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Medicina di Laboratorio ETS

Schweizerische Gesellschaft für Klinische Chemie
Société Suisse de Chimie Clinique
Società Svizzera di Chimica Clinica
Swiss Society of Clinical Chemistry

CLINICAL MASS SPECTROMETRY:
VALIDATION AND ACCREDITATION OF IVD AND LABORATORY DEVELOPED TEST (LDT) IN THE NEW "REGULATION EU 2017/746" ERA

20-21 MAY
2023

VENUE:
ROME
LA NUVOLA CONGRESS CENTER
ROOM 1

ITALY

Satellite Meeting

21-25 May
WORLDLAB · EUROMEDLAB
ROMA 2023

AUSPICES

The event is promoted by:

SIBioC
Medicina di Laboratorio ETS

Schweizerische Gesellschaft für Klinische Chemie
Société Suisse de Chimie Clinique
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Swiss Society of Clinical Chemistry

And organized under the auspices of:

ifcc
International Federation of Clinical Chemistry and Laboratory Medicine

EFLM
EUROPEAN FEDERATION OF CLINICAL CHEMISTRY AND LABORATORY MEDICINE

INTERNATIONAL ASSOCIATION OF
THERAPEUTIC DRUG MONITORING AND CLINICAL TOXICOLOGY

INTRODUCTION

Dr Marco Cantù

Clinical mass spectrometry: validation and accreditation of IVD and Laboratory Developed Test (LDT) in the new "Regulation EU 2017/746" era

Over the last 10 years, mass spectrometry (MS) has become extremely popular in clinical chemistry laboratories. At the same time, there has been an evolution in regulations, standards and protocols for both validation and verification of analyses on this instrumentation (EMA, ISO, CLSI, etc.), up to the most recent European Regulation 2017/746 (IVDR).

To efficiently integrate mass spectrometry in laboratory, a clinical chemist must therefore face new challenge related to the impact of the new European Regulation 2017/746 concerning the verification and validation of analyses.

During the meeting, you will therefore acquire the skills to prepare

- Experimental designs to verify/ validate an analysis in MS
- Dossiers for the national competent authority for Laboratory Developed Test (LDT) assay, in accordance with the requirements of the new European Directive IVDR 2017/746
- Dossiers for the accreditation of mass spectrometry In Vitro Diagnostic (IVD) Kit,

The meeting aims at providing participants with a complete overview of procedures and experimental designs to prepare the documentation for the analysis accreditation process (IVD & LDT) and/or for the national competent authorities inspection (LDT).

Dr Marco Cantù

COMMITTEES

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Sergio Bernardini
Rome, Italy

Pierre-Alain Binz
Lausanne, Switzerland

Marco Cantù
Bellinzona, Switzerland - SC Chair

Dario Cattaneo
Milan, Italy

Alessio Cremonesi
Zurich, Switzerland

Bianca Maria Goffredo
Rome, Italy

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Basel, Switzerland

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Modena, Italy

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Bellinzona, Switzerland

Fabrizio Dal Piaz
Salerno, Italy

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Rome, Italy - OC Chair

Viviana Izzo
Salerno, Italy

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Brescia, Italy

David Ballantyne
Wilmslow, UK

Pierre-Alain Binz
Lausanne, Switzerland

Giuliana Cangemi
Genoa, Italy

Marco Cantù
Bellinzona, Switzerland

Dario Cattaneo
Milan, Italy

Alessio Cremonesi
Zurich, Switzerland

Fabrizio Dal Piaz
Salerno, Italy

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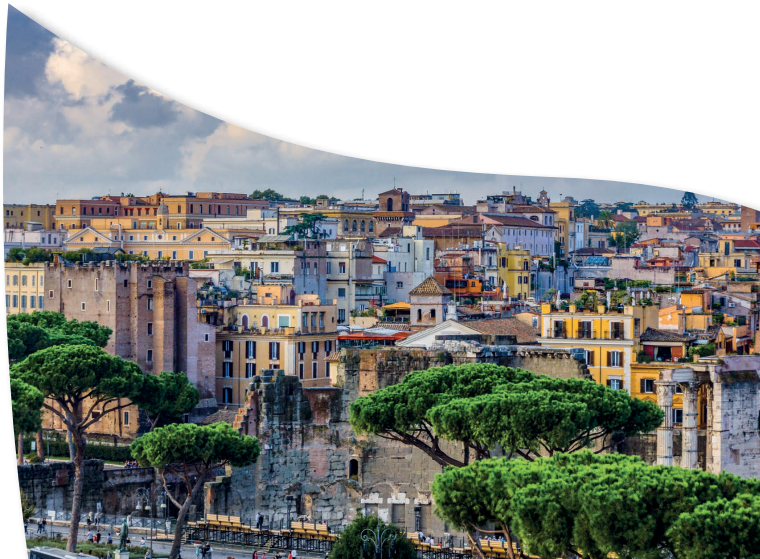

May 20

IVDR and analytical performance

12:00-12:45	Welcome & Registrations
12:45-13:00	Greetings and introduction
	Chairs: Pierre-Alain Binz, Marco Cantù
	Session: "Current regulations"
13:00-14:00	Plenary Lecture: the new Regulation EU 2017/746 LDT: Validation of endogenous/exogenous molecules *Michael Vogeser*
	Session: "LDT: Validation of endogenous/exogenous molecules"
14:00-14:40	Is it really that? Analytical Specificity/Interference/matrix effect/cross reaction/carry *Amedeo De Nicolò*
14:40-15:20	How much is it? Analytical sensitivity/LOQ/measurement interval/Linearity *David Tonoli*
15:20-15:40	Break
	Chairs: Giuliana Cangemi, Christoph Seger
15:40-16:20	How far we are? Trueness/Precision/Accuracy/Recovery *Pierre-Alain Binz*
16:20-17:00	What, how, when...Preanalytic, sample manipulation, stability of reagent and sample *Sara Baldelli*
17:00-17:30	*Presentation sponsored by SHIMADZU* Analytical and clinical performance evaluation in IVDR era, a LC/MS kit manufacturer point of view *Mikaël Levi*
17:30-18:00	*Presentation sponsored by PROMISE* Monitoring of mAbs using LC-MS: from lab-developed methods to CE-IVD kits *Dorothee Lebert*
18:00	Closing day

May 21

Analytical performance & clinical performance

Chairs: Bianca Maria Goffredo, Pierre Lescuyer

Session: "IVD: performance verification"

08:30-9:10 IVD performance verification and comparison among different methods
Nora Gibitz-Eisath

09:10-09:50 Post validation: allerts and tips
Fabrizio Dal Piaz

Session: "Clinical Performance evaluation"

09:50-10:30 Diagnostic sensitivity/specificity/PPV/NPV/likelihood ratio
Michel Rossier

10:30-11:00 *Presentation sponsored by WATERS*
MassTrak LC-MS/MS solutions – Solving problems in an IVD-R laboratory
David Ballantyne

11:00-11:20 Break

Chairs: Alessio Cremonesi, Ugo De Grazia

11:20-12:00 "Biological variance & Reference range" expected value
Dario Cattaneo

12:00-12:40 Case study: validation Protocol examples
Daniel Müller

12:40-13:10 *Presentation sponsored by TECAN*
Integrating Dexamethasone in routine LC-MS analysis using IVD Steroid Panel LC-MS Kit - Minimizing regulatory burden by choosing commercially available solution
Federico Ponzetto

13:10-13:40 *Presentation sponsored by ROCHE DIAGNOSTICS*
Importance of LC-MS/MS in a highly robotized central laboratory: our opinion and experience at Centro Diagnostico Italiano (CDI)
Fulvio Ferrara

13:40-13:45 Closing day

GENERAL INFORMATION

REGISTRATIONS

A limited number of places is available. All delegates must register for the congress.
Registration fees are as follows:
Early registration (until 31st March) - € 180 (VAT included)
Regular registration (after 31st March) - € 220 (VAT Included)

INDUSTRY EXHIBITION

An industry exhibition will be open and accessible in the congress room, according to the times of the scientific programme.

CONGRESS LANGUAGE

The congress' official language is English.

NAME BADGE

A name badge will be required for access to the congress area. Participants will receive a name badge when they check in at the registration desk. It must be always worn.

CERTIFICATE OF ATTENDANCE

All properly registered attendees will be entitled to receive a certificate of attendance. Certificates of attendances will be sent via email after the end of the Congress.

CONGRESS VENUE

ROOM 1
LA NUVOLA - ROMA CONVENTION GROUP
Viale Asia, angolo Viale Cristoforo Colombo
00144 Roma
Italy

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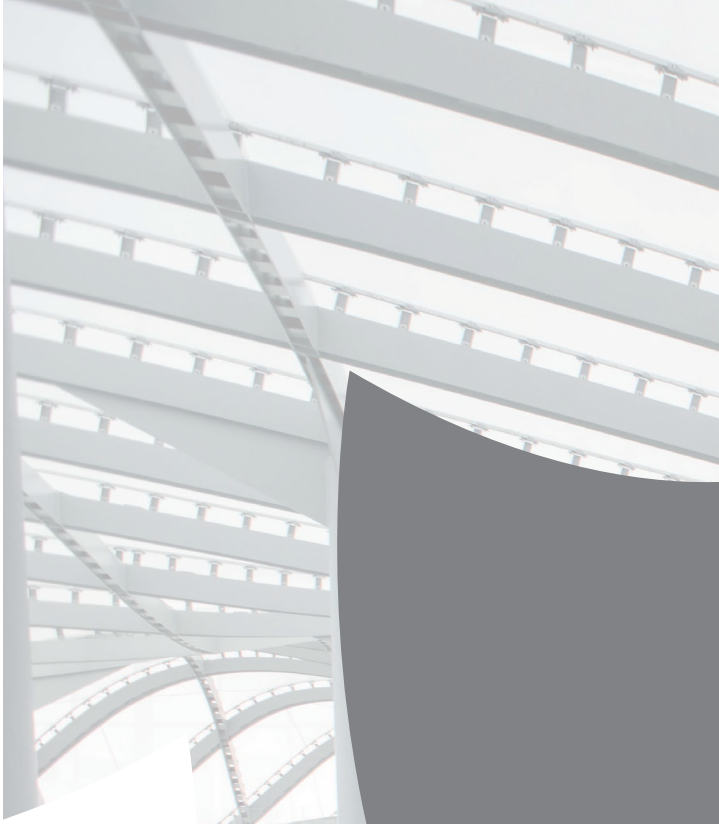

MZ EVENTS

ORGANISING SECRETARIAT
MZ Events srl
Via Carlo Farini, 81
20159 Milan, Italy
nicholas.vergani@mzevents.it
Ph. + 39 02 66802323 ext. 924