IMD School
International Medical Device School

EUROPE 2021 AGENDA

28 - 29 September 2021 GMT+2 (CET)
Free (Pre-registration Required)
Online (Conducted via Zoom)

Easy Medical Device

ARPA
Asia Regulatory Professionals Association

ARQon Asia Regulatory & Quality Consultancy Medical Device & Drug

MediHeroes
B2B Medical Platform

Day 1: 28 September 2021

09:00 – 09:15 AM
Introduction Day 1 & IMDS Overview
Monir El Azzouzi
Founder of Easy Medical Device & Partner of IMDS Europe

Jack Wong
Founder of ARPA & IMDS

May Ng
Founder of ARQon & IMDS
Global Regulatory Consultant

09:15 – 09:45 AM
European Medical Device Regulations (MDR): Immediate impact on Medtech companies
TBC

09:45 – 10:15 AM
MDR: Legal ramifications
Erik Vollebregt
Lawyer, Axon Lawyers

10:15 – 10:45 AM
MDR: Perspectives and way forward from Notified Body
Martin Witte
Auditor, TUV SUD

10:45 – 11:15 AM
MDR: Challenges in Clinical Evaluations
Helene Quie
Consultant, Qmed Consulting

11:15 – 12:15 AM
IMDS Networking (Panel Discussion): Commercialization - Bio Clusters in Europe/Asia
Moderator: **Joanne Lee**
Founder of Mediheroes & IMDS

12:15 – 12:30 PM
Closing
Jack Wong
Founder of ARPA & IMDS

Day 2: 29 September 2021

09:00 – 09:15 AM
Introduction Day 2 & EU Person Responsible for Regulatory Compliance (PRRC) and Swiss Representative Requirements
Daniel Shoukier
ARQon Europe

09:15 – 09:45 AM
In Vitro Diagnostic Medical Device Regulations (IVDR): Performance Evaluation
Hakan Inan
Founder of Requalite GmbH

09:45 – 10:15 AM
Brexit and Swixit: Updates and impacts
Monir El Azzouzi
Founder of Easy Medical Device
Partner of IMDS Europe

10:15 – 10:45 AM
EU MDR & IVDR: Importance of independent importer
Edgar Kasteel
Founder of Medenvoy

10:45 – 11:15 AM
Interpretation of significant change during the grace period for manufacturers
Bassil Akra
AKRA TEAM GmbH (Ex TÜV SÜD)

11:15 – 11:30 AM
Closing
Monir El Azzouzi
Founder of Easy Medical Device
Partner of IMDS Europe