QUICK REFERENCE GUIDE

PHARMALEX
CONFIDENCE BEYOND COMPLIANCE

IN VITRO DIAGNOSTICS REGULATION (IVDR)

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Tiina has worked in the highly regulated medical device and diagnostics industry in quality and regulatory affairs for over 10 years. She has extensive experience in conformity assessment as a lead auditor and technical/clinical assessor. Additionally, she has been working in the MDCG mirror working group as a Team-NB member. She has versatile scientific, conformity assessment and industry background and has in-depth knowledge of various medical technologies, state-of-art methods as well as EU MD/IVD regulatory requirements, and quality management systems covering the entire life cycle of a medical device or combination drug-device.

Tiina is a graduate of University of Jyväskylä, Finland where she completed her M.Sc. (Chemistry) studies. She also graduated from the University of Tampere, Finland with a PhD degree on medical technology.

The In-Vitro Diagnostic Regulation (IVDR - (EU) 2017/746) present a significant challenge for IVD manufacturers.

Our highly professional and experienced regulatory affairs and compliance teams are available to provide support as required. Our team members' experience includes Regulators, Notified Bodies and Industry covering a wide range of products.

How can PharmaLex help?

EUROPE

- (EU) 2017/746 In Vitro Diagnostics Regulation strategy development, planning and execution (including gap analysis for In Vitro Diagnostic Directive 98/79/EC)
- Device classifications review
- Labelling compliance including Instructions for Use
- QMS development for ISO13485 including SOPs, Quality Manual, implementation, and training support
- Audit support – mock audits and inspection support and training
- Regulatory Affairs strategy, development, and support
- Labeling and promotional regulatory requirements
- In house tests market and support
- Post Market Surveillance strategy and support including Adverse Event Reporting
- Interpretation and guidance on harmonized standards and product testing for Class A, B, C and D devices

USA

- QMS development for 21 CFR Part 820
- Regulatory Affairs strategy, development, and support
- Labeling and promotion regulatory requirements
- FDA mock inspections
- FDA recalls and product support
- Q-Submission support for FDA – to draft, support and liaise with client companies to assess and navigate the appropriate regulatory pathway for their products form early-stage design conception through to submission and market clearance and approvals
- Labeling and promotional regulatory requirements
- Lab Developed tests markets and support
- Advise and support FDA 483 observations
- Advise on and management of Warning letters
- MDSAP pre-certification assessments and Internal audits

REST OF WORLD

- QMS development for MDSAP
- Regulatory pathways and strategy for ISO 13485 and MDSAP
- Brexit navigation and support
- Regulatory intelligence for global markets support

OTHER / GENERAL

- Due diligence and acquisition activities support
- Design and development support strategy for New Product Development from design conception to market launch including analytical and clinical plans, reports and review
- Supplier evaluation and control processes including audits
- Software considerations for development and compliance for diagnostic products
- Support and partner SMEs in their development and growth through outsourcing and contract placements

IVDR Transition Timeline

2022 | 2023 | 2024 | 2025 | 2026 | 2027

All NEW Devices Placed on the Market Must be EU IVDR Compliant

MAY 26
Existing non-sterile **Class A** devices must be EU IVDR compliant.

MAY 26
Existing **Class D** devices must be EU IVDR compliant.

MAY 26
Existing **Class C** devices must be EU IVDR compliant.

MAY 26
Existing sterile Class A and **Class B** devices must be EU IVDR compliant.