First-class Risk Management from Second-Use Data Sources

How Intelligent Data Processing Could Make Risk Management More Efficient and Affordable for SMEs

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***Abstract*— In modern manufacturing, large data sets from different sources are permanently generated along the production chain. This data are supposed to be used to optimize products and production chains. However, in most cases, process participants only focus on acquiring data and leave it then to decision makers for interpretation. While there is nothing wrong with that on principle, comparable results might be achieved in a more efficient and productive manner by preprocessing already collected data and analyzing the outcome of legacy decisions. This requires connecting information from different sources within the product life cycle (horizontally: product stages, vertically: stakeholder – decision maker – implementer) and enriching models in an iterative way (comp. software engineering, consumer marketing). The goal of this paper is to describe how to use existing data in the industry in order to reduce the translation of "idle" information into failures in decision making. Often, critical characteristics have been discovered already, in a legacy product, a former product version or an abandoned project, and recognizing them in new product structures can be facilitated with IT-based quality management. In addition, the paper shows how intelligent selection and recombination of second-use data sources can help to detect and treat risks proactively, before adverse effects occur. Examples from our current research in risk identification for MedTech and during injection molding processes shall illustrate the fields of opportunities.**

Keywords— model-based risk management; MBSE++; IT-based quality; industry 4.0; medical technology;

I. INTRODUCTION

Especially small and medium-sized enterprises (SMEs) which are currently certified according to ISO 9001 and which want to keep this certification are facing a big challenge. Many SMEs in the manufacturing sector struggle to practice systematic quality and risk management (QM, RM) [1,2]. Most of the time, this is not a result of missing knowledge of decision makers, but attributable to a lack of resources and organizational experience [3,4,5]. Whereas big corporate groups maintain whole departments for quality assurance or risk management, product developers and project managers of SMEs are often operating the RM processes by themselves. While this is certainly an advantage in ever-shorter innovation cycles, it keeps SMEs from implementing labor-intensive systematic approaches [1]. The workload of classic approaches exceeds the proportional growth of the product lifecycle's complexity, which makes innovation drivers with complex products or such applied in complex networks (e.g. manufacturers in MedTech or automation) shy away from expanding their RM activities.

At the same time, more complex product lifecycles reduce the probability of a comprehensive RM process significantly, as subject complexity is likely to provoke uncertainty and errors in classic document-based RM methods and techniques [6]. An increasing number of parts, extended networks and complicated operation cases will also increase the number of stakeholders in an RM process; and that implies more data sources for product information.

This junction of several information sources regarding process and product risks is a special challenge in the context of industry 4.0. In modern production, gathering data for risk management is progressively characterized by an increasing target-oriented cross-linking of different systems and sensors: a big amount of data needs to be validated, merged and analyzed. Particularly in self-controlling production, the complexity of systems and models complicates a substantiated risk-assessment. Additional obstacles for the intake of risk data in the connected production are the lack of system-independent interfaces as well as the dissolving of clearly structured hierarchies.

This paper presents solutions for an efficient gathering and use of risk management data. Therefore, section II presents the relevant literature on the current risk management requirements and situation. Section III presents two approaches on how to overcome the shortcomings of the quality data generation concepts in use today.

II. Literature on Current Situation

A. Model-Based System Engineering

In nearly every innovative manufacturer's shop floor, Model Based System Engineering (MBSE) is fully implemented in all stages of production and throughout the process chain. Although many product models feature interfaces to pass-through related data (e.g. CAx-class software families), a product and its lifecycle will usually be captured in many different models throughout its development. There are miscellaneous reasons why SMEs cannot reduce the amount of applied product models to a functional minimum. In spite of their limited resources, SMEs are hindered from decreasing product model count by heterogeneous software environments where only a certain combination of tools brings the needed features, missing links in a software tool chain, software preferences of suppliers or customers that do not fit the own tool chain [7].

This diversity will very probably lead to inconsistencies at some point in the process chain, the more complex the product lifecycle, the earlier and more numerous. The plenitude of product models torpedos the biggest computational advantage of MBSE: providing a model as a single source of truth [8]. Instead, developers are working with parallel models that, with the first adaption, logically base on coexisting data structures, whose congruence and co-dependency are uncertain.

At this point, it is important to understand how the current situation of coexisting data structures evolved. Most product models follow a purpose-driven design that is described best by Stachowiak's pragmatic modeling approach. Once a model is introduced, its further evolution is driven by the users, be it through direct feature requests or pushed features that fill in functional gaps. The quality of the projection is secondary to functionality [9]. As a trade-off, these product models will cling to the professional mindsets of their prime users and hinder interdisciplinary exchange in the organization [6,10]. Now, model operators will even resort to press information from model-based systems into document-based data tools in order to communicate with other departments. Thus, it is recommendable to examine the models' state with the key criteria of the pragmatic model (purpose, context, method, functionality, user), as outlined by Steinmüller, rather than looking at the analogy of model and product [11].

Considering the pragmatic evolution of the targeted product models, standardization for information interchange is required to automate data processing. This is achieved by the Open Services for Lifecycle Collaboration (OSLC) [12,13]. With the definition of an OSLC Core Specification [14] the necessary support level to enable the built of open APIs is reached. The prospects for OSLC to establish a sufficient market penetration are good [15].

Bajaj et al. propose an extended model-based systems engineering across system lifecycle (MBSE++), which they demonstrate in their own MBSE platform *Syndeia*, linking a powerful SysML model of the system's architecture with product models, libraries and customer repositories. A sophisticated authentication management allows to feed and push information from all linked models [7]. Albeit *Syndeia* can assist in model-based risk management, its SysML core is designed to suit what they call a Total System Model that focuses on the junction of all software and hardware implementations. This approach does not fit the demands for analytical computation in complex RM models [10].

B. Risk Management in Product Lifecycle

A collection and analysis of all necessary information of product life cycle by a central module with a universal interface further allows an integration of the risk-based approach. Using different statistical methods, several risks in the production environment can be quantified and united to a decision relevant characteristic risk figure [16]. The analyses can include both the risk source as well as trends and future development and enables a preventive risk assessment. Many suppliers of quality management software already offer functionalities for risk management. This software usually includes single methods, such as an FMEA, allowing a statistical evaluation based on post measured product data [17]. However, the current software is not focusing on a standard-conforming risk management and is working reactively, not preventively. The joint of a generic system model with augmenting databases in a single-purpose module for quality and risk data analysis as it will be described in this paper, has not been established yet, since the concurrence between different system suppliers is high, which is why no standard software became accepted yet.

As aforementioned, another driver for IT-integrated RM is the growing importance of ISO certification as a supply chain requirement. The most relevant reform in the last revised version ISO 9001:2015 for companies (comp. ISO 9001:2008) is the demand for the implementation of risk-based thinking. This additional requirement affects many companies: an ISO-survey from 2015 showed that 1,1 Million companies are certified according to ISO 9001 and therefore need to prove or establish this concept of risk-based thinking [18]. Increasing network integration and multi-branched interactions of complex devices make for proportionately more products to become safety-critical [19].

Both approaches covered in this text follow the RM process scheme of the ISO 31000 family, even though we are aware that there are competing ISO standards for the affected target industries. Here, the demarcation of the RM steps and the differentiation between uncertainty and adverse effect[1] are the determining factors. Also, the assessment of RM techniques regarding subject complexity match our recommendations based on experiences made in earlier project in our research group [6]. Furthermore, the holistic definition of stakeholders stands for a point of view that embeds RM into the whole product lifecycle. Of course, all regulatory requirements that are based on rival standards, especially ISO 14971 in MedTech, shall still be met [20,21].

III. Description of the Approaches

Next, we will present two data processing approaches conceived in research projects with differing targets, one that

[1] in contrast to defining risk as constant negative

strives for comprehensive computer-aided risk management for complex products with safety-critical applications, here medical devices (A), another that pursues a cross-linked software system for quality and risk data as a service for safety-critical processes (B).

The underlying methods can be subordinated in the *Aachen Quality Management Model*; both will have the quality stream rise in all lifecycle stages[2], but method A is expected to have a bigger impact on the quality forward chain due to its focus in recognizing critical characteristics from legacy products, while method B is likely to deploy its strength in the quality backward chain, gaining decisive power with each analytical loop [22].

Both approaches are based on the theorical rationale that the more similar models are regarding their key criteria based on Stachowiak's General Modeling Theory, the more compatible are they in terms of interchanging structure-related information. While there are certainly more parameters influencing data flow between product models, the rationale holds up quite well for pragmatic user mindsets as found in professional environments like manufacturing, serial production or hospitals.

A. MBR Core

The model-based RM strategies for this project are engineered around comprehensive identification of critical characteristics[3] in the medical device's product lifecycle. The MBR Core consists of a generic RM model, whereof the individual product versions' models are spun, and a database system comprising expert knowledge linked directly to the concerning model element, fragmented legacy RM models and libraries of standards and nomenclatures used as framework for the model's semantic settings.

The MBR is designed as an iterative process, where each revision may consist of a sequence of one to all RM steps. While this is common in software engineering, it is very unusual for medical devices. However, we deem it an appropriate response to increasing device complexity and network integration [10]. A process flow of one RM iteration is illustrated in Fig.1.

The MBR Core is addressed by a single API, so that the user does not need to care in which part the data being displayed is stored. As it is crucial to the comprehensiveness of the RM process, the software layer blocks write access to certain parts of the core with a role-based access control mechanism (RBAC). For example, changes to the physical properties (adding a component to an assembly a.s.o.) would only be accepted by an authorized operator in the treatment step, whereas descriptive material (failure protocols, x-rays, etc.) may be added at any time. The RM operator can set servicing points alongside the whole process chain,

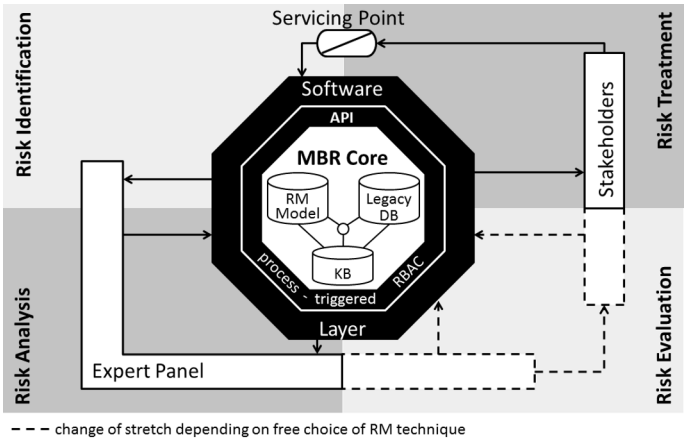

Fig. 1. Process Flow of one MBR Iteration

whereupon a new RM iteration starts and the current model version is transitioned to legacy. By this means, the change log of the model will feature a comprehensive list of all treatments and their impact. The element hierarchy follows the product breakdown structures as found in all major CAx and PLM tools. In SysML/UML, system boundaries or lifecycle stages may be set with packages, all elements within, such as assemblies, components or users, are represented by blocks with respective classes. The transitioning from CAx software tested so far works quite stable and we were able to finalize running XML formats. E.g. in a STEP-file (ISO 10303-21), analyzing the relative nodes and counterchecking with geometrical proximities, has shown to be satisfyingly reproducible.

New is the usage of an own block class for interactions instead of relational elements; that way interactions can be equipped with all attributes needed. The relation is expressed by a parent/child (composite) connector.[4]

Elements of the physical product can be tagged with approved industry classification; in our MedTech test cases we chose the Global Medical Device Nomenclature (GMDN) for assemblies[5] and a custom-made code for components based on the terminology of the Unified Medical Language System (UMLS).

All OSLC-compliant properties can be assigned to the model elements directly via our MBR Core API, non-compliant product information may be added through our model wizard (in the software layer), if it can be put into computable attributes. The remaining information that is deemed helpful to the RM participants, be it text or binary, may be stored in the database (KB), interlinked with the related model element. And because interactions are modeled as elements in their own right, risk analysis can be augmented with legacy information, if a critical characteristic is rated sufficiently similar in the risk identification [23]. For example, chemical abrasion as an interaction of a liquid with a tube

[2] The quality stream is the entity of all quality activities, which help to transform client-side requirements into company products, consisting of a quality forward chain per product and a common quality backward chain for all field data.

[3] A characteristic is critical, if its noncompliance with a safe state or value bears a hazard.

[4] Thus, an interaction block with only one parent may be describing a critical characteristic affecting the very element, like wearing.

[5] as they are often already registered under a GMDN code

could be illustrated with pictures of a leakage from a similar product application.

All descriptive data are attributed to the unique identifier(s) of the affected model element(s) in order to serve as briefing information for potential critical characteristics. While it is possible to operate the MBR Core from the software layer alone[6], the open API[7] facilitates the integration into software in stock. Then, all necessary views and documents can be generated and augmented in real time without the need for the user to leave their accustomed working environment [23].

B. Quality Data Module

In the second approach, which was developed in the research project *quadrika*, risk analysis is executed by a cross-linked software system. This approach is not designed for a special industrial sector and can theoretically be applied everywhere, provided that a usable IT infrastructure is available. Nevertheless, it will tap the full potential in implementations that combine safety-critical processes with the need for prompt decisions.

For a junction and joint analysis of the data from different software systems, a central, so called Quality Data Module (QDM), was developed, as it is shown in Fig. 2. In the QDM, data are collected from all departments and their sources, e.g. MES, CAQ, CRM, ERP or PLM. It includes historical and legacy as well as real-time data.This data is the basic requirement for the further risk analysis. The QDM risk management flow is shown in Fig. 3. It is a continuous improvement process and consits of three repeating steps:

1) Process Analysis

First, critical product characteristics are determined by analyzing data extracted from the Failure Mode and Effects Analysis (FMEA), which is already established in many companies [24]. In addition, expert interviews are conducted to determine critical product characteristics. For these identified, critical product characteristics, the belonging processes and environmental parameters that directly influence the product characteristics, need to be detected. This is realized by means of historical process data of the CAQ and MES, which are analyzed both manually and through a pattern recognition algorithm that is integrated in the QDM. As this algorithm is currently being developed, the product-process analysis is not fully automated yet. However, it is the aim to forgo the manual analysis.

After the analysis of the processes and environmental parameters, which directly influence the product characteristics, all indirect parameters and processes are detected and summed up in a cause-effect-diagram. The processes and parameters of the cause-effect are traced back to their fundamental cause according to 5M method (man-power, method, milieu, matter, means) [25]. For each process of the cause-effect-diagram, specification limits are determined in between which the processes do not cause any risks.

[6] The SysML/UML 2 parts are here represented in XML code, compatible to Modelio.

[7] PHP 5, Javascript with JQuery 1.11

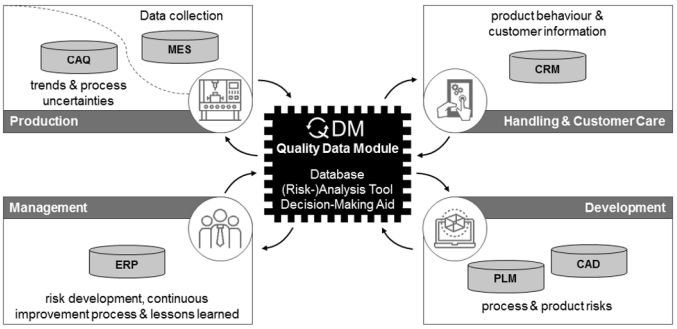

Fig. 2. Quality Data Module as Platform between Several Departments

These limits are also extracted from historical data. Moreover, process patterns and trends causing risks are analyzed. This analysis is again done both manually and with the pattern recognition algorithm. This way, the process analysis creates a causal network, which shows how errors arise. The causal network is the basis for a preventive risk management.

2) Scenario-Based FMEA

The identified causal network of the process analysis (step 1) is the basis for scenario-based FMEA. The aim of the scenario-based FMEA is to minimize both risk and life cycle costs. Therefore, occurrence probabilities for fundamental risk causes and process patterns are calculated. Then, conditional probabilities of direct and indirect effects of each risk cause and pattern are calculated. In a third step, costs of each failure scenario (including the risk cause and all direct and indirect effects) are calculated. These could be costs for production stops or product callbacks, which resulted from the failure scenario. Both probabilities and cost data are gained by analyzing historical data of CAQ, MES, CRM or ERP systems.

To finally standardize the risk and therefore be able to compare the risks with each other, a characteristic risk number (CRN) is calculated as follows:

$$CRN = p\,(cause) \times p(effect \mid cause) \times C_{Failure\ Scenario}$$

where p is the probability of occurrence and C the cost.

The standardized cost based risk number CRN of different failure scenarios is dimensionless. Since multiple risks can occur at once, QDM needs to prioritize risks and their measures. The CRN allows a risk ranking and prioritization based on the costs a failure would cause. Currently, many companies use the risk priority index to compare risks which each other. This index is the product of importance, probability of occurrence and probability of detection of a failure. However, many experts doubt the expressiveness of this index and are increasingly discouraging the use [24]. Therefore, this new characteristic risk number was established for the QDM.

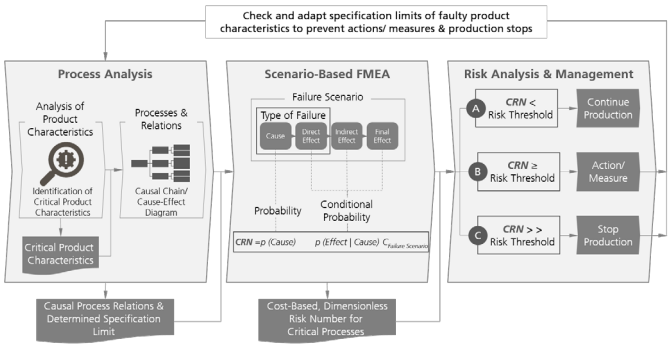

Fig. 3. Risk Management Flow of the QDM

3) *Risk Analysis & Management*

By means of the calculated characteristic risk number of scenario-based FMEA, risks are evaluated in the third part of the risk management model. Therefore, a risk threshold needs to be defined individually for each process in advance, including costs of potential measures, production stops or callbacks of defect products. These costs are also taken from historical data.

QDM compares the CRN with the defined risk threshold and serves as decision-making tool by giving the following recommendations:

1. CRN < Risk Threshold: Continue production
2. CRN ≥ Risk Threshold: Take action
3. CRN >> Risk Threshold: Stop production

In case of scenario two (CRN ≥ Risk Threshold) or scenario three (CRN >> Risk Threshold), QDM sends a signal to the worker and either stops the machine or, at best, takes counter measures so that the process continues without failure. Then it needs to be checked whether an actual risk occurred in the process. In case that no actual risk occurred, the specification limits for the processes can be widened (step 1 of the risk management model), so that unnecessary additional measuring or process operations are reduced.

Consequently, QDM fulfills the requirements of the ISO 9001:2015. By analyzing processes and giving back aggregated information to management, production, development and customer care, the risk-based thinking approach is achieved.

IV. Data Selection Criteria

As mentioned above, we consider Stachowiak's pragmatic modeling approach [9] as the best option to conceive RM models of complex product lifecycles. His reduction principle sacrifices a model's refinement in projection wherever it would depreciate its fitness for purpose unreasonably. In terms of RM data selection then, attributes are rendered unnecessary wherever their computational deadweight is not outperformed by their informational value to the RM process. All generic RM models will have to adhere to this policy by implementing respective selection criteria.

The principle data selection strategy of the MBR Core follows the division principle of RM model and descriptive database explained in section III A. In complex product lifecycles, all "unnecessary weight" added to the model will increase computing time in multiples slowing down all queries and tuning searches for semantic similarity with legacy model fragments will be complicated by bloating results with false positives that show similarity, but have no effect on critical characteristics.

Data that helps to locate, describe and (mathematically) evaluate critical characteristics is integrated in the RM model, while all remaining information may be brought into the descriptive database at the discretion of the user, provided it can be linked to a model block element. The former criterion can be subdivided in four categories defining the data on a modeling level:

- *Structural Data*
  - hierarchical data shaping the physical product and product lifecycle, e.g. product breakdown structure, topology, application scenarios
  - relational data shaping the interactions in product and lifecycle, e.g. use cases, process parameters, supply chain meta-data

- *Content Data*
  - attributes influencing the critical parameters, e.g. dimensions, material properties, quality criteria
  - medical classifications, e.g. GMDN codes and terms, UMLS terms

For this purpose, we are developing building rules that are based on a matrix crossing the dominating product models and current data interchange standards with inclusion criteria and data types and formats.

Besides the informational criteria, there are also technical restrictions that act as exclusion criteria which – while sometimes acting as a barrier for actually desired data – are intentional to keep the model lean and tidy. There is restricted entry to the model to data that either exists in an OSLC-compliant form or can be brought into by the operator via the model wizard. Here, OSLC secures comprehensiveness by making sure that all selected information from compliant product models is echoed in the RM model. The self-restriction to only three modeling elements from SysML/UML 2 – packages, blocks and composite connectors – simplifies the model fragmentation. Technically, it operates as an exclusion criterion, too, as no data can enter the model that cannot be expressed as an attribute of said elements. Virtually, the implications will be minor; it is expected that the affected portions of product model data will be minimal.[8]

The data, which will be integrated in the RM analysis of QDM, is selected with a similar strategy as in MBR Core, also

[8] However, this is only an educated guess. At the deadline of this paper, analysis is still under way.

pursuing the goal to reduce "unnecessary weight". As it is described in section III B, data is selected based on critical product characteristics, which are determined manually by FMEA and expert interviews. Second, processes and environmental factors that influence the product characteristics are identified using historical MES-data. Then, causal chains between product characteristics, processes and environmental factors are detected and traced back to their fundamental cause according to 5M. To keep the QDM-computing efficient, collected data needs to be reduced as much as possible. Therefore, only data of processes and environmental factors that are part of the detected causal chain are integrated in the QDM. Moreover, the recording interval of the data will be set as big as possible to further decrease the amount of data. The interval has a big influence on the total amount of collected data and totally depends on the considered process.

As the QDM is currently still being developed, the processes, as well as their specification limits are entered in the QDM by hand, based on the prior analysis as it was described in this paper. For the future, it is planned that this step is done automatically through the pattern algorithm, meaning that the detected processes, environmental factors and their specification limits are transferred in the QDM.

By improving the risk management process continuously (see Fig. 3), the necessity of the data is double-checked. In case that some of the data is not needed anymore for the risk analysis (e.g. due to a wrong causal process chain), this data will not be collected anymore, meaning the QDM-computing of the risk analysis gets more efficient. This is as well done by hand for now but should be done by the pattern recognition algorithm in the future, meaning that if the algorithm has not realized any failure due over a certain period of time, data will not be tracked anymore.

V. Conclusion and Outlook

Ever more complex product lifecycles, enabled by an increasing digitalization, impede RM process significantly. However, it also means that there are sound sampled second-use data at hand, so digitalization can open opportunities to improve and systematize risk management processes as we propose with our approaches.

The first approach aims to tackle the deficits in comprehensiveness and cognitive uncertainties that arise from the coexisting verities in product models with an iterative RM process inspired by software prototyping. The MBR Core is fed by low-threshold data processing that picks up stakeholders in their specific professional environment thanks to an OSLC-compliant API that allows to augment product lifecycles with very diverse information on critical characteristics. Furthermore, it offers the possibility to integrate data from suppliers without the necessity to acquire additional tools. This allows for quick respond times to changes, while it keeps cost on software, training and IT maintenance down and increase the ability to respond to changes and increase productivity.

In the second approach, a central data module, the QDM, was established. This data module serves as database and risk analysis tool at the same time. It analyses critical processes and controls or stops the process in case of an occurring failure. Through proactive risk and fault management, the system will not only reduce rejections, but over time also the number of measurements in the process chain. Thus, it increases the product and process quality and decreases production cost.

Both approaches, the MBR core and the QDM, not only improve the risk management in SMEs, they are also fit to build the procedural RM basis for an ISO 9001:2015 certification. The postulated risk-based thinking is proliferated by reutilizing and processing already acquired data that would otherwise lie idle. Pitted against massive and expensive QM schemes, they may help levelling marketing conditions, where big corporations are favored by regulatory necessities, and to keeping products of SMEs competitive.

Besides the economical and organizational advantages for SMEs with limited QA resources, we are confident that – medium term – model-based RM will drive the internalization of safety-critical systems engineering. On the long run, it will contribute to integrate risk-based thinking in all stages of the product lifecycle.

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