ISO Life Sciences

Are you wondering if you've missed anything important in your EU MDR compliance plans?

Notwithstanding the MedTech Europe call to stop the clock on the EU MDR[1], there is a lot to do on this business-critical activity and increasingly less time in which to do it. There is also a growing realisation that compliance will be a major programme. It has been forecast* to cost 3.5-5% of revenue, that's $35-50M for a company with $1B in sales (*Source MedTech Europe 2013 and supported by our own, more recent Client Gap Analysis work) and it's difficult to think of a business function that won't be actively involved.

Of course, complex business-critical, multi-region, cross-functional programmes with multiple interdependencies have been with us since businesses became big and complex. However, we can add to that the uncertainties recently highlighted by MedTech Europe of lack of infrastructure and system readiness in term of; NBs, Implementing Acts, Expert Panels, Reference Laboratories and Common Specifications, Standards and Guidelines and EUDAMED. Onto that heady mix we can also throw resource and expertise constraints and so our view is that it's worth putting some considerable thought into how on earth we deliver this by the 26th May 2020.

From our long experience of complex programmes in general and more recently from analysis and planning of EU MDR Compliance programmes, we can, we think, offer a considered list of Critical Success Factors to help in that regard:

1. **Ensure Business Ownership and Priorities;**

   Non-compliance with EU MDR is, obviously, an existential risk to any Medical Device business and the clear risk mitigation is to comply. The changes from the EU MDD to the EU MDR are however, significant. A budget of 3.5-5% of revenue and the fact that most, if not all, business functions are implicated makes this a major project which should be considered alongside all the other major, business critical issues with which we are faced.

   …the response needs to be Regulatory led but sponsored and executed by the Business.

2. **Communicate and mobilise across the total business to ensure engagement;**

   EU MDR compliance requires major changes across the business in terms including, but not limited to; products, product development and labelling, portfolio rationalisation, QMS, processes, risk management, hazardous substances, clinical evidence, post-market surveillance, post-market clinical follow-up, technical documentation, engagement with EUDAMED, resource needs for compliance and sustainability, and the relationship with Notified Bodies. The functions implicated include; Regulatory, Quality, R&D, Clinical, Medical Safety, Supply Chain, Procurement, Legal, IT, Finance, HR and Commercial. In consequence this should be a major, business-wide initiative and the people in the business need to understand that and to be behind it.

…the engagement of your people is fundamental to successful, business-wide change.

3. **Establish and Maintain 'One Source of the (EU MDR) Truth';**

The EU MDR are complex and as *MedTech Europe* has highlighted, the 'infrastructure and systems' are both subject to change and incomplete. As your complex compliance programme progresses, someone or some coordinated group of EU MDR Regulatory Experts needs to be on top of these changes and their correct interpretation. The changes and interpretations need to be communicated to the workstreams and functional teams involved in the programme so that everyone is 'singing from the same song sheet'.

…the various parts of the business need to end up in the same place and in the right place.

4. **Undertake Robust Gap Analyses and Solution Proposals;**

Good design of your EU MDR Compliance Programme is essential to ensure budgets are in place, resource needs and skillsets are understood, long lead-time items (e.g. clinical studies and IT systems) are known and can be initiated early and critical interdependencies are recognised. The precursor to good design is of course a robust gap analysis and development of solution proposals to close the gaps. It is not necessary to analyse all the Technical Files and relevant aspects of the business Operating Model, an '80:20' approach of analysis of a representative sample has proved sufficient and is much faster. Solution Proposals do need to be specific and detailed to support an effective plan.

...a solid foundation is essential to achieve compliance in the limited time remaining.

5. **Obtaining Commercial input is critical to decisions to Retire, Replace or Remediate;**

The cost and resource burden to achieve EU MDR Compliance is going to be high. This is driving most manufacturers to consider pruning their product portfolios in response to their choices for products of; 'Retire, Remediate or Replace'. It is possible in Product Rationalisation to set some rules around strategic value, compliance cost, margin contribution and payback period. Products that don't make the grade can be phased out[2] and, where possible, replaced by other similar products within the portfolio to safeguard revenue and customer base. Similar actions can also be taken to simplify or prune within product ranges which have proliferated over the years. Early engagement with Commercial, whose Commercial Strategies will be challenged by this, is crucial. Effective engagement will be strongly supported by Finance-verified compliance costs and this is critical to achieving timely decisions for products which may no longer be economically viable.

[2] It should be remembered that phasing out of products may not eliminate all costs especially in cases where the manufacturer still has post-market regulatory responsibilities.

…without the right players involved, decisions may be sub-optimal or more likely too late.

6. **Engage Support from Finance early on;**

   Involve and engage Finance early, at least from the early stages of Gap Analysis, so they understand and are ready to positively support the case for the EU MDR Compliance Programme. Early involvement will smooth the path to validating the compliance costs identified by the robust Gap Analysis and obtaining the budget for the programme. Additionally, Finance will be better placed to participate in the likely Product Rationalisation review, supporting the trade-off between product compliance costs, revenue and margin.

   …it's not all about the numbers but they are important in support of rational decisions.

7. **Undertake detailed X-Functional Planning and Resource Management (Programme Management Office - PMO);**

   Once the Gap Analysis and Solutioning are complete, the next step is detailed cross-functional planning and resource management. For a complex, cross-functional programme it will be necessary to establish a PMO. To be effective, the role of the PMO needs to extend far beyond just creating the plan, defining the resource needs and monitoring delivery. PMO should help leadership deliver the programme design and provide the infrastructure and tools for the workstreams and it should facilitate the creation of the plan by the functional experts to ensure both correct content and ownership. It should subsequently support the workstream teams in the 'process' of delivery, in effective teamworking and reviews and in managing the interdependencies and inevitable course corrections once the 'first shots are fired'.

   …ensure great design is supported by great execution.

8. **Remember EU MDR Implementation has 3 distinct Remediation Pathways;**
   The remediation pathways for EU MDR implementation initially focus on Product and Operating Model remediation. The extent of changes at the product level will vary from simple to complex to be delivered by a cross functional task team. Many business processes will be affected and these are likely to require major support from IT teams and they are also likely to have long lead-times. These two pathways converge to a Business Continuity pathway where Regulatory and Supply Chain coordinate between recertification and supply of EU MDR compliant product to the market. Although the remediation pathways are distinct, all 3 form part of the same plan within the EU MDR Compliance Programme.

   …all changes need to be conducted using updated EU MDR compliant QMS procedures, making QMS remediation a priority.

Of course this considered list is not completely comprehensive but, in taking a step back for the purely technical, regulatory aspects of a compliance programme, we believe they offer a summary of what are critical for success. We are interested to hear your thoughts on our 'distilled critical success factors' for EU MDR Compliance and are happy to engage in a dialogue.

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[1] http://www.medtecheurope.org/node/1280