MDR/IVDR
Change, Challenge and possibilities?

Peter Löwendahl, May 2019

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Content of presentation

- Change for everyone – quick view
- Common Misconceptions with MDR
- Strategical perspective
- From strategy to tactic plan

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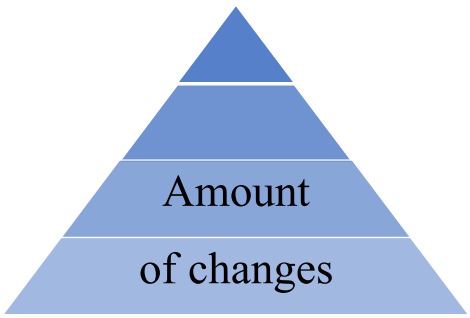
Change for everyone – Quick view

- A brand ”new” regulation or is it?
  - Regulation instead of directive
  - Most parts already in MEDDEVS for MDD
  - IVDR huge change for most manufacturers
  - Distributor/agent/authorized rep

Change for everyone – Quick view

- Potentially biggest impact for lower classes



Extra watch out if you are.....

- Class I manufacturer
- Have/need clinical data without having scientific data
- Class I that get´s upgraded to IIa or higher (mainly software)
- Authorized representative

Common misconceptions

Based on recent discussions with leaders in Swedish companies

Misconceptions of EU MDR Implementation

Our MDD certificate expire several years away , We don't need to worry about it right now!

- True if you do no want to release new products or do significant changes on existing ones!
- Also note that NB´s already use more strict interpretation of MEDDEVS

RA/QA deals with it, after all it's there responsibility

- This effect all areas of the business. An experienced project leader is recommended to use

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Misconceptions of EU MDR Implementation

Each function can deal with it separately it is not that much for each area!

- There are many different departments that should work together to "keep one way of working"
- Distributors/agents and authorized reps needs to do the same!

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Misconceptions of EU MDR Implementation

We can absorb the effort into normal business.

- It's a strategic decision that every company needs to make.
- Impact on your existing resources?
  - Clinical
  - QA/RA
  - Admin activities like handling of UDI, labelling and instructions for use
  - Purchasing, Logistic and warehouse for e.g. checking CE marking and compliance
  - Vigilance and postmarket surveillance

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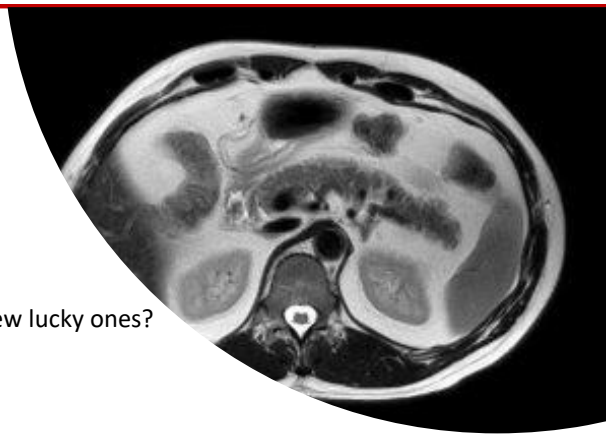
Misconceptions of EU MDR Implementation



Its just minor changes let's go straight into implementation

- For a few companies yes but are you among the few lucky ones?

The only way to find out, Do a gap assessment:

- What effort is needed and what budget is required.
- A test pilot can confirm any conclusions made during the gap assessment.
- Test your subcontractors or distributing partners, and then refine your budget.

Ensure senior leadership takes ownership and oversight during this phase.

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Misconceptions of EU MDR Implementation

It's a one-time project?

The only thing we know is that there will be more changes coming around the corner not only for MDR/IVDR

Build a robust foundation for future change management

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How to achieve market advantage and comply with MDR/IVDR at the same time

- Strategic view

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Strategical considerations

- Phase of product lifetime
- Market situation (turnover-profit analyze)
- Existing customer agreements

- Secure
  - Supply
  - Distributors

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Strategical perspective

From strategy to tactic plans

What, when, how and by whom

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What

- Get to know where you are, gap analyze towards MDR and MDD
  - Create a project team, or
  - Appoint one trusted person in your staff, or
  - Hire an Experienced consultant(s)

Typical outcome:

- Issues with product documentation and clinical data	➡	To expensive to keep product live!
- Issues in post market activities	➡	Need to hire more resources/clinical expertise
- Quality system, non existing, missing elements etc	➡	Changing way of working is always worst….

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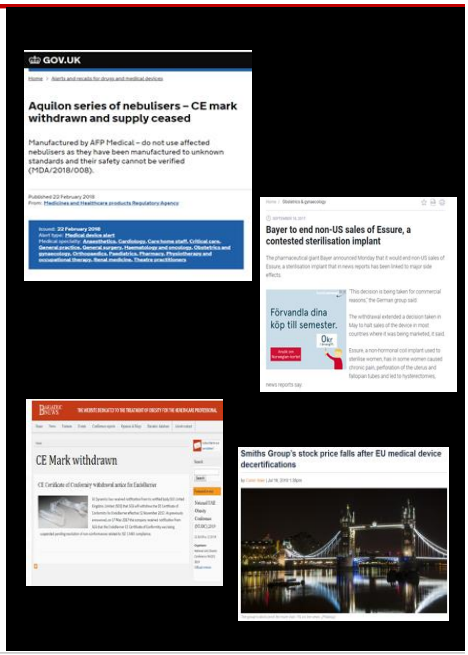
Strategy considerations

- Ensure you have a strategy covering the whole business
- Include
  - Compliance
  - Effective organization
  - Simplify vs just add more things

- Helicopter view! Get the complete picture!!
- How does good enough look like
- Competition weaknesses and strength



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When?

- Yesterday!

- Time is running, but still plenty of time if you start now!
  - Do what you can now!
  - Do not wait for advice or guidance documents!

- Business Priority among identified activities
  - Time critical activities like..
    - find a Notified Body
    - CE mark a new released product, waiting time……

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How?

- Dense the cracks from below?
- Create a new system?
- Re-create?

Will existing infrastructure and documentation take you to the next level?

Can regulatory be a Competitive edge rather than cost!

Are you prepared for the soon to come EMS, CRS, EHS requirements!

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Whom

- Define a tactic plan on how to implement the strategy
- Break down to departments
- Inhouse vs hired consultants or temps
  - Not easy to hire people
  - Not easy to find good consultants

Do you have the competence to hire the right people or consultants

Key take aways

- Get involved now, this is a key part of your Business
- No one have claimed compliance with MDR
- Do what you can yourself

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