INTERNATIONAL

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MASTERCLASS

COMPANION DIAGNOSTICS (CDx) - NAVIGATING THE REGULATORY CHALLENGES

3 & 4 DECEMBER 2025 | VIENNA, AUSTRIA

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COURSE **OVERVIEW:**

The implementation of the EU In Vitro Diagnostic Device Regulation 2017/746 (IVDR) has introduced new processes for the authorization of performance studies and conformity assessment of companion diagnostic devices (CDx) in Europe. These processes are proving challenging and, in the absence of detailed guidance, often result in roadblocks and delays to development of CDx. EU Competent Authority, Notified Body and Regulatory Consultant CDx experts will share their experience at this seminar, to demystify the EU regulation of CDx and how it differs from US legislation. They will provide guidance on the alignment of medicinal product and CDx development, applicability of the IVDR and how to ensure smooth performance study and conformity assessment applications. There will be opportunities to discuss and learn from real examples at interactive workshops, as well as to hear inside knowledge on activities ongoing within the European Union to streamline these processes. The output from the workshop will be invaluable to ensure the success of your predictive biomarker-guided medicinal product development.

KEY **TOPICS:**

- Predictive biomarker-restricted medicines
- Regulation of companion diagnostic devices (CDx) in the US and EU
- Alignment of medicinal product and CDx development
- EU authorisation processes for CDx performance studies and CE marking
- Interactive workshops with opportunity to submit examples and questions to a competent authority, notified body and regulatory consultant experts

KEY **TAKEAWAYS:**

UNDERSTAND
regulatory frameworks for CDx in EU and the US

DEEP DIVE
into CDx analytical performance considerations

GET TIPS
to meet the EU CDx authorization requirements

DISCUSS
your examples on performance studies and conformity assessment

LEARN
more about CE marking of CDx

GAIN
first-hand experience from a Notified Body, Competent Authority & Regulatory Experts

BE PREPARED
for the future changes in CDx requirements

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SPECIAL **FEATURES:**

- Experts from a Notified Body, Competent Authority and Regulatory Consultants
- Case studies and practical examples
- Discussions
- Comprehensive course documentation
- Certificate of completion issued by the trainers

TRAINING **AUDIENCE:**

Pharmaceutical, Biotech, Medical Devices and Life Sciences companies:

- Precision Medicine
- Regulatory Affairs
- CDx Project Leaders
- Medicinal Product Development
- Biomarker Development
- IVD Product Development
- Clinical Affairs
- R&D Scientists

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MEET THE **TRAINING LEADERS:**

JÖRG ENGELBERGS

Paul Ehrlich Institute (PEI), Germany

Jörg Engelbergs is working for the Paul-Ehrlich-Institut (PEI, German National Competent Agency for Medicines & CDx) as a regulatory-scientific assessor for biopharmaceuticals with focus on targeted & predictive biomarker restricted personalized biomedicines (Quality/ Analytics, Non-Clinic, Biomarkers, CDx). He is involved in the European process of marketing authorization and medicine's life cycle comprising scientific assessments and advices. Further tasks encompass scientific advices and assessments for European CDx consultation procedures, and national clinical trial and correlated CDx performance study applications. He is member of several CDx related European working groups, e.g. EMA Methodology Working Party (MWP), EMA SIA PGx, EMA ESEC Oncology, EMA CHMP/CAT CDx Expert Group (co-chair), EU Combine Project, EMA MWP drafting group for a new guideline on predictive biomarker-assay development. Further he is responsible for the national implementation of the new regulatory processes for CDx performance studies at PEI. Jörg holds a Diploma in biology and a PhD in cell biology and biotechnology. Before joining the PEI, he has gained large experience as project leader in experimental cancer and neuropharmacology research with focus on R&D of diagnostic and predictive biomarkers and correlated assays (Omics).

HILKE ZANDER

Paul-Ehrlich Institute (PEI), Germany

Hilke Zander (Ph.D., MDRA) is clinical assessor at the Paul-Ehrlich Institute (PEI) in the section of monoclonal and polyclonal antibodies. After receiving her Ph.D. in antibody engineering from the TUMunich, she worked several years in cancer research at the University Clinic Hamburg-Eppendorf. Since 2013 she has been working on oncological antibody therapies at the PEI and in particular on the marketing authorisation of checkpoint-inhibitors. With her involvement in the evaluation of targeted therapies, her focus has shifted to the co-development of companion diagnostics and medicinal products and the implementation of the In Vitro Diagnostic Regulation 746/2017. In addition to the implementation of a new official task, the evaluation of IVD performance studies, at the PEI, she is member in various European committees e.g. EMA SIA PGx, EMA ESEC Oncology, EMA CHMP/CAT CDx Expert Group, EU Combine Project, EMA MWP drafting group for a new guideline on predictive biomarker-assay development and the scientific advice working party (SAWP) of the EMA

HEATHER JOHNSON

Granzer Regulatory Consulting & Services, Germany
Senior Consultant Device

Heather Johnson (PhD, RAC) is a senior consultant with over 20 years' regulatory expertise in drug-device combinations, borderline products and companion diagnostic devices. With a PhD in chemistry, her initial regulatory experience was with oral pharmaceutical products, followed by over 10 years leading global submissions for implantable, resorbable and drug-eluting orthopaedic devices with DePuy Synthes companies of Johnson & Johnson. Her career continued developing strategies for implementation of the EU Medical Devices Regulation across Johnson & Johnson devices companies. She then contracted for QIAGEN GmbH, to support clinical performance studies and marketing submissions for oncology companion diagnostic devices in US, EU, China and Japan. Heather now supports clients with US and EU regulatory strategies and submissions for drug-device combination products, novel devices, companion diagnostics and combined device and medicinal product clinical trials.

ROLF THERMANN

TÜV, Germany
Section Manager IVD and Companion Diagnostics Lead

Dr. Rolf Thermann is a Lead Auditor, IVD Product Expert and TÜVs leading Expert for Companion Diagnostics (CDx). Prior to joining TUV Rheinland, Dr. Thermann spent over 10 years in the Pharmaceutical and IVD industries in various leading roles on product development, including CDx products.

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DAY 1

3 December 2025

8:45 REGISTRATION & MORNING COFFEE

9:00 WELCOME AND OPENING REMARKS

9:05 **Participant introductions and networking**

- Participants share their roles, experience and key challenges they aim to address during the training.

9:15 **Introduction to Precision Medicine**

- Precision medicines and interface with IVDs
- Companion diagnostic device (CDx) current and future developments
  - Oncology and other areas
  - Software and potential future use of AI

Jörg Engelbergs
Hilke Zander
Heather Johnson

10:00 **US FDA pathway for CDx (and complementary diagnostics)**

- Drug and IVD co-development and FDA interactions
- Investigational device exemptions (IDE)
- Premarket authorization (PMA)
- Coming changes: regulation of lab-developed tests (LDT) and CDx down-classification

Heather Johnson

11:00 BREAK

11:20 **Overview of EU regulatory framework for CDx**

- Comparison of EU versus US regulatory framework
- Introduction to biomarker requirements in medicinal product Marketing Authorization Applications (MAA)
- Phases of development of a CDx and co-development with a medicinal product
- Determination as a CDx and health institution exemptions
- Timing of performance study authorisations
- Overview of CE marking and conformity assessment of CDx
- CDx consultation procedures

Jörg Engelbergs
Rolf Thermann

12:50 LUNCHEON

13:50 **Companion diagnostic device performance**

- Analytical performance considerations
  - Developer perspective
  - Clinical trial (predictive) biomarker assays
  - For CE marking of the CDx
- Scientific validity of biomarker
- Clinical performance
  - For CE marking and medicinal product MAAs

Jörg Engelbergs
Rolf Thermann
Hilke Zander
Heather Johnson

15:20 BREAK

15:40 **EU Authorisation Requirements**

- Applicability of EU In Vitro Diagnostic Regulation (IVDR) to clinical trial biomarker assays and CDx studies
- CDx Performance study authorization submissions
  - National requirements, case study Germany
  - European multinational challenges

Hilke Zander
Heather Johnson

16:50 CLOSE

- Summary of day 1
- Plan for Day 2: opportunity to submit examples and questions on performance studies and conformity assessment for review during workshops

Jörg Engelbergs

17:00 END OF DAY 1

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DAY 2

4 December 2025

8:45 REGISTRATION & MORNING COFFEE

9:00 **Recap of Day 1**
- EU regulatory framework, CDx performance and authorisation requirements

Heather Johnson

9:15 **INTERACTIVE WORKSHOP: Clinical performance study authorisation**
- Case studies
- Participant examples and questions

Jörg Engelbergs
Hilke Zander

10:45 BREAK

11:10 **CE marking of companion diagnostic devices**
- Notified body conformity assessment
- Notified body / competent authority interactions and CDx consultation

Rolf Thermann
Hilke Zander

12:10 LUNCH

13:10 **INTERACTIVE WORKSHOP: Conformity assessment of companion diagnostic devices**
- Case studies
- Participant examples and questions

Jörg Engelbergs
Rolf Thermann

14:40 **Challenges and future changes in EU regulation of companion diagnostic devices**
- Observations from interactive workshops
- Ongoing initiatives and working groups
- Scientific advice

Jörg Engelbergs
Hilke Zander

15:10 BREAK

15:40 **PANEL DISCUSSION**
- Q & A

Jörg Engelbergs
Rolf Thermann
Hilke Zander
Heather Johnson

16:10 **Key takeaways**

Heather Johnson

16:20 END OF TRAINING

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COMPANION DIAGNOSTICS (CDx) - REGULATORY & QUALITY REQUIREMENTS

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DASA JANOSIKOVA
Production Manager - Life Sciences

MONICA JONES
Marketing manager

VIENNA

The iconic French croissant originates from Vienna. These buttery and soft delights are based on an Austrian pastry called Kipferl (meaning 'crescent' in German). They were made by Viennese bakers to commemorate the Austrian victory over the Ottoman Turks in 1683. The shape of the pastry was based on the crescents that adorned the uniforms of their enemy. When Marie Antoinette married King Louis XVI, she introduced her favorite pastry to France, few changes were made, and the croissant was introduced to the world.

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