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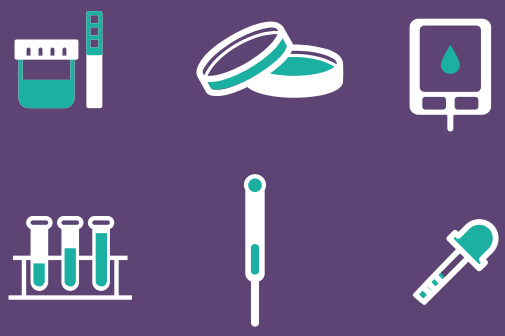

Implementation Model for In-Vitro Diagnostic Medical Devices Regulation

Step by Step Guide

MEDICAL DEVICES CHANGE OF LEGISLATION

What you need to know!

STEP	INTENTION / ACTION
1 **Pre-assessment**	Brief management to ensure a clear understanding of the importance and business implications of the IVDR
	Consider organisational challenges: management awareness, staffing capability and availability, budget implications
2 **GAP analysis and actions resulting from this**	Assess impact on products, internal resources, organisation and budget
	Check new classification rules (IVDR Classes A–D) and confirm conformity assessment routes for existing and future products. Check the requirement for involving the Notified Bodies
	Review the changes needed to existing technical documentation (Technical Files)
	Review and upgrade quality management system (QMS) (point 3 below)
	Check the adequacy of available clinical evidence and risk management and identify any gaps (Article 56)
	Review product labelling (Annex I Chapter III)
	Ensure post-market surveillance (PMS) arrangements are adequate (Chapter VII Section 1)
	Prepare a post-market performance follow-up plan (PMPF, Annex XIII Part B)
	Get ready for the new vigilance requirements (Chapter VII Section 2)
	Ensure the respect of traceability obligations (Chapter III)
3 **Quality Management System (QMS)**	Review adequacy of QMS to meet standards and processes for IVDs under the new Regulation
	Build new regulatory requirements into the QMS
	Identify/hire the person responsible for regulatory compliance within your organisation (Article 15) and be sure it is adequately qualified and trained

Internal market, Industry, Entrepreneurship and SMEs

4 Legal entities	Clarify how the company is affected: legal entities, obligation of economic operators, organisational structures and resources
	Consider organisational challenges: management awareness, staffing capability and availability, budget implications
	Ensure product liability insurance is adequate
5 Portfolio	Do a cost/benefit analysis for your product portfolio; bear in mind costs related to the new risk classification system and the need of involving a Notified Body and costs for post-market surveillance and gaps in the technical documentation, and plan your transition to the IVDR accordingly
	Review supply chain provisions, and clarify roles and responsibilities of business partners (authorised representatives, importers, distributors)
6 Master implementation plan	Build a roadmap for implementation, including definition of sub-projects, resource requirements and a steering group, and ensure overall responsibility for IVDR implementation has been established
	Give special consideration to certificate expiry dates, bearing in mind the transitional period, transitional provisions and availability of your Notified Bodies
7 Notified Bodies	Contact the selected Notified Bodies and determine their capacity and availability to service the implementation plan
8 Regulatory training	Empower and train staff through IVDR implementation and transition workshops
9 Execute master implementation plan	Implement the various sub-projects (performance evaluation, technical documentation, relations with other economic operators, Unique Device Identification, labelling, post-market surveillance, vigilance, and reporting IT systems)
	Ensure a cross-functional project management team is in place to cover all aspects of implementation
	Ensure overall and individual responsibilities for IVDR implementation have been established
10 Review efficiency and effectiveness	Implement regular meetings on project status and progress, discrepancy and gap analyses, risks, next steps and requirements
	Hold regular progress reviews against the IVDR implementation plan and include these in the management review process
11 Notified Body submission	Discuss submission dates to avoid delays in the approval process
12 Ongoing monitoring	Actively monitor the still-developing European regulatory environment and guidelines expected in the coming months (check DG GROW web pages on medical devices and subscribe to the newsletter)
	Establish a procedure for dealing with unannounced inspections from Notified Bodies
	Regularly review the IVDR implementation plan, identifying and addressing key areas of risk

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