eurofins | Medical Device Testing

LI-MED RA & QA Experts

Conference:
Clinical Evaluation MDD vs MDR

January 17th, 2019
Leonardo City Tower Tel Aviv Hotel
Zisman Shalom St 14, Ramat Gan, Israel

Top Speakers:

Danielle Nusimovici-Avadis MD
DNA Consulting

Ruth Reiss
Li-Med

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Introduction

Medical devices require CE Marking for their commercialization in the European Union. When submitting devices for a CE Mark, manufacturers must provide the necessary technical documentation which includes the the Clinical Evaluation Report (CER) that documents the entire on-going clinical evaluation process to ensure safety and performance of the device throughout its life cycle. CE Mark strategy and CERs issued under the previous Directive were primarily based on product equivalency and often associated to data from equivalent or similar devices.

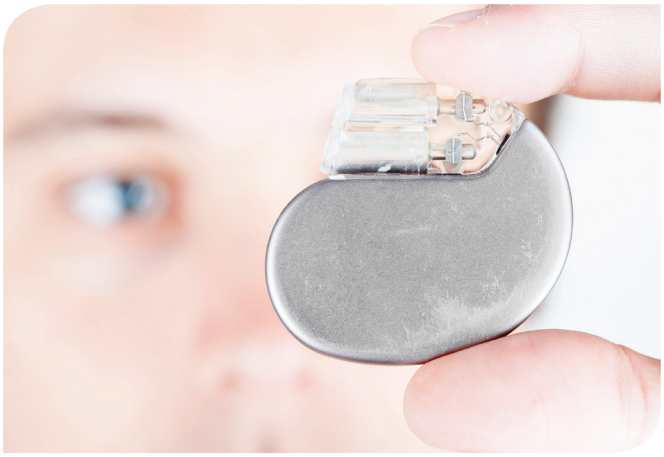
The regulatory scenario has evolved. As of today, manufacturers must produce and maintain a CER that complies with MEDDEV 2.7/1 rev 4. Also the new Medical Device Regulation (MDR) that will become fully applicable in mid 2020, will affect the CE Mark Strategy and Clinical Evaluation Process compliance requirements.

The EU MDR that aims to ensure a higher level of safety for medical devices, has become more stringent and has tightened requirements for Clinical Evaluation Process and Reports. More in depth assessments are necessary and CERs should provide strong clinical evidence to demonstrate that medical devices are not exposing users and patients to risk. To avoid the risk of product removal from the market manufacturers should present compliant CERs.

For new products it has become very challenging, if not impossible, to rely on data from equivalent devices manufactured by other companies. As the MEDDEV 2.7/1 rev 4 guidance document has established stricter clinical investigation and evaluation requirements that lead to more clinical investigations, probably of larger size, Notified Bodies are already looking more closely at how all the essential requirements are met, including those regarding usability.

For medical devices that are already on the market or products that wish to enter it, companies should, during the CER, identify residual clinical risks and clearly define a PMS plan that includes wheather a PMCF study is necessary or not. The collected data during the post marketing activities should support safety, performance and usability of the device throughout its life cycle.

Clinical evaluation has become an extremely important step in the path to CE Marking, representing the greatest challenge for manufacturers of medical devices and combination products. Extensive effort is required from all involved parties to be able to correctly provide the technical documentation in the near future, and to avoid pitfalls of clinical regulatory submissions.



Benefits in attending

This conference is designed to deliver valuable insights to manufacturers on how to demonstrate clinical safety and performance of their products in compliance with the strict requirements of the MEDDEV 2.7/1 rev 4 in compliance with the new EU MDR. By attending the conference participants will be able to:

- Understand what is included in the term ‘Clinical Data’
- Understand what is required regarding ‘Current Knowledge & State of the Art’
- Understand how clinical evaluation is a process, and how this process needs to be interlinked with Risk assessment, Usability and Biological Risk assessment
- Determine when a clinical trial is required
- How to provide documentation in support of the clinical safety and performance of devices
- Ensure continuing compliance throughout device lifecycle

Target audience

This conference will be extremely useful to the following job profiles that work for manufacturers that market devices in the EU:

- All levels of management and departmental representatives, who need to improve their understanding of the MEDDEV 2.7/1, rev 4
- Senior Management
- Regulatory & Quality Affairs professionals
- VP of Design, Development, Manufacturing, Marketing & Sales Management
- Project Managers
- Clinical Affairs
- Legal Counsel
- Consultants
- CRO’s

Programme

9.00 - 9.30: Registration

9.30 - 10.30: Objective of Clinical Evaluation Process & Report
Danielle Nusimovici-Avadis MD, DNA Consulting

10.30 - 10.45: Coffee break and refreshments

10.45 – 12.45: Clinical Evaluation: MDD vs MDR
Danielle Nusimovici-Avadis MD, DNA Consulting

12.45 – 13.45: Lunch

13.45 – 14.45: CER and relevant Harmonized Standards:
• EN ISO 14155:2011 and expected updates in 2019
• EN ISO 14971:2012 Risk Assessment
• IEC 62366-1/2 Usability
Danielle Nusimovici-Avadis MD, DNA Consulting
Ruth Reiss, Li-Med

14.45 – 15.00: Coffee break

15.00-16.00: Clinical Evaluation: New definitions; Procedure & Report
Danielle Nusimovici-Avadis MD, DNA Consulting

16.00-16.30: CER Table of Content – Template
Danielle Nusimovici-Avadis MD, DNA Consulting

16:30-17:30: One on one personal meeting

Workshop language

The official workshop language will be English.

Speakers

Danielle Nusimovici-Avadis
Danielle Nusimovici-Avadis is a Medical Doctor. She is an International clinical & regulatory expert. Owner of MedTech DNA-Consulting, she has more than 17 years' experience in the medical device development industry, and extensive knowledge of clinical applications of new technologies. Her expertise in regulatory and clinical affairs led to several successful clinical trials and regulatory submissions in Europe and in the US. She is a seasoned subject matter expert in taking new products from R&D to the medical market. She has worked as Medical Director for several companies. She is aso taking part in board meetings, business strategy, due diligence processes and audits (M&A). Sample Achievement: She took part in the deve-lop-ment of the first percutaneous heart valves for PVT and joined upon creation (Merged with Edwards Life science in 2004) which lead to publications. Danielle has also experience as a Qualified Medical Reviewer on behalf of a European Notified Body.

Ruth Reiss
Ruth has more than 16 years' experience in the Quality Assurance and Regulation acquired from pharmaceutical companies, storage and distribu-tion of drugs, diagnostics and medical device companies. She has substantial experience in FDA and CE submissions, ISO 9001, ISO 13485, ISO 17025 & Validations. In addition, she has set up a qualitysystem various companies including startups andlead the companys' to GMP inspections of the Israeli Ministry of Health.

Registration:

Online registration: **https://goo.gl/forms/pbtBHbnj6LGK5gOU2**

Registration fee:

Early bird registration fee (Valid until 27.12.2018): 1390 NIS
Full registration fee: 1590 NIS

The registration fee includes:
Conference documentation, lunch and refreshment.
The registration fee is payable in advance.

A certificate of attendance for professional development will be given to each participant who completes the workshop.

General terms and conditions:

If you cannot attend the conference you have two options:
1. We are happy to welcome a substitute colleague at any time.
2. If you have to cancel entirely we must charge the following processing fees:
- until 1 week prior to the conference 50% of the registration fee will be charged;
- less than 1 week prior to the conference full registration fee will be charged.

Organizers reserve the right to cancel/alter the programme, the speakers, the date or venue. If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. Organizers are not responsible for airfare, hotel or other costs incurred by registered delegates.

Terms of payment:

The registration fee is payable in advance.

Means of Payment:

On-line credit card:
https://secure.cardcom.solutions/e/3SH/

Bank transfer:
Top Li-Med Technology
Bank: Hapoalim
Branch: 537
Account No. 187391

Please send a reference of the transfer by email at sivan@li-med.com. Invoice will be issued and emailed separately.

Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message.
Only after we have received your payment, you are entitled to participate in the conference.

Date:

January 17th 2019, 09.30h - 17.30h
(Registration 09.00h-09.30h).

Leonardo City Tower Hotel
Zisman Shalom St 14, Ramat Gan, Israele
https://www.google.it/maps/place/Leonardo+City+Tower/@32.084689,34.7995847,15z/data=!4m2!3m1!1s0x0:0x625d346a3c96efdf?sa=X&ved=0ahUKEwju1bmTz6LWAhUEIJoKHWQGAIcQ_BIInwEwCg

Organisation and Contact:

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We very much look to welcoming you to the Clinical Evaluation MDD vs MDR Conference on January 17th in Tel Aviv.