Regulatory and Quality Compliance Requirements to Access the EU Diagnostics Market

Greer Deal

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Interreg North-West Europe Codex4SMEs

European Regional Development Fund

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What am I going to talk about today?

Regulatory & Quality Compliance Strategy

The impact of changing regulatory requirements for IVD companies

The importance of your Quality Management System (QMS)

But first ……

Brief introduction to Med-Di-Dia

- Consultancy dedicated to regulatory and quality compliance in MedTech Sector
- Based in Galway, Ireland – ‘hotbed’ for innovation
- ‘Powered’ by Global Regulatory Services (GRS)
- Love Regulatory Strategy
- Dream about Quality Management Systems (QMS)
- Good natured ‘banter’ with regulatory authorities
- Get a ‘buzz’ from helping companies navigate the maze of regulations through to the market

www.med-di-dia.com

‘above & beyond’ services

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Europe (Med-Di-Dia)

- Authorised Representative for Medical Devices/IVDs
- Person Responsible for Regulatory Compliance (PRRC)
- Responsible Person for Cosmetics
- Clinical Trial Legal Representative

USA (Med-Di-Dia/GRS)

- US agents to liaise with the FDA on behalf of MDD/GRS clients

United Kingdom (GRS)

- Responsible Person for Cosmetics
- Responsible Person for Medical Devices/IVDs

GRS
global regulatory services

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Regulatory & Quality Compliance Strategy

What is it?

- Defines a regulatory pathway for successful commercialisation of your product to your target market
- Encompasses key milestones and decision points
- Considers regulatory objectives, landscape, and characterises risk
- Acts as a roadmap to Innovators to market their product in other target regions
- Ultimate goal is to enable patient access

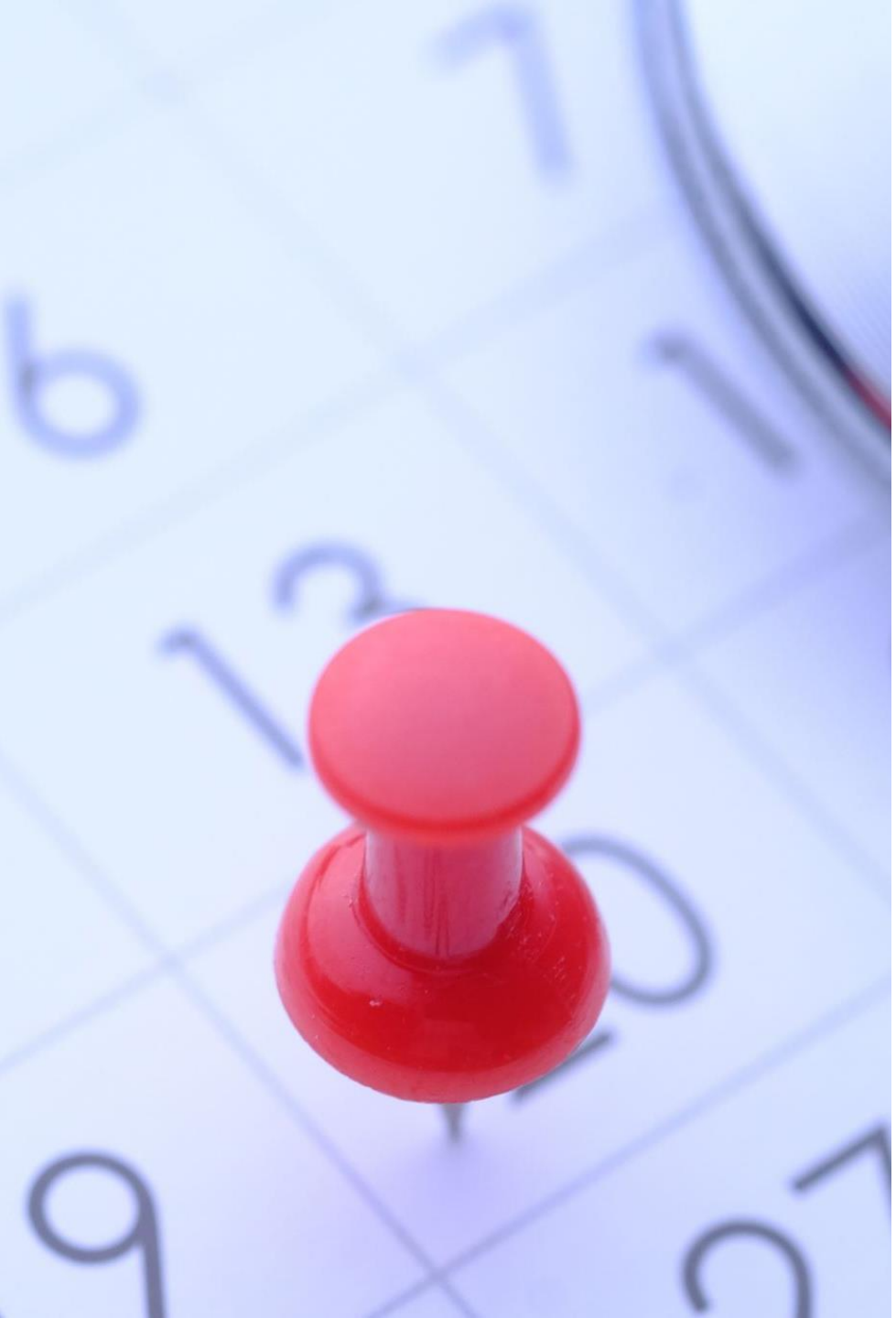
Aspects of a Regulatory Strategy

Comprises 3 essential elements:

1. **Device definition & classification**
2. Compliance requirements
3. Compliance ownership

Estimation of cost, timeline and complexities of approval activities are dependent on regulatory requirements

Considerations and requirements differ depending on target market



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Why is a regulatory strategy important?

MDR (2017/745) and IVDR (2017/746) - stricter requirements, broader scope and increased responsibilities

Access to regional markets is always preceded by regulatory approvals

Avoids regulatory mishaps, potential business risk and delays to innovation

Highlights the work that is required – what/where/when/why/who?

Competitive advantage

Impressive to potential Investors

- Risk mitigation
- Confidence

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Ring in the Changes!

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The impact of changing regulatory requirements for IVD companies

In-Vitro Diagnostic Regulations (EU/UK)

Regulatory Affairs – why bother?

Developed from the desire of governments to protect public health by controlling the **quality, safety and efficacy** of products via an increase in regulations and guidance documents

Europe:

26 May 2021: Medical Device Regulation (2017/745)

26 May 2022: In-vitro Diagnostic Regulation (2017/746)

Great Britain:

UK Medical Device Regulations 2002

Classification – 'old' Directive

Based on a ***list-based approach*** consisting of Four Classes:

1. General – low risk: Annex III excluding section 6 (self-certification)
2. List B – Significant risk: Annex II
3. List A – Highest risk: Annex II
4. Devices for self-testing not listed in Annex II – Significant risk: Annex III, including Section 6

Classification – ‘new’ Regulation

In-Vitro Diagnostic Medical Devices Regulation
(EU) 2017/746 (IVDR)

Based on a ***rule-based approach*** *(10 implementing rules and 7 classification rules, Annex VIII)* consisting of Four Classes:

A: low individual risk and low public health risk (self-certification)
B: moderate individual risk and/or low public health risk
C: high individual risk and/or moderate public health risk
D: high individual risk and high public health risk

IVDR – Is Date of Application Postponed?

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No!

Longer transition period has been agreed due to:

- COVID-19
- Very few EU Notified Bodies have been designated
  - 6 vs 3 UK Approved Bodies
  - NANDO
  - Needed to conduct conformity assessments as per EU Directives and Regulations
- Substantial changes for industry to cope with
  - 15-20% vs at least 85% now need to engage an NB

Class A and new products must be fully compliant as from 26 May 2022

IVDR Transition – key dates for compliance

26 May 2022

- Vigilance and PMS requirements apply to all IVDs
- all new IVDs and Class A (non-sterile, self-declared e.g. sample containers)

If self-declaration prior to 26 May 2022 under IVDD (need NB under IVDR) can continue to place IVDs on the market up until:

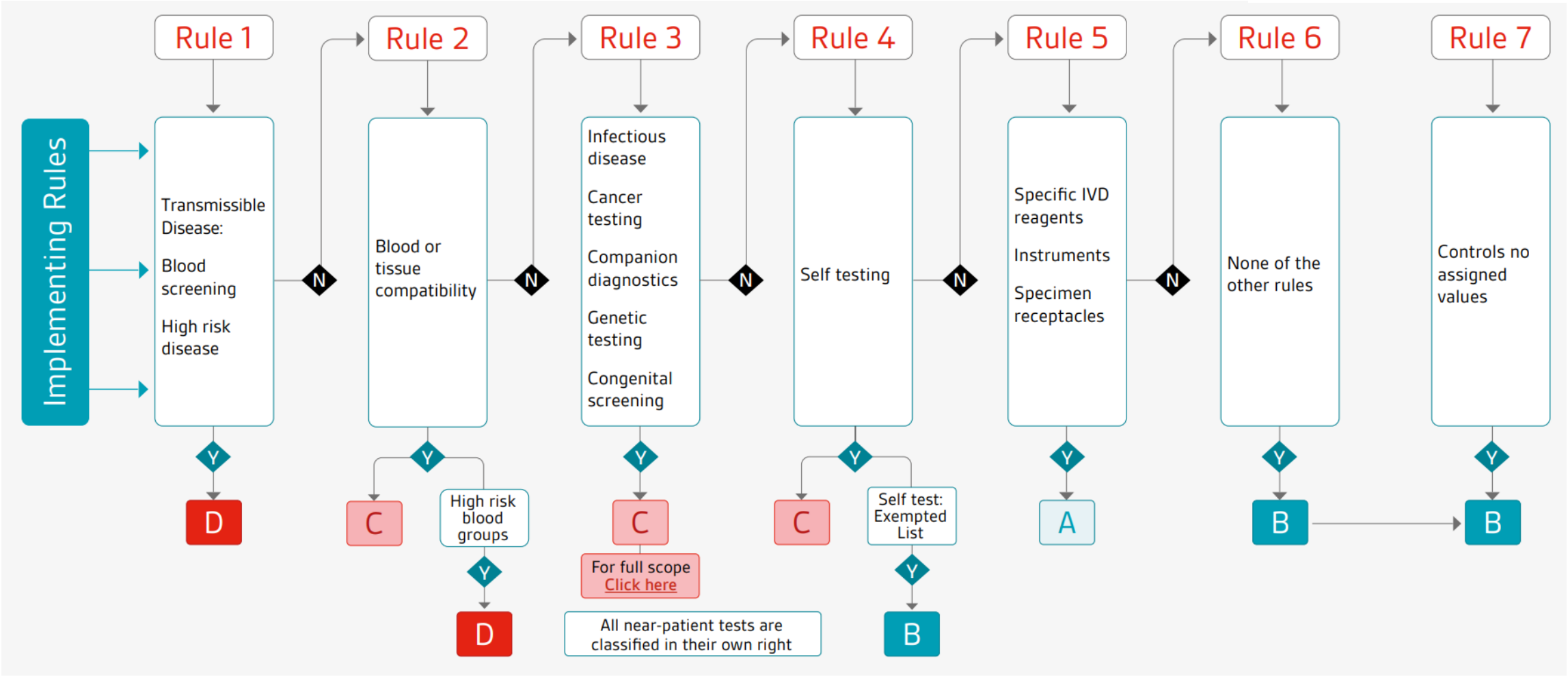

Image courtesy of BSI, UK

Up-classification

Many IVDs will be up-classified

- SARS-COV2 test – self-declaration (IVDD) to Group D (IVDR)

Up-classification requires engaging with an EU Notified Body

- At least 85% of IVD manufacturers will need a Notified Body

Must revisit intended purpose statement, complexity of the device, and the environment it's to be used in to re-confirm classification under IVDR

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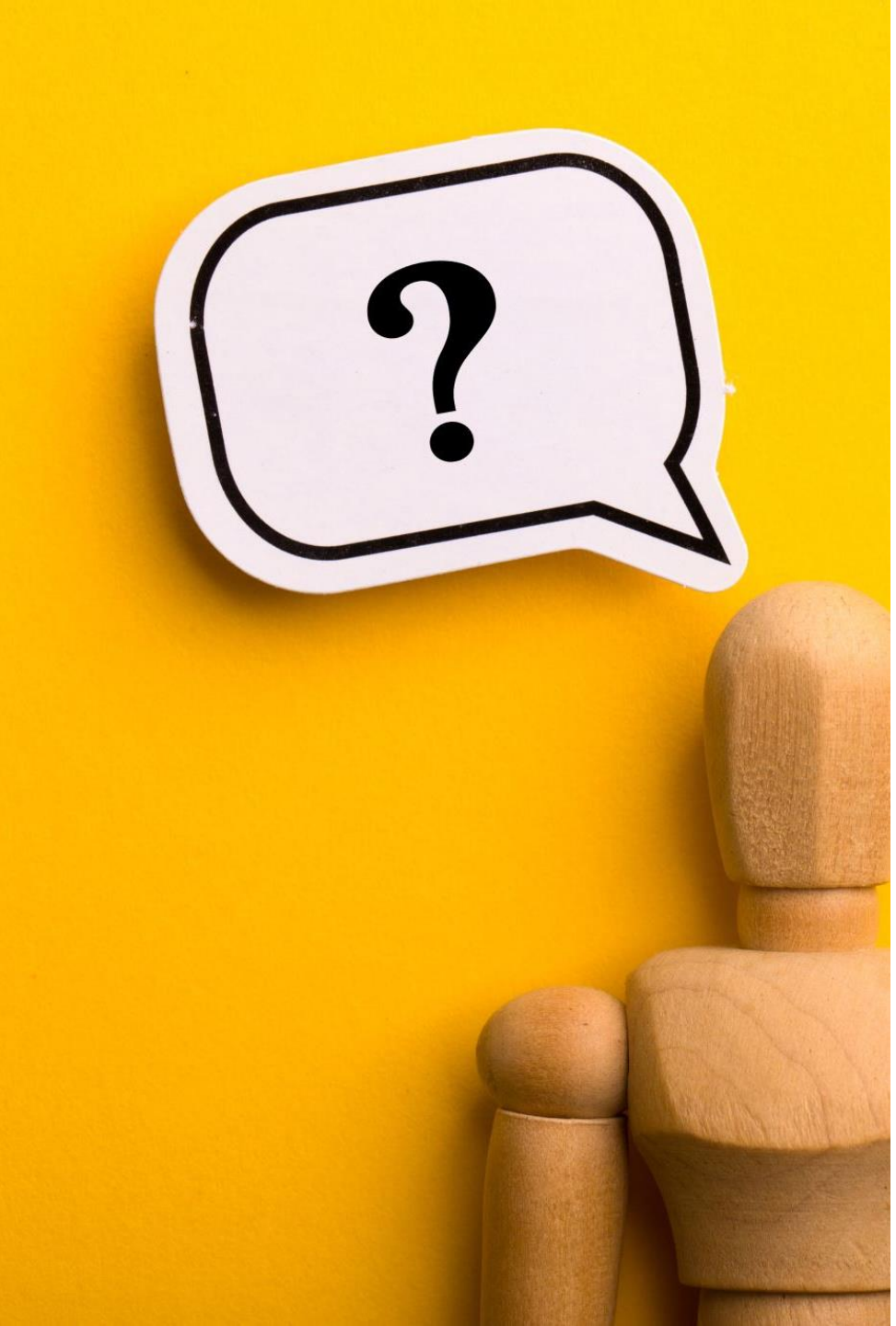
The importance of your Quality Management System (QMS)



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Think ‘Risk’

- What if … ?
  - apply the 5 Ws
    what / where / when / why / who?
- How do we deal with the ‘what if’?
- How do we prevent the ‘what if’ from happening?
- Responsibility?

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One size does **not** fit all!

Quality Management System (QMS)

ISO 13485:2016

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- QMS is the **heart** of the company – evaluate and monitor to check ‘fit for purpose’
- Makes a statement to both clients and regulators that you are committed to quality
- Increases access to markets worldwide
- Increases efficiency, reduces costs and readily monitor supply chain performance
- Is seen as ‘evidence’ that you produce safer and more effective medical devices
- Meet regulatory requirements and customer expectations

What else?

Clarification on the obligations of legal manufacturers, authorised representatives (AR), importers and distributors

EU AR – equal liability

New role – Person Responsible for Regulatory Compliance (PRRC)

Risk Management and Quality Management Systems

Post-Market Surveillance

Unique Device Identifiers (UDIs)

EUDAMED – transparency

Clinical evidence, performance evaluation and performance studies

Life-Cycle Approach

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