ISOCS Winter School 2024

“Chemical Sensing for Biomedical Applications: from a proof of concept to a medical device”

DAY 0 (Dinner/ after dinner) - Sunday, 14th

Saverio De Vito (ENEA, President of ISOCS, ITALY): 30 min
Welcome to participants and presentation of ISOCS

Laura Capelli (Politecnico di Milano, ITALY): 45 min
Outline and organization of the school

DAY 1 (Mon, 15 Jan 2024): Translating technologies to biomedical applications

Corrado Di Natale (Università di Roma Tor Vergata, ITALY): 30 min
Chemical sensing for biomedical applications for the development of innovative and non-invasive diagnostic methods

Raffaele Dellaca' (Politecnico di Milano, ITALY): 1-1.5h
Using technologies for diagnosis and treatments: identification of needs and specific requirements for diagnostic devices. Scientific validation and clinical validation of novel biomedical technologies: challenges and approaches. The STARD guidelines and checklist. Examples.

Chiara Veneroni (Politecnico di Milano, ITALY): 1h
Designing clinical trials for developing and validating medical technologies. Type of clinical trials. Statistical analysis of data. Estimation of the sample size. Ethical Review Board, informed consent and ethical and privacy procedures.

AFTERNOON SESSION

Alessandro Gobbi (Restech, ITALY): 1,5h
Certification procedures for medical devices: Overview of the medical device regulations. Device classification. Addressing regulation and compliance need. The medical device design control process. Verification and validations. Examples.

Raffaele Dellaca', Chiara Veneroni, Alessandro Gobbi (Politecnico di Milano, Restech, ITALY): 1h
Students will be organised in groups of 4/5 for developing a project during the school. The project will consist in the definition of the procedures for the development of an innovative medical device. Students will be asked to define how they should approach the planning of activities for scientific and clinical validation of a biomedical device based on chemical sensing. Three different diagnostic technologies will be introduced by tutors and each group will be assigned to one of these technologies. The students will need to: 1) define the necessary activities for the scientific validation of the technology; 2) select the proper clinical trial design and estimate the proper sample size of the trial; 3) define the procedures for obtaining ERB approval and 4) draft a possible list of documents, tests and data required for MDR approval. The activity will be carried out during the school, and the tutors will support the groups providing the relevant literature references and information for the considered technology. The groups will present their work with a presentation given at the end of the school (afternoon of day 4), following a structure that will be provided by the tutors.

DAY 2 (Tue, 16 Jan 2024): Sampling, storage and analysis of biological fluids: **what you should take care of**

Fabio Di Francesco (Università di Pisa, ITALY): 30 min
Challenges in chemical sensing: filling the gap between research and clinical applications

Jonathan Beauchamp (Fraunhofer Institute for Process Engineering and Packaging, GERMANY): 1h
Analysing volatiles in exhaled breath: challenges and considerations:

1. collection of representative samples: sampling procedures, cross-contamination, stability
2. origins of volatile constituents: endogenous vs. exogenous compounds, confounding factors, temporal aspects

Tommaso Lomonaco (Università di Pisa, ITALY): 1h
Specific challenges associated to urine headspace analysis:

1. Problems related to storage and stability, management of interferents
2. Analytical hurdles related to headspace analysis
3. Interpretation of data

AFTERNOON SESSION:

Specific technological challenges related to chemical analyses

TIME FOR WORKING AT GROUP PROJECTS

DAY 3 (Wed, 17 Jan 2024): Calibration of high order chemical sensor systems

Santiago Marco (Inst. for Bioengineering of Catalonia - IBEC, Univ. of Barcelona – UB, SPAIN): 30 min
The importance of calibration development and maintenance in the deployment of higher-order chemical sensor systems

Fengchun Tian (Chongqing University, CHINA): 45 min.
Optimal selection of calibrants and calibration of electronic nose

Jordi Fonollosa (Polytechnical University of Catalonia – UPC, SPAIN): 45 min
Approaches to improve sensor systems reliability and Classical Methods in Calibration Transfer

Lei Zhang (Chongqing University, CHINA): 45 min
Transfer learning algorithms for chemical sensor arrays

AFTERNOON SESSION:

Luis Fernández (Inst. for Bioengieneering of Catalonia (IBEC)-Spain, University of Barcelona (UB)-Spain): 2h
Computational Exercise on Data processing & calibration transfer

TIME FOR WORKING AT GROUP PROJECTS

DAY 4 (Thu, 18 Jan 2024): Examples of high-TRL projects of chemical sensing systems for healthcare applications

Marcis Leja (University of Latvia, LATVIA): 20 min
Introducing new approaches for cancer screening. The example of colorectal cancer

Speaker (tbc):
title tbc

Sascha Kreuer (Saarland University Medical Center and Saarland University Faculty of Medicine, GERMANY): 45 min
Measuring Exhaled Propofol from the Lab to a Medical Device - A long and expensive Journey

Marcis Leja (University of Latvia, LATVIA): 45 min
Lessons learned from clinical studies in breath analysis for cancer detection

AFTERNOON SESSION:

Carmen Bax (Politecnico di Milano, ITALY): 30 min
Challenges in the development of an e-nose for the diagnosis of prostate cancer: focus on the management of interferences, drift and calibration transfer

Anne-Claude Romain (University of Liège, BELGIUM): 30 min
From Environmental Monitoring to Breath Analysis: Leveraging Sensor Networks for Healthcare - Lessons from the PATHACOV project

Jan Mitrovics (JLM Innovation, GERMANY): 30 min
From LCAOS to VOGAS, experiences of 12 years, 5 research projects and clinical studies on 3 continents with breath analysis devices.

Discussion Round: practical issues

TIME FOR WORKING AT GROUP PROJECTS

DAY 5 (Fri, 19 Jan 2024): Group projects presentation

Discussion of the group projects prepared by the participants

AFTERNOON SESSION (optional):

Workshop for position paper