Model-Based Risk as a Path to Safer Medical Devices

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Abstract *All major trends in MedTech have one thing in common: medical devices are going to be more complex than ever - and so are the networks they belong to. A necessary measure to cope with this and other emerging challenges is a satisfactory risk management process. Today, manufacturers address safety hazards with a multitude of techniques, all of which are document-based approaches. This paper presents research on how applying model-based risk management could eliminate disadvantages that are endemic to existing methods, like uncertainty of coverage, incompatibility of professional mind-sets or typical bias-by-design flaws. Risk management, based on a structured, computerised model of both the physical product and its lifecycle, has the potential to improve processing in all stages. We explain how our concepts allow for comprehensive risk identification, interconnected expert judgements and standardisable classification for better risk evaluation; they also help enforcing risk treatment by reducing process cost.*

1 Introduction

1.1 New Challenges

Nowadays, most companies are forced to shorten product development cycles as they are coping with fast technological changes and competitive time-to-market. In addition, globalisation of the marketplace significantly increases the number of

competitors and the complexity of the product life cycle as more companies and partners have to interact in the value chain (Oehmen et al. 2010). An adequate Risk Management (RM) is one of the most crucial tools to face all these changes. RM in MedTech is fundamental to guarantee device usability, safety, and regulatory compliance (Ganeshkumar 2002).

Manufacturers of medical devices traditionally have been small or medium enterprises (SME) operating in national or regional markets. While their venture capital is more or less the same, innovation cycles shorten and products become more complex, as do the services and the networks they work in. To achieve rapid sufficient turnaround, specialized medical devices are introduced into new market fragments (Pammolli et al. 2005, MedTech Europe 2014) that do not have the same backgrounds as the traditional markets. Many developing and emerging nations do have the need for specialized medical care and would like to acquire modern medical devices. However, manufacturers struggle with lower technology levels and missing a supply chain to support their products with high quality consumables and spare parts (WHO 2010, Chan and Larsen 2010). Also, globalized production implies taking responsibility for RM of your component suppliers as well. One can imagine many other examples that show the need for a consistent and cost-effective RM for the whole product life cycle and alongside the complete process chain. Nevertheless, everyday work life in said companies reveals a different picture.

1.2 Barriers for Comprehensive and Pervasive RM

A survey among 180 manufacturing companies, conducted by Fraunhofer Institute for Production Technology (IPT) (Zentis et al. 2011), showed that the majority of those companies who think of their own products as innovative and complex, state that they implemented an RM process and value the capability of avoiding failure in early stages of product development. The very same panel of companies commentated that they cope with challenges such as insufficient clarity and precision of RM methods, costly risk assessment methods, inaccurate methods to determine primary risks, and inadequate methods of risk analysis to determine risk causes.

Interestingly, with 59% the financial security of the respective companies comes in first in the list of motivations to run risk analysis, even before preventing product failure and compliance to laws, standards and guidelines. At the same time, 62% admit placing risk analysis procedures mainly after failure has occurred. Now, when this very same companies argue to not go through with risk treatment because they fear it to bring low return on investment (ROI), it shows that many top managers have not understood how RM affects production processes or at least that RM reports and recommendations do not sufficiently pervade their decision making. If a risk is already identified and evaluated, inhibiting its treatment may not be financially profitable, but virtually always to provoke un-

necessary flaws down the line in product life cycle. Additionally, it will often bring the documentation of, and communication about, the particular risk to a halt. Decision makers seemingly tend to disregard the iterative nature of RM alongside the process chain and thus see investments in RM as lost when they still might pay out later on (Zentis et al. 2011).

These behavioural patterns are not well understood yet and, looked at from outside, often contradictory. We need to learn more about the obstructing and promoting factors, the underlying circumstances and prejudices. That is why we are currently preparing an empirical social study directed at the motives and mindsets of the RM players in MedTech companies. We wish to question those performing RM as well as the leaders controlling them in semi-structured expert interviews.

2. Deficits of Document-based RM

In this section will be described seven deficient areas in RM that were identified with the help of the studies mentioned and an extensive literature research links directly to the document-based approach. Naturally, those are areas of opportunities for model-based risk management (MBR).

2.1 Missing Comprehensiveness

As Risk Identification is the first of a number of consecutive steps, it must be implemented in a comprehensive fashion. While the execution cannot be infallible, methods and processes must be designed comprehensively (Grubisic et al. 2011, ISO 31000 2009). As IEC/ISO 31010 illustrates in a coherent manner, document-based methods cannot master the concurrence of complexity and comprehensiveness. Methods like FMEA that show good procedural control are only realisable for product structures of very limited scale. The product life cycle of a medical device is more often than not a highly-hierarchical entity with multi-level dependencies and plenty of manipulators; complexity is implied. The resulting workload will inevitably destroy the comprehensiveness. However, failure to identify a risk in MedTech is fatal. A risk not identified is a risk not evaluated and therefore is a risk not treated. On top of that, all document-based approaches drop in comprehensiveness step by step due to transcription and copy errors, bureaucratic loops or simply files getting lost (IEC/ ISO 31010 2009, comp. Delligatti 2013).

RM that does not deal with the complexity of the analysed system and its likewise complex interactions leads to residual risk. This risk will likely appear in a later RM iteration in the product life cycle, but odds are it resurfaces as failure. In MedTech, that means people being harmed too often (Radermacher et al. 2004).

2.2 Uncertainty of Coverage

Usually, organisations do not possess a significant database of their legacy products which would allow them to build the probability distribution function or determine statistically sound risk probability (Škec et al. 2013). While uncertainties concerning with a single risk and organization can be faced with sensitivity analysis, solid documentation and risk communication (IEC/ ISO 31010 2009), the uncertainty of coverage cannot be dealt conveniently with these methods. The documents informing the RM panel about product breakdown structures of prior versions, application scenarios, functionality criteria or regulatory work come in all sorts of styles and formats, typically not accompanied by any quantitative estimate or calculation of error. The workload that would have to be shouldered to quantitatively equalise all demands, suitably discuss and agree on acceptable coverage levels and how to calculate their probabilities, operate the accounting and finally interpret, document and communicate the results, would be enormous and in most cases unbearable. In fact, QA departments regularly struggle with the straightforward task to find and execute measures for linear processes that can be agreed on from shop floor to top-tier of the organization.

2.3 No formalization of Risk Identification as Single Step

On the majority, organisations implementing general RM processes (as against applying RM by team or project) accomplish a reasonable overall level of standardisation. But taking a closer look at the singular steps often reveals them being executed in different manners according to their perceived importance and accuracy. It is perfectly human - though false - to assume that those steps dealing with exact values would need to be more formalised than the rest. Hence, the risk identification: the recognition of critical characteristics, are regarded as a primary stage of the risk analysis rather than a to-be-concluded step of a consecutive process. This bears consequences: substandard documentation quality, vague procedural instructions and lose ends in form of undiscovered critical characteristics.

2.4 Incompatibility of Results: Multitude of Techniques

Numerousness RM techniques are available on the market which all have their own procedures and dissimilar features concerning complexity, need for expertise, etc. (Grubisic et al. 2011). All these techniques are based on human observation, judgment and creativity. The selection of techniques follows those skills and, hence, depends on the skills recognised by the selector and, of course, his/her own skills. This chosen set has an effect on the hazard identification as every technique

has its own strengths and weaknesses. As no available method for risk identification can find all the hazards, a combination of the techniques is more likely to increase the chance of success (Redmill 2002). The selector may chose a combination of techniques that makes the best use of the panel's skill set, one that minimises structural information loss in the transcription of the documentation between techniques or try to find reasonable compromise. For example, in early RM iterations, when there is little known about a new product or a new version brings a major feature change, it is a powerful approach to let a Preliminary Hazard Analysis (PHA) in risk identification be followed by FMEA. Later on, PHA usually will not unravel sufficient detail. Although it still fits the panel's skill set, it should be exchanged for another technique. The selector will have to put up with one of the shortcomings or actually exchange the techniques after a fixed number of iterations and accept even more workload and incompatibility (IEC/ ISO 31010 2009, Škec et al. 2013, p.2).

In many cases though, selection of techniques is not an arbitrary process. Suppliers, authorities, operators, investors and many more bring their own choice of techniques or are themselves bound to standards and guidelines that favour different techniques than the ones considered by the selector. The amount of RM standards around is not beneficial to the selection process (Hall 2011, p.173). So as not to be misunderstood, we praise the line of thought behind most of these standards and guidelines, but the considerable differences in form and ingredients of RM processes they promote proliferates more incompatibility, which is surely contrary to the intended guidance.

2.5 Human Factor

Bias by design. Asking experts for their opinion is often the most promising way of adding new information to your RM process. Their contribution does not only depend on their expertise, but in large parts also on their social skills, creativity, professional background and readiness to judge. These factors are amplified when brought together (which is why an expert panel is worth more than the sum of its "parts"); fueling them will enhance coverage and outcome volume, but also the emergence of any bias held by the experts. For this matter, a biased expert should not be regarded as a liability though. Just as the condition carries negative implications like prejudice against other disciplines so it may feature perseverance at documenting controversial findings and also a certain sophistication in tackling problems. As long as the impact of the bias is clarified, it does not need to deteriorate the results. Again, this is where document-based RM fails. HAZOP, for example, strongly relies on the expertise of the product developers who involved in the RM process show to restraint pointing out flaws in and proposing changes to their own assemblies. The HAZOP structure, though, does not provide a form to record such behaviour and on this aspect proves quite vulnerable to bias.

Mindsets and value systems. Throughout the whole process, good RM actively entails multidisciplinary groups such as design engineers, clinicians, service personnel, and quality and regulatory personnel (Rakitin 2006). One important reason for it is the demand that product life cycle assemblies should not be treated as isolated technical systems as this could lead to missing recognition of the critical characteristics within the interactions (Schmitt and Zentis 2011). Yet, document-based RM approaches are very limited in addressing different professional mindsets. Very much the same way that forms which are used in one profession on a daily basis can perplex outsiders, mindsets might make the difference whether RM documents trigger whole trains of thought - or not. On that matter, coalitions do not always form along traditional departmental lines, because risk culture is influenced also by our value system. Engineers and pharmacologists usually work within feature-driven mindsets, whereas both surgeons and IT security specialists would by any means prefer to avoid failure. Much of a mindset is tacit and not communicated explicitly. This hinders capturing the reasoning behind decisions in interdisciplinary groups, especially in heavily-structured document-based techniques such as FMEA or Hazard Analysis and Critical Control Points (HACCP).

Environmental influence. Additionally, all consecutive steps of risk analysis - identifying consequences, evaluating their severity and determining likelihood of occurrence - are widely influenced not only by the choice of experts joining the panel, but even by environmental factors affecting the panel . Although as an experiment unlikely to be practical, one can easily imagine that the same panel with the same level of expertise, scope of knowledge, mindsets etc. analysing the very same device described by an identical documentation, just given a different time or place, would not reproduce the results of the risk analysis process (Redmill 2002).

2.6 Incompatible work environments

RM alongside the process chain implies confronting stakeholders with RM tasks in their own work environments. Although it is common practice for engineers and medics to collaborate in MedTech RM, they tend to know too little about each other’s daily routine. Whereas panel meetings are low on resources, implementing RM tasks conceived in a different work environment can be anything between discomforting and impractical. Missing software resources, regulatory restrictions, unknown routines or the absence of trained personnel can render simple requests impossible.

2.7 Poor Risk Treatment

In comparison to the steps in risk assessment, risk treatment has hardly been researched. A review of the existing literature showed its place in current research not to reflect its importance at all. Similarly, Oehmen et al. found that there is no scientific discussion on evaluating alternative treatment options. While their conclusions are about RM in general, our findings support them for the field of medical devices. Thus, the indifference towards improving risk treatment processes among scientists seems to level with those of practitioners. Both barriers: the fear of lowering ROI and the disinterest in evaluating alternatives, are so high that many decision makers consider the benefits of risk treatment as very low (compare section 1.2). Aversion to accept challenges such as high initial investments (time, money, personnel) and tedious tracking of treatment measures is evident and seems to grow with company size (Zentis et al. 2011, Zentis and Schmitt 2011).

3. About Model-Based Risk

> Model-based systems engineering (MBSE) is the formalized application of modeling to support system requirements, design, analysis, verification and validation activities beginning in the conceptual design phase and continuing throughout development and later life cycle phases (INCOSE-TP-2004-004-02 2007).

In that sense MBR is a construct that provides a structured model, independent of the type or classification of medical devices, supporting the risk management process by formalization and giving systematic guidelines to all the stakeholders during the whole product life cycle. As all RM documents would be generated in real time from the underlying model, MBR takes control over them away from stakeholders and panel members. This step drastically reduces human error and red tape, but also creates the need for a software layer between database, model and tools on the one side and human beings and their decision processes on the other, for all stages of a RM iteration. Figure 1 shows a rough scheme of the information flow in an iterative RM approach with such a software layer. As the process chain is continuous, a servicing point (a feasible point for recurring install of the MBR), conveys a virtual halt to start the iterative RM process at a certain status quo. From there on through all stages of the process, all input is strictly separated from the actual changes in model and database by the measures of the software layer tools. And while we acknowledge the potential for conflict and refusal to cooperate because of the perceived loss of control, we estimate that the advantages of ubiquitous access, an environment-sensitive display (e.g. an API for the tools you are already using at your workplace) and the bias-reducing uncoupling of content and contributor outweigh them by far. Experience from transfor-

mation in other engineering areas and also the INCOSE SE Visions support that estimate (INCOSE 2007, comp. Murray 2012).

RM alongside process chains means picturing RM stages as a sequence of events in an iterative process, which penetrates the continuous product lifecycle at what we have named servicing points. At each of these points in time, all risk treatment actions of the former iteration have to be finished, so all changes are fed to the model and its old version now becomes part of the database. As for the implementation of our MBR approach, we are analysing the potential of various UML derivatives. At the time of this article going to press, we are envisioning the launch of a SysML fork, as SysML seems to be most adequate in specification and documentation, but lacks some functionalities we need to consider for the human-machine-interfaces. It would also allow us to connect our MBR tools to IPT's in-house RM technique iFEM (innovative function-effect modelling). These techniques currently do not hold an underlying modelling language, but were planned with a possible SysML implementation in mind (Schmitt and Zentis 2011)

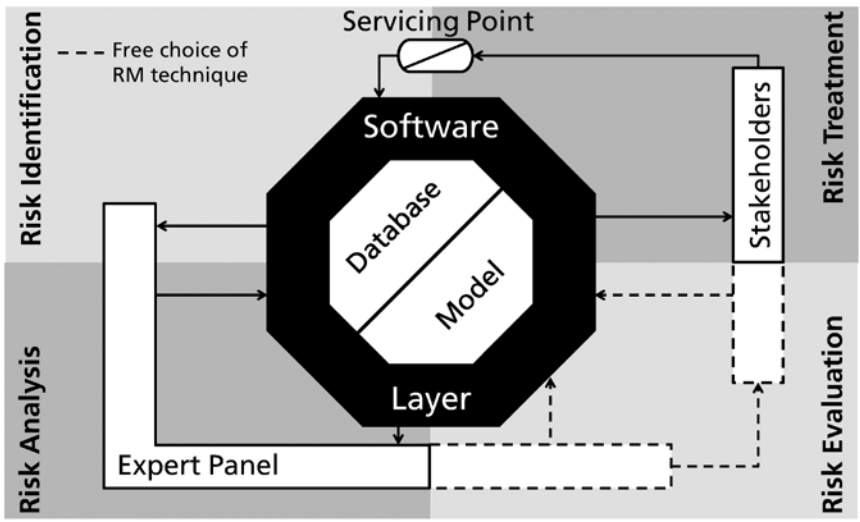

Fig. 1. MBR Approach with Software Assistance

4. Possible Improvements through MBR

With MBR, the deficits mentioned earlier (ch. 2) of a document-based approach can be addressed or at least be dramatically improved. The areas of opportunity span through all stages of an RM process and are be tackled with software tools.

4.1 Comprehensive Risk Identification

An organization already using MBSE is able (with some support) to provide a finite model of the whole product life cycle, which is the main requirement to start a MBR process. Others can transform their document-based information about the product life cycle into a valid model through data inquiry, e.g. parsing builds from CAD/CAE or human-machine interface (HMI) as in wizards.

We are establishing building rules for such databases including all relevant standards and existing best practice. As we aim to develop tools for a broad application for any kind of medical device, it is crucial to take all points of view of all stakeholders and all guidelines they follow into account. At the same time, all queries must be engineered in a way that excludes unnecessary data sets as early as possible, while guaranteeing to ask every question necessary to complete the model.

4.1.1 Nomenclature and Syntax for Human-Machine Knowledge Transfer

Every discipline has its own approach to specify a product using specific terminology well known in its field. As a consequence, every person from each discipline will have a different description of the same product. In order to keep the descriptions of known critical characteristics comparable by a searching engine, it is necessary to find a common terminology to reduce the inconsistencies of language. Our approach to this mainly consists of the following five parts:

1. A finite vocabulary of interactions. In this context, interactions are all actions occurring between one or more active components and any number of components influenced by this action. Users choose from a list of describing verbs with as few intersections between any two words as possible. This reduces the probability of list items being used synonymously. Nevertheless, any two list items are linked by a relevance value to encompass substitutional use when computing search queries. Suitable list items may come from a broad variety of literature, including international standards on manufacturing and machine tools, guidelines for implementation and maintenance of medical devices (e.g. implant check lists, user manuals for medical disposables), practical training and service material, manufacturer's instructions, health and safety plans and many more. For instance, in the standard DIN EN ISO 4135, estimates of the number of verbs used in modern English vary widely, but are almost always considered five digits. A feasible verb list should probably have some hundred items, but surely no more than a few thousand. So here, further literature review is necessary to decide on a short list that then can be interconnected with different long lists.
2. A set of adpositions clearing relation, location, direction, orientation etc. This set needs to describe each one-to-one correspondence between all physically and logically existing instances of components of the product life cycle in a

clear way that states how the instance pointed affects the reference (One component can have many logical instances, even pointing to each other) In comparison to the interactions vocabulary, this is a rather manageable task. Human language has a very limited amount of adpositions[1].

3. A finite list of possible component types within MedTech products. The standard ISO 15225 gives the requirement for the development of the Global Medical Device Nomenclature (GMDN), which is a generic way of supplying information to identify medical devices. The GMDN Agency, the organization responsible for development, control and distribution, is supporting us with their proprietary databases required for the licensing and registering of medical devices under GMDN. Their generic terms provide us with the “drawers of our cabinet, while our building rules decide where to place which drawer in order to receive short sorting times, a very important threshold when aiming for accuracy in human beings”. Plus, medical devices, whose predecessors have been classified and tagged in GMDN, will be much easier to sort in.
4. A hierarchic classification of MedTech products by function and application. GMDN's collective terms cover, among others, sorting by medical condition, application background or special features and by that allow us to classify assemblies in hierarchies from general to specific. Decision trees based on those hierarchies would reduce inquiry by cutting off branches irrelevant to the device. But even more important, the risk identification queries could contain straight dependencies that can retrieve cross-section information undiscovered when using only generic terms. For instance, peristaltic pumps can shear blood cells and hereby provoke clotting, which is one limiting design factor pumps for bodily fluids are subjected to. Classification under the collective term for the medical condition "renal failure" would make this a critical characteristic that needs to show up in risk identification. If, instead, the pump used for the application background "production of blood serum", where the blood is coagulated on purpose, it may be irrelevant.
5. A classification of possible application and maintenance cases. As we advocate RM alongside process chain, the whole product life cycle needs to be classified, hierarchically organised and fed to the product breakdown structure. GMDN's collective terms can help to realise this task for application and maintenance. Design and production phases are usually well-documented through CAD/CAM which we envision to be integrated using software interfaces and parsers. At present, we do not have a suggestion on dealing with the phases from obsolescence to disposal. Today, those phases are not in the focus of RM. But MedTech scenarios that may put them in focus like the use of nuclear materials or information sources for green markets in this case e.g. radiation protection rules or environmental compliance forms.

[1]While German and English feature several hundred, the about twenty to twenty-five in Spanish already exceed the needs of our syntax.

4.1.2 Identification of Critical Characteristics

After establishing a finite syntax to capture modelling information, modelling fragments may be received from CAD/CAM, guidelines, field data, whitelists, RM documentation from legacy products, or a wizard querying the user directly etc. and will end up in the database for known critical characteristics. In the next step, a highly customisable search engine will compute the identification of critical characteristics which lead to known hazards that then can be grouped on multiple levels, e.g. according to the potential sources of harm, and prepared for graphic display (Fig. 2). Our approach to model interactions of two elements as a new element within the breakdown structure allows us to treat them the same way than actual components. The identification tool will deliver comprehensive results which only depend on data quality and not on processing, sampling known critical characteristics for discussion in the expert panel and - just as important - alerting the panel of all lose ends, that is each node intersecting at least two components where no record was found. Results obtained in computerised risk identification are reproducible and comparable, added information can be traced in input/output tests. A change of information can be done in the model and automatically will spread the change to all the points related to it. In terms of cost, investments can be reduced as all documents are real time outputs of the underlying model and substantial parts of the risk identification/comparison process are switched from man- hours to more cost-effective compute-time, the better the data collected, the more so. Besides, compute-time is much easier to estimate than panel sessions, which reduces process delays and time pressure on the experts.

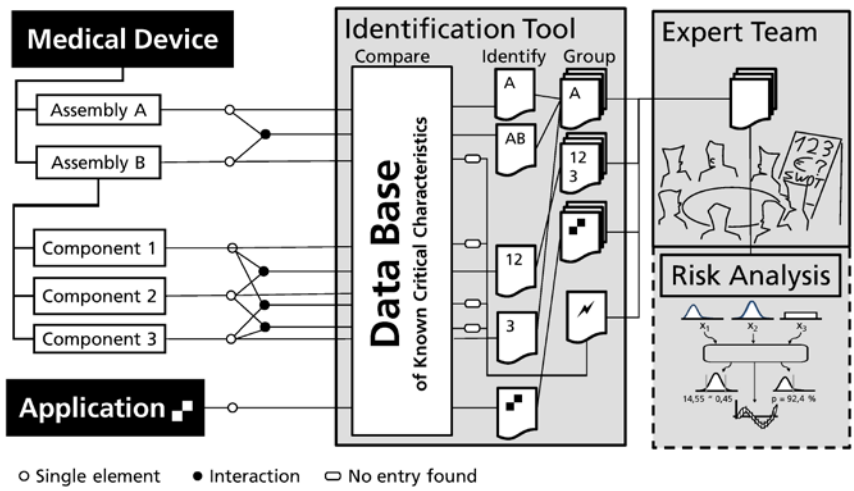

Fig. 2. Formalised Identification of Critical Characteristics

4.2 Statistical Control of Coverage

Database calculations allow for comprehensive coverage of known critical characteristics. Statistical tools can be applied revealing level of coverage, coverage probabilities and numeric error. Even though the database will grow steadily, there will be minimal process overhead and the time consumption will stay predictable. Computerised RM data makes it possible to statistically compare a RM project to similar projects giving RM stakeholders an idea which areas need more development as well as which areas are saturated, improving the impression of spread and profundity of coverage. An organisation computerising the search for known critical characteristics will gain more statistical grip with each product rolled out and each RM iteration finished.

4.3. Risk Identification as a Single Formalized Step

At this point, it is advisable to explain why we have chosen the structure of the more general ISO 31000 over DIN EN ISO 14971 even though it actually specifies RM application to medical devices. By no means is it meant to reject the guidelines found in each step, but rather highlight the importance of a self-consistent risk identification, as ISO 31000 does. If RM alongside the process chain is understood as iterative, the values of contained, consecutive RM steps become clear. Only a risk identification, whose inputs and outputs stay comparable when repeated, makes changes in risk measurable between iterations or set alternatives. Moreover, the question of how comprehensive risk identification has been managed should be answered while concluding risk identification and when RM participants still have the chance to reduce residual risk if the level is insufficient. In the scheme of DIN EN ISO 14971 comprehensiveness is not fully ascertained until entering risk control. We therefore prefer ISO 31000 in setting up an explicit formal risk identification step.

The structure of the MBR identification process is driven by software design, not by participants, allowing RM steps to be segmented clearly. All RM events are constantly decoupled from the model through a continuous software layer. RM participants are never to look at or change the model directly, but only through software tools. The inputs to each step are requested by RM design and entries can be traced back to participants. If RM events prompt information display or documentation, software tools will generate all documents on demand from the model. As long as an application programming interface (API) is provided, risk identification and analysis may be carried out by the panelists with any RM technique desired. APIs enable a formalised execution of the identification step in the panel while the software layer ensures the consecutive execution of the RM stages.

4.4 Comparable Panel Results

Different information gathering techniques will always produce different documents, a fact that is not changed by a model-based approach. Mode and motive of the experts' decisions are woven into the procedural protocol and it is hard to undo that fabric. However, what can (and necessarily must) be done by MBR is to detach the decisions from the documentation, as they are changes to the model itself. So, the vectorised model is not influenced by the methods used; hence, there is a free choice of information gathering techniques.

Resuming the example from section 2.4, the selector is now not forced any longer to choose between approximating a skill set or task. A model-based approach brings the synthesis of "hard" fact data that is stored in the model structure itself and "soft" meta and description data that offers information about the evolutionary history of both the component and its risk assessment. Any changes to the actual product or its lifecycle “mutate the model genome”; any generated document will automatically carry the change. The meta data makes changes traceable. Depending on the utility, the software layer could emphasise or withhold that information from the user. Writing information back, very specific descriptions and protocols can be saved in raw text in the database and be linked with the concerning element's unique identifier, keeping the model lightweight.

Furthermore, combining model and database allows us take advantage of the component and composite structure diagrams to compare possible treatments in input/output testing. While each component or even part or property of it stays traceable, interchangeable elements can be compared regarding to their impact on risk.

4.5 Human factor

Human bias is of negative impact to RM processes if it stays unidentified or produces a gap between a participant's capacity and willingness to perform. The latter can occur to the biased person as well as someone else whose disposition to contribute is affected by bias-driven behavior. A smart task design in MBR could reduce that impact by separating generation and evaluation of RM material in the panel from its reorganisation and display, helping participants to examine the current task without the inhibiting consequences to their or others' roles as stakeholders. Engineers could be more prone to accept changes to their designs and medics more open to discuss hints to application errors coming from medical laymen. Predetermined visualization obscures the origins of the risk identification data from experts, which should lead to a more objective view to complete data sets. For example, it is not relevant to the process of identifying critical characteristics if such a one is derived from field data or as a theoretic formation stemming from another RM process. Overall, an integration of all stakeholders through unified

visualization and ubiquitous access should diminish the bias or subjective thinking as it will serve database information to experts with clear and limited assignments.

The same mechanisms within MBR that help balance human bias can be used to integrate the different professional mindsets of stakeholders into an interdisciplinary RM process. The high level of formalisation we propose for the modelling syntax should assist participants in understanding what fellow panelists from other backgrounds want to communicate, while the possibility for raw descriptions assures each expert can express his thoughts as detailed as desired. Nevertheless, not all connotations can be saved in the procedure, as non-document-based RM still is text-based. For that reason it is still important to choose the RM techniques wisely according to the mindsets and work history of the participants.

Eventually, MBR will not eliminate all circumstantial effects on the RM process, but its ability to separate automate workflow from task design can support and enable RM to achieve better results, where we need the special faculties of human minds, as it can spare humans paper work and factor out human distortion wherever a computer can do the better job. We do not think of an MBR software layer as a way to replace human experts, but rather a front desk assisting them and letting them focus on their expert work.

4.6 Incompatible work environment

Because all documents would be generated in real time and at the interface requesting them, MBR natively supports all kind of API connecting it to the software already common to the different work environments. The latest versions of UML bring new features with the XML Metadata Interchange (XMI) specification, for the first time allowing porting of certain aspects not only on model level, but on code level between different modelling environments. Exchanging properties of model components in XMI will make non-trivial transformations dispensable and thus creating APIs easier.

As the model evolves through RM iterations, the transformation within the software layer needs to stay persistently linear, meaning all vectorisation (RM process -> model) and visualization (model -> RM process) must be reversible. It must be ensured that different, but congruent entries stemming from different mindsets automatically trigger the identical change to the model as well as that identical changes triggered by different participants would result in identical documentation and visualization.

4.7 Poor risk treatment

MBR can encourage decision makers to call for better risk treatment in two main ways: by immediately lowering investments exchanging expensive man- hours

and back office for computing time and by making information about treatment alternatives easier accessible and thus offering better estimates on ROI.

The drastic reduction on red tape and document management does not only express itself in lower cost, but also in time savings, which again will allow more servicing points alongside process chain with less side effects on latter. More servicing points stand for more iterations, so the model can be compared at different developmental stages; showing impact on ROI ahead of time. More time at hand also means that there is margin for running tests on alternative treatment options, at least for the most basic test of control and treatment. All this simplifies and safeguards the decisions about which risks need treatment or not and lead to the realisation of further required risk treatment.

5 Conclusion

The demands that the production of modern medical devices holds for RM can no longer be met by document-based approaches. The concurrence of higher complexity with shorter innovation cycles finds them more and more on the edge of operability. Besides, document-based RM does already not fulfill the requirements in the fields of comprehensive risk identification, predictability, interoperability of techniques, multidisciplinary integration of stakeholders and their work environments or RM enforcement throughout all stages. Our approach to combine modelling of the product life cycle with database supported RM procedures has potential to improve on these conditions. In the next step, software prototypes and trials against document-based RM will approve the assumptions.

Model-based system engineering is not the holy grail of production system engineering and MBR will not spare anyone the effort and expense of a well-designed RM process carried out by expert human beings. But in the best case, it can combine the strengths of human faculties and computing power and extract more comprehensive and numerically better assessable results from RM. Utilising this advantage throughout the product life cycle is viable path to safer medical devices.

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