THEMATIC CONTENTS

A MODULE: INTRODUCTION TO EUROPEAN MEDICAL DEVICES REGULATORY REQUIREMENTS **(4 HOURS)**

- EU regulatory framework: Basics, Definitions, Scope and Classification
- Placing on the Market of Medical Devices: essential requirements and conformity
- Registration requirements and Post-Market Surveillance by Authorities and Operators
- Review, further info and self evaluation

B MODULE: MEDICAL DEVICES DESIGN AND DEVELOPMENT LIFECYCLE: FOCUS ON BIOMEDICAL DEVICES **(4 HOURS)**

- Development Lifecycle: From planning analysis requirements to practical examples
- Technical File and Technical Design Verificatiorn & Validation
- Review further info and self evaluation

C MODULE: MEDICAL DEVICES RISK MANAGEMENT, USABILITY ENGENEERING AND CLINICAL EVALUATION: FOCUSING ON BIOMECHANICAL DEVICES **(8 HOURS)**

- Medical Devices Risk Management
- Medical Devices Usability Engeneering
- Medical Devices Evaluation

D MODULE: MEDICAL DEVICES QUALITY SYSTEM REQUIREMENTS **(8 HOURS)**

- Introduction and General Requirements
- Resources and infrastructure
- Review, further info and self evaluation
- Manufacturing processes
- Analysis, monitoring and measurements
- CAPA Process
- Process Validation
- Review, further info and self evaluation

E MODULE: MEDICAL DEVICES VIGILANCE SYSTEM AND POST-MARKET REQUIREMENTS **(4 HOURS)**

- Medical Devices Post-Market Surveillance and Post-Marketing Clinical Follow-up
- Medical Devices Vigilance System
- Review, further info and self evaluation

F MODULE: BIOMATERIALS **(4 HOURS)**

- Introduction
- Metallic materials
- Polymeric materials
- Ceramic materials
- Applications
- Review, further info and self evaluation

MORE INFO

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This project has been funded with support from the European Commission.

Lifelong Learning Programme

This publication reflects the views only of the author, and the Commission cannot be held responsible for any use which may be made of the information contained therein.

BGU Murnau Berufsgenossenschaftliche Unfallklinik Murnau

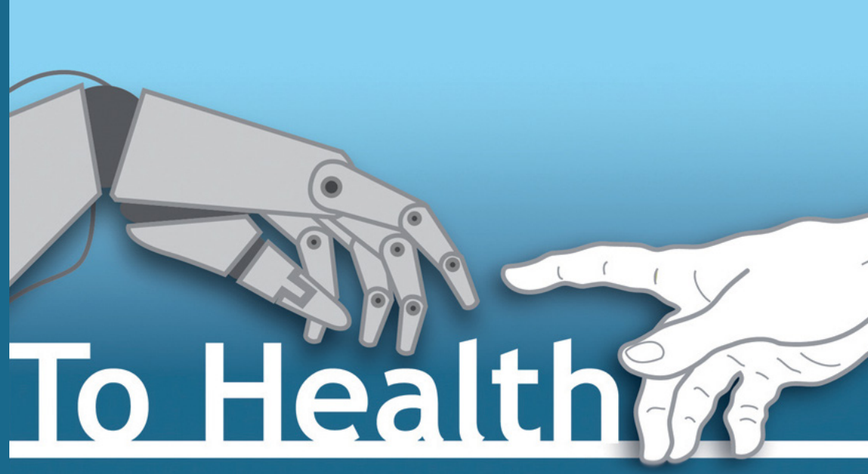
IBV Instituto de Biomecánica de Valencia

Tecno-med Ingenieros

fenin spanish federation of HEALTHCARE TECHNOLOGY companies

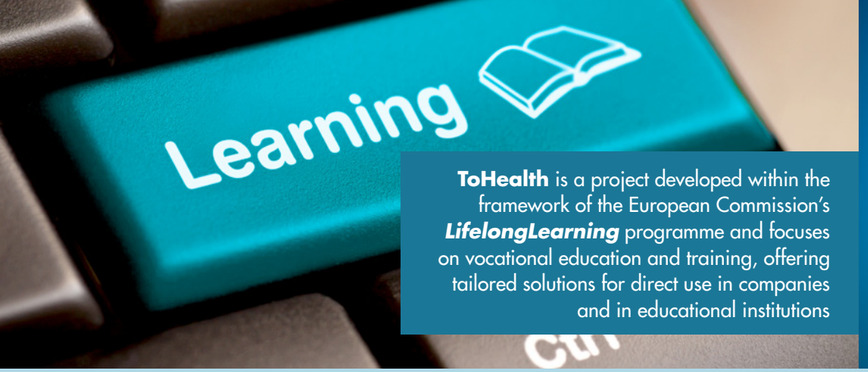
udg net University G.d'Annunzio NEW ENTERPRISE TECHNOLOGY

DANMAR COMPUTERS



ONLINE TRAINING COURSE IN BIOMECHANICS, MEDICAL DEVICES AND RELATED EUROPEAN REGULATIONS

www.tohealth.eu



ToHealth is a project developed within the framework of the European Commission's ***LifelongLearning*** programme and focuses on vocational education and training, offering tailored solutions for direct use in companies and in educational institutions

ToHealth will provide and enhance skills and knowledge of companies who are already working in the European market or companies which are planning to diversify into the healthcare technology sector

ToHealth course is available in English, Spanish, German, Polish and Italian.

WHO ?

ToHealth is developed by several European institutions from Germany, Italy, Poland and Spain. Each of these institutions has long lasting experience in their working field (research, development regulatory affairs, IT, e-learning services).

WHAT ?

ToHealth will provide an online e-learning course on medical devices focusing on regulatory affairs and requirements for placing medical devices on the market within the European Union. The **ToHealth** online course will include contents on:

- EU Medical Device Regulatory Overview
- Medical Device Quality System and Process Requirements
- Medical Device Technical Specifics

TO WHOM ?

ToHealth is being developed for companies or organizations involved in the design, development, manufacture and/or distribution of medical technologies, medical devices and associated services.
These organizations often need background information, specific advice and on-going consulting concerning the regulations and requirements applicable to their devices and activities.

WHY ?

The **main objective** of the **ToHealth** project is the transfer and update of knowledge in **biomechanics, regulatory affairs,** and **medical devices**. The project is aimed at companies and organizations involved in the production, development and certification of medical devices.
ToHealth project **result** will be an **online training course** about:

- Medical Devices regulations
- Human body biomechanics
- Medical Devices Technical Specifics

HOW ?

ToHealth is a training course developed online highly interactive which includes:

- Communication and learning tools
- Dynamic teaching units (figures, charts)
- Activities (quizzes, assignements, self evaluation)
- Forum

GENERAL LEARNING OBJECTIVES

ToHealth will enable users to accomplish general learning objectives:

- To gain an overview of the **Europen regulatory framwork for Medical Devices**, the applicable requiremenents for the placement into the market and how to comply with the current pan-european **registration requirements**
- To understand requirements applicable in the Medical Devices **design** and **development process** as well as in the life cycle phases
- To acquire knowledge on **risk management**, **clinical evaluation**, **quality system** requirements, **vigilance** and **post-market system**
- To identify different groups of **biomaterials** and to learn about their applications