BBMRI.at
Biobanking and BioMolecular resources Research Infrastructure Austria

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

The course organized by Institute of Pathology, SPIDIA4P, QIAGEN and BBMRI.at and held in Graz, Austria, raised awareness about the existence and relevance of the CEN Technical Specifications and ISO Standards and of standardizing pre-analytical processes in R&D and medical diagnostics.

International participants learned about which CEN Technical Specifications (CEN/TS) **"In-Vitro Diagnostic examinations - Specifications for Pre-examination Processes"** have already been published and which pre-analytical CEN/TS and ISO Standards are under development.

The main focus of the course on May 16, 2018 was on demonstrating their relevance for medical diagnostics and research and development (R&D), particularly in the context of the new In-Vitro Diagnostic Regulation. The development process of standards was introduced and an overview on the structure and scope were given.

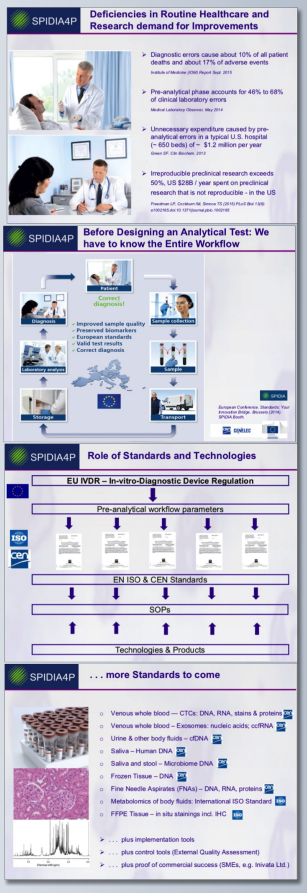
The major pre-analytical factors and their influence on analyses results in pathology and human genetic laboratories were addressed and examples of how to implement the standards were given. Participants also had the opportunity to test the BBMRI-ERIC online Self Assessment Tool.
All participants rated the course 'excellent'.

Set of presentations given included:

- Dr. Uwe Oelmüller, QIAGEN GmbH, SPIDIA4P Coordinator, Germany: "New CEN and ISO Standards for Improving Diagnostics and Research"
  - How they are developed ...view presentation
  - What they mean for us ...view presentation

- Univ.-Prof. Dr. Kurt Zatloukal, BBMRI.at & Institute of Pathology, Medical University of Graz, Austria: "Pre-Analytical Errors" ... view presentation

- Mag. Cornelia Stumptner, BBMRI.at, Medical University of Graz, Austria:
  - "Meeting CEN and ISO Standards: BBMRI Self Assessment Survey Tool" ...view presentation



Bundesministerium Bildung, Wissenschaft und Forschung

Funded by
GZ 10.470/0016-II/3/2013 (2013-2018)
BMBWF-10.470/0010-V/3c/2018 (2018-2023)