2023 SYMPOSIUM ON MEDICAL TECHNOLOGY

Join experts for an engaging discussion on MDR transition periods, how to get competitive and sustainable medical devices to market, and more!

12th Medical Technology Symposium
Steigenberger Hotel Hamburg
Hamburg | September 14th–15th, 2023

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THE TOPICS ON EVERYONE'S MIND

Don't miss this year's gathering of industry leaders and SMEs as they discuss Regulation (EU) 2023/607 and offer insights, observations, and analysis on:

- Successfully navigating MDR transition periods
- How to bring competitive medical devices to market
- Practical guidance for sustainable implementation
- New transitional provisions for certain medical devices

The Symposium on Medical Technology is presented by NSF in partnership with Life Science Nord.

JOIN THE SPECIALISTS

Be part of this important gathering and experience the engaging and informative discussions of leading authorities and experts from:

- The European Commission
- BIOTRONIK
- BVMed
- BfArM
- Notified Bodies
- Manufacturers
- Hospitals
- Other Stakeholders

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AGENDA – 12TH SYMPOSIUM ON MEDICAL TECHNOLOGY

SEPTEMBER 14th, 2023

MDR Outlook		
08:30 AM - 09:00 AM	Registration & Networking	
09:00 AM - 09:10 AM	Welcome & Opening	**Oliver P. Christ** I NSF & **Dr. Jürgen Walkenhorst** & **Prof. Dr. Heike Wachenhausen** I LSN
09:10 AM - 09:30 AM	**EU MDR: Risks and benefits for patients/physicans/organizations – 5 Theses**	**Prof. Dr. Jens Fiehler** I UKE
09:30 AM - 10:10 AM	**New transitional provisions for EU MDR - What has changed & what stays un-changed?**	**Frank Matzek** I BIOTRONIK
10:10 AM - 10:50 AM	**Practical experience & concerns of BVMed members regarding Regulation (EU) 2023/607**	**Christopher Kipp** I BVMed
10:50 AM - 11:20 AM	Break and Networking	
11:20 AM - 12:00 PM	**HERAs view on Medical Counter Measures related to Medical Devices and the implementation of the new regulations**	**Dr. Matthias Neumann** I EU Commission
12:00 AM - 12:40 PM	**The product life cycle of a digital medical device meeting EU Regulations**	**Randolph Stender** I NSF PROSYSTEM
12:40 PM - 01:00 PM	Dialog: Q & A	**Oliver P. Christ** I NSF & **Prof. Dr. Heike Wachenhausen** I LSN
01:00 PM - 02:00 PM	Lunch & Networking	
Sustainability & Clinical Evidence		
02:00 PM - 02:30 PM	**Sustainability in gathering Postmarket data for Medical Devices – application of real world evidence**	**Rachel Mead** Notified Body I BSI Group
02:30 PM - 03:00 PM	**Sustainability and Clinical Claim Management**	**Heather Howell** I NSF USA
03:00 PM - 03:30 PM	**Usability & market comparison studies provide evidence on intended use claims**	**Torsten Gruchmann** I USE-Lab
03:30 PM - 04:00 PM	Break and Networking	
04:00 PM - 04:40 PM	**Regulatory Challenges with Pediatric Medical Devices under the Medical Device Legislation (MDR)**	**Dr. Thomas Fischer** I Bundesinstitut für Arzneimittel und Medizinprodukte
04:40 PM - 05:20 PM	**Incentives for pediatric medical devices in the US and Japan. Implications for the EU**	**Dr. Stephanie Hübner** I OLYMPUS Surgical Technologies Europe
05:20 PM – 06:00 PM	**"Don't Wait, Automate! Intelligent Automation for MDR/IVDR Success"**	**Marc H. Miller** I TransPerfect Medical Device Solutions
06:00 PM - 08:00 PM	Symposium Dinner	
	Welcome & Reception Opening	**Oliver P. Christ** I NSF & **Prof. Dr. Heike Wachenhausen** I LSN
08:00 PM - 08:30 PM	Dinner-Speech: **An FDA perspective on Quality Management requirements including ISO 13485 & other recognized Standards**	**Scott Colburn** I FDA

SEPTEMBER 15th, 2023

FDA - Regulatory issues outside the EU		
09:00 AM - 09:10AM	Welcome & Opening	**Oliver P. Christ** I NSF & **Prof. Dr. Heike Wachenhausen** I LSN
09:10 AM - 09:50 AM	**An FDA perspective on Quality Management requirements including ISO 13485 & other recognized Standards**	**Scott Colburn** (invited) I FDA
09:50 AM - 10:30 AM	**How European Standards get harmonized under EU-MDR**	**Jennifer Ogbonna** I CEN/CENELEC Brussels
10:30 AM - 10:45 AM	Dialog: Q & A	**Oliver P. Christ** I NSF & **Prof. Dr. Heike Wachenhausen** I LSN
10:45 AM - 11:10 AM	Break and Networking	
11:10 AM –11:40 AM	**New requirements for reprocessing of medical devices (ISO 17664-1 & -2) – implications for EU-MDR use**	**Dr. Florian H.H. Brill** I Dr. Brill + Partner
11:40 AM - 12:10 PM	**Risk-Management & Post-Market Surveillance are backbones for Regulatory Compliance**	**Eljar Amini-Nejad** I NSF PROSYSTEM
12:10 AM - 12:40 PM	**User perspective: Do innovative medical devices Go to the US market first**	**Prof. Dr. Jens Fiehler** I UKE
12:40 PM - 01:00 PM	**Q & A Closing discussions** **How to comply with global MD Regulations to create a sustainable future**	with all (remaining) Speakers & Participants
01:00 PM - 02:00 PM	Lunch