



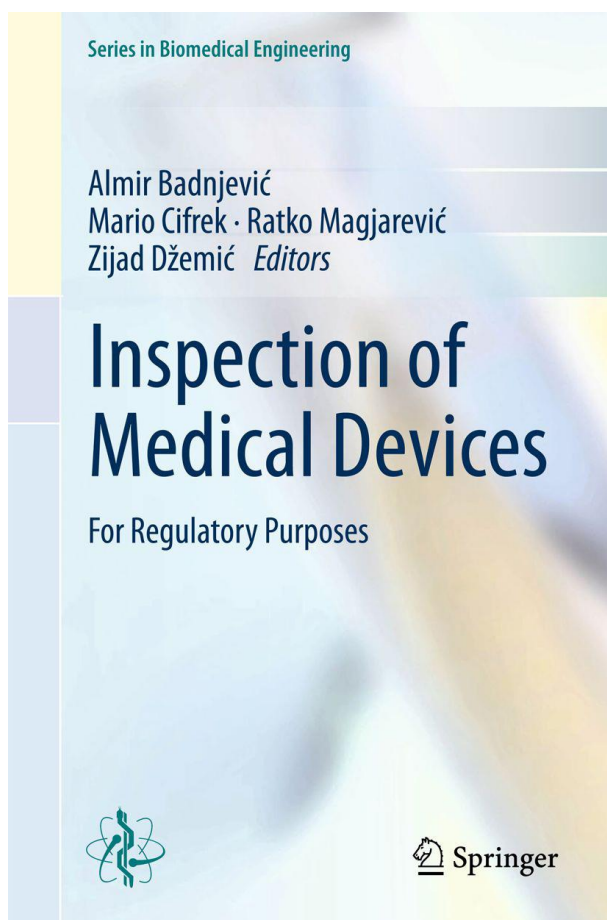
Predstavljanje knjige

Inspection of Medical Devices For Regulatory Purposes

28. svibnja 2018., 12:15

Sveučilište u Zagrebu Fakultet elektrotehnike i računarstva

Siva vijećnica



Program

Ponedjeljak, 28. svibnja 2018.

12:15–12:30	Pozdravni govori Izv. prof. dr. sc. Gordan Gledec, prodekan za znanost FER-a Branka Marijanović, mag. bibl., voditeljica Središnje knjižnice FER-a Prof. dr. sc. Ratko Magjarević, HDBIMF, IFMBE, IUPESM
12:30–13:00	Promocija knjige Prof. emer. dr. sc. Stanko Tonković Izv. prof. dr. sc. Branko Breyer
13:00–13:15	Pauza za kavu
13:15–13:45	Predavanje Maja Vitt, mag. ing. „Medical Devices – From Idea to Market Placement“
13:45–14:15	Predavanje Doc. dr. sc. Almir Badnjević „Medical Devices Post-Market Surveillance Experiences“

Medical Devices – From Idea to Market Placement

Abstract

Medical devices play a crucial role in the healthcare system. They are used for the purpose of diagnosis, prevention, monitoring, treatment or alleviation of diseases, injuries and handicaps. In other words, they are here to save and improve that what is most important to humans – their life.

When talking about medical devices it is important to remember that patient and user safety is always a priority number 1. When developing a new device or improving an existing one, the manufacturer must always assure that the safety and performance of the medical device fulfils the essential requirements.

The aim of this presentation is to bring you closer to the manufacturers point of view when developing and placing a medical device on the market. We will take a short look on the broad spectrum which is covered with the term medical device. Our focus will be on the European Economic Area (EEA) and the regulations, directives and standards that need to be considered and fulfilled before affixing the CE mark to a Medical Device.

Our goal is to bring a safe and effective medical device to the market which will save and improve human life.



Maja (Peklić) Vitt received her master degree in Information and Communication Technology, with emphasis on information processing, in 2011 from the University of Zagreb, Faculty of Electrical Engineering and Computing. Her focus has always been oriented towards medical engineering and already during her university studies she was working in close cooperation with physicians in clinics and universities.

Her way into the industry has first led her to a Product Manager position at inomed Medizintechnik GmbH where she was responsible for product development while also creating and maintaining technical and user documentation, with the main emphasis on clinical evaluations, risk management and post market surveillance. Her following position as Risk Manager at Maquet Cardiopulmonary GmbH has further broadened her knowledge for product conformity, safety and product oriented risks.

She is currently working as a Clinical Evaluation Expert at Merz Pharmaceuticals GmbH in Frankfurt (Germany). Parallel to her employment she also has her own company in Freiburg (Germany) where she offers regulatory and clinical affairs consulting and training for medical device manufacturers.

Medical Devices Post-Market Surveillance Experiences

Abstract

Many EU countries regulate metrological concepts for variety of devices, from military applications, food, drugs etc., to ensure consumer confidence to quality and safety of provided service and fair trade. Some of the countries have already recognized the importance of regulating the assessment of specific types of medical devices that are already in use in healthcare institutions, through jurisdiction of the National Metrology Institutes (NMI) and Legal Metrology Concepts. This practice has been enforced and conducted in Bosnia and Herzegovina by the Institute of Metrology of Bosnia and Herzegovina and their laboratory Verlab (operating by ISO 17020). Medical devices that have been introduced into the legal metrology system in BH include both diagnostic and therapeutic devices. Standardized procedures of post-market safety device performance assessment have been developed with precisely defined units of measurement for each type of medical devices, their ranges and allowed output error ranges. Specific multi-parameter phantoms were calibrated with traceability to SI units. In this way, traceability of medical measurements was established. The safety and performance assessments/inspections are performed once a year.

Three-year study results show that this framework caused increase of safety and performance of medical devices, directly and indirectly increased efficiency of diagnosis and treatments for the patients. In 2015, 12% of inspected devices didn't satisfy safety and performance requirements. In 2017, that number was 8%. In period 2016–2017 a number of inspected devices increased for 55.6%. Due to that, faulty rate in 2017 increased for 138% in reference to 2016. Also, cost benefits for healthcare institutions regarding management of medical devices were recognized. All collected data are stored in an online database eVerlab. Therefore, eVerlab presents the first digital database of medical devices used in healthcare system in Bosnia and Herzegovina and for such reason it is a useful tool for post-market surveillance of medical devices both for healthcare institutions and policy makers, but also for researchers and the scientific community. These results are indication that such standardized assessment methods are good indicators of device status and lead to the increase of the quality of care provided to patients, since with traceable medical measurements reliability and interoperability of results is enabled. This positive practice was recognized by IEEE Standards association, where the authors are working on implementation of performance standards for medical devices.



Almir Badnjević received his PhD in Electrical Engineering at the University of Zagreb Faculty of Electrical Engineering and Computing, Zagreb, Croatia in 2015. For the last eight years he has been gaining an experience in business and academic sector in parallel.

He worked in medical devices industry, in the field of respiratory technology and blood gas analysis. He is the founder of idea of including medical devices into the legal metrology framework, which was accomplished in 2015 in Bosnia and Herzegovina. In 2014 he founded and established Verlab – one of the most equipped laboratories for testing and verification of medical devices in the Europe. The main purpose of the laboratory is to perform annual verification of medical devices in all healthcare institutions in Bosnia and Herzegovina. In 2017, as one of the editors in Springer Nature, published a book about this topic entitled “Inspection of Medical Devices – For Regulatory Purposes.”

In academic sector, since 2015 he has been working as the Head of Genetics and Bioengineering Department at Faculty of Engineering and Natural Sciences at International Burch University, where he was involved in establishing the first Bachelor and Master Degree program in Bioengineering. He is also working as an Assistant Professor at the Faculty of Electrical Engineering Sarajevo, University of Sarajevo in the field of Biomedical Engineering and Expert Systems.

In 2014 founded and became a President of Bosnia and Herzegovina Medical and Biological Engineering Society, which is country’s representative in IFMBE and EAMBES. He is a board member of IEEE TC on Cardiopulmonary Systems, board member of ESEM (EU organization for Educating Students in Engineering and Medicine) and Councillor for Regulatory Affairs in EAMBES (European Alliance for Medical and Biological Engineering and Science). He is the author or co-author of more than 70 publications. His CV is included in Marquis Who’s Who in the World in 2016. He is an IEEE Senior Member.