BIO PRO
Baden-Württemberg GmbH

Website address:
https://www.bio-pro.de/en/events/past-events/ivdd-ivdr-smart-transition-im-possible-classification-clinical-evidence-evaluation

Classification - Clinical Evidence - Evaluation

From IVDD to IVDR – smart transition (im-)possible?

On 25 May 2017, the new EU regulation on in vitro diagnostics (IVDR) came into force with a transitional period of 5 years and will be fully applicable from 26 May 2022. Take the chance and inform yourself free of charge and clarify your questions with experts!

Date:
08-Jul-2020
09.00 am - 03.00 pm

Venue:
Online

Registration deadline:
30-Jun-2020

Costs:
free

Type:
Information seminar

Target group:
Manufacturer of In-vitro Diagnostics, employees quality management, R&D as well as Regulatory Affairs Manager, Qualified Persons and management

Organiser:
BIOPRO Baden-Württemberg GmbH
Alexanderstr. 5
70184 Stuttgart

Contact:
Dr. Sandra Sapich
E-mail: sapich(at)bio-pro.de
Phone: +49 (0)711 218185-43

Dr. Claudia Luther
E-mail: luther(at)bio-pro.de
Phone: +49 (0)711 218185-05

The IVDR poses great challenges for manufacturers of in vitro diagnostics. It is strongly recommended that companies deal with the changes and implement the new requirements at an early stage. Both new and existing products on the market must be re-certified according to the IVDR. The implementation of the new regulation is time consuming and associated with and high costs. Important changes include the risk classification of products, stricter requirements for clinical evaluation and for post-market surveillance of *in vitro* diagnostics. The IVDR will also affect the cooperation between Original Equipment Manufacturer (OEM) and Private Label Manufacturer (PLM).

Event Agenda

08:50 **Login & Digital Networking**

09:20 **Welcome Words BIOPRO Baden-Württemberg GmbH**

09:30 **Michael Maier, Medidee Services AG**
"IVDR classification & lessons learned from the MDR transition"

10:00 **Robyn Meurant, NSF Health Sciences Limited**
"The extent of clinical evidence required for conformity assessment"

10:30 **Dr. Sebastian Grömminger, Johner Institut GmbH**
"Qualification and Classification of IVD-Software under IVDR"

11:00 **Q&A Expert Session with Medidee Services AG, Johner Institut GmbH & NSF International**

12:15 **Lunch Break**

13:00 **PD Dr. Micha Nuebling, Paul-Ehrlich-Institut**
"Expectations from the Paul-Ehrlich-Institut, vision on evaluation of class D IVD"

13:40 **Dr. Silvia Anghel, Medidee Services AG**
"Transition to IVDR: compliance, tactics and business cases"

14:10 **Sabine Ohse, mdc medical device certification GmbH**
"The View of a Notified Body: Maintenance of IVDD Certificates during the Transition Period"

14:50 **Get together & Questions**

How to participate

Registration is closed.

Organiser

BIO PRO Baden-Württemberg GmbH

Event partners

medídee®

Johner Institut

NSF®