

Your Partner for IVDR Compliance



Beaufort®

Accelerating Medical Innovation

IVDD to IVDR: The Clock is Ticking

May 5, 2017 - May 26, 2022



2017

Adoption of IVDR
(May 5, 2017)



2021

Deadline Approaching
(Today)



2022

Last Date of
Application
(May 26, 2022)

A recent poll of IVD manufacturers reported that **70% of participants have not started, or are just beginning**, the process of implementing the IVDR requirements into their Quality Management Systems (QMS).

With the May 2022 deadline looming,
where do you stand with your IVDR implementation?

Key IVDR Compliance Requirements



Beaufort Provides the Experience, Processes and Tools to Help Your Business Realize IVDR Implementation

Beaufort IVDR Services

QMS / Risk Management

- ✓ Strategy for Regulatory Compliance
- ✓ IVDR-Specific QMS Changes
- ✓ Classification & Conformity Assessment
- ✓ Other EU IVD Directives & Regulations
- ✓ Risk Management Evaluation Criteria / Benefit Risk Analysis
- ✓ IVDR Readiness Audits

Clinical Evidence

- ✓ Guidance on New Clinical Evidence Requirements
- ✓ Legacy Product Data Review
- ✓ Performance Evaluation Plan / Report (PEP/PER)
- ✓ Analytical Performance Report
- ✓ Clinical Performance Plan / Report
- ✓ Clinical Performance Study Plan (CPSP)
- ✓ Scientific Validity Report

Labelling & UDI

- ✓ Intended Purpose / Claim Review
- ✓ Labels & Instructions for Use Requirements
- ✓ Applicable Standards
- ✓ UDI Requirements & Symbols

Technical Documentation

- ✓ Technical Documentation Review & Preparation
- ✓ GSPR Gap Assessments & Traceability Matrices
- ✓ Test, Hardware, Software Requirements

Post-Market Surveillance / Vigilance

- ✓ Post-Market Surveillance Plan / Report
- ✓ Post-Market Follow-up (PMPF) Plan / Report
- ✓ Incident Reporting
- ✓ Periodic Safety Update Report (PSUR)

Economic Operators / EUDAMED

- ✓ Person Responsible for Regulatory Compliance (PRRC)
- ✓ Registration of EO's & Devices
- ✓ Control of Suppliers (Process/Method)

Our IVDR Specialists Support All Stages of the IVDR Certification Process

Put Beaufort's IVDR Team to Work for You



Contact Us Today For More Information

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