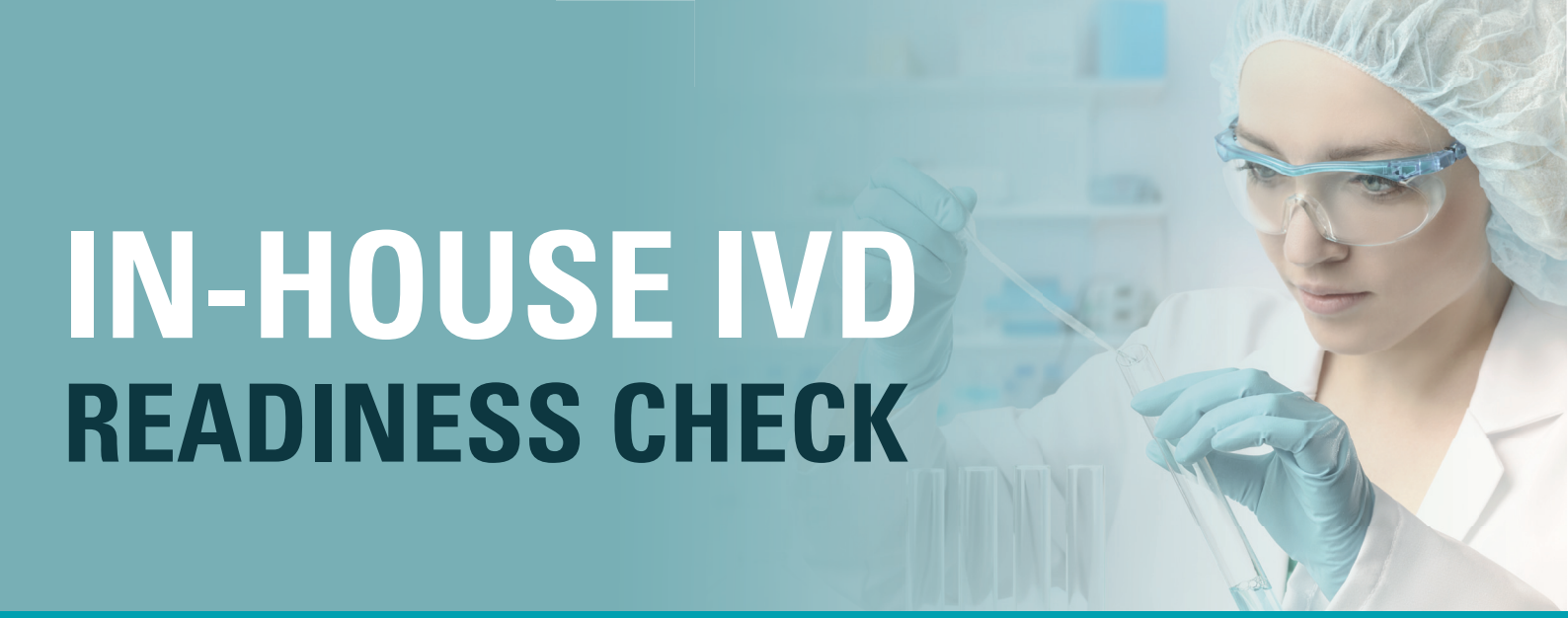

IN-HOUSE IVD READINESS CHECK

Expert strategies for ensuring compliance and continuity of in-house IVDs in routine practice.

Valentin Chapuis
Senior Expert
Quality Engineer

Alicja Ritz, PhD
Senior Expert IVD

The IVDR has introduced consistent and harmonized regulation on in-house IVDs (aka LDTs, Laboratory Developed Tests) on a European level. Consequently, in-house IVD manufacturers shall demonstrate compliance with additional requirements regarding their quality management system and technical documentation.

Our IVD experts offer practical solutions to help you translate the new IVDR requirements into compliant documentation, ensuring acceptance by the authorities and enabling the continued use of your in-house IVDs in clinical practice.

Introduction Videos

You will gain access to three videos (approx. 25 min. each) before consulting with our experts. The videos cover the following topics:
– In-house IVDs key concepts and regulation
– Introduction to QMS and risk management requirements
– Outline of technical documentation requirements and structure

Individual Consultation

Our IVD experts will address your concerns and help you develop practical solutions to meet regulatory requirements.

Checklist

Our checklist aims to allow the laboratory to self-assess its readiness for meeting the requirements of Article 5(5) of Regulation (EU) 2017 / 746 (IVDR) and specific requirements that apply in Switzerland or may apply in the relevant EU Member State.

Readiness Check Includes:

3 Introduction Videos
2 Hours of Consultation
1 Checklist
1 Certificate of Attendance

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