MDR&D 2018

Where Innovation Meets StartUp Wizards

Medical Device Research and Development Summit

Convention | Workshops | Networking

22 - 23 October 2018

David Intercontinental Hotel, Tel-Aviv, Israel

Learn How to Develop Medical Device in Start-Up Situation

We are proud to announce the **MDR&D 2018 - the Medical Device Research and Development Summit**, to be held on October 22nd and 23rd, 2018, in the luxurious David Intercontinental hotel in Tel-Aviv, Israel.

The Startup nation's medical device gurus gather to share and exchange winning methodologies, tools and practices that boost return on investment.

Join us for 360-degree coverage of the medical device development lifecycle concentrating on the development stage. Learn how to fast track proof of concept , get up close and personal with lean prototyping methodologies, product-centered and patient centered design, manage practical aspects and approaches to design qualification, design transfer to productionand small-scale production.

Familiarize yourself with the regulatory requirements and quality assurance standards and learn how to fit them to meet your start-up constraints. Understand the significance and role of your business plan, storyboard, patent strategy and regulatory pathway to market. Be inspired by the personal stories of Israel's serial entrepreneurs and connect to the best-in-class vendors.

Chairman:

Gadi Ginot
CEO, Physio-Logic

PHYSIO-LOGIC

Co - Chairman:

Eran Toledo
PhD., CTO, Sanara Ventures

SANARA VENTURES

Steering Committee

Tal Biran Ben-Gal, Director, BeWell.il

Ofer Doron, Director, Lahav Research Institute

Diego Falletti, Technical Specialist & Scheme Manager Vascular - BSI Group, Italy

Maier Fenster, Head of Medical Devices Department, Ehrlich Group

Ofir Gamliel, CEO, ITL Israel Testing Laboratories

Moshe Klaiman, CEO, Medix Software

Shlomi Rom, Director, Business Development, Quasar

Eyal Sandach, General Manager, Nordson Medical

Prof. Mickey Scheinowitz, PhD., Director, Sylvan Adams Sports Institute, Tel Aviv University

Nadav Sheffer, Head of Medical Device Division, Israeli MOH; and Lecturer, Medical Engineering Department, AFEKA Academic College of Engineering

Doron Stern, **Adv**., Tulchinsky Stern Marciano Cohen Levitski & Co., Law Offices

Supported by:

Israel Advanced Technology Industries

Platinum Sponsors:

EHRLICH GROUP
TURNING IDEAS INTO VALUE

Lahav C.R.O
Comprehensive Pre-clinical Services

Medix
Software to your success

ITL ISRAEL TESTING LABORATORIES
Global Certifications You Can Trust

quasar
medical device manufacturer

Nordson MEDICAL

TSMCL
TULCHINSKY STERN MARCIANO COHEN LEVITSKI & CO.
LAW OFFICES

bsi.

Media Partner:

BeWell.il
INNOVATIVE HEALTHCARE & WELLBEING

Day 1 - Monday October 22nd, 2018

08:30-09:15 **Registration & Reception**

09:15-09:30 **Welcome and Introduction**

09:30-09:50 **The Marriage Between Med-Tech and the Computer World**
Benad Goldwasser, MD, MBA, Chairman, Goldmed Ltd.

09:50-11:45 **Session A - Conception**
Session Moderator: **Eran Toledo**, CTO, Sanara Ventures

How to Survive the Early Stage R&D Phase
Eran Toledo, CTO, Sanara Ventures

What an Engineer Needs to Know about Intellectual Property
Maier Fenster, Head of Med. Devices Department, Ehrlich group

Conception from the Investor Perspective
Aimee Fisher, VP Business Development, Sanara Ventures

Everything You Always Wanted to Know About NDA (But Were Afraid to Ask)
Doron Stern ,Adv., Tulchinsky Stern Marciano Cohen Levitski & Co., Law Offices

Development of Ultra-Thin, Wireless and Flexible Retinal Prosthesis
David Rand, Ph.D. Neurobiology, Research Associate, Lab of Prof. Y. Hanein, Center for Nanoscience and Nanotechnology, Faculty of Electrical Engineering, Tel Aviv University

Panel - Early Stage - Do's & Don't 360 Perspective
Doron Stern, Adv., Tulchinsky Stern Marciano Cohen Levitski & Co., Law Offices
Maier Fenster, Head of Med. Devices Department, Ehrlich group
Aimee Fisher, VP Business Development, Sanara Ventures
David Rand, Ph.D. Neurobiology, Research Associate, Lab of Prof. Y. Hanein, Center for Nanoscience and Nanotechnology, Faculty of Electrical Engineering, Tel Aviv University
Eran Toledo, CTO, Sanara Ventures

11:45-12:15 **Coffee Break**

12:15-14:00 **Session B - Design & Development**
Session Moderators: **Barry Schnur**, CEO, DSA & **Eran Toledo**, CTO, Sanara Ventures

From Dream to Production - The Importance of Design for Manufacturability
Shlomi Rom, Director, Business Development, Quasar

Critical Choices in Outsourcing R&D and Production
Barry Schnur, CEO, DSA

Taking the Fast Lane: Medical Device Development in a Rapid and Agile Environment
Elad Lachmanovitch, VP R&D, Tytocare

Material Selection - Biological Safety Considerations
Ophir Lavon, M.D. Head, Clinical Pharmacology and Toxicology Unit, Carmel Medical Center

Success Story - From a Scoliosis Treatment Simulator to the Transmedtech Institute
Carl-Eric Aubin, Ph.D., P.Eng., Chief Executive and Scientific Officer - Montreal TransMedTech Institute

Full-Cycle Multi-Scale Prototyping at INL
Dmitri Petrovykh, Corporate Expert, International Iberian Nanotechnology Laboratory (INL)

Day 1 - Monday October 22nd, 2018

Panel - Enabling Methodologies and Technologies to Boost R&D in Startups and Corporates
Barry Schnur, CEO, DSA
Shlomi Rom, Director, Business Development, Quasar
Carl-Eric Aubin, Ph.D., P.Eng., Chief Executive and Scientific Officer - Montreal TransMedTech Institute
Dmitri Petrovykh, Corporate Expert, International Iberian Nanotechnology Laboratory (INL)
Elad Lachmanovitch, VP R&D, Tytocare
Ophir Lavon, M.D. Head, Clinical Pharmacology and Toxicology Unit, Carmel Medical Center

14:00-15:00 **Lunch Break**

15:00-16:30 **Session C - Regulatory & Quality Considerations**
Session Moderator: **Gadi Ginot**, CEO, Physio-Logic

Strategies to Regulatory Compliance in Startup Situation
Gadi Ginot, CEO, Physio-Logic

CE Marking of Medical Device Under the New EU MDR
Paolo Valsecchi, Scheme Manager and Technical Expert Vascular Medical Devices, BSI

The Conflict between R&D and Regulation
Israel Citron, VP Q&R, Aspect Imaging

Can Startup and Quality Management System Coexist?
Efrat Shamgar, Accelerated Medical Device Approval & Certification Program Leader, Physio-Logic

Product Safety: What Do You Need to Know?
Steli Loznen, M.Sc. SM-IEEE, ITL Israel Testing Laboratories

Panel - How to Integrate Q&R into the R&D Process
Israel Citron, VP Q&R, Aspect Imaging
Steli Loznen, M.Sc. SM-IEEE, ITL Israel Testing Laboratories
Paolo Valsecchi, Scheme Manager and Technical Expert Vascular Medical Devices, BSI
Efrat Shamgar, Accelerated Medical Device Approval & Certification Program Leader, Physio-Logic
Gadi Ginot, CEO, Physio-Logic

16:30-16:50 **Keynote Lecture**
Ascher Shmulewitz, Owner, Medgenesis Partners

Workshops day 1

10:00-11:30	**Workshop A1 - Design Control to FDA Standards** Best industry practices **Gadi Ginot**, CEO, Physio-Logic	**Workshop B1 - Preclinical Studies** Do's and don'ts in preclinical studies: tools to plan and execute your animal trials **Ofer Doron**, Director, Lahav Research Institute
11:30-12:00	Coffee Break	
12:00-13:30	**Workshop A2 - Digital Health** Practical guide to data science in health care **Moshe Klaiman**, CEO, Medix **Oz Levi**, CTO, MatrixBI **Yaniv Almog,** MobileODT, Head of Software Development **Yitzi Pfeffer,** IMedis Medical, CTO, Co-founder **Yardena Peres**, Manager, Innovative Solutions, IBM Watson Health	**Workshop B2 - Medical Electrical Equipment Certification (IEC60601)** Common pitfalls in safety tests and how to avoid them **Steli Loznen**, M.Sc. SM-IEEE, ITL Israel Testing Laboratories **Slava Pilyagin** ,Senior product safety engineer, ITL Israel **Anthon Nikitin**, Product safety engineer, ITL Israel
13:30-14:30	Lunch Break	
14:30-16:00	**Workshop A3 -Contracts and Legal Affairs** Use your engineering skills to negotiate your contracts - an interactive simulation **Doron Stern**, **Adv.**, Tulchinsky Stern Marciano Cohen Levitski & Co., Law Offices	**Workshop B3 - Production Considerations During R&D** **Shlomi Rom**, Director, Business Development, Quasar **David Ben Shitrit**, Global NPD& Technologies Director, QIL

Day 2-Tuesday October 23rd, 2018

08:30-09:15 Registration & Reception

09:15-09:30 Welcome

09:30-10:00 **The Life-Cycle of an Invention: From an Academic Paper to a Product**
Prof. Zeev Zalevsky, Faculty of Engineering, Bar-Ilan, University; Entrepreneur and CTO of several startups

10:00-11:30 **Session D - Product Centered Development**
Session Moderator: **Eran Toledo**, CTO, Sanara Ventures

Product Development Considerations
Aimee Fisher, VP Business Development, Sanara Ventures

Product management from the corporate perspective
Noa Ben-Asher, Director of Product Management, Philips

Medical IOT Device Product Lifecycle - The Product Manager's Nightmare: Who is My Customer? What are My Requirements?
Zohar Horovitz-Limor, Director of Product, Nuvo-Group

Weighing Reimbursement in Product Development
Amir Inbar, CEO, Mediclever Reimbursement Consultants

How to Become/Maintain a Global R&D center-of-excellence in the Medical-Devices Arena? (Keys to success)
Amir Lichter, VP Technology & Ventures, Lumenis

Panel - Technology VS. Product - the Startup Dilemma
Eran Toledo, CTO, Sanara Ventures
Aimee Fisher, VP Business Development, Sanara Ventures
Noa Ben-Asher, Director of Product Management, Philips
Amir Inbar, CEO, Mediclever Reimbursement Consultants
Amir Lichter, VP Technology & Ventures, Lumenis
Zohar Horovitz-Limor, Director of Product, Nuvo-Group

11:30-12:00 Coffee Break

12:00-13:30 **Session E - Design Qualification V&V**
Session Moderator: **Gadi Ginot**, CEO, Physio-Logic

Design Qualification - Regulatory Considerations
Gadi Ginot, CEO, Physio-Logic

Animal Models - Is It the Animal's Fault?
Sigal Meilin, CSO, MD biosciences

AMAR Approval and Medical Device Quality
Nadav Sheffer, Head of Medical Device Department, Israeli MOH and Lecturer, Medical Engineering Department, AFEKA Academic College of Engineering

The Role of Usability Engineering in Design Qualification
Noa Ben-Dov, Accelerated Medical Device Approval & Certification Program Leader, Physio-Logic

Panel - Design Qualification - How Much is Enough
Ofer Doron, Director, Lahav Research Institute
Gadi Ginot, CEO, Physio-Logic
Nadav Sheffer, Head of Medical Device Division, Israeli MOH; and Lecturer, Medical Engineering Department, AFEKA Academic College of Engineering
Noa Ben-Dov, Accelerated Medical Device Approval & Certification Program Leader, Physio-Logic
Sigal Meilin, CSO, MD biosciences

13:30-14:30 Lunch Break

Day 2-Tuesday October 23rd, 2018

14:30-15:00 **AI Disruption in a Regulated Environment**
Eyal Gura, Co-Founder & CEO, Zebra

15:00-16:30 **Session F - Digital Health & Medical Software**

Session Moderator: **Moshe Klaiman**, CEO, Medix

The Landscape and Challenges of Digital Health and Medical Software Development
Moshe Klaiman, CEO, Medix

Your Security in the Eyes and Process of Your (US) Client (Kaiser Permanente)
Chen Heffer, Cytech

The Future of Healthcare is in the Cloud
Daniel Levit, Business Manager, Google Cloud

Convergent Design: Prototyping at the Intersection of Physical and Digital Experience
James Luther, Creative Director, Frog Design

Panel - R&D for Digital Health
Moshe Klaiman, CEO, Medix
Chen Heffer, Cytech
Daniel Levit, Business Manager, Google Cloud
James Luther, Creative Director, Frog Design

Workshops day 2

10:00-11:30

Workshop C1 - Digital Health - Software Architecture Challenges
An interactive touch-and-go architecture for your medical application for selected innovative companies

Moshe Klaiman, CEO, Medix
Oleg Gohman, Cloudzone by Matrix
Amit Einav, Google Cloud
Moshe Sambol, Google Cloud

Workshop D1 - Hit The Expert – Technical Panel
Technical problems solving

Barry Schnur, CEO, DSA

11:30-12:00 **Coffee Break**

12:00-13:30

Workshop C2 - Surprised by Intellectual Property
An Interactive Intellectual Property Protection Simulation

Maier Fenster, Head of Medical Devices Department, Ehrlich & Fenster, Ehrlich Group
Gil Perlberg, Perl IP Consulting

Workshop D2- Software Development Methodologies
Agile, Scrum and other modern software development methodologies - how to reconcile with FDA/CE

Keren Elghouzzi-Kazachinsky, Head of SW Q&R and Certification Project Manager, Physio-Logic

13:30-14:30 **Lunch Break**

14:30-16:00

Workshop C3 - Human Resources
How to attract, select and retain R&D talents in a competitive environment

Keren Razon, Talent Acquisition Leader, Philips Israel
Ira Iozsef, HR Manager, Healthcare Informatics, Philips Israel

Workshop D3 - Overview on ISO 14971: Risk Management for Medical Devices
ISO 14971 defines the international requirements of risk management systems for medical devices, defining best practices throughout the entire life cycle of a device

Paolo Valsecchi, Scheme Manager and Technical Expert Vascular Medical Devices, BSI

*The program is subject to changes. I **English is the official language of the conference**