BBMRI.at
Biobanking and BioMolecular resources Research Infrastructure Austria

Presentations from the "Regulatory Konferenz für Medizinprodukte und In Vitro Diagnostika 2020"

15 hours of virtual live lectures and discussions over two days October 20 and 21, 2020 - over 520 interested people - around 200 questions. This was the Regulatory Conference for Medical Devices and In-Vitro Diagnostics 2020, which BBMRI.at, LISAvienna and en.co.tec jointly organized together.

Here you will find presentations. Missing sets of slides will be added on an ongoing basis.

The LISAvienna Regulatory Conference for Medical Devices and In-Vitro Diagnostics took place digitally over two days for the first time in 2020. With this conference, we are contributing to the exchange of knowledge about the implementation of the Medical Devices Regulation (MDR) and the In Vitro Diagnostik Regulation (IVDR). The program was designed in close cooperation of BBMRI.at (the Austrian node of the European research infrastructure for biobanks and biomedical resources) with LISAvienna (a life science platform jointly operated by Austria Wirtschaftsservice and the Vienna Business Agency), and with en.co.tec (a consulting and training service provider for medical devices and IVD).

Martin Schmid, Managing Director of en.co.tec, points out that the regulations for medical devices (MD) and in-vitro diagnostics (IVD) in the EU are becoming increasingly demanding in order to protect patients. In order to comply with the currently valid law and the MDR and IVDR to be observed in the future, extensive know-how is required. As the feedback on the conference once again shows, the participants appreciate the free lectures and discussions on the latest developments and experiences at the notified bodies and authorities as well as the practical reports from the development, manufacture and use of medical devices and in-vitro diagnostics. Around 200 questions were received from the audience, the most frequent of which could be answered by the speakers at the event. Selected points from this intensive discussion will be incorporated into the activities of the coming weeks and months.

Kurt Zatloukal, Med Uni Graz and BBMRI.at Director, states that the conference organizers jointly managed to clearly anchor important messages regarding MDR and IVDR to all relevant groups. This includes the fact that analytical performance evaluation studies require biological samples that have been obtained using standardized processes and that include a defined range of pre-analytical parameters. The standards, such as the "Molecular analytical in vitro diagnostic procedures - specifications for pre-analytical processes" represent the state of the art in this regard. Austrian biobanks, which are members of the European Biobank Research Infrastructure (BBMRI), are preparing for the IVDR anticipated need for standardized samples in order to be able to provide either archived samples or samples specifically generated for studies.

In order to learn more about your current status with the preparations for the MDR or IVDR, we ask you to fill out a short questionnaire (in German) (duration: 1 minute): https://de.surveymonkey.com/r/Z5XJLG7

Conference Program

LISAVIENNA REGULATORY KONFERENZ FÜR MEDIZINPRODUKTE UND IN-VITRO DIAGNOSTIKA 2020
(PDF/389 KB)

Presentations Day 2: 21.10.2020, Focus: IVD and IVDR

BEGRÜSSUNG, JOHANNES SARX, LISAVIENNA (PDF/1 MB)

WISSENSCHAFTLICHE UND MEDIZINISCHE RELEVANZ VON STANDARDS IN DER DIAGNOSTIK,
KURT ZATLOUKAL, MED UNI GRAZ / BBMRI.AT (PDF/6 MB)

BEDEUTUNG VON PRÄANALYTISCHEN ISO UND CEN STANDARDS AUS SICHT EINES IVD ENTWICKLERS UND HERSTELLERS,
UWE OELMUELLER, QIAGEN(PDF/2 MB)

ENTWICKLUNG VON EUROPÄISCHEN UND INTERNATIONALEN STANDARDS FÜR DIE PRÄANALYTIK,
ULRIKE SCHRÖDER, DIN(PDF/1 MB)

KONSEQUENZEN DER NEUEN IN-VITRO-DIAGNOSTIKA VERORDNUNG (IVDR) FÜR HERSTELLER,
MARTIN SCHMID, EN.CO.TEC (PDF/1 MB)

NORMEN UND DIE IVDR, MICHAEL PÖLZLEITNER, MDC / ASI
(PDF/966 KB)

LEISTUNGSBEWERTUNG VON IVDS UNTER DER EU-VERORDNUNG 2017/746,

WOLFGANG ECKER, FH TECHNIKUM WIEN / FH MEDIZINTECHNIK LINZ
(PDF/479 KB)
PERFORMANCE EVALUATION IM RAHMEN DER IVDR,
HEIKE MÖHLIG-ZUTTERMEISTER, BSI(PDF/6 MB)

REGULATORISCHE ANFORDERUNGEN AN LEISTUNGSSTUDIEN DURCH DIE IVDR,

NEBOJSA SERAFIMOVIC, BASG - BUNDESAMT FÜR SICHERHEIT IM GESUNDHEITSWESEN
(PDF/3 MB)

Presentations Day 1: 20.10.2020, Focus: MD and MDR

BEGRÜSSUNG, PHILIPP HAINZL, LISAVIENNA (PDF/3 MB)

MDR - UPDATE | NACH DEM CORRIGENDUM: STRATEGIEN, UM DIE VERLÄNGERTE MDR-ÜBERGANGSFRIST OPTIMAL ZU NÜTZEN, MARTIN SCHMID, EN.CO.TEC
(PDF/1 MB)

ERFAHRUNGEN MIT ZERTIFIZIERUNGEN NACH MDR ALS BENANNTE STELLE – WIE SICH HERSTELLER AM BESTEN VORBEREITEN KÖNNEN, MEINRAD GUGGENBICHLER, MDC
(PDF/1 MB)

ERFAHRUNGEN AUS DEN BISHERIGEN MDR-AUDITS: WAS MEIST GUT LÄUFT UND WO DIE FALLSTRICKE LIEGEN, MARKUS WAGNER, TÜV SÜD
(PDF/1,013 KB)

KLINISCHE PRÜFUNGEN GEMÄSS MDR - ÄNDERUNGEN IM BEHÖRDENVERFAHREN, STEFAN STRASSER, BASG - BUNDESAMT FÜR SICHERHEIT IM GESUNDHEITSWESEN
(PDF/892 KB)

MEDICAL SOFTWARE & APPS: IMMER WIEDERKEHRENDE SCHWACHSTELLEN IM RAHMEN VON „TECHNICAL FILE REVIEWS" UND „ON SITE AUDITS", MARKUS WAGNER, TÜV SÜD
(PDF/797 KB)

PRAXISLEITFADEN FÜR SOFTWAREHERSTELLER, MARTIN SCHMID, EN.CO.TEC
(PDF/2 MB)

DIE GRÖSSTEN HERAUSFORDERUNGEN AUS HERSTELLERSICHT BEI DER MDR-UMSTELLUNG, MARKUS SPEISER, SYNEDRA INFORMATION TECHNOLOGIES GMBH
(PDF/605 KB)

KLINISCHE BEWERTUNG VON MEDIZINPRODUKTEN: KLINISCHE DATEN VS. NICHT-KLINISCHE DATEN UND TIPPS FÜR DIE ERSTELLUNG VON CLINICAL EVALUATION REPORTS (CERS), FLORIAN MARTYS, MEDUNI WIEN
(PDF/845 KB)

NACHWEISE ZUR VERIFIZIERUNG UND VALIDIERUNG IN DER TECHNISCHEN DOKUMENTATION – DO'S UND DON`TS, VOLKER SUDMANN, MDC
(PDF/1 MB)

UPDATE ZU EUDAMED & UDI-KENNZEICHNUNG | REGISTRIERUNG VON LEGACY DEVICES, POPPY ABETO KIESSE, GS1 AUSTRIA
(PDF/2 MB)

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BMBWF-10.470/0010-V/3c/2018 (2018-2023)