Technical Risk Management in Medical Technology

Posted in **Quality Assurance** by Thomas Klein on May 9, 2014

High innovation rates and short innovation cycles in medical technology can increase the risk of failures and product errors. Companies need to deploy a systematic risk management strategy to avoid costly problems.

Increasing Number of Recalls
Steady growth of the competitive medtech market intensifies these innovation dynamics [1-3]. Trends like sharing medical information in massive networks, using robots in surgery and diagnostics, advanced telemedicine and portable technology are expressions of such innovations [4]. Such innovative technologies are intended to benefit both users of medical products and patients by lowering costs and increasing availabilty.

But innovation often comes at a cost. These novel and quickly developed technologies can lead to an increased number of potential product, application, and use errors that can endanger patients' lives [5-8].

Each year, the Directorate General for Health & Consumers of European Commission publishes the vigilance report, which consists of National Competent Authority Reports (NCAR) containing data on and classification of adverse events that resulted in permanent disability, injury, or death [6-7]. Since 2008, the number of NCARs in the 19 participating EU countries has more than doubled, as seen in Figure 1. [5]

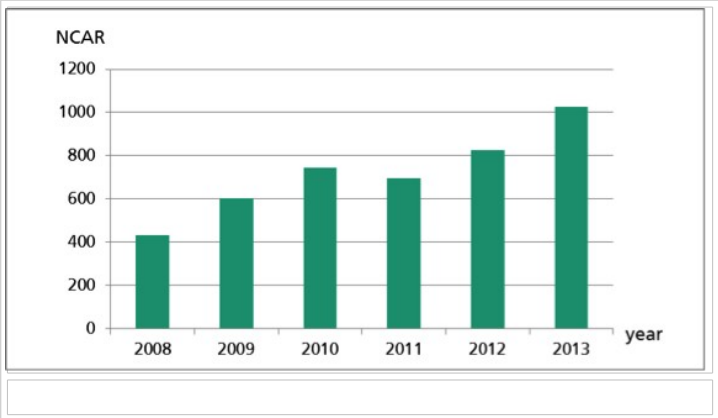

Figure 1NCARs of All-Time Participants 2008 to 2013 [5]

Unlike FDA, the European Commission does not publish direct statistics on recalls. However, it stands to reason that such a dramatic growth in NCARs would indicate a potential uptick in recalls as well. Analysing adverse event statistics from the world’s three biggest medtech markets—the United States, Japan and Germany—similarly points to this trend, as illustrated in Figure 2.

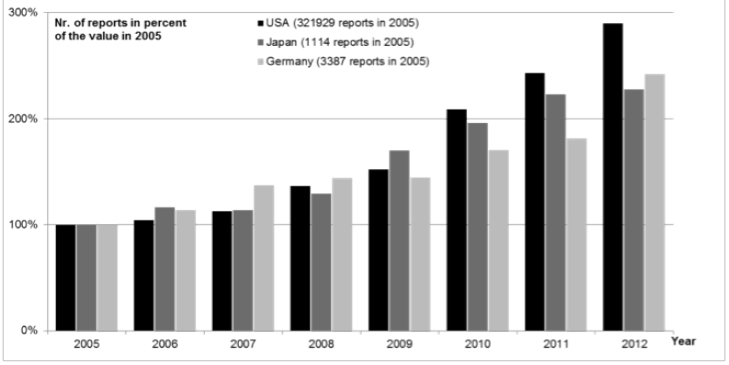

Figure 2: Adverse Event Reports in world's biggest Medtech markets [8-10]

Rethinking Risk Management

Current risk-management (RM) strategies do not seem to adequately address the tasks that developers face as devices become more complex and markets become more challenging. It also seems unlikely that simply enhancing existing strategies would lead to the necessary outcome. As such, manufacturers and developers will have to rethink their risk-management processes. [12]

While there are many techniques for RM, a survey conducted by the Fraunhofer Institute for Production Technology IPT in 2011 revealed that among the 180 analysed medtech companies, failure mode and effects analysis (FMEA) is the overwhelmingly preferred method [12]. Many of them, though, leave their RM assessment half-done, mainly because they do not consider it to be worth the price.

A complete RM process, however, should consist of the steps presented in Figure 3 (below), including a cross-project approach allowing manufacturers to feed back experience from previous RM and carry know-how to future projects. Instead, practice shows that manufacturers have an isolated view of the device, not taking into account interfaces and networking in their risk assessment, thus missing out on critical characteristics arising from interaction. Additionally, tools for a comprehensible visualisation of analysed medical devices are needed to support risk assessment within interdisciplinary teams.

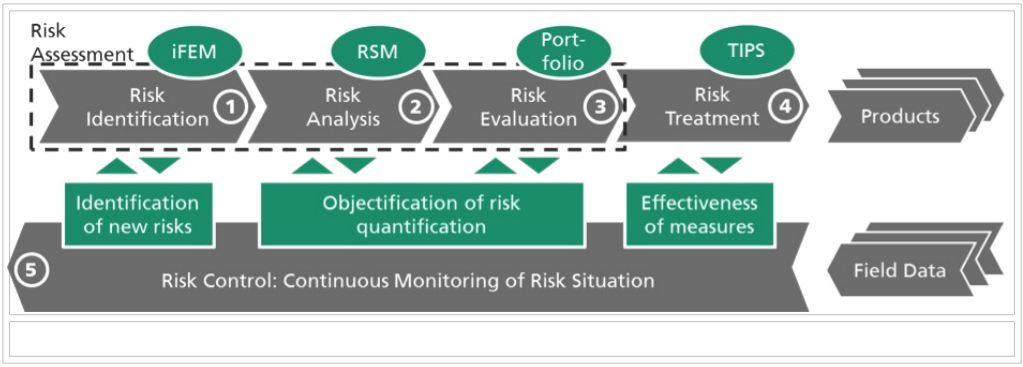

Figure 3: Innovative methods located in Risk Management Process (1) to (5) referring to EN ISO 14971

Integrative Approach to Risk Management

In addition to the mentioned gaps in RM process, manufacturers often fall short of demands on techniques and their execution. Using classic RM methods often is both ineffective and inefficient because they neither cover risks arising from multicause complexes, such as unpredicted interactions between subsystems, nor do they include risks originating from newly developed devices and their components' influences.

New methods will have to eliminate such flaws through an integrative, comprehensive approach to risk identification. Proximate risk analysis frequently stalls because of insufficient cause-effect modelling. Complex systems are not uniformly understood concerning potential risk; that is to say, expert panels cannot take all effects into account. Ever-shortening product-development cycles in combination with particularly high-risk impact in medical technology thus call for significant improvement in modelling and visualization techniques.

Finally, risk assessment must be followed by a comprehensive risk treatment that has potential for improvement. For example, similar or same risks are treated in different ways because corresponding measures are not documented and not controlled in closing the RM process. [13-14]

New requirements arise from the above demonstrated deficits of technical risk management in medtech companies: An increasing numbert of more technical and complex risks need to be analysed efficiently and treated effectively. Within the context of research and industrial projects, Fraunhofer IPT has developed new methods affecting each phase of the RM process referred to in EN ISO 14971.

Risk Identification
Risk identification is put on a strictly analytical base. One example is function effect modelling (iFEM). Its advantage over established methods like FMEA, in particular, comes into effect in technical complex systems where interacting risks play an important role. Experience in different application and validation projects showed that iFEM identifies approximately 50% more risks in complex systems than FMEA does.

Figure 4 illustrates how iFEM is applied to a pacemaker manufacturing processes. In the first step, the technical system is modeled with Theory of Constraint's reality tree. Reality trees map the system at its initial position by showing all effects that influence the systems risk. Because of the effect's relations holistic modeling, reality trees help to identify the system's root-effect that causes the highest risk. They display different areas of the total system, where risks can be controlled directly or indirectly and those where no influence is possible. The advantage of this modeling approach is that not only risks emerging from individual system components are being recognised, but attention is also drawn to interacting risks.

Risk Analysis
In the second step, identified risk areas are modelled with objects to determine desired and undesired interactions, which present functions of the system. These system functions are classified as productive (PF), auxiliary (AF) and harmful functions (HF). Effects resulting from interactions of functions are divided into useful (UE) and harmful effects (HE) categories. Functions and effects are now connected in the function effect model (iFEM), as shown in Figure 4. This approach enables the systematic identification of risks and their division into risks within a function (snippet A), risks from interaction of functions (snippet B) plus risks from effects (snippet C). The probability of occurrence and extent of damage are quantified subsequently in the phase of risk analysis and can be displayed in a risk portfolio.

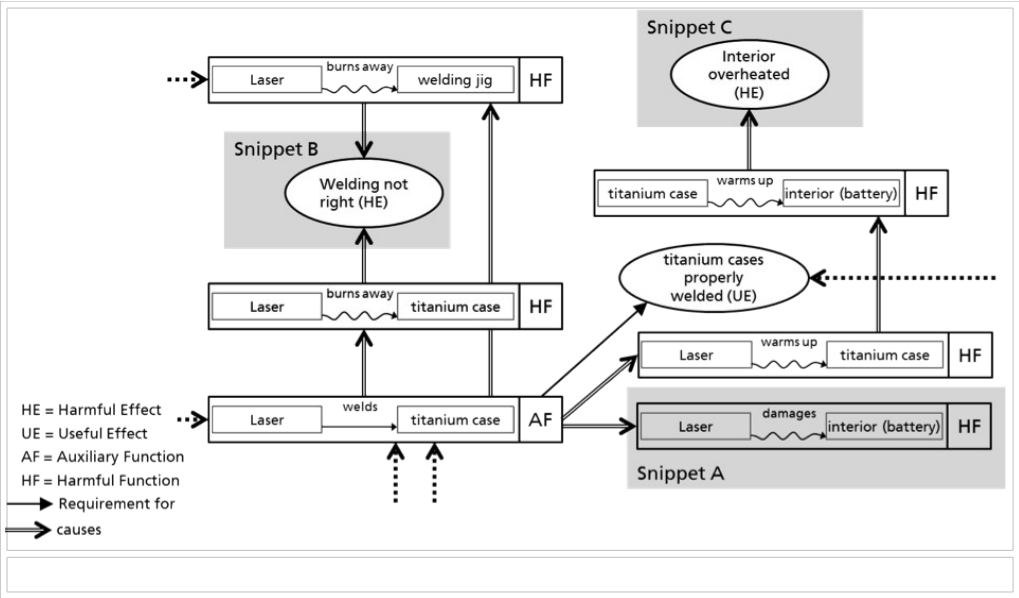

Figure 4: innovative Function Effect Model (example of a pacemaker manufacturing process)

Risk Evaluation

In the evaluation phase, according to EN ISO 14971, quantified risks are rated concerning need for action. Accepting the residual risks or developing measures for risk treatment are two possible results. To come to a decision, the manufacturer needs to know the potential severity of the identified risks. Event tree analysis (ETA) can be a suitable method for this purpose.

With Boolean algebra, risk effects are analysed concerning their logical structure, probability of occurrence and severity. Evaluating interactions between effects incorrectly or simply forgetting them is a weakness of ETA. Severities can mutually reinforce or mitigate each other or be neutrally related. The risk structure matrix (RSM) offers a simple solution to systematically identify such interactions by contrasting single risk sources in the RSM and pairwise evaluation concerning possible positive, negative or neutral interactions.

Risk Treatment

After having identified, analysed and evaluated all risks in this manner, decisions concerning different risk-treating strategies are made by comparison of probability and severity with defined risk criteria (risk treatment, see figure 3). A widespread method for visualisation of this decision situation is the risk portfolio. Not only does it allow evaluating risks by absolute comparison with acceptance criteria, it also provides the possibility for relative time comparison and monitoring risks along the lifecycle of a device.

In contrast to this approach of deriving measures for risk treatment, medtech companies often act unsystematically. This is particularly problematic in late phases of product development or in case of threatening field operations; measures are developed aimed at short-ranged suppression of symptoms and not upon addressing causes of risk. A methodical approach at this stage would provide the chance to develop more effective and efficient risk-treatment measures.

As a result of numerous past risk-management projects, Fraunhofer IPT has abstracted concrete measures and condensed them into 41 principles of risk treatment (see figure 5). These principles can be applied to the appearance of random concrete technical production and usability-oriented risks in order to develop targeted steps to reduce risk.

Risk Control

Field data is a valuable source for RM. Many medtech companies underrate this fact, and risk-control activities like market observation according to EN ISO 14971 become a pure matter of duty in that case. Not only do field data analyses provide the chance to systematically monitor effectiveness of risk-treatment measures, it can also be used, in case of statistically relevant base populations, to validate risk analyses of

medical products by comparing relative error rates and actual severities with initially quantified error probabilities and potential severities.

In this context, building up systematic risk inventories is the appropriate instrument for monitoring risks along their whole lifecycle. By a suitable structure, e.g. the structure of a monitored product family, such inventories open up the possibility for a systematic reutilisation of once-developed measures of risk treatment. Compared with industrial practice, this approach makes risk-treatment processes more efficient by avoiding redevelopment of measures that were already applied to same or similar risks in the past.

In practice, methods of technical RM in medtech must be implemented not only in terms of organisational structures and processes—that is, considered individually, already a challenge—but also need to be efficiently supported by software. In this area, companies often still use stand-alone and nonintegrated software applications that lead to several interfaces. This might lead to loss, damage, expiry or redundancy of information.

Summary
Risks arising from medical products have been increasing in recent years. However, the effectiveness of traditional methods of technical risk management is steadily undermined by the increasing complexity of medical devices and their production processes. Thus, continuous advancement of risk-management methods must keep pace with the innovation dynamics in medtech to ensure patient safety and obtain competitive advantages by making use of innovative approaches to effective and efficient technical risk management.

Authors:
Martin Plutz, researcher at the Fraunhofer Institute for Production Technology IPT,
Steinbachstr. 17, 52074 Aachen, Germany, +49 241 8904-309, **martin.plutz@ipt.fraunhofer.de**
www.ipt.fraunhofer.de

Prof. Dr.-Ing. Robert Schmitt, head of the Chair of Metrology and Quality Management and member of the board of directors for the Laboratory for Machine Tools and Production Engineering WZL of the RWTH Aachen University. He is also head of the department Production Metrology and Quality of the Fraunhofer Institute for Production Technology IPT as well as member of the board of directors of the Fraunhofer IPT.

Carmen Castaño Reyes, guest researcher at the Fraunhofer Institute for Production Technology IPT.

References:
[1] Lenkungskreis für den Nationalen Strategieprozess (Ed.): Nationaler Strategieprozess „Innovationen in der Medizintechnik“. Berlin, 2012.

[2] PricewaterhouseCoopers (Ed.): Medical Technology Innovation Scorecard. URL: ***http://www.pwc.com/us/en/health-industries/health-research-institute/inn....*** *[As of 18.03.2014].*

[3] Bundesverband Medizintechnologie (Ed.): Branchenbericht Medizintechnologien 2013. [As of 12.02.2013]

[4] World Health Organization: Trends in Medical Technology and Expected Impact on Public Health. Background paper. [As of 07.10.2010].

[5] European Commission: Medical Devices. Market Surveillance and Vigilance. Medical Devices. URL: ***http://ec.europa.eu/health/medical-devices/market-surveillance-vigilance...*** *[as of 06.03.2014]*

[6] The Global Harmonization Task Force: Application Requirements for Participation in the GHTF National Competent Authority Report Exchange Program. GHTF/SG2/N38R19, 2009.

[7] World Health Organization: Medical Device Regulations Global Overview and Guiding Principles. Geneva, 2003