is to carry out an inspection of the products, in accordance with the defined instruction or requirements, specified in another form. To carry out inspections, in particular of products in transport and at the customer's site, companies often involve specialized companies, that provide such inspection services. In this case, it seems even more important to properly prepare and pass the requirements for such a check. An alternative to carrying out an inspection of products at the customer's site is

the transport of the customer's inventory to the company. However, the customer's needs, including temporary ones, should be taken into account here.

The next most frequently indicated answer, in terms of corrections, is the replacement of a defective medical device with a new one, what was indicated by over 50% of respondents.

Additional quality control of manufactured products, before release for shipment, is an activity indicated by 40% of the surveyed companies. The difference between the most frequently indicated corrective action and the currently discussed one is that it concerns products that have not yet been transferred to the warehouse in the company, i.e. they are in the production area, which does not mean, however, that the products are still going through some production processes. In this case, however, precise requirements should also be indicated for carrying out additional control and handling products that do not meet the required parameters.

Slightly less indications were given to the answer regarding additional quality control on the production line (35.6%) - in this case, medical devices are still subject to production processes, i.e. we can determine that, at this stage, they are semi-finished products.

Stoppage the production of the medical device was given as another correction activity (33.3%). This may mean that the company is not able to continue the production of the product with the assurance that the requirements for the product are met.

Additional laboratory tests, production line audit or service activities at the customer's site were indicated, as part of the study, by about a quarter of the surveyed companies. Referring to additional laboratory tests, it can be stated that it is also a kind of control of semi-finished products or finished products (as discussed earlier), but in a different, specialized environment, using dedicated control and measurement equipment.

Respondents were also asked to indicate whether similar corrective actions are also taken for other types of products, manufactured on the same production line as the claimed product. A significant proportion of companies (almost 70%) answered positively the question asked. This proves the high level of quality awareness of people who supervise the process of dealing with customer complaints. Focus is given not only on the claimed product, but also on potential other devices, in order to minimize the risk of further abnormalities, including those related to the safety and effectiveness of the medical device.

4.3. Corrective actions – study results

As part of the survey, respondents indicated corrective actions that they take in connection with the received complaint regarding medical device, after confirming the nonconformity and after analyzing the root cause, causing this nonconformity. Figure 3 shows the indications of the companies examined.

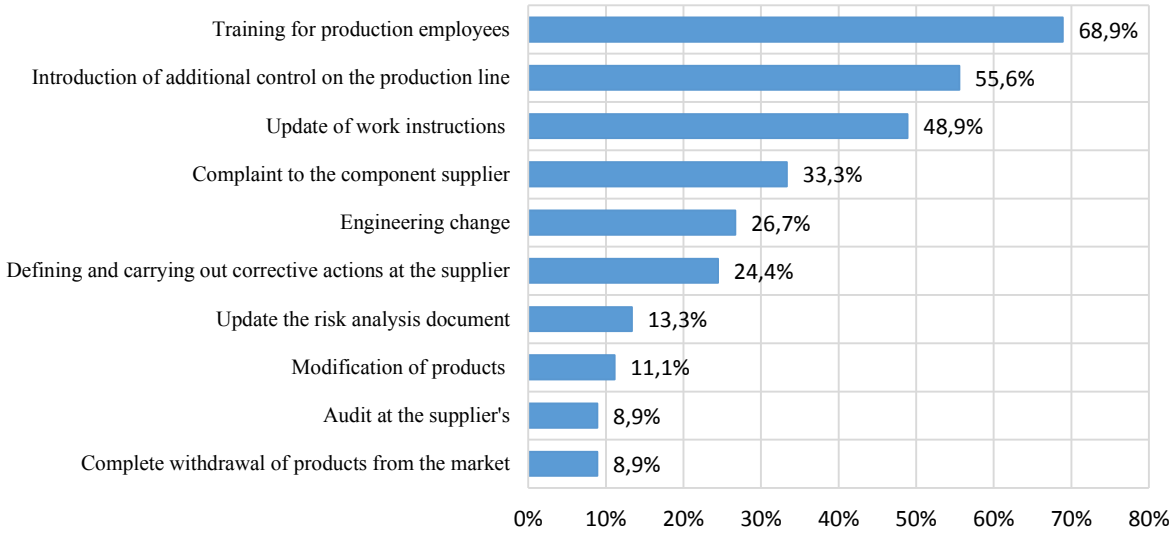

Figure 3. Corrective actions. Source: Own study.

Around 70% of the companies indicated that within the corrective actions taken there are trainings for direct production employees. Training is a very important element of the quality management system in the medical device industry, and employees should be aware of the nonconformities generated in production processes. A well-designed and implemented training system can bring measurable results in the company. However, such a high share of employees' trainings may come as a surprise, as usually the most desirable solutions are permanent solutions of a technical nature (e.g. machines, process parameters). Such solutions, as a rule, are to ensure that the abnormality that caused the complaint does not occur again, due to the identified cause. By analyzing the answers to additional questions asked to respondents, it is possible to explain the reason for such a high level of response related to trainings. Almost 50% of the root causes of complaints lie on the side of operator errors, according to the declaration of the surveyed companies. At the same time, this may mean that among the surveyed companies in the medical device industry, a significant part of the organizations are characterized by manual production processes, where the operator's participation plays a very important role and there is also a high level of probability of making a mistake (Feliczek, 2022). Probably increasing the level of automation, also as part of corrective actions and making the production process independent from the direct influence of the operator, is a direction of reducing the number of operators' errors.

The introduction of additional control on the production line is another corrective action taken by the surveyed companies in terms of the share of indications (55.6%). It can be observed that the additional control of the products was also an important correction activity. This, in turn, may mean that corrections turn into corrective actions over time. Such decisions can be made, by company, in a situation where the root cause cannot be properly identified or there is no possibility, at a certain moment, of introducing another type of corrective action. Additional control on the production line will often also be associated with a change in the production instructions and with operator training, as described above.

The third, in order, corrective action is the update of work instructions, what was indicated by almost 50% of respondents. This corrective action seems to be very much related to the action of operator trainings. If the need to update the documentation is identified in the company, then it is natural to conduct training on the new content of the updated instructions. On this basis, it can be concluded that these 50% of companies, updating documentation, at the same time train operators. The remaining almost 20% of companies (out of 68.9%) train operators without making changes to the instructions, i.e. remind employees of the principles described in the applicable documentation.

Engineering change, indicated by 26.7% of respondents, is an action that is taken primarily due to the fact that the current design of the process generates abnormalities. This is a type of corrective action, which is strongly desirable due to its durability and definitely less dependence on the human factor.

Historical analyses of medical device recalls, from the US market, have shown that defects generated by suppliers of components or services for the production of medical devices accounted for a significant share, immediately after defects related to the design and production of the finished product (Feliczek, 2013). The current research shows that almost a quarter of corrective actions also concern suppliers. In the case of defects, where the source is related to suppliers, the complaint handling process is additionally difficult, for example due to the time frame, where after confirming the nonconformity of the product, the topic is redirected to the supplier. Then it is best to ensure immediate corrective actions on the part of both the company and its supplier.

Analysis of the risk evaluation document, product modification, audit at the supplier and complete recall of the product from the market are the following corrective actions with a share of 13.3%, 11.1%, 8.9% and 8.9% respectively.

On the basis of the above-presented responses from the companies, in the scope of corrective actions taken, it can be concluded that these activities concern many aspects of the organization's functioning, from the design of the device, suppliers of components and services, to the production of the medical devices itself. It should be noted, however, that several actions can be implemented simultaneously, in particular when the defect of the medical device is of a complicated nature or the organization is not able to clearly determine the root cause of the abnormality. Then the implemented corrective actions eliminate various potential causes.

5. Conclusions

Level of medical devices quality is represented by the parameter of safety and effectiveness of the device. The point is that a device, that is used in the case of a person already affected by some form of injury, impairment or other, requiring medical intervention, does not generate an unacceptable risk and fulfills its intended purpose (Feliczek, 2014).

In the supply chain of products of every industry, abnormalities in the functioning of products appear, and can be caused by the design of the product, suppliers of components and services or the production process of the finished product itself. Similarly it is in the dynamically developing medical device industry, with the consequences of abnormalities threatening the health or life of people.

Any abnormality requires an appropriate response and analysis, including analysis for medical incident reporting. Reporting the product nonconformity from an external customer triggers the complaint handling process. As part of this process, corrections are taken to protect the customer on an ongoing basis against receiving nonconforming products and corrective actions, within the framework of which the company tries to eliminate the root cause of the resulting nonconformity. The ultimate goal of the company, in this regard, is not to receive a complaint in the future for the same defect, generated by the identified cause.

As part of the survey, among the medical devices' companies in Poland, carrying out the production processes, the most common corrections and corrective actions were indicated. In response to the received product complaint. It should be emphasized that the actions taken should always be adequate to the level of risk that a given irregularity represents.

The most important correction activities (over 50% of indications) include verification of suspicious products throughout the whole supply chain and replacement of a defective product with a new one. Verification of finished products, throughout the supply chain, seems to be quite demanding (in particular in the case of many places where products are stored), but at the same time necessary.

When it comes to corrective actions that are implemented by the companies, almost 70% of respondents indicated training of production employees. This is strongly related to the identified root causes, by these companies, and related to operator errors (50% of the causes lie with such errors). In addition, almost 50% of respondents declared the update of work instructions as a corrective action, which is also related to the high number of indications for operator trainings (to a large extent, training is made based on updating documentation). More than 50% of the surveyed companies determined that additional control of products on the production line is also a corrective action for them. This may mean that the corrections, in this form, transforms into a target corrective action, with it being difficult to say that such an action eliminates the root cause of the nonconformity.

References

1. Feliczek, P. (2013). Supplier management in medical devices industry. *Towaroznawcze Problemy Jakości, 2(35).* Radom: Wydawnictwo Uniwersytetu Technologiczno-Humanistycznego im. K. Pułaskiego, Wydawnictwo Naukowe Instytutu Technologii Eksploatacji – PIB.
2. Feliczek, P. (2014). *Determinanty skuteczności systemu zarządzania jakością w przedsiębiorstwach branży wyrobów medycznych. Praca doktorska*. Uniwersytet Ekonomiczny w Poznaniu.
3. Feliczek, P. (2022). Ocena świadomości wpływu pracowników branży motoryzacyjnej na kształtowanie jakości wyrobu. *Problemy jakości, 3.* Wydawnictwo SIGMA-NOT.
4. Medical Market Research Report 2022, https://www.fortunebusinessinsights.com/enquiry/request-sample-pdf/medical-devices-market-100085, 7.08.2022.
5. PN-EN ISO 13458:2016 – Wyroby medyczne – Systemy zarządzania jakością – Wymagania do celów przepisów prawnych.
6. PN-EN ISO 9000:2015-10 – Systemy zarządzania jakością – Podstawy i terminologia.
7. Queen, D. (2021). Impact of COVID-19 on the medical device companies who serve wound care. *International Wound Journal, 18(3),* 247-248.
8. Rozporządzenie Parlamentu Europejskiego i Rady (UE) 2017/745 z dnia 5 kwietnia 2017 r. w sprawie wyrobów medycznych, zmiany dyrektywy 2001/83/WE, rozporządzenia (WE) nr 178/2002 i rozporządzenia (WE) nr 1223/2009 oraz uchylenia dyrektyw Rady 90/385/EWG i 93/42/EWG.
9. Rutkowski, E. (b.d.). *Rynek urządzeń i sprzętu medycznego w Polsce*, https://medical.trade.gov.pl, 8.08.2022.
10. Sakłak, M. (2016). *Zarządzanie ryzykiem w procesie wytwarzania aktywnych wyrobów medycznych*, https://ruj.uj.edu.pl/xmlui/bitstream/handle/item/150510/saklak_zarzadzanie_ryzykiem_w_procesie_wytwarzania_2016.pdf?sequence=1&isAllowed=y, 22.08.2022.
11. *Sektor wyrobów medycznych w Polsce. Wielkość, oddziaływanie, znaczenie. Raport Polmed 2022*.
12. Szczerba, B., Białecka, B. (2016). Ogólne założenia do budowy systemu zarządzania reklamacjami. *Systemy Wspomagania w Inżynierii Produkcji, 4(16).* Wydawnictwo STE Group.
13. Urząd Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych, https://www.urpl.gov.pl/pl/wyroby-medyczne/nadz%C3%B3r-rynku/program-nadzoru-rynku, 20.08.2022.
14. Wąsik, D. (2017). Prawnokarne aspekty wytwarzania i obrotu wyrobami medycznymi. *Prokuratura i Prawo, 9.* Wydawnictwo Prokuratury Krajowej.