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► **To cite this version:**

Roberto Castaneda, Tomislava Majić, Egon Ostrosi, Jean-Claude Sagot, Josip Stjepandić. Multi-interfaces Entity Model for Summative Risk Management of Medical Products. 18th IFIP International Conference on Product Lifecycle Management (PLM), Jul 2021, Curitiba, Brazil. pp.157-170, 10.1007/978-3-030-94399-8_12 . hal-04195234

HAL Id: hal-04195234

<https://inria.hal.science/hal-04195234v1>

Submitted on 4 Sep 2023

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Multi-interfaces Entity Model for Summative Risk Management of Medical Products

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Abstract. Currently, product development of highly regulated products is usually aided by modern PLM systems as an information backbone that reflect and support various business processes. Changes are systematically handled and the overall impact is made transparent through configuration management. In the search to maintain the integrity of all systems and components over the span of the product's life, a tightly integrated Risk Management process and system shall enable a discrete but frequent enough method. The goal is to evaluate if further product development or changes are needed. Also clearly give quantifiable values to assess if the next step in the product's lifecycle can be started and closed. The challenge is finding a methodology where risk management is living process throughout the lifecycle, which is cumulative, so the risk assessments refine with the product's definition. It should be enabled to be done at the component level so risks add up modularly to the complete product's risk assessment. This process should be embedded in the PLM processes so it is able to accompany the product throughout its life. We investigated the usage of the Multi-interfaces Entity Model (MIEM) integrated with a summative risk management concept that allows an incremental risk analysis, as the entities in the MIEM are refined. The results were a recursive methodology that supported with a PLM integrated risk management, can be automated to make sure the risk assessment is complete, reusable and configurable. The next steps are the implementation in this concept with the PLM architecture and make it possible to support further views of the products for the next lifecycles. With this approach the intention is to avoid having a very heavy risk management at the definition and design phase that is later left to a lower plane in the life of the product.

Keywords: Product Risk Management, Configuration Management, Modular Design, Product Lifecycle Management.

1 Introduction

Contemporary products are developed against ever stricter functional requirements and in shorter development time. This requires new solution approaches as well as supportive methods and tools, in particular when regulatory bodies monitor and validate the compliance of products to ensure the patient's health and wellbeing, as failure of these devices can have fatal or long lasting consequences. While product development is both regionally distributed and shared among partners in the supply chain, the pre-requisites for a good product and technology management are even higher and hard to fulfil without a comprehensive product lifecycle management (PLM). Product development of highly regulated products as known in medical industry is usually aided by modern PLM systems as an information backbone that reflects and supports various business processes. Through this system, changes can be systematically tackled and their impact is made continuously transparent through configuration management [1].

The functional relationships of a product are determined based on customer requirements and taking into account a large number of legal requirements in product planning and development. Without knowledge of these relationships, the product behaviour in operation that the real asset records and makes available in its later product life cannot be correctly understood [2]. From a PLM point of view, the starting point for such considerations is a specific configuration of the product. This includes not only mechanical, electrical / electronic and software components with their models, but perhaps also service-relevant information, such as the service life of certain components. The expectation of today's PLM systems is to operate all product related processes based on the specific product configuration [3].

The dominating approach of the industrial process improvement is its orientation on quality enhancing activities, which advance a competitive position of manufacturing companies [4]. In the search to maintain the integrity of all systems and components over the span of the product's life, a tightly integrated product risk management process and system shall enable a discrete but frequent enough method to assess potential hazards, and to evaluate whether changes are necessary or if the next step of in the product's lifecycle can be started [5]. The challenge is finding a methodology where risk management is living process throughout the lifecycle, that is (a) cumulative so the risk assessments refine with the product's definition from the first idea on and the sum of the component risks add up to the entire product's risk assessment, and (b) embedded in the PLM processes so it is able to accompany the product throughout its life representing all variants and changes [6]. It shall comprise all activities, from the technology roadmap to the start of production, including common and approved methods; e.g. Failure Mode and Effect Analysis (FMEA), Value Analysis, Kano model [7].

In this paper we answer the question how to utilize a comprehensive product risk management application for products within a modular architecture in Product Lifecycle Management (PLM) by considering configuration management and making Risk Management a decision driver. Firstly, we explain the necessity of product risk management. Then we refine the problem statement. Based on this we derive the briefly describe the Multi-interfaces Entity Model (MIEM) which should solve as the basis for future implementations. Discussion and conclusions close this paper.

2 Background

Risk is a natural companion of all activities of the company, at all levels, and can result in visible deterioration in the quality of products and services, and, therefore, a decline in competitiveness. [8]. Therefore, risk is often subject of internal and external regulation and audits (e.g. by a regulation body). The business environment described in this paper, in which the global medical device manufacturer operates, is strictly regulated [9]. Just as regulators have increased their ability to receive information electronically, in terms of the speed and growing capacity to analyze large amounts of data, so do medical device manufacturers who need to anticipate and detect risks resulting from product failure or poor performance. In this sense, they should have higher reaction rates than regulators [10].

Risk management must be a downstream but complete process within the strategic and operational management of the company, due to the possible consequences on the competitiveness and fundamental objective of the company and its the capability to fully retain risks [11]. It involves frequent communication with regulators and providing an appropriate oversight policy with forecasts [12].

Unlike risk, which is defined as a known but potentially unfavourable outcome, the probability of which can be estimated, called uncertainty, is a situation where a decision has more than one possible outcome and in which the probability of adverse outcomes is unknown, due to lack of information or unstable variable structure in the given environment [13].

Complete information that guarantees complete security rarely appears in business, so the consequences of the decisions of basic economic entities - companies and households - cannot be considered ignoring uncertainties and risk. The greater the variability - the higher the number and the broader the range of outcomes - from past situations or from market evaluation of possible outcomes, the higher the risk associated with a given activity [11].

Bad decisions are usually based on risk neglect - this is especially true in the medical device industry, where all decisions must be based on identifying and measuring risks that may affect product quality. Understanding the data is not only important in order to minimize the risks of entering into bad business ventures, but also in order to identify potential opportunities, and thus, prevent harmful and suboptimal activities for the company [11].

Risk management involves the use of consistent and repeatable procedures with the aim of identifying, assessing and interpreting risk in the given scenarios so that risky activities could be monitored [14]. Risk management does not seek to eliminate risks - it is unable to do so, but it creates an environment in which optimal business decisions can be made taking into account identified risks, developing potential risk management alternatives and identifying their associated costs and benefits [15]. The technical risks associated with the product primarily are based on insufficient knowledge and experience with the used technology, and may have consequences for quality, costs and deadlines. They often arise due to the budgetary constraints during the development project [16].

Once the risks have been identified and gone through the above procedures, it is crucial to select an appropriate technique that will effectively eliminate or control the risk exposure. There are four potential responses to risks: acceptance, avoidance, control, transmission. When making decisions, compromises are inevitable. Trade – offs are made based on the logic that it is better to embark on a lower but known cost, in order to in turn reduce the potentially higher unknown costs associated with the risk [6].

As the main purpose of a medical device is related to the health of patients and human life, the risk management process must go through the lifecycle of the medical product in order to avoid potential dangers [17]. Product quality metrics in the future will go in the direction of data enrichment in order to get a clearer picture of product quality risks [9].

Addressing the cumulative risk assessments, it is necessary to create an appropriate product risk model with interdependencies in a product structure. For this end we use a system analysis methodology. The chosen methodology is the Multi-interface Entity Model (MIEM) **Erro! Fonte de referência não encontrada.**, which delivers two main benefits: 1. It recognizes interfaces and an inheritable relationship to sub-elements and 2. It creates a structure that can easily be translated into PLM structures for the next steps of the concept. With this, the usage MIEM will be investigated in order to achieve a summative risk management concept for sake of an incremental risk analysis based on an adjustable refinement. After a certain degree of product maturity, the risk assessment of the product a functional architecture of the product can be produced where the risk analysis validated confirming the gate for the next step in development, namely the creation of the functional structure.

There are a number of risk evaluation methods available focused on different goals; e.g. project management, products, organization [11]. However, the purpose of this paper is to explore an implementable model for risk handling in a more precise and integrated manner rather than to develop a new method. This enables a holistic risk assessment based on reused components, systems and modules of the product as family of variants. The outcome would yield a recursive methodology that supported with a PLM integrated risk management, can be automated to make sure the risk assessment is complete, reusable and configurable [6]. If this concept would be implemented with the PLM architecture, it would make it possible to support further views of the products for the next lifecycles: production planning, production, assembly, usage, maintenance and recycling.

3 Problem Statement

The goal of an effective product risk management system is to allow continuous business operation and achieve the goals of an organization [14]. In order to achieve this product risk management should be a living actor of the design process, linked to regulatory compliance needs to roll-out a product while meeting market and customer requirements. Integrating risk management to the design process enforcing it as real-time development driver ensures better design and project decisions, shortening time-to-

market and reducing the risk of cost intensive product failures during the phases of usage and maintenance [10]. As risk management is a process that accompanies the product during these later life-cycle phases it becomes also a driver of better new product development.

The sustained success of technical risk management is possible only through the efficient control of risks based on singular items or systems of a product. Different methods (FMEA, DRBFM etc) need to be applied for any instance of a product or product families, for this reason risk management needs to be used within the context of reusable assets, browsing through the product structure and considering all configured items [18]. Therefore, the risk assessment and control methods need to become fully interoperable with configuration management within PLM as a fully integrated process, method and application [19]. As basis for the method, leveraging the structured nature of PLM product representation, the items in the product structure can be associated to a tuple of failures, evaluations and controls, enabling a systematic identification of risks based on the aggregation of the singular items and their associated risk tuples. The goal is the transparent presentation of all risk consequences, which then will be assessed qualitatively and quantitatively based on a specific product configuration. The impact on each change of an item and the associated risk assessment of the singular parts can be directly identified being able to extrapolate the impact in case that the items is reused in several product configurations.

With an appropriate model and method, the elimination of deficits (time delay, lower accuracy, etc.) within the assessment of interdependencies in risk consequences and the efficient control of technical risks becomes possible. The assessment and control of technical risks for any configuration need to complete the closed loop of technical risk management within PLM that contains the process phases identification, analysis and assessment and control. In such a way, the overall gain of knowledge in form of verification and validation of technical risk assessments can be realized. The impact of any design change can be investigated and predicted in the early phase of the product development. The simulation of risk control measures should ensure the success of product risk management. The developed conceptual solution should fulfil the requirements for product development of medical products based on international standards (FDA, ISO14971) [20].

Finally, the formalisms for product assessment of medical devices should be proposed. To make these formalisms fully operational, several research issues should be addressed [21]. What are the relevant characteristics of a configured system-based product with regard to technical risk management? How these characteristics can be described in a formal way to propose appropriate methods [22]? How the risk structure matrix can be mapped to the product structure and used subsequently in similar products [24]?

4 Conceptual Solution

For the product emergence, a functional specification needs to be created. Based on the functional specification the designers start ideating the product in a top-down manner

using the Multi-interface Entity Model (MIEM). This model will aid the risk assessment allowing the risk manager to assign risks to the different entities or interfaces of the model. For sake of the risk assessment, the risks are assigned to the MEIM elements as a function of the functional specification. The risk values are derived from the information in the specification in analogy with FMEA. Doing so, each authorized user gets the possibility to assign the risk to each component of a product and therefore to contribute to the total risk assessment.

During the product lifecycle, the typical data evolution from the early beginning (requirements, draft functionalities) to the end-of-life (operation, maintenance, and recycling) is often practiced based on the exchange of filtered views of the product. PLM systems possess primarily the ability to create these views and make the product data available for different processes and needs of business. PLM systems and authoring systems (MCAD, ECAD etc) are usually tightly coupled, the risk assessment and monitoring should be initiated on the basement of the product structure (singular parts and carry-over assemblies) and extended or maintained during its development. Furthermore, the product structuring is one of the most important benefits of PLM, which can be realized by IT-frameworks and used with different views [2]. The product structure evolves steadily while the product matures. Specific configurations such as E-BoM, M-BoM, as designed, as ordered, as serviced, etc. represent different views for different purposes [25]. This can be optimally realized by assigning all information to the corresponding node in the product structure that corresponds to their tasks and view [1]. In the opposite direction, each node needs to be decomposed into components and their interfaces (Figure 1).

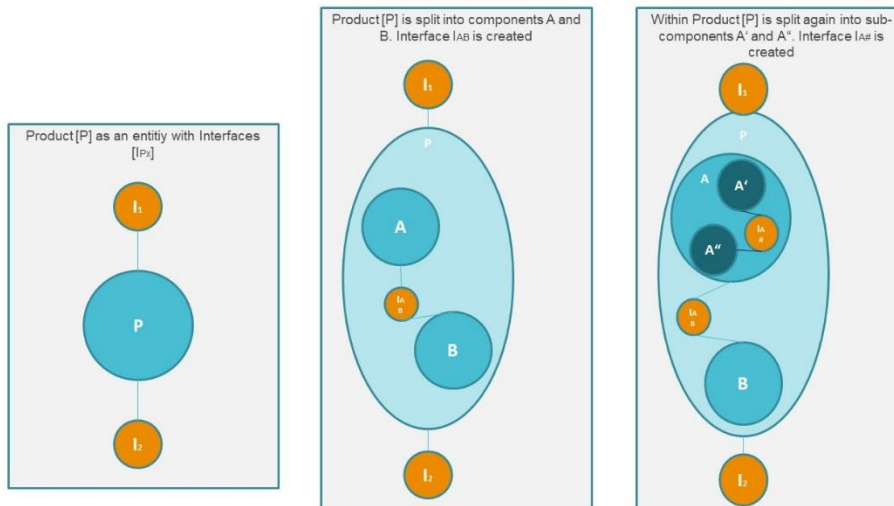


Fig. 1. Decomposition of a Product into its Components

In MEIM, the product is seen a collection of Entities and their directly associated Interfaces. In a top-down MEIM approach, the product is first seen as a black box with

an original single Entity (P) and its external Interfaces (I_1 and I_2) are recognized (Figure 1, left). These interfaces are the interaction of the product with other products, user, environment, etc. For each further functionality, the product is then split into Sub-Entities (A) and (B). A result of this split is the creation of a new Interface (I_{AB}) associated to both Sub-Entities (Figure 1, middle). It is important to note that the newly created interface is valid within the boundaries of the product and does not create a further product interface (I_x). The decomposition can be done again for Sub-Entities with the same effect. The Sub-Entity (A) is decomposed into two Sub-Sub-Entities (A' and A'') with a resulting new Interface ($I_{A\#}$) within the boundaries of the decomposed Sub-Entity (Figure 1, right). This way, a product can be described by its entities, the related interfaces and interdependencies.

The emergence of the executable MIEM will be explained in the further decomposition of the medical device lancet as illustrated in Figures 2 and 3. The device of this example is the Accu-Chek Softclix lancet which aims to piercing the patient's skin. The lancet consists of a polymer body with a unique rectangular cross section specially designed to be inserted into the Softclix Lancing Device. Once the lancet is fixed into the Lancing Device the user retrieves the cap of the lancet leaving the needle exposed. The needle is covered with the head of the Lancing Device. The user can adapt the deepness of the needle insertion. The Lancing Device has a mechanism where the lancet is charged and can be released pressing a button. The mechanism pushes the needle of the Lancet outside the Lancing Device quickly piercing the patient's skin to draw the blood needed for a glucose measurement. Instantaneously the needle is retrieved back into the Lancing Device. The lancet shall not be reused but disposed of in a sharps box like other used needles.

To apply the MIEM to this product the Lancet is first seen as a whole product (P) and its external interfaces I_1 , interaction between Lancet and Lancing Device also referred to as pen; and interface I_2 between the lancet and the human user's hand (Figure 2).

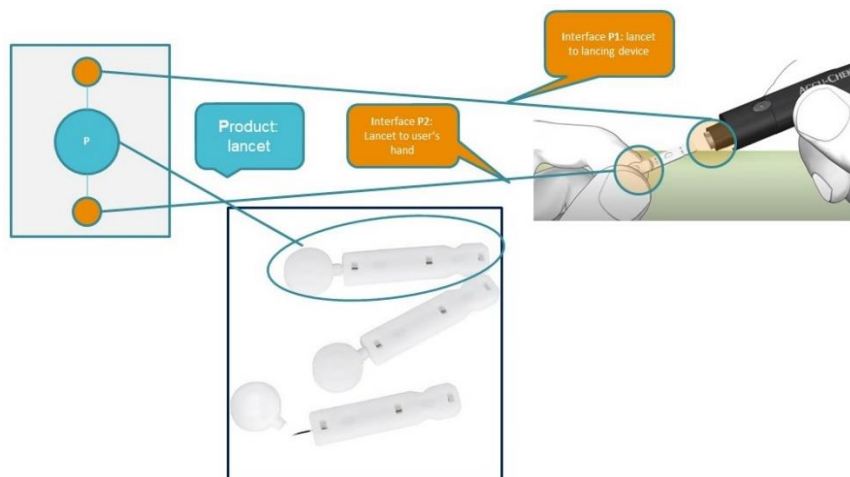


Fig. 2. MIEM applied to a Medical Device Lancet

The decomposition approach has hence been found to be more suitable to investigate the basic relationships between the product constituents [23]. In this case, the risk manager will try to find optimal product decompositions and allocations from subassemblies or components with mutual interfaces, assigning the risks of failure to the singular entities. To begin the product decomposition, we can declare (P) as the first entity seen in Figure 2 as the blue circle plus two interfaces represented as orange circles. Analysing the composition of the product we recognize the product (P) has two distinct components with different form and function, namely the round cap that can be detached through a twist movement from the main body of the Lancet. These are represented as two new entities (A) for the body and (B) for the cap. Each time that an entity is decomposed into sub-entities a new interface emerges, in this case, interface I_{AB} : the polymer weld holding both together as seen in Figure 3.

These new entities and the interface are within (P) and together they fully describe, resolve and replace (P) in the model.

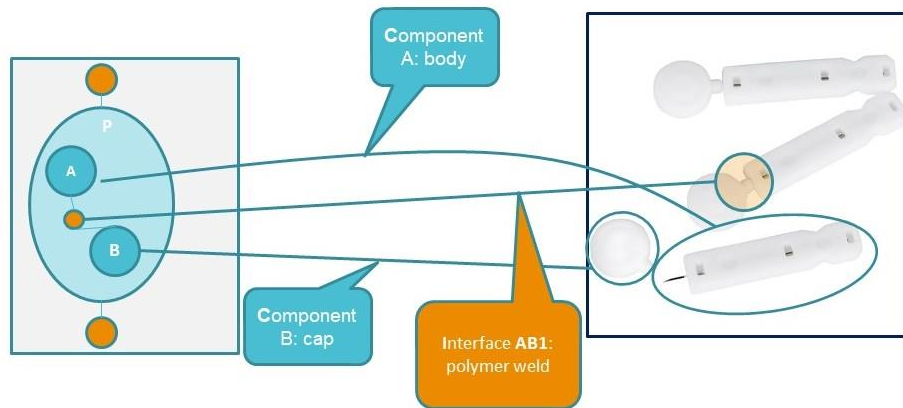


Fig. 3. Applying the MIEM to medical device lancet (detailed view)

In the same manner, the sub-entity (A) can be further decomposed into two more entities with different form and function. In this case the housing of the body in polymer and metal, sterile needle, represented with dark blue circles as (A') and (A''). Because of the decomposition, a new interface is generated between the two new entities ($I_{A\#}$) which ensures the needle is securely fixed within the housing in such a way that when the Lancing Device the needle pushes the housing is securely pushed along and retracted with housing. These new entities and interface are seen in Figure 4.

This exercise ends the creation of an MIEM, the sum of entities and interfaces describe the next lever entity until the whole product is seen as one entity with its interfaces. This exercise of decomposition delivers the designer deep product information, independent of the specifics of the product design [24]. This information is enough to create a functional architecture of the product.

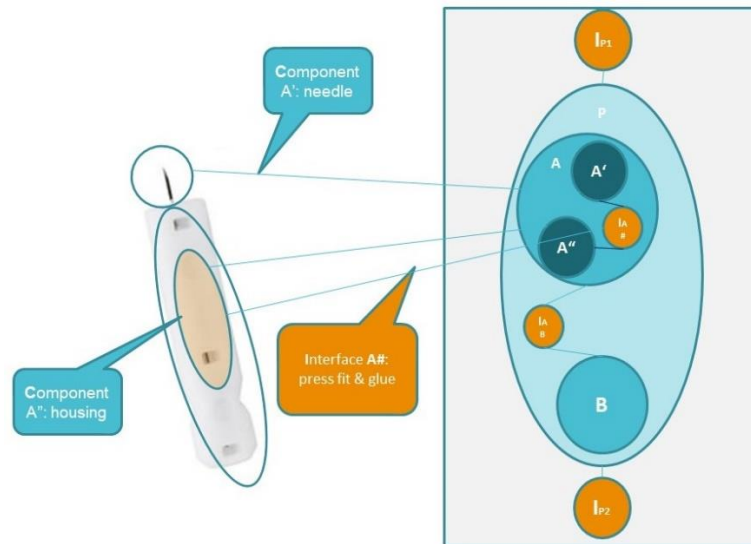


Fig. 4. Applying the MIEM to a medical devices lancet (interface view)

From the MIEM we can extract the following information paring functionalities to entities:

- Interface I_1
 - interacts with the user,
 - is the medium of how the user imports human energy that interacts with the product in the form of mechanical energy such as place and move through space, inserting the lancet into the pen and twisting the cap to remove it.
- Entity B
 - protects the user from getting hurt with the needle
 - protects the needle keeping it sterile
 - Interacts with A through the interface I_{AB}
- Interface I_{AB}
 - Keeps the cap welded to the body
 - It strong enough to protect the user from being hurt with the needle
 - Has an intended breaking point that will release the cap if the user applies sufficient mechanical energy
- Entity A
 - Interacts with B through the interface I_{AB}
 - Contains to entities A' and A'' , and an interface $I_{A\#}$
 - Entity A'
 - Securely contains and fixes the entity A''
 - Interacts with entity A'' through the interface $I_{A\#}$

- Interacts with the external product pen through the interface I₂
- Entity A''
 - Interacts with entity A' through the interface I_{A#}
 - Interacts with the patient

The functional architecture, although based in functionalities, a bridge can be built to the MIEM, containing entities, interface actors such as the user, the kind of energy being imported, transformed and transmitted. This extracted information is then used to create a functional architecture with assignment to the interfaces and entities as seen on Figure 5.

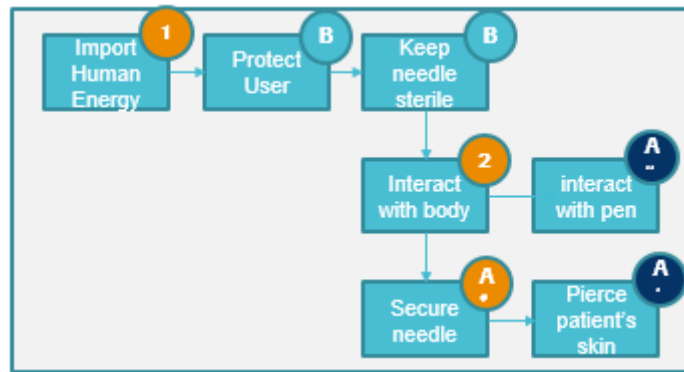


Fig. 5. Creating a functional architecture of the product and assigning the functions to the MIEM entities

Based on the functional architecture, a risk analysis is performed. The risk factors are assigned to the MEIM elements. After these tasks are performed the design team has already been able to perform a risk assessment as a function of the functional elements of the product that can be traced to its elements that could be entities or interfaces. This product risk assessment is being based on the function and requirements only is free of any solution bias. It should give a clear view if the product is feasible or not acting as an essential artefact for the milestone decision to move on with the product development or not from the design point of view. Clearly, other aspects of the product development are not covered in this assessment around the associated disciplines of project management such as costs and timeline.

The subsequent step is to create a functional structure in the PLM system, based on the MIEM that will tie the entities and interfaces to the product requirements and these to their associated recognized risks. This creates the first (of many) PLM product view. At this point the overall Risk Assessment (R) of the product is the accumulation of risks recognized and associated the structure of the PLM view as shown in Figure 6.

At each milestone in the product development project, a sum of the risk is calculated. Based on this, a decision for further step can be made.

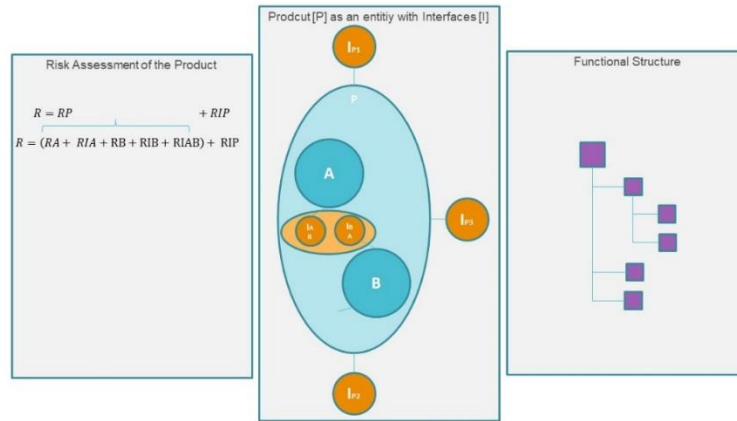


Fig. 6. Decomposing Product [P] into assemblies [A] and [B].

5 Discussion

In this paper, a conceptual solution for the integration of product risk management in a comprehensive PLM approach for highly configured, modular medical devices is explored. In this way, the standard PLM system is being enhanced by an additional capability as an intelligent collaborative and distributed platform for assessment, maintenance and monitoring of each product capability during the product lifecycle [2]. Thus, the proposed, generic solution has the potential to fulfil the demand of the continuous, software-aided risk assessment and to provide the appropriate user-friendly support within PLM system [25]. Finally, the resulting risk management process looks as seamless as possible, with the purpose to provide a basis for the software solution to achieve the desired goal: identifying, assessing, prioritizing, or monitoring risk like other summative properties (e.g. the cumulative weight of the configured product) are examined in an assembly.

Methods implemented by software solutions simplify the daily work of risk engineers and managers that all risks which are accompanied with a product configuration are properly considered and minimize the subjectivity of subsequent human risk assessments. Although the risk values do not provide the absolute results, their comparison is a valuable basis for reproducible risk assessment. This generic methodology can be used for all types of product risk assessments, not dependent on the domain, the type and the genesis of the risk. Risk assessment emerges while the product emerges during its product lifecycle. The uncertainty remains only through little human assistance and judgment. However, the comparison stabilizes this activity too. The proposed solution can also facilitate that the effects of cognitive biases are documented within the risk matrix [15].

The approach to map the function architecture in the functional structure is just the first step. It needs to be extended by mapping the functional structure to the design structure and, subsequently, to design architecture. In that way, a methodology can be

defined which is valid for the entire product lifecycle. Assumed a performant software implementation, the method monitors the potential technical risks in a systematic manner at each moment in the product lifecycle. In particular, a standardized risk assessment is beneficial in case of product change.

6 Conclusions and Outlook

Focusing cumulative risk management methodology, we investigated the usage of the Multi-interfaces Entity Model (MIEM) integrated with a summative risk management concept that allows an incremental risk analysis, as the entities in the MIEM are refined. After a certain degree of maturity, the risk assessment of the product a functional architecture of the product is produced where the risk analysis validated confirming the gate for the next step in development, namely the creation of the functional structure. Within the functional structure the same principle is applied the sum of the risks of the component and the interfaces will define the risk assessment of the product. Further from this paper, if this assessment is validated the next step is to create a configured design structure, applying recursively the same cumulative properties of the risk assessment where a new configuration would create new interfaces [3]. The configured structure describes the product in the design view and should create the next level of traceability from the requirement to the function over to the solution. This construct consisting of the architectural levels and the product views allow for a risk assessment that can be performed both bottom-up as well as top-down adding the chance to analyze the product in terms of modules. The modular approach can be scaled up product systems and down to design elements and features in a CAD model or at any necessary level where re-use is possible. Performing a risk assessment at the functional level provides a new dimension of risk management of components or modules using as a parameter they function they provide.

This enables a holistic risk assessment based on reused components, systems and modules of the product as family of variants. Further views of the product shall be created and the recursive methodology applied. This supported with a PLM integrated risk management as described in previous papers, can be automated to make sure the risk assessment is complete, re-usable and configurable.

The next steps are the implementation in this concept with the PLM architecture and make it possible to support further views of the products for the next lifecycles: production planning, production, assembly, usage, maintenance and recycling. With this approach the intention is to avoid having a very heavy risk management at the definition and design phase that is later left to a lower plane in the life of the product.

References

1. Stark, J.: Product Lifecycle Management (Volume 4): The Case Studies, Springer Nature Switzerland AG, (2019), <https://doi.org/10.1007/978-3-030-16134-7>.

2. Stark, J.: *Product Lifecycle Management (Volume 2): The Devil is in the Details*, 3rd edition, Springer International Publishing AG, (2016), <https://doi.org/10.1007/978-3-319-24436-5>.
3. Rusu, M.: The configuration management requirements for aviation, space and defense organizations, *INCAS Bulletin*, 11(1), pp. 239-253, (2019), DOI: 10.13111/2066-8201.2019.11.1.19.
4. Manz, S.: *Medical Device Quality Management Systems. Strategy and Techniques for Improving Efficiency and Effectiveness*, Academic Press, London, (2019), <https://doi.org/10.1016/c2017-0-01146-1>.
5. ISO (2018), *ISO 31000:2018-05 Risk management - Guidelines*, International Organization for Standardization, Geneva.
6. Riascos Castaneda, R., Ostrosi, E., Majić, T., Stjepandić, J., Sagot, J.C.: A Method to Explore Product Risk in Product Lifecycle Management of Configured Products, *Proceedings of the Design Society: DESIGN Conference*, Vol. 1, pp. 687-696, (2020). DOI: <https://doi.org/10.1017/dsd.2020.318>.
7. Zhao, X. and Bai, X.: The Application of FMEA method in the risk management of medical device during the lifecycle, *2nd International Conference on E-business and Information System Security*, 22-23 May 2010, pp. 455-458, (2010), DOI: 10.1109/EBISS.2010.5473713.
8. Aven, T.: Foundational Issues in Risk Assessment and Risk Management, *Risk Analysis*, Vol. 32, No. 10, pp. 1647-1656, (2012), <https://doi.org/10.1111/j.1539-6924.2012.01798.x>.
9. Hatchliff, J., Vasserman, E.Y., Carpenter, T. and Whillock, R.: Challenges of distributed risk management for medical application platforms, *2018 IEEE Symposium on Product Compliance Engineering (ISPC)*, 14-16 May 2018, (2018), DOI: 10.1109/ISPC.2018.8379270.
10. Hall, D.C.: Making Risk Assessments More Comparable and Repeatable, *Systems Engineering*, Vol. 14, No. 2, 2011, pp. 173–179, (2011), DOI 10.1002/sys.20169.
11. Pongrac, B., and Majić, T.: *Business Risk Management*, *Technical Journal*, Vol. 9, No. 1, pp. 94–98 (2015).
12. Teferra, M.N.: *ISO 14971 - Medical Device Risk Management Standard*, *International Journal of Latest Research in Engineering and Technology (IJLRET)*, Vol. 3, Issue 3, pp. 83-87, (2017).
13. Aven, T., Zio, E.: Foundational Issues in Risk Assessment and Risk Management, *Risk Analysis*, Vol. 34, No. 7, pp. 1164-1172, (2014), <https://doi.org/10.1111/risa.12132>.
14. Oehmen, J., Dick, B., Lindemann, U., Seering, W.: *Risk Management in Product Development – Current Methods*, *International Design Conference - DESIGN 2006 Dubrovnik - Croatia*, May 15 - 18, 2006, pp. 1551-1558. (2006).
15. Smith, E.D., Siefert, W.T., & Drain, D. (2009). Risk Matrix Input Data Biases, *Systems Engineering*, Vol 12, No. 4, pp. 344–360, (2009), DOI 10.1002/sys.20126.
16. Kirkire, M.S., Rane, S.B. and Jadhav, J.R.: Risk management in medical product development process using traditional FMEA and fuzzy linguistic approach: a case study, *Journal of Industrial Engineering International*, Vol. 11, pp. 595–611, (2015), <https://doi.org/10.1007/s40092-015-0113-y>.
17. ISO (2012), *ISO 14971:2012 Medical devices. Application of risk management to medical devices (Standard for the application of risk management to medical devices)*, International Organization for Standardization, Geneva.
18. Ostrosi, E., Stjepandić, J., Fukuda, S., and Kurth, M.: Modularity: New trends for product platform strategy support in concurrent engineering, *Advances in Transdisciplinary Engineering*, Vol. 1, pp. 414-423, (2014), DOI: 10.3233/978-1-61499-440-4-414.

19. Raudberget, D., Elgh, F., Stolt, R., Johansson, J., and Lennartsson, M.: Developing agile platform assets – exploring ways to reach beyond modularisation at five product development companies, *Int. Journal of Agile Systems and Management*, Vol. 12, No. 4, pp. 311–331, (2019), <https://doi.org/10.1504/IJASM.2019.104588>.
20. Flood, D., McCaffery, F., Casey, V., McKeever R., and Rust, P.: A roadmap to ISO 14971 implementation, *Journal of Software: Evolution and Process*, Vol. 25(5), pp. 319-336, (2015), <https://doi.org/10.1002/smr.1711>.
21. He, B., Xue, H., Liu, L., Pan, Q., Tang, W., Ostrosi, E.: Rigid-flexible coupling virtual prototyping-based approach to the failure mode, effects, and criticality analysis, *International Journal of Advanced Manufacturing Technology*, Vol. 100(5-8), pp. 1695-1717, (2019), DOI: 10.1007/s00170-018-2641-2.
22. Keski-Rahkonen J.K.: Probabilistic framework for product design optimization and risk management, *IOP Conf. Series: Materials Science and Engineering*, Vol. 351, 012007, (2018), doi:10.1088/1757-899X/351/1/012007
23. Deng, X., Huet, G., Tan, S., Fortin, C., Product decomposition using design structure matrix for intellectual property protection in supply chain outsourcing, *Computers in Industry*, Volume 63, Issue 6, 2012, pp. 632-641, (2012), <https://doi.org/10.1016/j.compind.2012.03.007>.
24. Fontem, B., Keskin, B., Melouk, S., Vaughn, C.: An exact decomposition algorithm for a chance-constrained new product risk model, *Operations Research Letters*, Vol. 47, Issue 4, pp. 250-256, (2019), <https://doi.org/10.1016/j.orl.2019.04.001>.
25. Bruun, H.P.L., Mortensen, N.H., Harlou, U., Wörösch M. and Proschowsky, M.: PLM system support for modular product development, *Computers in Industry*, Vol. 67, pp. 97–111, (2015), <https://doi.org/10.1016/j.compind.2014.10.010>.