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QUALITY ASSURANCE OF MEDICAL DEVICES. COURSE OF THE STUDY PROGRAMME IN BIOMEDICAL ENGINEERING

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***Summary**: The paper presents the main problems of quality management system regarding to medical devices, a short presentation of the Romanian certification body for medical devices and the objectives and topics of the course Quality Assurance of Medical Devices and its importance for the specialists in Biomedical Engineering.*

***Key words:** quality management system, quality assurance, medical devices, bachelor studies, Biomedical Engineering programme.*

KONTROLA KVALITETA MEDICINSKIH UREĐAJA. TOK STUDIJSKOG PROGRAMA U BIOMEDICINSKOM INŽENJERSTVU

***Rezime:** U radu su predstavljeni glavni problemi upravljanja sistemom kvaliteta medicinskih uređaja, kratka prezentacija Rumunskog registra medicinskih uređaja, i ciljevi i teme kursa Kontrole Kvaliteta Medicinskih Uređaja i njen značaj za biomedicinsko inženjerstvo.*

***Ključne reči**: upravljanje sistemom kvaliteta, kontrola kvaliteta, medicinski uređaji, osnovne studije, program biomedicinskog inženjerstva.*

1. INTRODUCTION

Generally, an effective quality management system is recognised as a key regulatory consideration for allowing medical device manufacturer to market their products around the world. Free trade of medical devices within the European Union is achieved through compliance with the requirements of the applicable EU Directives [1].

In order to demonstrate the conformity with the essential requirements and to enable conformity to be verified, it is desirable to have harmonized European standards to protect against the risks associated with the design, manufacturing and packaging of medical

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devices. Romanian manufacturers have to respect both EU Directives regarding medical devices and harmonized European standards in accordance with the general guidelines established by competent bodies.

For example, the COUNCIL DIRECTIVE MDD 93/42/EEC of 14 June 1993 concerning medical devices and ISO 13485:2004 *Medical devices - Quality management systems - Requirements for regulatory purposes* have to be enforced by any medical device manufacturer [1]. For the purpose of this Directive, Romanian documents have been adopted:

- Government Decision HG 911/11.08.2005 establishing the conditions for marketing and operation of medical devices;
- Government Decision HG 466 / 23.05.2007for amending and supplementing of HG 911/11.08.2005;
- Government Decision HG 54/29.01.2009 on conditions of the marketing of medical devices;
- Health Minister Order no. 92/2007 regarding the registration of medical devices and medical device manufacturers.

According to Council Directive 93/42/EEC, medical devices must meet the essential requirements which apply to them, taking into account the basic functions of the device. All the medical devices have to be tested in order to ensure that they may be placed on the market and put into service. Thus, in addition, before the certification, medical devices have to be tested in OTDM laboratories (or other accredited laboratory) and clinical investigations have to be made.

From the last years, in Romania, the medical devices manufactured, placed on the market and put into service have been affixed CE marking.

As it is known, the CE marking is not a quality certification. It is used by the European Competent Authorities as a way to quickly determine whether the product has met all of the requirements of the Medical Device Directive 93/42/EEC or other specific directives and standards.

Nowadays, many Romanian customers (hospitals, clinics, doctors, etc.) ask their medical device suppliers to be SR EN ISO 9001:2008 certified. However, the European Union does not require device manufacturers to comply with SR EN ISO 9001:2008 in order to obtain a CE mark. Thus, our manufacturing laboratory has an implemented quality system, but not yet a certified one.

The Romanian Certification Body OTDM – CERTIFICATION was assessed by RENAR notified Romanian body according to the SR EN 45011:2001 Standard and was accredited for the medical devices conformity certification activity. By Order of the Minister of Ppublic Health, OTDM – CERTIFICATION was designated to perform the assessment of conformity of medical devices [4].

OTDM – CERTIFICATION is the only notified Romanian body in Brussels for the European Directive 93/42/EEC referring to medical devices. OTDM – CERTIFICATION have been notified for the following [4]:

- Total quality assurance;
- EC type examination;
- EC Verification;

- Production quality assurance;
- Product quality assurance.

2. OBJECTIVES AND TOPICS OF THE DISCIPLINE *QUALITY ASSURANCE OF MEDICAL DEVICES*

After a common-core courses for two years, students can opt for packages of elective courses according to their specialisation. Thus, the discipline is provided in 8th semester in the Curriculum of *Medical Engineering* specialization, in Politehnica University of Timisoara. The discipline has 2 hours per week for lectures and other 2 hours per week for project. At the end of the teaching period is provided a distributed evaluation, having assigned 2 ECTS Credits. The student's evaluation is made upon a written paper work, the final mark being calculated in relation with project activity in percentage of 50 %.

The purpose of the course *Quality Assurance of Medical Devices* is to create the student ability regarding the main problems of product quality, knowledge of the standards of quality management system, knowledge of the legal requirements concerning the marketing and the use of medical devices and the evaluation of medical device conformity.

The main topics of the lectures are:

- General knowledge about legislation and New Approach;
- General knowledge about standardization. European Directives;
- Quality, Quality management, Quality system's elements, Quality management documents;
- Model of quality management system based on process;
- SR EN ISO 9001:2008, Quality management systems – Requirements;
- SR EN ISO 13485:2004, Medical devices. Quality management systems. Requirements for regulatory purposes;
- Methods for Quality assurance, auditing and certification for product quality;
- Essential Requirements;
- Specific requirements for different categories of medical devices: Development and manufacturing of medical devices. Testing of Medical devices;
- Risk Analysis;
- Medical devices conformity evaluation according to UE directives. Market surveillance;
- Medical devices clinical trials on human subjects: conditions necessary for clinical trials, clinical trial plan, the role of clinical investigator;
- PDCA Principle (Plan-Do-Check-Act);
- SWOT Analysis.

The lectures present in detail two important standards: ISO 9001, an internationally recognized Standard, and ISO 13485 which contains the functioning requirements of a quality management system for medical devices.

The objective of ISO 9001 Standard is to establish general requirements for the quality management system in any field (producers, services). Quality management represents the organization practice in order to provide products and services according to the customers' requests. A ISO 9001 certificate proves that the quality management system of the manufacturer meets all the requirements of this international standard [2], [4].

Each management system is based on the requirements of the ISO 9001 standard, completed by other requirements specified in other standards, specific to the field of activity. The main objective of ISO 13485 Standard is to facilitate the use of regulation requirements harmonized for medical devices within the quality management system. As a result, it includes a few particular requirements for medical devices and excludes a few of the requirements of ISO 9001 that are not suitable as regulation requirements [3], [4].

The project consists in elaboration of the documents for a certain medical device certification. The students have to choose one of implants designed in the framework of the discipline *Dental and Orthopedic Implantology*. Thus, the project content has two parts: one regarding the quality management system of the manufacturing entity, and the second one regarding the documents neccessary to certificate a certain medical device.

Topics for the quality management system of manufacturing entity:

- Quality manual;
- Quality system procedures;
- Quality documents;
- Documents of quality recording.

Topics for certification of a certain medical device:

- Essential Requirements;
- Technical specification of the medical device;
- Configuration of the medical device;
- Technical manual or instructions of the medical device;
- Risk analysis;
- List of Romanian standards which adopt the harmonized European standard;
- Conformity declaration.

3. CONCLUSIONS

The course *Quality Assurance of Medical Devices* offers to the students basic knowledge on the quality management system, legal requirements concerning the marketing and use of medical devices and the evaluation of medical device conformity. Quality management system is important for any field of activity, including medical devices or equipments. Also, knowledge about certification of medical devices and legal requirements concerning the marketing and use of medical devices is important for specialists in Biomedical Engineering.

4. REFERENCES

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