

SAVE-THE-DATE

"IVDR – State-of-the-art requirements for analytical performance testing" „IVDR – Stand der Technik an analytische Leistungstests“ VIRTUAL SEMINAR

LISAvienna, BBMRI.at and en.co.tec will organize this virtual seminar with the goal to inform manufacturers and users of IVDs about these implications and to give insight into the current situation on the IVDR and related ISO standards and CEN Technical Specifications. Special emphasis will be put on the issues scientific validity and requirements for analytical performance testing, including pre-analytical requirements, and clinical performance testing.

Date: 21 Oct 2020 in context of the "LISAvienna - Regulatory Konferenz für Medizinprodukte und IVD" 20 Oct 2020

Time: 09:00-17:30 (tbc)

Location: Vienna, Austria

Target group: Employees of IVD-developers, IVD-users (incl. ISO 15189 accredited organizations)

Aims:

- Raise awareness for pre-analytical standards as state –of-the-art for selected molecular analyses
- Inform about relevance of pre-analytics and corresponding standards in the context of IVDR (incl. lab developed test)

Speakers from

- European Committee for Standardization (CEN)
- Austrian Standard International (ASI)
- TÜV Süd (Notified Body)
- LISAvienna
- QJAGEN GmbH
- Analytical performance testing from a **users' perspectives** (e.g. pathology, clinical lab)
- BBMRI.at
- **Question & Answers Session:** with all speakers and selected invited persons representing the Austrian Cluster and Network initiatives e.g. Human technology Styria
- **Organizers:** LISAvienna, BBMRI.at & en.co.tec

Registration: NO registration fee, but registration required as number of participants is limited - link will follow soon

Language: German

Organizers:

