Announcement of a workshop

Development and Regulation of in-house IVDs

The DZIF Product Development Unit (PDU) would like to invite you to the workshop **"Development and Regulation of in-house IVDs"** on the **7th of November 2024**.

Content of the workshop
In vitro diagnostics (IVDs) are tests used for detection, monitoring, prediction or prognosis of diseases and are essential in clinical practice as well as clinical studies. Based on biological samples (e.g., blood, urine, tissues), the status of a person's health is assessed. Whether it's an infectious disease or another serious health threat, IVDs can be used to identify or monitor diseases, help in treatment decision or prevent disease spreading. This underlines their important role within the health care system. In the European Union, IVDs fall under the scope of Regulation (EU) 2017/746 (in vitro diagnostic medical devices regulation, IVDR). In-house IVDs are exempted from most of the provisions of Regulation (EU) 2017/746, provided the health institution adheres to the conditions laid out in Article 5(5) of the relevant Regulation.

To gain more insight in the definition and regulation of in-house IVDs, this webinar focuses on:

- Definition of in-house IVDs and differentiation from other devices
- Regulatory framework and responsibilities in Germany
- Case study from academia

Schedule
The webinar will be held on Thursday, 07.11.2024 starting at 3:00 pm CET.

Registration
Participation **only** for members of the DZG and CARB-X network.
For **registration**, please send an e-mail to **OSRA@pei.de** including your **DZG or CARB-X affiliation** and, if applicable, your **DZIF or CARB-X project number**.
Knowledge of the previous workshops is *not* required.
Participation is **free** of charge.

We are looking forward to welcome you in our Workshop!

Best regards,
DZIF-PDU

(Subject to change without notice.)

Agenda

Development and Regulation of in-house IVDs

Time	Topic	Speaker
3:00 pm – 3:05 pm	Welcome & introduction	**DZIF-PDU**
3:05 pm – 3:55 pm	Definition of in-house IVDs and differentiation from other medical devices	**Dr. Sophie Bartsch** Consultant for IVD Medical Devices (Johner Institut)
3:55 pm – 4:45 pm	Regulatory requirements for in-house IVDs development	**Dr. Heinrich Scheiblauer** Head of test laboratory for IVD (Paul-Ehrlich-Institut)
4:45 pm – 5:35 pm	Case study from academia	**Prof. Dr. Christian Drosten** Director – Institute of Virology (Charité – Universitätsmedizin Berlin)
5:35 pm – 5:45 pm	Closing remarks	

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