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A METHOD TO EXPLORE PRODUCT RISK IN PRODUCT LIFECYCLE MANAGEMENT OF CONFIGURED PRODUCTS

R. Riascos Castaneda [1]✉, E. Ostrosi [2], T. Majić [3], J. Stjepandić [4] and J.-C. Sagot [2]

[1] Roche Diabetes Care, Germany, [2] Université Bourgogne Franche-Comté, France, [3] Croatian Academy of Sciences and Arts in Diaspora and Homeland, Switzerland, [4] PROSTEP AG, Germany

✉ roberto.riascos@gmail.com

Abstract

Today high quality and low product development turnaround time are company-wide priorities. Quality supporting processes such as an effective risk management system shall support continuous business running and meeting the goals of an organization. In this paper, an approach is presented on how to integrate the product risk management in Product Lifecycle Management for configured products by definition of an additional software module and its implementation.

Keywords: risk management, configuration management, configured product, product lifecycle management (PLM)

1. Introduction

In today's highly competitive market environment, particular attention must be payed to quality issues such as malfunction and inadequate performance, because a modern product emerges by implementing challenging requirements with a short timeline. That is a natural concomitant which appears in the enterprise's activities at all levels, what is called risk (Aven, 2012). This is the environment in which act a medical device manufacturer. Regulators have increased their abilities to receive information electronically thus enhancing their speed and ability in analyzing vast amounts of data. Medical device manufacturers need to be doing the same enhancements to speed and ability. Medical device manufacturers need to use these new abilities to look forward and predict risks. They need to be able to understand their own product quality and react to faster than regulators (Manz, 2019).

Due the significant potential impact of risk factors on enterprise objectives and the incapability to be entirely detained by the organization, risk management is a downstream process within strategic and operational management of the enterprise which implies the completion of the whole cycle of risk assessment (Aven and Zio, 2014). Uncertainty is a state when a decision has more than one possible outcome and in which the probability of the occurrence of each specific outcome is unknown or even meaningless. This may be due to insufficient information and knowledge from the past or the instability of the structure of the variables. Risk can also be defined as the intentional interaction with uncertainty. In reality, complete information and total certainty are very rarely encountered in the economy. In any case, neither economic life as a whole, nor particular economic processes, and in that context processes that occur in basic economic units such as a company or household, cannot be fully considered without taking into account uncertainty and risk (Pongrac and Majić, 2015).

Risk is the state in which the decision has more than one possible outcome and in which the probability of each specific risk is known or can be assessed. The likelihood of any possible outcome can be assessed from an earlier experience or from a market evaluation. The greater the variability (ie the higher the number and the broader the range) of the possible outcomes, the higher the risk is associated with the decision or the action in a given scenario (Pongrac and Majić, 2015).
Although the risk is an integral part of the business, in particular in medical device industry, it is necessary to know how to manage the risk by making informed decisions based on modern analyzes of quality data. Understanding data is extremely important, mostly because it helps to identify and understand potential opportunities, but also to minimize the risk of entry into business ventures that do not have coverage. Without the insufficient understanding of the data and the appropriate methods for data analysis, the most common results can be detrimental to the company (Pongrac and Majić, 2015).
Configuration describes the functional and physical characteristics of existing or planned hardware, firmware, software or a combination there of as set forth in technical documentation and ultimately achieved in a product (Rusu, 2019). Configuration management (CM) is one of eight subprocesses within the crosscutting technical management process for establishing and maintaining consistency of a product's performance, functional, and physical capabilities with its requirements, design, and operational information throughout its life (Stjepandić et al., 2020). CM applied over the life cycle of a system provides visibility and control of its performance and attributes. CM verifies that a system performs as intended, and is identified and documented in sufficient detail to support its projected lifecycle (Figure 1). It ensures the system integrity over the time (Stark, 2019).

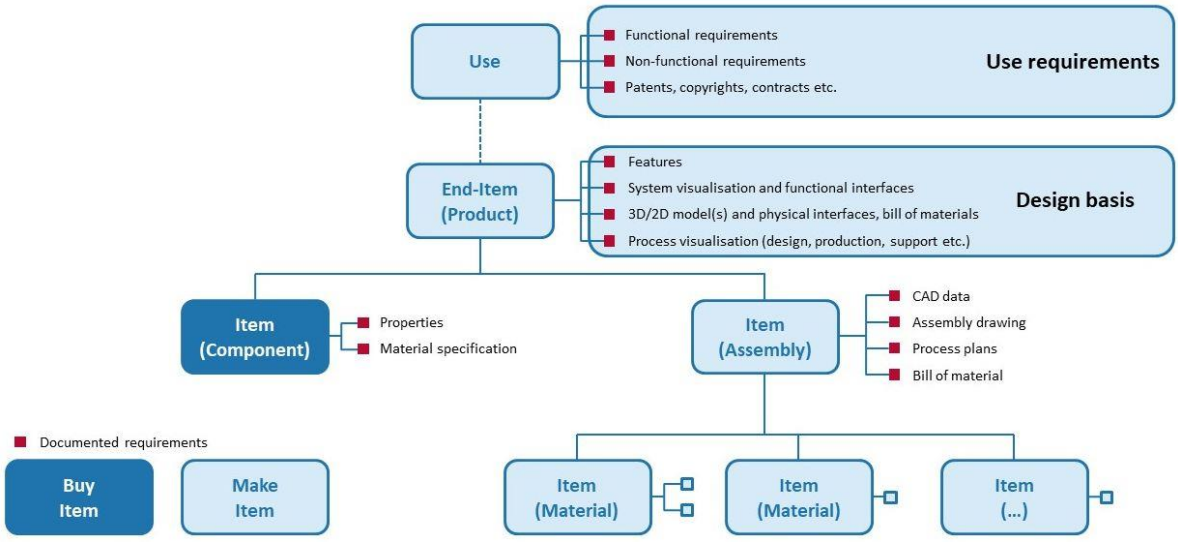

Figure 1. Usage of configuration management in PLM

CM helps to drastically limit the number and cost of changes: (1) Link, trace and version data sets throughout their life cycle and in their context of use, (2) Carry out a reliable analysis of the overall coherence and impacts in the event of evolution or modification, (3) Automate and secure the process of managing changes in development projects and in mass production (Stark, 2019).
One of the powerful means for a good configuration management lies in the modularity. It is a relevant way to meet customer requirements with a wide range of variety and customisation of products, from unique to standard ones. Modularity can intersect technical aspects with the business aspects. The use of modular technology has wide-reaching implications for any design and development company that undertake to use this paradigm. In the context of engineering, modularity combines technical aspects with business aspects, both from a qualitative and a quantitative viewpoint and can be also applied to methods and processes (Ostrosi et al., 2014).
In this paper we answer the question how to explore product risks in Product Lifecycle Management (PLM) of configured products. The research methodology consists of five stages: (1) theoretical foundation, (2) identification of needs, (3) architecture design for a solution, (4) implementation, (5) test and operation. The remainder of this paper is structured as follows: in Section 2 the background is

given, followed by the description of the solution concept in Section 3. In Section 4 the implemented solution is presented, Section 5 summarizes the conclusions and outlook.

2. Theoretical foundation

2.1. Configuration management and modularity

Configuration Management captures the functional relation between parts, subsystems, and systems for effectively controlling system change. It preserves the verification that proposed changes are systematically considered to minimize adverse effects. Changes to the system are identified, proposed, evaluated, and implemented using a standardized approach that provides consistency. The proposed changes are evaluated against their anticipated impact on the entire system. CM verifies that changes are conducted as prescribed and that documentation of items and systems reflects their true configuration. A complete CM program includes provisions for the storing, tracking, and updating of all system information on a component, module, subsystem, and system basis (Stark, 2016).

CM is the activity of documenting initial product specification, controlling and documenting changes to these specifications. CM is a formal discipline to help assure the quality and long-term support of complex products through consistent identification, and effective monitoring and control, of all of this information. ISO 10007:2003 (ISO, 2003) provides guidance on the use of configuration management within an organization. Applicable across the product lifecycle, it describes the configuration management responsibilities and authorities, the process and the planning, as well as the four activities of configuration: identification, change control, configuration status accounting and configuration audit (Stark, 2016). Thus, many companies use configuration management in order to establish consistency with requirements, ensure accuracy of meeting targets, and maintain performance throughout a product's entire lifecycle.

The modular product design heavily supports CM by reducing the complexity to a lower extent. Interoperable medical systems and their associated components may be developed, operated, and maintained by many different organizations. Such systems may be built using platform concepts designed to facilitate reuse of both platform infrastructure and assurance artifacts when the platform is used to build different systems (Hatcliff et al., 2018). From the managerial perspective, odularity can be seen as a business strategy for efficient design and structuring of complex products, procedures and services with the objective to rationalize the enterprise. By now, modularity can be considered a basic development methodology inside the product strategy for a variety of technical Product and Product Service System designs (Sun et al., 2017). The integration of different product variants does not come with any monetary benefits if it is not organized through a holistic controlling approach. Cost schemes of modular products can also be established by decomposing the product family into generic modules to support cost calculation (Raudberget et al., 2019). Thus, enterprises use configuration management in order to establish consistency with requirements, ensure accuracy of meeting targets, and maintain performance throughout a product's entire lifecycle.

The concept of an intelligent product should maximize the design space of architects and system designers. How to design intelligent modules is an important issue related to the design of intelligent products. Thus, the development of intelligent multidisciplinary collaborative and distributed platforms can better handle the modularity and variant management problem. The multi-agent paradigm has the potential to respond to this challenge and to pave the way for the introduction of innovative technologies in a dynamic environment characterized by important changes and evolution.

The design of a modular product is considered to resolve a system-based interdependency problem. The modular design should be the result of a coherent and rational design process, where the options, modular or integral, are explored early, in response to technical constraints and the set of requirements. A task in modularity assessment is also the increasing the effectiveness of modularity which should be supported by all down-stream business processes (e.g. change management, risk management).

2.2. Product risk management

Risk management is a process that identifies, assesses and processes risks in given scenarios by using consistent and repeatable procedures to base the report on and to monitor risky activities. Risk management does not endeavour to eliminate risks, but create an environment in which optimal business decisions can be made taking into account the identified risks and develop potential risk management alternatives and determine their associated costs and benefits (Pongrac and Majić, 2015). An overview of the risk classification is given in Figure 2.

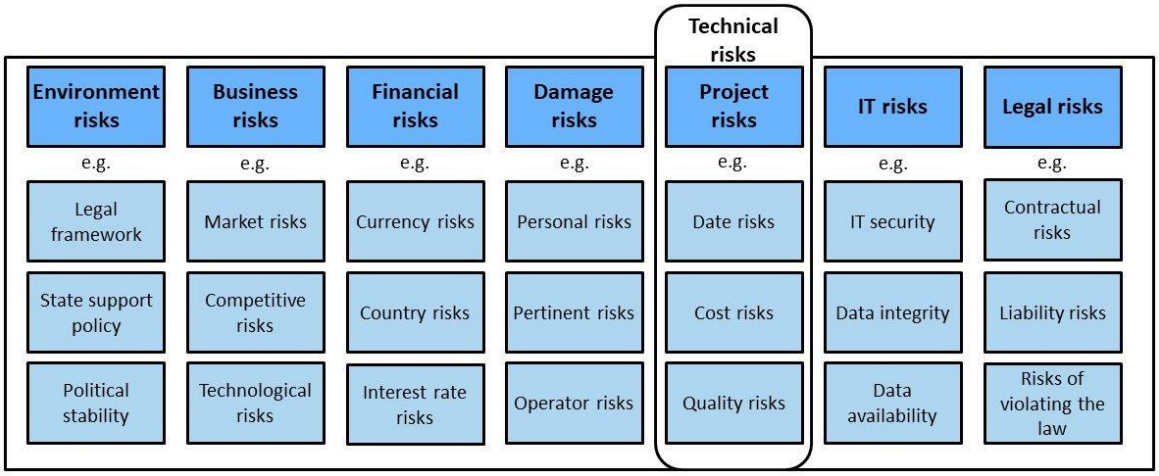

Figure 2. Risk classification

Once the risks are identified and passed through the above procedures, it is very important to choose the appropriate technique that will effectively remove or control exposure to risks. Basically, there are, four potential responses to risks (acceptance, avoidance, control, transfer). Trade-offs mostly are necessary. Frequently, Trade-offs can provide accepting a smaller known cost in order to reduce a potentially larger unknown cost (Pongrac and Majić, 2015).

For a technical product such as medical device, while the main objectives are the patient health and human life, the process risk management must run through the lifecycle of the medical device to avoid potential hazards. Product Quality Metrics will be used increasingly in the future to add additional data that paints a clearer picture of product quality risk (Mainz, 2019).

ISO 31000 is a basic standard for risk management (ISO, 2018). Specific for the healthcare, ISO 14971 is the standard for "Application of risk management to medical devices" (ISO, 2012). It describes a risk management process designed to ensure that the risks associated with medical devices including in vitro diagnostic (IVD) medical devices, are known and controlled and that they are acceptable in comparison to the benefits (Teferra, 2017). The requirements of ISO 14971 are applicable to all stages of the lifecycle of a medical device (Flood et al. 2015). Both standards are implemented by using appropriate reliability methodologies (Table 1) such as Failure Mode and Effects Analysis (FMEA).

FMEA is an analytical method used during development and planning to analyze and avoid potential risks that are applied at system, design and process levels (Kirkire et al., 2015). During the planning phase, the FMEA should detect potential errors during the development of a product and avoid them by taking suitable measures. It evaluates and mitigates the potential malfunctions in a system, process, design or service according to their significance for the customer, their probability of occurrence and their probability of discovery, each with a key figure. Furthermore, with the help of the FMEA, it is possible to systematically collect and make available existing knowledge of error contexts and quality influences.

FMEA also serves to systematically analyze existing defect images and thus enables product or process improvement after the planning phases have already been completed. The systematic approach is supported by forms to document the results (Zhao and Bai, 2010). A distinction is made between design, process and system FMEA, which share a similar approach. It is an effective quality improvement and risk assessment tool widely used in practice (Leimeister and Kolios, 2018). FMEA and ISO 14971 risk analysis receive the most attention from manufacturing companies; therefore,

FMEA is used as a prevention and improvement tool to analyze the risks in the medical product development process (Kirkire et al., 2015). The risk during each stage and the associated consequences related to its occurrence were discussed with the development team. Calculation of risk priority numbers (RPN) for identified risks as prescribed by ISO 14971 (ISO, 2012) guidelines for risk analysis is one noticeable step in FMEA to prioritize the failure modes. RPNs are determined by an evaluation of three factors: occurrence (O), severity (S) and detection (D) (Kirkire et al., 2015).

Table 1. Excerpt of reliability methods (Leimeister et al., 2018)

Method	Results	Capabilities	Limitations
FMMA, FMEA, and FMECA	FMs	Easy implementation; employable from the beginning of the project	Competent facilitator for reaching consensus in scoring is required
Quantitative FMEA	Prioritisation of FMs	Straightforward application due to well-defined bands of scores	Appropriate scoring for different classes of application
Correlation-FMEA	Weak points	Coping with mutual correlated FMs	Complexity in case of multiple FMs
Threat Matrix and FMECA	Components requiring high reliability or good maintainability	Visual representation of FMs and associated consequences	No incorporation of detectability factor in 2D representation
FTA, ETA, and BBN	Decision making	Visual representation of interdependencies of events	Cumbersomeness in case of highly granulated system analysis
Dynamic FTA	Maintenance references	Coping with sequentially dependent and redundancy failures	Effect of inappropriate sequencing of events on analysis results
BTA	Real time risk monitoring	Efficient link of ETA and FTA; visualisation of dependencies	Common cause and dependency failures
HAZID/ HAZOP	Monitor integrity; operational risk factors	Structured description of hazards and system effects of deviations from design intent	Extensive documentation; only to be applied to well-defined system

2.3. Product Lifecycle Management (PLM)

Product Lifecycle Management (PLM) is widely understood as concept for the creation, processing, storage, and retrieval of data, information and, ideally, knowledge throughout the lifecycle of a product from its conceptualization or inception to its disposal, recycling or recovery (Lämmer and Theis, 2015). PLM is seen in the industry as one of the core concepts to fulfil a number of business requirements in the manufacturing industry with respect to the completeness, high transparency, rapid accessibility and high visibility of all product data during a product's lifecycle (Pfouga et al., 2018). Those requirements also are related to financial aspects like cost management and revenue growth, to the product itself like innovation, competitive functionality, time to market, quality and high productivity, and to regulatory aspects as compliance, product risk management and documentation. PLM is implemented by deploying IT systems like Product Data Management (PDM) systems and induces a high level of interoperability of related applications. With PLM industrial companies attempt to gain advantages in shorter cycles, lower costs, better quality by avoiding errors and misunderstanding (Lämmer and Theis, 2015).
In modern PDM systems, the overall structure of a modular product is mapped in a generalized product structure (Baylis et al., 2018; Bruun et al., 2015). Alternative or optional items are initially managed in the database of PDM systems in the same way as all other items, i.e., items as master records with corresponding attributes. Differences to the usual article management arise only in the structuring of the product in the form of bills. Through the use of variants in product structures, PDM systems are able to manage order neutral BOMs with varying and optional positions. This approach is beneficial for product development, and less for production and accompanied departments, because explicit BOMs are needed for each product variant to be produced. Furthermore, there is a risk that data management is very complicated, while compromising the performance of the system needs to be tolerated, especially when a

large number of product variants need to be managed. To resolve these conflicts, modern PDM systems are extended by the variant manager module (Riascos et al., 2015). In the base module, all master data (parts, structures and processes) are managed. In the case of variants, explicit ones are derived by the configuration and clone modules. For risk management, a coherence of the single-part-related risk estimation (e.g. FMEA) with a certain product variant is necessary. This can be fulfilled by an application which conducts FMEA calculation for each part in the product structure and, afterwards, generates a product FMEA parsing each variant by using appropriate product FMEA reports.
Under the term mass customization, a business strategy is defined that utilizes modular design for complex offerings of products and services that are configured on demand to achieve the best fit with customer-specific needs (Stark, 2016). Generally, a fixed and a variable area of product structure can be identified, in which mandatory and optional spaces are foreseen for individual implementation. Product customization is usually supported by configuration systems (Custódio et al., 2018). Integration of risk management supporting methods like FMEA is also possible.

3. Solution concept

Following to the overall concept of PLM, the demand is given last but not least by regulatory rules (Hatcliff et al., 2018). For our purpose, a solution which continuously maintains the relationship between PLM and risk management is necessary. Like for similar demand, it is supposed to be a module which makes products risk management an integrated value adding component of the product development. Product risk management, modularity and PLM are related fields of engineering that can ideally be combined in a process chain and implemented as a technical solution by a software module which works on PDM data. Complete product with all variants and instances lies in focus - with no gap in the timeline between the first idea and disposal. A market study has discovered many tools for risk management on a high level of abstraction, in particular for project risk management, but no one commercial tool which handles the product risk management under PLM, in particular for PTC Windchill (Ostrom and Wilhelmsen, 2019). Therefore, a proprietary solution based on standard tool set must be drawn and implemented.
Since the authoring systems (MCAD, ECAD etc) are tightly coupled with PDM systems, the risk treatment and monitoring should be initiated on the level of singular parts and assemblies during their development. In this context, another opportunity could be an analysis of risks that may arise due to errors caused by improper usage of complex modelling and analysis processes and procedures. We consider a solution which builds the product risk line based on risk case and supportive information (Figure 3). Such a tool must be available for risk managers at desired time and provide functionality for the entire product as well as each extent of the product structure.

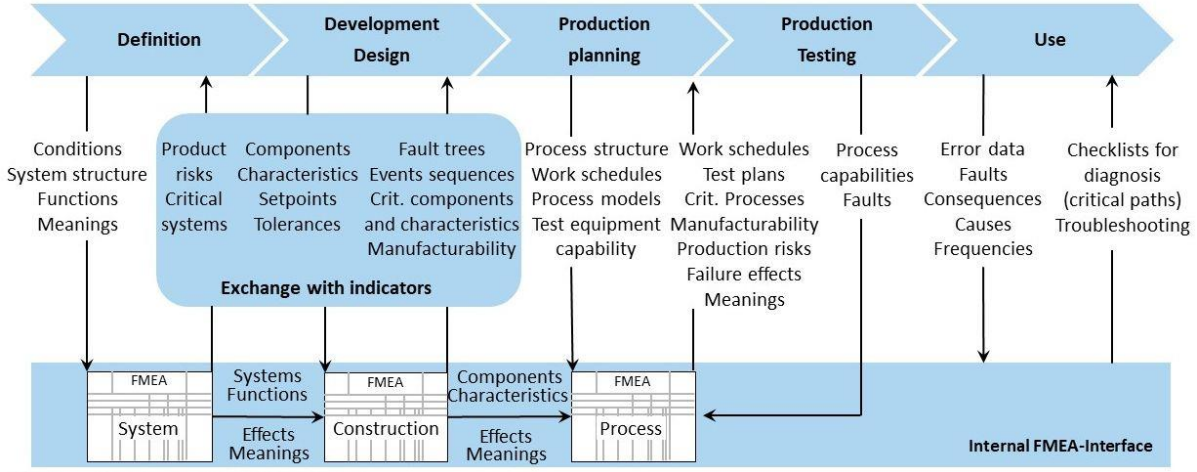

Figure 3. FMEA embedded in risk assessment

Basically, a risk case is initiated by the product owner and consists of the target, the input and the description and, subsequently, is the subject of risk evaluation. The main drivers are requirements,

CAPA (Corrective and Preventive Action), complaints and portfolio. A risk case discovers a 1:n relationship to an evaluation which consists of the root cause, the failure mode and failure mechanism. Technical file elements are the product risk file, the risk document and the risk line (Figure 4).

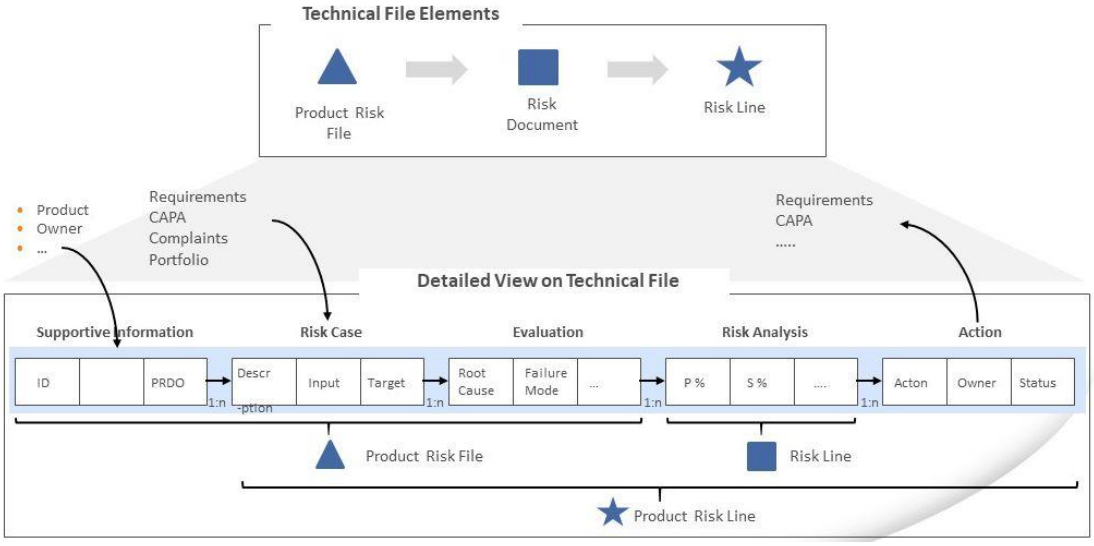

Figure 4. Data model for risk management based on Product Lifecycle Management

Risk evaluation yields a 1:n relationship to risk analysis which consists of probability, severity, occurrence and detection. Based on the risk analysis, appropriate actions can be incurred and assigned to an owner. Each action has a status and is related to the afore-mentioned main drivers. In such a way, a circular flow with four items of the product risk line is built.

This data model easily allows decomposition of the risk chain. Modularity is achieved by partitioning information into three categories: Architecture, Interfaces and Standards. The architecture specifies system modules and their functions. Interfaces describe the interaction of modules. Standards test a module's conformity to the design rules and compare the performance of competing modules. Usually, engineers use decompositions to describe a product or process. Describing a process like risk management leads to structuring the process in terms of its structural or functional properties. The structural and functional decomposition can again be decomposed using some new engineering properties leading to new sets of decompositions. By embedding this process into PDM system, singular items can be assigned to the nodes in the product structures. This facilitates the evaluations for certain trees in the product structure (e.g. specific variant).

Figure 4 shows decompositions of the supporting information, the risk case, the evaluation, the risk analysis, and the action which allow a high level of transparency and provide several possibilities for monitoring and tracking of risk cases.

4. Implemented solution

This concept is realized in an early agile implementation as a Product Risk Management (PRM) module of ThingWorx Navigate within the PDM system Windchill. Implementation is conducted by using the Navigate Toolkit with appropriate templates and standard functions. It is a standard application now and fully embedded in the typical workflows like configuration, release and change management.

Although it is mainly dedicated to the risk managers, the module provides several roles (risk manager, FMEA moderator, product owner, user, administrator) as well as several workflows (create, edit, delete, administration, reporting). Products owner creates a new PRM data objects and hands over to FMEA moderator who creates a FMEA for a product concept first. At a certain level of maturity of PRM, risk manager is able to conduct the product risk assessment (PRA) and define the countermeasures for all the product configurations. The main benefit of this solution is the instant availability of needed information with a reference from hazard to functional description (Figure 5). For example, a FMEA

Moderator/Risk Manager is able to easily get an overview of the status and the type of controls defined in a FMEA/PRA so that they can drive implementation of those controls. Thus, this module drastically reduces time for product risk estimation from days/weeks to hours and opens high scalability independently of the product range within scope. It enables a risk manager to make the daily work in a proactive way considering multiple configurations in parallel.

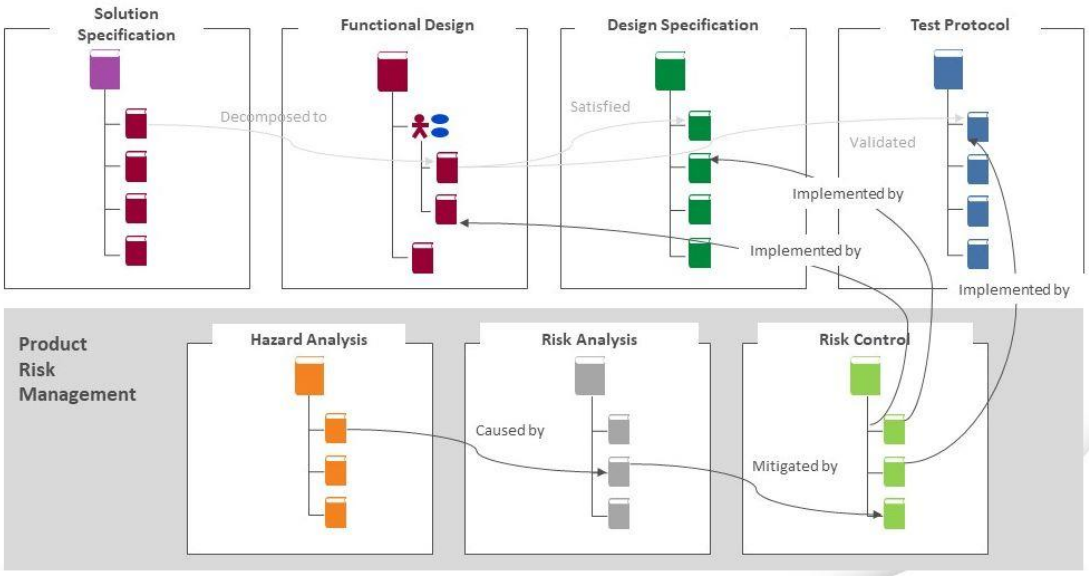

Figure 5. Solution model

One of the obstacles identified in the productive use is depicted in Figure 6. It belongs to the copy (clone) function which is frequently used when a similar case needs to be derived from the existing one. Windchill allows the copy function for the content, and not for the linked object itself. The copy requirements cannot be fulfilled by the current data model, as Failure Effect and Failure Controls are separate objects and cannot be copied with the Failure Line. Four options were discussed to address this concern and will be implemented in the maintenance mode. Furthermore, a link to the requirement management is not considered yet and then will be subject of a further implementation.

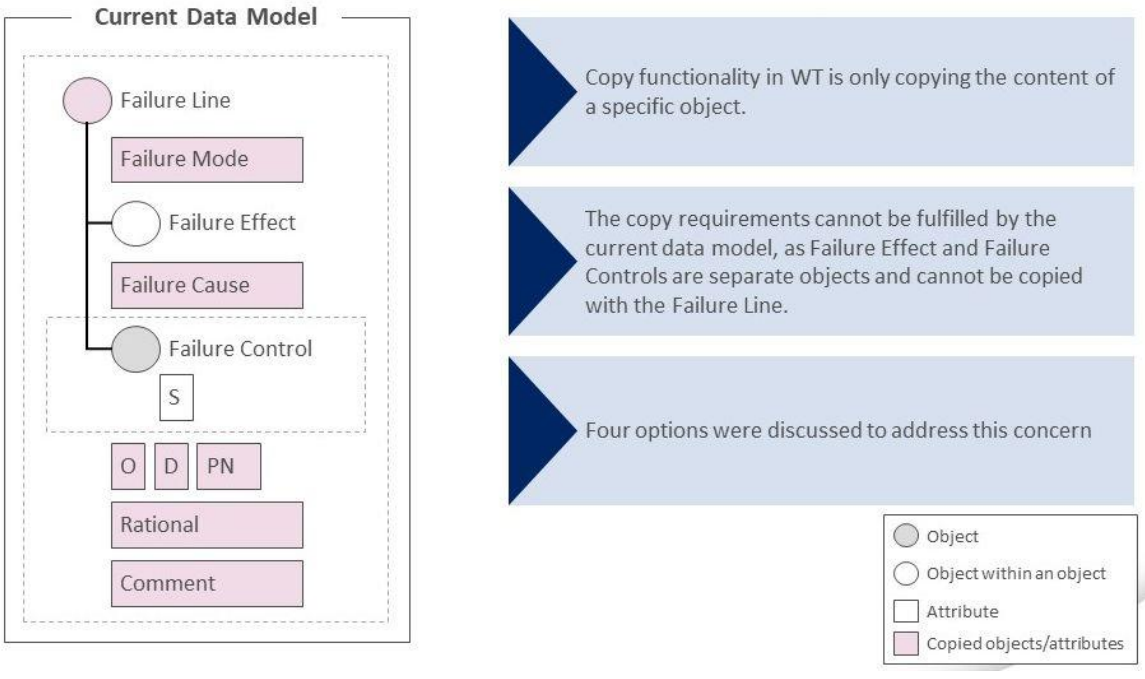

Figure 6. Current concerns regarding the data model

5. Conclusions and outlook

Enterprises are realizing the role of product risk management in enhancing the performance of their businesses and gaining competitive advantage. Hence, this could be achieved only when the enterprise can embed their product risk management in the Product Lifecycle Management to continuously discover risk figures, in particular for configured products. Product development is inherently linked to taking and managing risks.

This paper presented how to explore product risks in Product Lifecycle Management by considering configuration management for medical devices. The usage, extension and integration of different modules (e.g. application of analytics and evaluation (Wallis et al., 2014)) into comprehensive PDM systems, is the current trend in the manufacturing industry. Development of intelligent models and intelligent tools on the one hand, and the development of intelligent modular products, on the other, which can communicate and cooperate between them, need holistic and intelligent engineering approaches which also include risk consideration based on ISO 14971. These approaches can offer the possibility of the design of self-sustainable models and self- sustainable products. Consistency (e.g. in case of change) is preserved by Configuration Management. Thus, the development of intelligent collaborative and distributed platforms within Product Lifecycle Management can better handle modularity and risk management (Beckett and Vachhrajani, 2017). The presented solution has been developed to respond to this challenge and to pave the way for the introduction of innovative technologies in a dynamic environment characterized by important changes and evolution (Mathiasen and Mathiasen, 2017). Similarly, further cross-cutting issues can be addressed to improve safety and security of interoperable components, systems, and reusable platform-based infrastructure.

In the broader view to a transdisciplinary process from a system's perspective, we can easier identify possible errors or malfunctions in specific configurations that requires specific attention while taking into account the context in which this system exists (Wognum et al., 2019). The impact of the system context on the system under consideration as well as the impact of changes made to the system on its context can be better identified and taken into account because we still live in the information age, where an instant availability of important information is the pre-requisite for a successful business.

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