



SBMD Qualification and Classification: Pre-clinical Approaches to Mechanism of Action

Milan, 9 FEBRUARY 2023

Excelsior Hotel Gallia
Piazza Duca D'Aosta, 9
20124 Milano

Seminar Objective

VitroScreen has been a pioneer in developing and proposing pre-clinical experimental protocols on 3D reconstructed human tissue models: they are currently applied to demonstrate the mechanism of action of SBMD and they are relevant to comply with the safety and efficacy requirements of the EU MDR 2017/745.

The seminar has the ambition to open a discussion on MDCG 2022-5 with stakeholders involved in Medical Devices (Health Authorities, Notified Bodies, Academia, Industry and ISO representative) analyzing the state of the art of scientific approaches to qualification and classification issues.

Program

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| 8.30 - 9.00 | Registration |
| 9.00 - 9.15 | Welcome
Marisa Meloni, <i>VitroScreen Founder and CEO</i> |
| 9.15 - 9.30 | Introduction to MDCG 2022-5
and industry perspectives
Giulia Magri - <i>Confindustria DM</i> |
| 9.30 - 10.15 | Pre-clinical efficacy on 3D reconstructed
tissue models: case studies
Paolo Buratti and Francesca Urso - <i>VitroScreen</i> |
| 10.15 - 10.30 | Maria Grazia Leone - <i>Ministero della Salute,
Direzione generale dei dispositivi medici
e del servizio farmaceutico</i> |
| 10.30 - 11.00 | Coffee break |
| 11.00 - 12.30 | Open Discussion with Notified Bodies
Alessia Frabetti - <i>KIWA CERMET</i> , Chiara Novi - <i>TUV</i> ,
Roberta Marcoaldi - <i>Istituto Superiore di Sanità</i> |
| 12.30 - 12.50 | Looking for a common perspective
Alessandra Semenzato - <i>Dipartimento di Scienza
del farmaco, Università degli studi di Padova</i> |
| 12.50 - 13.10 | Updates on ISO activities
Christian Pellevoisin - <i>Convenor of ISO Group 8
Technical Committee 194</i> |
| 13.10 - 13.30 | Conclusion |
| 13.30 - 15.00 | Networking Lunch |

General information

The official language of the seminar will be Italian.
Speakers' presentations will be supported by slides in English.
Translation in English will be available for on-line foreign participants.

Registration details: registration in presence is limited to 100 participants and will close latest on January 31st.

Payment

Registration fee: € 150,00 + VAT 22%

The quote include:

- English translation for on-line foreign participants
- Coffee break and Lunch

[CLICK HERE TO REGISTER](#)

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