IVDReady timeline

PLATOMICS

Program Announcement
May 26, 2023

Kick-off
Jun 20, 2023

OPEN THE GATES
Sep 30, 2023

IVDR compliance achieved
May 26, 2024

JUN 20, 2023 – 14:00 CEST

IVDReady by May 2024 with Platomics

Our kick-off webinar will introduce you to Platomics, our IVDReady Program, our partners, and IVD Assistant, our platform for compliance.

JUL 25, 2023 – 14:00 CEST

2. Give it a purpose

The next step is formulating the intended purpose for your in-house tests. From here this webinar will also cover documenting qualification as a medical device and risk classification under IVDR.

SEP 2023

4. Workflow by design

Perhaps the most daunting aspect of the IVDR for labs are the new requirements for clinical use surveillance. We'll explain what active vigilance throughout the life cycle of your in-house tests means for your lab.

NOV 2023

6. Standards are beautiful

GSPRs are challenging, and therein lies the beauty of established standards: they are state-of-the-art and as such can reliably fulfill the GSPRs. Find out what your lab needs to do and how best to get it done.

FEB 2024

8. An ounce of validation

We'll explain how to fulfill both IVDR and ISO 15189 requirements regarding verification and validation, and how there is no "one size fits all" on this issue.

APR 2024

10. Vigilance: The shield, sword and light

Perhaps the most daunting aspect of the IVDR for labs are the new requirements for clinical use surveillance. We'll explain what active vigilance throughout the life cycle of your in-house tests means for your lab.

JUL 6, 2023 – 14:00 CEST

1. Let's talk strategy

The first thing your lab needs is a strategy for documenting workflows, whether you've got 50 or 250 in-house tests. This webinar will outline several possible approaches.

AUG 29, 2023 – 14:00 CEST

3. Perplexity is the beginning of knowledge

This webinar will outline Platomics' regulatory knowledge base that supports labs in understanding what exactly the IVDR requires of them.

OCT 2023

5. Meet the manufacturers

Here we would like to open the gates and connect you with our manufacturer partners. Meet them and learn about the best practice workflows we are developing with them on our platform.

JAN 2024

7. The real risk is not managing risk

Labs will need to have a robust risk management process in place to meet the requirements and ensure safety and reliability for patients. This webinar will provide orientation.

MAR 2024

9. Product excellence: Everything, everywhere, all at once

We'll take you through various aspects of product excellence required by IVDR, from instructions for use to labeling, SOPs and documenting the design and manufacturing of your in-house tests and components.

MAY 2024

IVDReady to go

Our final webinar will offer an outlook on important aspects for remaining IVDR compliant, including what is coming in the final phase of implementation in 2028.