MedDev Day

Date
21 - 24 September 2021

Language
English

Location
Online
Virtual Conference

SPONSORS

MEDIA PARTNERS

ABOUT

The MedDev Day keeps the discussion going!
Enrol in the online event to take place in 21st – 24th September 2021!
A 4-day event to discuss ongoing hot topics in the world of Medical Devices (MDs), In-Vitro Diagnostics (IVDs) and Software Medical Devices (SaMD).

The regulations are already tough – and getting tougher. The MDR and the IVDR place more emphasis on a life-cycle approach to safety, backed up by clinical performance data. Both regulations present stringent requirements for Notified Bodies, control and monitoring by competent authorities. Within this context, staying up to date with the latest news and discussions in the global medical device industry is a complex task.

The MedDev Day, organized by LS Academy has reached its third edition, and will once again serve as a central meeting place for the medical technology industry, bringing together lecture forums, interviews, workshops and networking opportunities. The event will be 360-degree overview of the evolving context of medical devices, in-vitro-diagnostics and software.
Hot topics in discussion will include:

- Strategic approach to the claims in the clinical evaluation and MDR requirements
- RWD & RWE in clinical evaluations
- Benchmarking clinical data for better study designs
- How to implement Post-Market Surveillance processes following MDR art. 88
- IVDR and technical documentation
- Regulatory management of medical devices under the MDR
- Cybersecurity of medical devices
- Scientific validation of algorithms

«Over the past 10 years, the medical device industry has been growing on average 4.2% per annum in the European medical device market. (...) Medical technology is characterized by a constant flow of innovations, which are the results of a high level of research and development within the industry, and of close cooperation with the users (1).»

Scientific Board
Francesco Dell'Antonio - *Head of Quality & Regulatory* at Inpeco SA
Laura Michellini -*Scientific Director* at Contract Research Organizations Latis Srl and Elle Research Srl
Sascha Wettmarshausen - *Head of Regulatory Affairs* at VDGH e.V. (German IVD-Association)
Arkan Zwick - *Corporate Regulatory Affairs Director* at CROMA Pharmaceutical, Austria

Laura C Collada Ali - *MedDev Day Scientific Coordinator*, LS Academy

Who should attend?
The event is designed for professionals in the field of Medical Devices, devoted to departments such as:

- Clinical Operations
- Product Managers

- Regulatory Affairs
- Quality Assurance/Control
- Risk Management
- Medical Device Engineering
- Device vigilance
- R&D
- Medical Affairs
- Medical Writring

from Pharmaceutical, Biotechnology and Medical Device companies, CROs, Universities/Hospitals, Academic Research, Patient Associations and Healthcare Organizations.

(1)MedTech Europe. The European Medical Technology Industry in figures 2020. Available here: https://www.medtecheurope.org/wp-content/uploads/2020/05/The-European-Medical-Technology-Industry-in-figures-2020.pdf

PROGRAMME

5 sessions to choose from based on your interests:

SESSION 1 | General: Medical Devices Clinical Evaluation & Clinical Investigation
SESSION 2 | General: Post-market Surveillance
SESSION 3: In-Vitro Diagnostics
SESSION 4: Regulatory Management
SESSION 5: Software Medical Devices

All the below mentioned times are CEST

21 September 2021	
	SESSION 1 | General: Medical Devices Clinical Evaluation & Clinical Investigation
10:00 am **10:20 am**	**Welcome**
10:20 am **10:50 am**	**Clinical Evaluation Reviews under MDR – Notified Body Experience since Designation** **Itoro Udofia** MHS-UK Director at TÜV SÜD
10:50 am **11:20 am**	**To claim or Not to Claim - Practical Considerations on How to Approach Claims within the Clinical Evaluation of a Medical Device** **Silvia Casagrande** Clinical Evidence Manager at Orthofix SRL

11:20 am **11:35 am**	**Break**
11:35 am **12:05 pm**	**Benchmarking Clinical Data for Medical Devices to improve your Study Design** **Jasminka Roth** Founder and Director of The Tao of Excellence
12:05 pm **12:35 pm**	**What are the Consequences of the ISO14155 update on Clinical Investigations set-up?** **Maurizio Cuocolo** Head of Quality Management Unit at OPIS Srl
12:35 pm **12:40 pm**	**Conclusion**
	SESSION 2 | General: Post-Market Surveillance
2:00 pm **2:10 pm**	**Welcome**
2:10 pm **2:35 pm**	**Post-Market Surveillance (PMS) Expectations of Notified Bodies under the EU MDR 2017/745** **Bassil Akra** Chief Executive Officer at AKRA TEAM GmbH
2:35 pm **3:00 pm**	**Post-Market Clinical Follow-up (PMCF) under the MDR: the Latest Insights** **Wiebe Postma** Sr Consultant & CRO Lead at Qserve CRO
3:00 pm **3:15 pm**	**Break**
3:15 pm **3:40 pm**	**IMDRF Adverse Event Coding Implementation in Clinical Evaluation and Post-Market Surveillance (PMS) Documentation: A Case Study** **Kelly Goodwin Burri** Senior Clinical Evaluation Specialist at Stryker
3:40 pm **4:05 pm**	**Interaction between Post-market Surveillance, Clinical Data, Clinical Evaluation and Risk Management** **Jan Bart Hak** Head Medical Device Department at ProPharma Group

4:05 **4:35**	**Panel Discussion** **Bassil Akra** Chief Executive Officer at AKRA TEAM GmbH **Jan Bart Hak** Head Medical Device Department at ProPharma Group **Kelly Goodwin Burri** Senior Clinical Evaluation Specialist at Stryker **Wiebe Postma** Sr Consultant & CRO Lead at Qserve CRO
4:35 pm **4:40 pm**	**Conclusion**
22 September 2021	
	SESSION 3: In-Vitro Diagnostics
10:00 am **10:10 am**	**Welcome**
10:10 am **10:40 am**	**New Classification System and Rules for IVDR** **Sascha Wettmarshausen** Head of Regulatory Affairs at VDGH e.V. (German IVD-Association)
10:40 am **11:10 am**	**Technical Documentation for IVDs according IVDR: a Case-Study** **Stefanie Giesener** Head of Quality Management & Regulatory Affairs at DiaSys Diagnostic Systems GmbH, Germany
11:10 am **11:25**	**Break**
11:25 am **11:55 am**	**IVDR Implementation & Audits in the time of Corona Pandemic** **Krutarth Patel** Vice President QM / RA at R-Biopharm AG
11:55 am **12:25 pm**	**Post-Market Surveillance for In-Vitro Diagnostic Medical Devices** **Marta Carnielli** Technical Officer IVD at TÜV SÜD
12:25 pm **12:30 pm**	**Conclusion**
23 September 2021	
	SESSION 4: Regulatory Management

10:00 am **10:10 am**	**Welcome**
10:10 am **10:40 am**	**Potential of Digital Documentation: Advantages, Disadvantages, and Future Trends** **Sarah Panten** Strategic Business Development at avasis solutions GmbH
10:40 am **11:10 am**	**Medtech Regulatory Overview and Tips to Get Registration Approval Quicker in Asia - First Part** **Jack Wong** Founder at Asia Regulatory Professionals Association (ARPA)
11:10 am **11:25 am**	**Break**
11:25 am **11:55 am**	**Medtech Regulatory Overview and Tips to Get Registration Approval Quicker in Asia - Second Part** **Jack Wong** Founder at Asia Regulatory Professionals Association (ARPA)
11:55 am **12:25 pm**	**Global Regulatory Management from a Corporate Regulatory Perspective. Common Principles and Regional Differences** **Igor Shchemelinin** Regulatory Affairs Director at Medical Devices Regulatory Compliance (Würzburg, Germany)
12:25 pm **12:30 pm**	**Conclusion**
24 September 2021	
	SESSION 5: Software Medical Devices
10:00 am **10:10 am**	**Welcome**
10:10 am **10:40 am**	**Software as Medical Device: how to valuably deliver end to end solutions!** **Sabine Dörhöfer** Standard Domain Lead at Roche Diagnostics International AG
10:40 am **11:10 am**	**How to make Market Access Pathways Work for Digital Health Solutions** **Danny Van Roijen** Digital Health Director at COCIR
11:10 am **11:25 am**	**Break**

11:25 am **11:55 am**	**Cybersecurity Requirements for Software as Medical Device (SaMD)** **Leon Doorn** Head of Regulatory Compliance [PRRC, DPO] at Aidence
11:55 am **12:25 pm**	**Additional Considerations for the Clinical Evaluation of Artificial Intelligence Driven Devices** **Ency Yao** Regulatory Manager at Qritive Pte. Ltd
12:25 pm **12:30 pm**	**Conclusion**

SPEAKERS

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REGISTRATION FEE

Full attendance | 5 sessions
€ 640,00* Early Bird fee until September 9th, 2021
€ 720,00* Ordinary fee
€ 370,00* Freelance, Academy, Public Administration

General sessions 1 and 2 + 2 sessions based from your interest
€ 580,00* Early Bird fee until September 9th, 2021
€ 650,00* Ordinary fee
€ 330,00* Freelance, Academy, Public Administration

General sessions 1 and 2 + 1 session based from your interest
€ 420,00* Early Bird fee until September 9th, 2021
€ 470,00* Ordinary fee
€ 240,00* Freelance, Academy, Public Administration

* *for Italian companies: +22% VAT*

Fee includes: access to the virtual conference, organizational support, certificate of attendance, slide presentations in pdf format provided post-event.
Please remind to indicate in the box "note" the session/s you would like to attend while registering.

CONFERENCE VENUE

Virtual conference with presentations, slots for Q&A and discussion among delegates.
LS Academy will provide the link to join the conference some days before.