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MDR and IVDR : Challenges and opportunities for SMEs and start-ups

A MedTech Europe event

The MedTech Forum

bringing HealthTech stakeholders together

Hogan Lovells

Objectives

- Identify key issues and opportunities for start-up and SMEs
- Obtain your feedbacks and comments

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Challenges

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Challenges

- Understanding the changes and the timelines
- Determine the appropriate budget to support transition to the new Regulations
- Obtain the management's support to ensure the transition
- Identify appropriate resources:
  - Internal: hiring new employees
  - External: authorised representative, notified body, consultants/experts
- Determine if clinical/performance data will be sufficient/if new clinical data is required

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Challenges

- Take the right strategic decisions for the company
  - Change to the business model: EU first?
  - In light of the transition provisions in the Regulation, is it a good time to launch a new product on the EU market?
- Assessing new obligations for economic operators (e.g. Legal manufacturer in Switzerland permitted?)
- Understanding the consequences for the ROW
- Plan and implement plan according to agreed timeline
  - Internal discipline
  - External factors (NB, implementing/delegated Acts, guidance, Brexit, harmonised standards…)

Opportunities

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Opportunities

- Rationalise portfolio
- Reevaluate the priorities of the companies
- Business opportunities – growing through acquisition?
- Market opportunities – taking advantage of competitors not ready for the MDR/IVDR (e.g. in tenders)
- A lighter transition process for SMEs and start-ups?
  - Easier to adapt for new/small businesses
- Implement now changes which are straightforward (e.g. QMS, labeling)

Other Challenges and Opportunities?

Thank you

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Questions

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