ISTITUTO
DI BIOROBOTICA

Scuola Superiore
Sant'Anna

WORKSHOP

The industrial process: from prototypes to medical products

09:00-09:10
Opening and introduction to the workshop

09:10-10:10
Dr. Sebastian Schostek
Compliance-oriented development of innovative medical devices – from research to market

10:10 - 11:10
Dr. Bernando Magnani
Risk assessment and management analysis for medical devices

11:10 - 11:40
Mr. Claudio Barella (CMC)
Regulations and standards for the lifecycle of medical and IVD devices (hardware and software)

11:40 - 12:40
Dr. Timo Weiland
Medical devices – paths of the clinical evaluation

12:40 - 13:00
Summary and discussion

February 10, 2016, from 9 am to 1 pm
Room 1, The BioRobotics Institute, Scuola Superiore Sant'Anna
Viale Piaggio 34, Pontedera (Pisa)

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Compliance-oriented development of innovative medical devices – from research to market
(Dr. Sebastian Schostek)

Abstract

Good ideas and good science is not enough to bring a medical device into the market. Being allowed to sell medical devices requires proof of safety and efficacy, which is achieved by showing compliance with directives and standards. The story of the brilliant researcher with really good ideas failing to bring his results into the market is not rare, since the effort to meet regulatory requirements are easily underestimated.

Decisive for a swift transfer of research into a marketable medical device is to implement a compliance-oriented development process already in an early stage, and to follow some essential steps that help steering the engineering work into the right direction.

This presentation aims at providing a recipe for engineers and scientists, who want to start a medical device development with the goal of regulatory approval.

Bio sketch

Dr. Sebastian Schostek graduated in Engineering Physics from the Munich University of Applied Sciences in 2004, and received his PhD degree from the Faculty of Medicine of Eberhard Karls University Tuebingen in 2010. He worked as research fellow and lecturer at the IHCI - Institute of Healthcare Industries, Steinbeis University Berlin, before he joined novineon Healthcare Technology Partners GmbH, Tuebingen, as Business Unit Director in the fields of technological and medical research, medical product development, contract research, and business consulting. Throughout his career, he was involved in a number of national and international research projects. His work led to numerous publications, patents, lectures and awards. In 2011, he accepted the position as Vice President of the Division Diagnostic Systems at Ovesco.

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Risk assessment and management analysis of medical devices (Dr. Bernardo Magnani)

Abstract

ISO 10993 and ISO 14971 are two of the main ISO standards for medical device design, CE compliance and production. The ISO 10993 set is composed by a series of standards for evaluating the biocompatibility of medical devices. ISO 14971 is an ISO standard for the application of risk management to medical devices. This standard establishes the requirements for risk management to determine the safety of a medical device by the manufacturer during the product life cycle. Moreover, the talk will address the method for selection of polymer material as a useful instrument for designing medical devices.

Bio sketch

Bernardo Magnani received the Laurea Degree in Mechanical Engineering from the University of Pisa in 1995 and in 1999 he obtained the Ph.D. in Microsystems Engineering at Scuola Superiore Sant'Anna di Pisa. He was Project Manager of the BIOMED2/MIAS project, coordinated by SSSA and aimed at the development of an integrated system for CAS for Minimally Invasive Arthroscopy. He was the Project Manager of the EU project "Medical Micro-Instrument Competence Centre" in the framework of Europractice. In 2000 he became General Manager of Ekymed. In the recent past he was responsible for the certification of 4 medical device in class IIa.

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Medical devices – paths of the clinical evaluation (Dr. Timo Weiland)

Abstract

According to the European Medical Device Directive 93/42/EEC, suitability for the intended use must be established for all medical products. For this, a clinical evaluation based on data from scientific literature, research and testing or clinical studies has to be submitted. The clinical evaluation analyses available clinical data as well as product and procedure-related risks. This analysis then forms the basis for a critical assessment of risks and benefits as well as an evaluation of the advertised product features. Consequently, the clinical evaluation plays a key role in the approval process, product launch and market surveillance of medical products. The clinical evaluation document is a crucial part of the technical file. It is submitted to the notified body as part of the official approval process.

Bio sketch

Dr. rer. nat. Timo Weiland studied biology at the University of Konstanz and gained his doctoral degree at the Department of Biochemical Pharmacology in 2007. There, he continued conducting research in the field of hepatic cell death and cytoprotective signalling pathways until 2008. Afterwards, he continued his work at the University Hospital Tuebingen within the Collaborative Research Centre SFB 773 "Therapy Resistance of Solid Tumours". In September 2011, Dr. Weiland joined novineon CRO & Consulting Ltd, where he is responsible for clinical evaluations. In 2013, he successfully completed the Certificate Course "Medical Device Regulatory Affairs" at the Centre for Further Education and Transfer of Knowledge (ZWW) at the University of Augsburg.

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Regulations and standards for the lifecycle of medical and IVD devices (hardware and software)

(Mr. Claudio Barella)

Abstract

The international regulatory framework for regulations and standards for the lifecycle of medical and IVD devices (hardware and software) has evolved over the past twenty years and is still evolving. Each market area has defined specific regulations taking into account the international unified standard ISO and IEC, however, they require adjustments to the local regulations. Medical devices and IVD hardware and software must implement these regulatory issues that affect the entire lifecycle in order to be placed in the local markets. The technological evolution of devices has led especially the software to play an increasing role in medical devices with increased functional responsibilities subject to special regulatory requirements.

Bio sketch

Certified Management Consultant (CMC) from ICMCI (International Council of Management Consulting Institutes), since 1990 Management Consultant in Organizational Management Systems, Strategies and Internationalization of the Companies and Medical Devices, IVD and Life Sciences. Project coordinator of hundreds development projects and certification of medical devices and IVD hardware and software for market access of the EU, USA, Canada, Brazil China, Russia, Australia. Member of the Italian standardization body UNI, member of European CEN PC381 group and head of the Italian delegation to ISO PC 280. Vice president of APCO Italian Management Consultant Association and Italian trustee in the ICMCI. Chair of Professional Standards Committee (PSC) of ICMCI.