EU Medical Device Regulations

Are you prepared for the IMPACT?

www.nsf.org
ATTENTION CEOs, CFOs and CTOs…

If your company currently or in future intends to place medical devices and in-vitro diagnostic products in Europe then your business is going to encounter changes that go beyond simply understanding the new regulatory requirements. These changes will affect many assumptions made within your business planning activities.

At NSF, we understand the medical device business especially the strategic planning processes employed to achieve both regulatory compliance and shareholder value. NSF understands that if you underestimate the impact of these new regulations then your company’s business results will be at risk.

To aid you, NSF experts have prepared a simple 5 step process to understand the business impact to both products already on the market and new product introductions in Europe. These steps form part of the NSF EU Medical Device PORTFOLIO assessment consulting service.
What should you do?

1. **RIGHT NOW**
   **Understand** the background to the changes and the product safety and regulatory influences that are shaping the whole structure of medical device regulation in Europe. Remember it is not just the regulation that is changing; it is the whole European Regulatory Framework consisting of healthcare providers, scientific committees, competent authorities, notified bodies, economic operators and the supply chain.

   **Prepare** ➔ A plan identifying your product groups likely to face the most significant impact and establish a team capable to undertake a business impact analysis (Financial, Legal, Commercial, Technical and regulatory).

2. **YOUR CURRENT PRODUCT PORTFOLIO WILL BE AFFECTED**
   **Understand** how this will affect your current product portfolio by assessing how the changes may impact notified body involvement, post-market reporting or the suitability of technical documentation to demonstrate product safety and performance.

   **Prepare** ➔ A plan identifying the products most affected by the change and identify the necessary additional quality, regulatory, technical and legal actions and costs to address these impacts.
YOUR PRODUCT PIPELINE WILL BE AFFECTED

**Understand** your planned new product introductions / product to market and commercialisation portfolio to determine if the changes may impact immediately, short term and long term your net present value and return on investment calculations based upon a tougher regulatory system, the potential of enhanced regulatory scrutiny and clinical data expectations.

**Prepare ➔** A plan for your commercialisation portfolio should challenge the product to market assumptions and organise your product to market projects by risk impact identifying the most vulnerable projects that may require revision of their commercialisation and ROI assumptions. This should include the regulatory, quality, technical and legal actions as well as costs.

YOU MAY NEED TO CHANGE THE STRUCTURE OF YOUR COMPANY

**Understand** your current organisational structure including your internal resource, supply chain, distributor networks and authorised representatives to determine if they have the necessary legal coverage (product liability), people (person responsible for regulatory compliance) and processes necessary to work within the boundaries of the new regulations.

**Prepare ➔** A plan detailing your internal and external commercial entities prioritised by risk and an operational plan of action outlining actions, timing, responsibilities and outcomes. Internally a resource plan needs to be identified to determine adequate regulatory, quality, technical and legal capability and capacity is in place to address actions.
YOU HAVE TO INCORPORATE THESE CHANGES INTO YOUR STRATEGIC, FINANCIAL AND BUSINESS MANAGEMENT CYCLES

Consolidate these plans and risks with a robust impact analysis and action plan, appropriately timed to manage immediate, short-term and long-term regulatory compliance in order to effectively manage your strategic, financial and operational goals and objectives. Essentially, you should understand the real BUSINESS IMPACT of the changes to the regulation and the regulatory framework.

Prepare ➔ A business impact assessment and action plan covering your whole business clearly consolidating the overall resource impact of the changes to current and future product portfolios and prepare the necessary business cases for short, medium and long-term investments in appropriate resource.

Act now and be ahead of the rest

By involving NSF as early as possible it helps you to shape your business and financial priorities to avoid any nasty surprises. DO NOT assume your notified body or your existing regulatory experts will update you on the changes as the regulatory requirements are a small part of the BIGGER PICTURE that requires business impact analysis.

Invest in one of NSF’s specific medical device services and enjoy peace of mind.
For more information please contact us:

Europe
James Pink, VP NSF Health Sciences,
call +44 1142 541 270 or email jamespink@nsf.org

USA
Kimberly Trautman, Executive Vice President,
call +1 202 822 1852 or email ktrautman@NSF.org

Or visit our website
www.nsf.org/info/md-training
EDUCATION

Training courses

> Planning for EU regulatory changes course – dates and venues are available on NSF’s website please click here.

Learning outcomes enable you to prepare for EU Regulatory changes and strategically evaluate the changes and prepare impact analysis and action plans against your company current and future product portfolio.

> Person Responsible for Regulatory Compliance.

Unique to NSF is the MSc post-graduate qualification aimed towards addressing the requirement for a person responsible for regulatory compliance (A requirement in the new regulation).

Dates and venues are available on NSF’s website, visit www.nsf.org/info/md-training or scan the QR code alongside.
CONSULTING

EU Medical Device Regulatory impact analysis

> CONFIDENTIAL face to face or remote consultations with our experts assessing your current and/future product portfolio to help determine the potential impact and provide pragmatic, value driven advice to overcome any particular impacts you may face.

This is consolidated into a professional report outlining the most appropriate actions to be taken now, short-term and long-term and the necessary resources required to address vulnerabilities.

Product specific portfolio assessment

> You may need to understand whether your product group is the most susceptible to impact including products intended to be ingested, inhaled or are administered vaginally or rectally. Similarly you may have products in your IVD portfolio that are likely to be reclassified into higher risk or you may be developing technologies that the European Commission deem likely to need enhanced regulatory scrutiny.

NSF has a range of product experts from dietary supplements, medical devices, in-vitro diagnostic devices and pharma biotech on-hand to be involved in the assessment of your product portfolio against the EU regulatory framework changes and able to consult on a range of technical, regulatory, quality, legal and business issues associated to your portfolio.

For more information please contact us:

Europe: James Pink, VP NSF Health Sciences, call +44 1142 541 270 or email jamespink@nsf.org

USA: Kimberly Trautman, Executive Vice President, call +1 202 822 1852 or email ktrautman@nsf.org

Or visit www.nsf.org/info/md-training