
Risk Management: Innovation's Friend or Foe?

By **Daniel L. Mooradian** Mar 7, 2018 8:00 am PST

When experts from the FDA and industry meet next week for the Medical Device Validation Conference in Minneapolis, Minnesota, the focus will be on the practical application of methods to the validation of medical products. I'll be there as an educator and medical device executive, to learn and also to share my thoughts on the relationship between the important work these experts carry out, and the innovative development of medical technologies that they contribute to.

Innovation is a critical contributor to business growth in most industries and as demonstrated by Robert Solow more than 60 years ago (1), technological innovation at the macro-level drives GDP growth. Innovation is not possible without risk. It requires an investment of time, money, human capital. There are factors beyond our control that will influence whether innovators are successful. Innovators are viewed generally more risk tolerant than others. Modern-day entrepreneurs like Elon Musk (Tesla, SpaceX) or latter-day entrepreneurs like Thomas Edison come to mind as examples of the combination of vision, creativity and willingness to take personal/professional risk that we associate with innovation.

However empirical their methods of assessing risk, they transform unknowns into risks (i.e., what can be reasonably anticipated and estimated) and reduce those risks where possible to maximize the probability of business success.

Of course, innovators can also be impatient and in highly regulated industries (e.g., medical devices/medical technology) the need to consider risk with breadth AND depth creates understandable tension.

This tension is inescapable. Even in small companies, investors, partners and board members expect that elements of a risk management process be put in place as a condition of funding. These minimally include; establishing a strategy, budget, timeline and milestones. Often a stage-gate process of some kind is implemented to permit review and an opportunity for "go/no-go" decisions by the leadership team.

In the face of significant and fundamental risk however, processes that would guide risk-management at the project level may be limited in the interest of "time-to-market". The approach is perhaps too frequently "standards-based" and focused on achieving a "minimally viable product" and compliance to essential requirements and little more. This is in stark contrast to large companies, whose enterprise risk management (ERM) processes and expertise mandate more rigorous compliance – even at the cost of innovation and speed. Such controls can have a negative impact on innovation and are often viewed as contributing to the difficulty large companies have with maintaining an innovative, competitive edge.

Innovators at companies both large and small get mixed messages. They are encouraged to accept and even embrace failure (2). Yet the need to limit the impact of such failures and to maximize the impact of successes also signals the need for caution and risk avoidance.

In response, innovators may seek more risk tolerant ventures elsewhere, they may operate at the margins, skip requirements, and cut corners to avoid this stifling influence. And as a consequence of this, companies assign risk management tasks to others, which can heighten the innovators sense of being managed.

What is clear in an era of rapid and sustained technological advances that outpace our ability to predict their impact is that an understanding of risk management is a core competency for innovators and businesspersons alike. Indeed, it is a core competency in life. Our very existence depends on risk management every day.

At the project level – risk management is a critical aspect of design/development to satisfy customer needs. ISO 13485:2016 and ISO 14791:2007 are essential to risk management as they relate to medical device product development. While project

risk management have been segregated to a great extent from the broader enterprise risk management activities of a company, the new Medical Devices Directive (MDD 93/42/EEC) with its stringent requirements for risk management throughout the product life-cycle, forces innovators to consider aspects of design and performance that may have been overlooked. If the goal is merely compliance then this new burden may feel like just another requirement that hinders innovation. But does it have to be so?

Can RISK MANAGEMENT stimulate rather than stifle innovation? Many believe the answer is yes. As Steve Culp noted several years ago in Forbes, "When properly fused, the two disciplines can help organizations pursue opportunities that a risk-averse culture might leave on the cutting room floor" (3).

Here are several ways in which Innovation may be enhanced by rigorous risk management:

- By more effectively transforming uncertainty into risk, risk management can reduce the threshold for action, help prioritize essential features/benefits and accelerate rather than hinder decision-making and progress.
- A thorough evaluation of product features that are critical to safe and effective use may lead to opportunities for platform innovation and new approaches to design from the ground up.
- This may lead to innovations in manufacturing processes, shipping, handling and even fundamental changes in the business model beyond the product itself to meet customer needs.

We can begin by creating awareness and an understanding amongst innovators of the benefits as well as the need for risk management, to shift the mindset from compliance as an OUTPUT of the process that is an obstacle to innovation, and view the identification and assessment of risk as an INPUT to innovative design (as defined by the FDA) as well as a means of differentiating a product in a competitive marketplace. This requires education. Scientists and engineers – particularly those who will work in medical device innovation - must have sound training in risk management principles at all levels of an organization. Seasoned experts in risk management will be on the front lines of this effort. This provides critical context and reinforces their role as stewards of key portions of the risk every company must manage. Armed with this knowledge and responsibility they are more likely to embrace risk rather than avoid it.

References:

1. The growth of growth theory (The Economist, May 18, 2006).
2. Creating an innovation Culture: Accepting Failure is Necessary (Forbes, June 20, 2012).
3. Risk Management Can Stimulate, Rather than Deter, Innovation (Forbes, Jan 7, 2013).

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