



Risk management challenges across Europe from the medtech perspective

“Risk management” is a term that has just slipped into our corporate vocabulary over the last few years, with the tacit assumption on the part of most executives that “it is something we do anyway” or “it’s a job for old Bob in the last few months before he retires”. The truth is very different ...

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MeddiQuest Limited in brief

MeddiQuest Limited is a UK-based regulatory affairs management company. MeddiQuest works in partnership with hi-tech and startup organisations to help them rapidly introduce products to new markets and maintain regulatory compliance

ADOPTION OF RISK management will cause as dramatic a change in management practices as the quality revolution of the 1980s and 90s did. Risk management will need to be integrated into almost every business process, affecting everybody's role within the company, just like quality management. Yet there is a more fundamental problem: while people had a good intuitive understanding of issues surrounding quality and customer satisfaction, there are fundamental misconceptions about risk and hazard that permeate everyday life.

Integration

Reading the two harmonised European Standards for Medical Technologies together: ISO 13485:2003¹ on Quality Management Systems and ISO 14971:2000² on Risk Management, it becomes clear just how deeply risk management needs to be integrated into the business process and that it is frequently an

implicit precursor in the currently defined activities. The integration of risk management into other standards affecting medical technologies is well underway: for example, IEC 60601-1 3rd Edition³ will move from the prescriptive 2nd Edition to a risk-based standard, where the manufacturer assesses and justifies the risk in its design irrespective of any “generally accepted safe parameters”.

There is undeniable logic in the contention that we should try to “design out” risks. The same logic would also dictate that we should consider, even analyse, the risks before commencing design to avoid making decisions in the design process that include risks that will have to be mitigated or eliminated later. Following this train of thought, it soon becomes clear that risk evaluation is a necessary precursor to setting the initial design requirements and an integral part of the design review system. The concept reaches further: meeting the product standard ►



may not be enough if the risk has not been reduced to as low as reasonably practicable. Risk management cannot just be “tacked onto” the design process; it has to be fully integrated and becomes a criterion at every decision point in the design process. Product design was just my example – try changing the process and you will soon see the extent of the integration.

Changing the way we make decisions

This is nothing new for the time-served executive. In the 1970s it was all about “productivity”. In the 1980s it was all about “quality” and in the 1990s it was all about “customer focus”, so in the 2000s it will be all about “risk”. There is something radically different, though: we all intuitively know what is meant by productivity, quality and customer focus ... but “risk”?

Misunderstandings and misconceptions

There is a great confusion in the public mind about the differences between “harm”, “hazard”, “risk” and “consequences”. The words are used almost interchangeably and in everyday speech tend to take their meaning from the context rather than a dictionary definition.

Reality and perceptions further complicate our use of language. When most people say “conducting a risky procedure” what they really mean is “a procedure with considerable ability to do harm and the possibility of traumatic consequences but with sufficient controls in place that the risk is tolerable”.

Industry is not alone in finding these concepts difficult – try looking again at FDA guidance on software validation. This should be the benchmark risk-based guidance, but the validation requirements are determined by “consequences”,

not “risk”. This gives major problems to the authors of the future IEC 62304 standard on software validation, targeted to be the international version of ANSI/AAMI SW6:4 follow the FDA guidance and have a universally accepted standard, or follow other standards in being risk-based and accept the standard will not meet with the approbation of the FDA.

Objective risk or subjective risk?

It is very tempting to think that the soft-woolly “perception stuff” does not really matter, that it is hard facts, figures, statistical analysis and information that need to drive decision-making.

Before we do, though, just consider what causes the big problems for products and even whole industries: media reports; investor concerns; and political interventions ... all of which are driven by perception. If you are not convinced, think of the MMR vaccine scare in the UK: the government was vilified for sticking to the objective data, and press and, hence, public perception was swayed on the basis of part-information and a willingness to believe in “pseudoscience”. Some companies found a major market had shrunk overnight, others that they could not produce enough “single vaccine” to meet the demand.

There is an inherent dichotomy in risk-based decision taking: we have to work with the objective data but be cognisant of perceptions and subjective risks. That is the perception of the population as a whole, not just our own or those of an educated elite.

This is a far more complex type of decision-making than improving productivity, quality or customer focus – and because of integration into all processes we need every decision-maker in the



business to be skilled at this risk-based decision-making.

Further complications

Medical technologies are not unique in suffering from a further level of complication, but it is particularly severe and frequently goes unrecognised by many medtech companies. Clinical practice varies considerably, not just from market to market, but frequently from one institution to another:

- Who will set up, operate and monitor a product?
- What level of training will they have, both on the specific product and in the general technique?
- In what environment will it be used?

Manufacturers have frequently been astonished to find out that their products are being used onsite by a paramedic or at home by a patient when they always assumed they would be used only in a hospital under physician supervision. Yet it is still common for risk assessments and reviews to be conducted by companies using only internal resources: no patient or clinician is asked for input, and certainly no international “user panel”.

If we are truly going to adopt risk-based decision-making at all levels in the company, then knowledge not just of a product’s intended use but also of its likely use is necessary at many critical decision-points within a company.

The subjective risk may vary from market to market, just as the objective risk does. Keen political or media scrutiny of a particular medical technique, local product liability, patient and clinician attitudes and familiarity, malpractice legislation and likely penalties imposed by the

courts may mean the whole company is put at severe risk by entering one market with a product that would have negligible risk in another.

Medtech roadmap

ISO 14971 sets out a 13-step process for risk management.²This is a superb analysis of the risk management process and can be a valuable checklist to ensure we have considered all possibilities. I find it just too detailed to be a useful model for implementing a system and prefer the simplified four-process model:² analyse; evaluate; control; and feedback real data.

The big question is, how do we build a roadmap for medtech industry incorporating all these ideas?

Top management buy-in

The first essential is to get senior management on board. Senior management need to understand that risk management is not some “state requirement” to be despised, but an essential for ensuring the viability of the business; more particularly, they need to be prophets of risk-based decision-making within the organisation.

Start early and follow through

During the first 20% of a project, 80% of the commitments are made – if risk management is to benefit the organisation, it needs to start early.

The corollary of this is that at the beginning of a project we have little real information, just predictions. For all we try to model with clinical trials and accelerated ageing, we will only really know the risks at the end of the product lifecycle. Hence our predictions from our early start will need to be continuously refined until the last product has been used. ▶



This “follow-through” needs to be a planned and scheduled activity in order to ensure that it maintains its priority as the remaining lifetime of the product decreases.

Risk management structure

The bulk of risk management activity can be successfully completed at the project team level, but there are bound to be certain cross-departmental issues for which a manager-level buy-in is essential and probably risks that are so significant to the viability of the project or even business that the senior management (or board of directors) need to make the decision. If the escalation criteria are specified at the beginning of the project, this can be a smooth process, but if not there is a danger that teams will feel compelled to take decisions they are not competent to make.

Education and tools

There is a lot to learn about risk management and many tools to use. Too often people see the format and ranking system used in a risk assessment, recognise it from a failure modes and effects analysis (FMEA) and assume the two things are the same. It is the old logical fallacy: “my dog has four legs; this animal has four legs; this is my dog”. Risk management is about management: there are a lot of tools, all of them have uses, but the key is using the right one, in the right way, at the right time. Moreover, no two situations, no two projects, are the same – what worked well on one project may not work on another. The golden rule when assessing risk is: when you have finished using the analytical tools, stop, and then start thinking “outside the box”.

The importance of teams

Risk management is difficult and time-

consuming – no one person has all the answers. Each member of a team brings different experiences and a different perspective; just because somebody is a “lone voice” does not mean they are wrong.

Teams need to be multidisciplinary and above all include patients and clinicians. The user of a product knows more about how and when it is used than a manufacturer ever can. The user also has one critical piece of knowledge – whether the risk is tolerable given the possible benefit; here the user will always surprise you, because this is a subjective judgement made on their perception of the risk and benefits. Any risk management team that does not have ready access to patients and clinicians is in my opinion fatally flawed, will make poor decisions and potentially jeopardise the future of the medtech business.

The danger of a structured process

Human beings have fantastic abilities to adapt and to make intuitive leaps; we ignore these at our peril. The danger of a structured approach is that we rationalise away our concerns through our natural enthusiasm for a project that we believe in and a desire simply to complete the process. Beware forgetting the subjective approach: a life does not always have the same value. Harsh, but true! Suppose you have a very beneficial medical device that saves many lives a year but occasionally causes a fatality through failure. If these failures randomly occur at a rate of 10 a year spread across the country, this will probably be “tolerated” by patients and clinicians. What if during the year there are just five deaths attributable to the failure, but all in one hospital in one week? This is the case that will make the national news and get politicians buying for corporate blood.



Convinced? If not, try comparing deaths on the roads in the UK with deaths on the railways ... and remember what happened to Railtrack following the Hatfield and Potters Bar rail crashes!

Realism

Many technologies have an inherent risk, but this is well tolerated because of the great benefits they offer. If we devote disproportionate resources to making incremental reductions in this residual risk, we run the risk of pricing the product out of the reach of the patient or healthcare provider. What use is the better product if nobody uses it?

Variation

Quality techniques such as statistical process control and “six-sigma” are good at reducing variation: keeping a production run within specification. They can never eliminate the risks originating from a poor specification that is intolerant to variation. The product needs to be designed around what the manufacturing process can achieve; just as you cannot “inspect in” quality, you cannot “control out” a tolerance mismatch between product design and manufacturing process.

Impact

Many organisations are only just starting to understand the full implications of a corporate risk management process and that it impinges on every area of operation. In exactly the same way as the adoption of a quality system defines interactions and processes within an organisation, so does risk management. Furthermore, just like a quality management system, a risk management system forces its way into the boardroom and requires the directors of the company to understand both the use issues

surrounding their product and the complex risk methodology.

Conclusion

Introducing risk management means changing the way we make decisions in our business, by educating our decision-makers to use the precise analytical language of risk management. The adoption of risk management practices will not just change the approach to decision-making; it will also alter the fundamental way we do business in Europe and may force changes in national laws within the community.

The challenge is to improve awareness, appreciation and education not just in the industry but across all of the society where our products are used. ■

References

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