



SAVE-THE-NEW-DATE

"IVDR – State-of-the-art requirements for analytical performance testing"

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

Time: 09:00-17:30

Location: Vienna

Organizers: LISAvienna and BBMRI.at

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Due to the corona pandemic the event was postponed from 18 May 2020 to 20 Oct 2020.

SAVE-THE-DATE

IVDR – State-of-the-art requirements for analytical performance testing

In May 2017, the European In Vitro Diagnostic Medical Device Regulation (IVDR) entered into force and replaces after a 5 year transition period which will end May, 2022 the In Vitro Diagnostic Medical Devices Directive. This has major implications on most in vitro diagnostic devices (IVDs) in development and those currently on the market as they have to be re-certified. Furthermore, this affects also called laboratory developed tests (i.e. devices manufactured and used only within health institutions) are now included in the IVDR requirements.

Goal of this event is 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: 18 Mai 2020 (in context of the "Vienna Start-up Week" (May, 11-20, 2020)

Time: 11:00-17:00

Location: Austria Wirtschaftsservice Gesellschaft mbH, Vienna Walcherstraße 11A - Entrance via aws Start-up Center, 1020 Wien

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 tests)

Speakers from

- European Committee for Standardization (CEN)
- Austrian Standard International (ASI)
- QMD Service GmbH (applied for Austrian Notified Body)
- LISAvienna
- QIAGEN GmbH
- Analytical performance testing from users' perspectives (e.g. pathology, clinical lab)
- BBMRI.at
- **Panel Discussion:** Questions & answers with all speakers and selected invited persons representing the Austrian Cluster and Network initiatives e.g. Human technology Styria

PROGRAM>>

Organizers: BBMRI.at & LISAvienna

The event will be in German.

