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Italiadomani
PIANO NAZIONALE
DI RIPRESA E RESILIENZA



Rome Technopole

Starting date: 1st July 2022
Ending date: 30th June 2025

Loredana Le Pera

Istituto Superiore di Sanità (ISS)



SERVIZIO TECNICO-SCIENTIFICO
**GRANDI STRUMENTAZIONI
E CORE FACILITIES**





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Rome Technopole

Approach to the medical device sector: Regulatory, Technical, and Practical aspects

Notified Body experts
ON ISS - Responsible: Dr. Roberta Marcoaldi





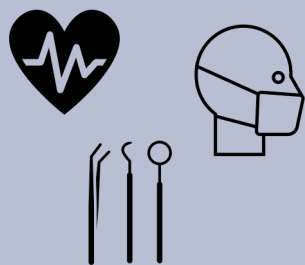
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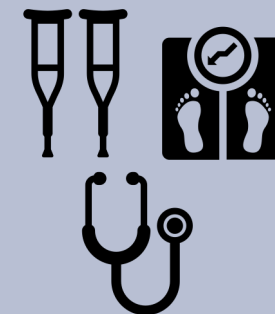
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A SMALL GUIDE TO THE WIDE WORLD OF MEDICAL DEVICES



Medical Devices



any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be **used for therapeutic purposes**

Organisers



Istituto Superiore di Sanità - **Notified Body experts**

Aim



present **basic notions and knowledge** concerning regulatory and productive issues related to production, safety, and clinical usage of medical devices



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COURSE TYPE → **interactive learning sessions** with a final assessment

COURSE LENGTH → **16 hours** in 9 lessons + **2 hours** for the final questionnaire

TARGET AUDIENCE → **20/25 PhD students** from Rome Technopole

HOW DOES IT WORK? → **on-line** lessons

WHO IS GOING TO TEACH? → **6 teachers** from the **Notified Body – ISS**



COURSE STRUCTURE

PART I: regulatory issues

- **Medical Devices:** definitions, players, roles, evaluation of conformity
- **Classification:** destination, rules, risk evaluation
- **Quality management, technical rules, specifications, and interpretations**

PART II: quality issues

- **Quality system:** technical documentation
- **Performance, safety and risk evaluation**
- **Audit activity**

PART III: technical issues

- **Sterilization**
- **Preclinical tests:** stability, challenge test, biocompatibility, etc.
- **Clinical evaluation:** and after market follow up

PART IV: assessment questionnaire



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Rome Technopole

The role of artificial intelligence in diagnostic imaging

Rossella Canese, Franca Moretti, Loredana Le Pera, Luisa Minghetti, Maurizio Mattia





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European Infrastructures involved



SPOKE3



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The role of artificial intelligence in diagnostic imaging

Area: Health & Bio-Pharma

Type: one-day in-person course

Target audience:

- PhD students
- specialisation schools students
- young researchers

Mainly aimed at physicists, biomedical engineers and radiologists

Maximum number of students: 40

Date: second half of October



SPOKE3



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SPOKE3

The role of artificial intelligence in diagnostic imaging

Course content

- Introduction (including **Explainable AI**, **digital twins** and possible applications in medical physics)
- Machine Learning as a support for **oncological diagnosis**
- Machine Learning applied to the study of the **brain**
- from **Machine learning** to **Deep Learning**: new research areas and **regulatory aspects**



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Approach to the medical device sector: Regulatory, Technical, and Practical aspects *March - April 2024*

The role of artificial intelligence in diagnostic imaging *October 2024*



Serena Camerini, Rossella Canese, Franco Cardone,
Guido Gigante, Paola Laricchiuta, Loredana Le Pera,
Maurizio Mattia, Luisa Minghetti, Elisabetta Pizzi