COURSE ANNOUNCEMENT

“CEN and ISO Standards for Pre-analytical Processes in Industrial Development and Medical Diagnostics”

Objectives:
The course will introduce the European standards for the pre-analytical processing of human biological samples (CEN/TC 140 Technical Specifications for Preexamination Processes (CEN/TS)) that are presently becoming ISO standards. Their implementation will become mandatory once the European In-Vitro Diagnostics Regulation enters into force in 2020. Besides explaining common structure and specific differences for different sample types and analytical techniques, the rationale and experimental evidence behind selected standards will be presented. With this course participants will obtain a solid understanding of purpose and aims of the standards, and will be able to implement them in their laboratories.

Target Group: Biobank management, diagnostic assay providers, diagnostic laboratories, medical professionals, quality managers.

Programme:

- Scientific evidence and unmet needs leading to international standards
- Standardized pre-analytical workflows – what is their benefit beyond mere compliance with upcoming regulations
- The consensus process of developing European and International standards
- Scope and common structure of CEN/TS
- Specific parts of the CEN/TS for different types of biological samples and biomolecules – examples and experimental basis
    - Nucleic acids (DNA, RNA) from tissue
    - Nucleic acids (ccfDNA, RNA) from liquid biopsies
    - Metabolites and Metabolomics from tissue and blood derivatives
- How to implement CEN/TS compatible workflows
    - Documentation and implementation of CEN /TS common elements
    - Verification and validation of methods
- Summary and discussion

Format: 1-day lecture course, limited to 30 participants

Date, Time & Venue: May 16, 2018, 11.00 a.m – 4.00 p.m., Medical University of Graz, MedCampus, Neue Stiftingtalstrasse 6, A-8010 Graz, Austria.

Registration & Cost:
Register by e-mail to peter.abuja@medunigraz.at by April 27. Course fee: €320.- including coffee and lunch break, course handouts. After registration you will be provided with the bank details. For definitive registration, the full course fee must be paid in advance, at least 14 days before scheduled course date.

Speakers:

- Dr. Uwe Oelmüller, QIAGEN GmbH, Germany
  He is an internationally leading expert in the field of pre-analytical workflow developments and standardization. At QIAGEN he is Vice President, Head of Sample Technologies Molecular Diagnostics. He coordinated the FP7 SPIDIA Consortium (2008-2013). He is the convenor of the ISO/TC212 WG4 and the deputy convenor of the CEN/TC140 WG3 and coordinates the H2020 project SPIDIA4P.

- Univ.-Prof. Dr. Kurt Zatloukal, Institute of Pathology, MUG, Austria
  His research focuses on molecular pathology of diseases as well as biobanking and related data management technologies. He coordinated the preparatory phase of the European biobanking and biomolecular research infrastructure (BBMRI-ERIC) and contributed to the development of new European standards and norms for pre-analytical processing of tissue samples for molecular testing. He is member of the Austrian Standards Institute and coordinates the development of standards for in-situ methodologies in the H2020 project SPIDIA4P.

- Dr. Karl Kashofer, Institute of Pathology, MUG, Austria
  He is technical director of the Molecular Pathology Division of the Institute of Pathology at MUG and heads the QM team working on ISO Accreditation of the Institute according to ISO 15189. Additionally he leads a research and development group which is introducing new technologies and methodologies into molecular diagnostics.

- Univ.-Prof. Dr. Ellen Heitzer, Institute of Human Genetics, MUG, Austria
  She is molecular geneticist and involved in both routine diagnostics of hereditary diseases and research. Her research focuses on the analysis of circulating tumor DNA (ctDNA) and cells (CTC), often referred to as "liquid biopsy". Currently she investigates the use of liquid biopsies in solid cancers as a tool for monitoring treatment response and the identification of resistance mechanisms.

- Univ.-Doz. Dr. Peter M. Abuja, Institute of Pathology, MUG, Austria
  He is biochemist and physicochemist, and is involved in several projects related to biobanking and pre-analytical quality determinants of tissue and biofluids, and is project leader in the K1 Competence Centre CBmed Biomarker Research GmbH, working on evaluation of standardized pre-analytics for Next Generation Sequencing.

- Mag. Cornelia Stumptner, BBMRI.at, Austria
  She has been working in the field of preanalytical sample processing and biobanking for many years. Currently she is project manager of BBMRI.at – the Austria Biobanking and BioMolecular resources Research Infrastructure. She is member of the Austrian Standards Institute and contributes to the development of CEN/TS and ISO standards for pre-analytical processing (e.g. of tissue samples for molecular testing, FFPE tissue for in-situ detection) in the H2020 project SPIDIA4P.

- v. h. Prof. Karine Sargsyan, MD, Biobank Graz, MUG, Austria
  She is managing director of Biobank Graz since 2007, and responsible for numerous cooperations and development of scientific/research, infrastructural and re-training projects. Together with her team, she developed the Biobank Graz as a sustainable, interdisciplinary institution and quality assured service unit of the Medical University of Graz. She has served in numerous managerial positions during her carreer.