Lifecycle Engineering in the Context of a Medical Device Company – Leveraging MBSE, PLM and AI

Gregor M. Schweitzer[1](✉), Michael Bitzer[1], and Michael Vielhaber[2]

[1] Fresenius Medical Care, Bad Homburg, Germany
[2] Saarland University, Saarbrücken, Germany

Abstract. Medical devices today often consist of complex mechatronic products which help to provide treatment services for patients. Beside safety and reliability also sustainability aspects need to be considered for such products and services. The ability to describe, analyze and predict products and services throughout all phases of its lifecycle is becoming a core competence of engineering departments (Lifecycle Engineering). In order to have a digital representation of the product and services along the lifecycle (digital model, digital twin), well-established engineering approaches need to be combined.

This paper builds on a stream of research, proposing to leverage and combine Model-based Systems Engineering (MBSE), Product Lifecycle Management (PLM) and Artificial Intelligence (AI) to strengthen the Lifecycle Engineering. The so called Engineering Graph is a key element of this research work to bridge those engineering disciplines and enable AI-driven engineering in the lifecycle context.

Keywords: Lifecycle Engineering (LCE) · Systems Engineering (SE) · Product Lifecycle Management (PLM) · Artificial Intelligence (AI) · Engineering Graph

1 Introduction

Mega-trends in society, economy, politics, regulatory and technology lead to increased volatility, uncertainty, complexity and ambiguity (VUCA) for companies in multiple industries [1]. Especially the trend of sustainability is getting more and more impact on products and services [2].

The ability to develop and assess products and services from a lifecycle perspective is a key success factor to operate in such a volatile and complex environment. Concepts such as Product Lifecycle Management (PLM) or Lifecycle Engineering (LCE) emerged to address this environment. The representation and assessment of the lifecycle in the virtual environment is the foundation.

By integrating and leveraging digital technologies – especially in early product development phases – innovative options and chances can be created. To represent products and services across the lifecycle, model-based engineering approaches can be used.

Published by Springer Nature Switzerland AG 2023
F. Noël et al. (Eds.): PLM 2022, IFIP AICT 667, pp. 557–566, 2023.
https://doi.org/10.1007/978-3-031-25182-5_54

These virtual product models can be analyzed by artificial intelligence (AI) and data science technologies to gain further information and support lifecycle spanning use cases such as Life Cycle Sustainability Assessments (LCSA).

This paper introduces the Engineering Graph as a concept that combines current engineering methods like Model-based Systems Engineering (MBSE) and PLM, modern theory from computer science for product modeling and machine learning to support LCE. This concept is applied at a leading medical device company.

2 Related Work for Engineering

Engineering as one of the core competences of manufacturing industries undergoes an evolution similar to the products and technologies developed by engineering itself. The digitalization is a main driver for this evolution in engineering: from geometry-oriented to behavior and meaning-oriented engineering and modelling approaches [3].

This section will point out disciplines and approaches of engineering which can be seen as a foundation for a lifecycle-oriented approach of engineering: LCE.

2.1 Model-Based Systems Engineering

The transdisciplinary and integrative approach of Systems Engineering (SE) enables the successful realization, use and retirement of engineered systems [4].

SE covers all processes of the system lifecycle: agreement and organizational project enabling processes; technical management processes and technical processes itself [5]. In the "Architecture Definition Process" the system architecture is developed. One core element of SE is the decomposition of a System of Interest in sub-systems. Those subsystems can be elaborated in System Elements. A System of Interest can also be described by its operational environment and enabling systems.

In order to describe those elements and relationships a model-based approach is used, typically supported by the modelling language System Modeling Language (SysML). SysML is a dialect of UML 2 that customizes the language via three mechanisms: Stereotypes, Tagged Values, and Constraints [6].

2.2 Product Lifecycle Management

PLM is a concept which enables representations, perspectives and validations of a product in its lifecycle phases. PLM is evolutionary based on Product Data Management (PDM). PDM was developed in the context of document management and Computer Aided Design (CAD). With the evolution towards PLM so called product models or virtual products were introduced [7].

PLM manages all data from development, production, warehouse and sales and supports single source of data through the entire lifecycle [8]. The whole product range is covered, from individual part to the entire portfolio of products [9].

2.3 Lifecycle Engineering

LCE is a sustainability-oriented engineering methodology that considers the comprehensive technical, environmental, and economic impacts of decisions within the product lifecycle [10]. In this context, the product lifecycle is formally defined by ISO 14040 as the "consecutive and interlinked stages of a product system, from raw material acquisition or generation from natural resources to final disposal." [11].

In recent years, modern concepts to LCE are emerging in the literature. These are leveraging different data sources and a high level of computational capabilities.

The Integrated Computational Life Cycle Engineering (IC-LCE) integrates data from the entire product lifecycle via coupled models [12]. The results of LCE can be visualized to be communicated to expert and non-expert users by combining LCE with Visual Analytics [13]. Also, knowledge-based engineering can be combined with LCE. A manual way to engineer knowledge and make it available for LCE is introduced [14]. Based on that, a framework to automatically collect data during a products lifecycle is developed [15].

Sakao et al. (2021) identify current challenges and opportunities of LCE and develop a vision for Adaptive and Intelligence LCE (AI-LCE) based on their findings [16]. Here, different engineering capabilities are supported by business intelligence tools based on a database called "memory" and external factors and requirements.

All studies identify issues of current LCE methodologies and therefore derive the need for a new concept. The issues identified are summarized in Table 1.

Table 1. Issues identified with current LCE

Issue #	Issue	Source
1	Lack of Speed	[12, 16]
2	Oversimplified models	[12]
3	Lack of comprehensiveness	[12]
4	Lack of transparency	[12]
5	Lack of integration between environments of core engineering disciplines	[13]

All concepts introduced to solve the issues identified require some sort of database, repository or memory. However, there is no concept of how to build that database and how existing methodologies like PLM and SE can be included into the database concept. Therefore, this paper proposes a new concept based on the Engineering Graph and combining the methodologies of PLM and SE.

3 Related Work for Computer Science

With increased digitalization in engineering and an increased amount of product data that needs to be stored and analyzed, theories from the field of computer science become important in engineering. This section introduces modeling languages that can be used to connect and store engineering data and technologies that are designed to derive information from large datasets such as AI and data science.

3.1 Modeling Languages

SysML has emerged as a machine and human understandable language which describes a product system through requirements, structure, and behavior [17]. The language was invented by the OMG in cooperation with the International Council of Systems Engineering (INCOSE) [6, 18], and was developed to support modeling and (re)-using of engineering information across the lifecycle [19].

Graphical databases focus on relationships between data points. They consist of nodes, which represent data points, and relationships, which connect them. Nodes and relationships can have properties that are used to filter and find data quickly [20]. Properties can be qualitative or quantitative information. The objects and their relationships are represented naturally and clearly by using abstraction concepts [21]. The schema of the graphical database is not fixed at its creation, contrary to relational databases [22]. This leads to their capability to include data from different sources without the need to match the schemas. Therefore, the graphical database can be extended with new and unexpected sources, which is especially useful in complex environments such as engineering [23].

The capability of graph databases to include data from different and unforeseen sources allows building a large and interconnected database from public sources. Thereby, public knowledge from semantic web sources such as Wikimedia [24] or the Google Knowledge Graph [25] can be harvested and linked to a company specific meta structure. That meta structure allows the connection of data from outside sources with company internal data, together building a dataset large enough to allow the application of AI technology.

3.2 Machine Learning and Graph Data Science

Machine Learning is a technology that is capable of making sense of large datasets and deriving information from them without explicit programming [26]. In recent years, several applications to engineering problems such as identification of new product ideas [27], requirements elicitation [28], creativity [29], configuration management [30] and decision support in early design phases [31] are explored.

Machine Learning works by showing a neural network a large dataset of training data. During the supervised training process, the internal weights in the neural network are adjusted automatically to create a model that achieves the desired outcome. This model is then tested on the verification dataset. If it passes, it can be applied to new data and moved to production [32].

Graph data science technology is especially developed to be used on graph databases [33]. The capabilities include community detection, centrality, link prediction and similarity, which will be described in the following.

Community Detection evaluates how a group is clustered or partitioned, as well as its tendency to strengthen or break apart [34]. The weakly connected components can analyze the graphs' structure and find not connected parts. Additionally, the number of communities within a graph can be identified, which brings an understanding of the number of subtopics a graph contains.

Centrality can be used to determine the importance of distinct nodes in a network [34]. One of the most widely applied algorithms is Pagerank [35].

Link prediction is done by using machine learning. A model is trained to learn where relationships between nodes in a graph should exist [34]. This model can then be used to predict further relationships.

Similarity algorithms compute the similarity of pairs of nodes [34]. The similarity between two nodes is calculated based on the nodes they are connected to.

4 Engineering Graph Enhancing MBSE for LCE

This section introduces the evolution in product modeling towards graph-based and summarizes the ongoing research on the Engineering Graph that brings this concept to live in the area of engineering. Lastly, a concept is introduced how the Engineering Graph can bridge PLM and SE and enable Data Science and AI to support LCE.

4.1 Evolution Towards Graph-Based Modeling

The scope of product development has increased. When a product was designed on its own, geometry-based models were sufficient. The increased scope and complexity to design product systems consisting of mechanic, electric and software parts and designing systems of systems where different product systems interact with each other to bring value to the end user needed a new modeling approach with higher abstraction: model-based [36].

Now that the scope is increasing again towards system environments, where product systems and systems of systems are viewed in their environment, e.g. by lifecycle assessments, there is a need for a new modeling approach with higher abstraction: graph-based. Figure 1 shows this evolution.

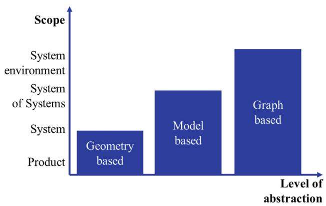

Fig. 1. Evolution of modeling

4.2 Engineering Graph

Previous research already explored the application of graphical databases in engineering. The Engineering Graph was introduced as a graph-based database to support engineering applications such as LCSA [37].

The Engineering Graph connects data from different sources within a company and from external sources such as suppliers, partners and public sources like the semantic web. Data is stored at a high level of abstraction, where the focus lies on the connections between data points and not the data itself. Already existing data and configuration information is not duplicated in the Engineering Graph.

4.3 Engineering Graph Bridging SE, PLM and AI to Support LCE

The Engineering Graph as a graphical database can be used to bridge different engineering methodologies and their underlying data and schemas. This results in a comprehensive and interconnected database.

SE offers the information of product breakdown, how parts are connected and how they work together using which interfaces. PLM offers the product data including configuration information. The information from both methods is connected and enriched with lifecycle data such as where and how a product is used, what norms and regulations it needs to comply with in its target market and additional information from non-government organizations such as the World Health Organization (WHO) or the United Nations (UN).

Graph database technology is able to support LCE and address the issues identified in Sect. 2.3 when the established engineering methodologies PLM and SE are combined. By leveraging already existing models, speed (Issue #1) is increased because there is no duplicate work. This also addresses the issue of oversimplified models (Issue #2) and lack of comprehensiveness (Issue #3) as the models from SE and PLM are very sophisticated. The integration between environments of core engineering disciplines (Issue #5) is increased because the graph can directly integrate the data from these different systems.

Many of the use cases of LCE such as LCSA or cost assessment are predefined in early design phases. The Engineering Graph can be one way to support design decisions in early phases to improve LCE measures by providing large amounts of data early. It contains all freely available LCE information and data from previous product generations. Data Science and AI technologies can be applied if the graph contains a large enough dataset for these technologies to be applicable.

5 Use Case in the Medical Device Industry

In this section the application of the Engineering Graph for LCE is demonstrated at a leading medical device company. First, it is described how the system is built and second, its application for LCE is shown.

5.1 Engineering Graph Connects PLM, SE and External Information

In order to move towards graph-based LCE and support the application of AI technologies, the Engineering Graph is created at a leading Medical Device Company using Neo4J software. The graph spans across different Systems of Interest that are defined as part of the companies SE activities. The “product system” data is stored in the PLM system and connected to the graph (see green nodes in Fig. 2). The brown nodes in Fig. 2 show norms such as the ISO 14044 that is relevant to LCSA. Additionally, it is important to include norms relevant to medical devices such as ISO 62304 as the medical device industry is highly regulated.

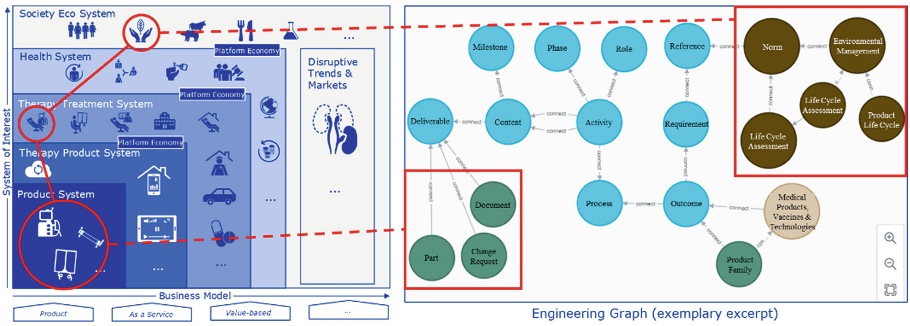

Fig. 2. Engineering Graph connecting data from SE and PLM

The data from the different sources is added to the graph via the import APIs of Neo4J and connected to each other by a predefined meta model (blue nodes). Company external sources such as the Google Knowledge Graph, Wikimedia Graph and information from the WHO as well as the UN are also added via the Neo4J APIs to further enrich the Engineering Graph. The connection to existing nodes is performed manually for the most obvious ones, other relationships can be proposed by the system as shown in the following section.

This database with many connections is made available in early phases of development. Here, it is leveraged to influence the sustainability impact of a products lifecycle. Having this information in early phases of development is important, as many decisions influencing its sustainability impact are made here.

5.2 Engineering Graph Supports LCE

After building the Engineering Graph, the following paragraphs will focus on the analyses that it enables to support LCE. These are the graph data science algorithms introduced in Sect. 3.2. Analyzing the graph across the entire product life cycle and considering relevant norms and regulations can lead to the detection of unknown and unexpected relationships. Discovering the impact of the elements in the graph on each other in an automated way can lead to decreased time to market due to less rework.

First, the graph is analyzed to ensure that it is well connected and that there are no unconnected nodes left. Therefore, the Weakly Connected Components is used. In this example, it could be shown that there exists only one component which means that the graph is well connected. Second, Label Propagation is used to identify communities of nodes in the graph. These can be an indication of how many subtopics the graph contains. In the graph for this paper, 7 communities could be detected.

After the graphs communities are analyzed, Pagerank is used to identify the most important nodes in the graph. In the case of the Engineering Graph in this paper, the "UN Sustainable Development Goals" is the most connected node in the graph.

Next, predictions for new relationships can be generated based on the existing graph. The predicted relationships can be used to complement the graph and to detect unexpected relationships that can represent cause-effect chains. This prediction is based on machine learning. Therefore, a model is first trained on the current relationships in the graph. Second, it is used to generate predictions for new relationships. In the Engineering Graph for this paper, it predicted relationships between all existing nodes with a probability of 49.9%. This result shows that the amount of data in the Engineering Graph is not large enough to successfully apply machine learning. Therefore, the database needs to be increased by adding product data and freely available data from the semantic web.

6 Discussion

The literature of LCE advances towards standardization, comparability and the adoption of new technologies. This paper proposes the application of the concept of the Engineering Graph to LCE to offer a standardized and easy to expand database that leverages existing models and concepts. The concept of the Engineering Graph was introduced in prior research and is here extended by adding data science and AI capabilities and showing its usefulness for LCE use cases.

Larger sample data in the graph will yield more exact data. Currently, the database is not large enough to yield robust results from machine learning technology.

Future research needs to be conducted to embed the creation and maintenance of the Engineering Graph into standard development processes such as the V-model or ISO 15288 for SE. Furthermore, it needs to be shown how the graph can be automatically extended leveraging Natural Language Processing technology. Additionally, the results based on a graph based on a larger dataset need to be reported. Lastly, the graph needs to be applied to further use cases to demonstrate general usefulness.

References

1. INCOSE. Systems Engineering Vision 2035. Accessed 02 Feb 2022
2. Dumitrescu, R., Albers, A., Riedel, O., Stark, R., Gausemeier, J.: Engineering in Deutschland – Status quo in Wirtschaft und Wissenschaft. Ein Beitrag zum Advanced Systems Engineering (2021)
3. Bitzer, M., Eigner, M., Faißt, K.-G., Muggeo, C., Eickhoff, T.: Framework of the evolution in virtual product modelling and model management towards digitized engineering. In: DS 87–6 Proceedings of the 21st International Conference on Engineering Design (ICED 17) Vol 6: Design Information and Knowledge, Vancouver, Canada, 21–25 August 2017 (2017)
4. Sillitto, H., et al.: Systems Engineering and System Definitions, p. 18 (2019)
5. ISO 15288. ISO/IEC/IEEE 15288:2015 (2015)
6. OMG. What is SysML? (2020). http://www.omgsysml.org/what-is-sysml.htm. Accessed 04 Mar 2020
7. Eigner, M., Stelzer, R.: Product Lifecycle Management: ein Leitfaden für Product Development und Life Cycle Management, 2, neu Bearb. Springer, Aufl. Dordrecht (2013)

8. Bracht, U., Geckler, D., Wenzel, S.: Digitale Fabrik: Methoden und Praxisbeispiele, 2. Aktualisierte und erweiterte Auflage. Springer, Berlin (2018). https://doi.org/10.1007/978-3-662-55783-
9. Terzi, S., Bouras, A., Dutta, D., Garetti, M., Kiritsis, D.: Product lifecycle management - From its history to its new role. Int. J. Product Lifecycle Manag. **4**, 360–389 (2010)
10. Hauschild, M.Z., Rosenbaum, R.K., Olsen, S.I.: Life Cycle Assessment: Theory and Practice (2018)
11. DIN EN ISO 14040. DIN EN ISO 14040:2009-11, Umweltmanagement_- Ökobilanz_- Grundsätze und Rahmenbedingungen (ISO_14040:2006); Deutsche und Englische Fassung EN_ISO_14040:2006. Beuth Verlag GmbH (2009)
12. Cerdas, F., Thiede, S., Herrmann, C.: Integrated computational life cycle engineering — application to the case of electric vehicles. CIRP Ann. **67**(1), 25–28 (2018)
13. Kaluza, A., Gellrich, S., Cerdas, F., Thiede, S., Herrmann, C.: Life cycle engineering based on visual analytics. Procedia CIRP **69**, 37–42 (2018)
14. von Drachenfels, N., Cerdas, F., Herrmann, C.: Towards knowledge based LCE of battery technologies. Procedia CIRP **90**, 683–688 (2020)
15. Dilger, N., et al.: Definition and reference framework for life cycle technologies in life cycle engineering - a case study on all solid state traction batteries. Procedia CIRP **98**, 217–222 (2021)
16. Sakao, T., Funk, P., Matschewsky, J., Bengtsson, M., Ahmed, M.U.: AI-LCE: adaptive and intelligent life cycle engineering by applying digitalization and AI methods – an emerging paradigm shift in life cycle engineering. Procedia CIRP **98**, 571–576 (2021)
17. Korthals, K., Auricht, M., Felten, M.: Systems engineering solution lab - experience model based systems engineering at CLAAS. In: Presented at the Prostep ivip Symposium 2020, 02 September 2020 (2020)
18. Incose. History of Systems Engineering (2020). https://www.incose.org/about-systems-engineering/history-of-systems-engineering. Accessed 04 Mar 2020
19. Estefan, J.A.: Survey of model-based systems engineering (MBSE) methodologies. Incose MBSE Focus Group **25**(8), 1–12 (2007)
20. Rawat, D.S., Kashyap, N.K.: Graph database: a complete GDBMS survey. Int. J **3**, 217–226 (2017)
21. Angles, R., Gutierrez, C.: Querying RDF data from a graph database perspective. In: Gómez-Pérez, A., Euzenat, J. (eds.) ESWC 2005. LNCS, vol. 3532, pp. 346–360. Springer, Heidelberg (2005). https://doi.org/10.1007/11431053_24
22. Angles, R., Gutierrez, C.: Survey of graph database models. ACM Comput. Surv. **40**(1), 1:1–1:39 (2008)
23. Vicknair, C., Macias, M., Zhao, Z., Nan, X., Chen, Y., Wilkins, D.: A comparison of a graph database and a relational database: a data provenance perspective. In: Proceedings of the 48th Annual Southeast Regional Conference, New York, NY, USA, pp. 1–6 (2010)
24. Wikimedia. Wikimedia Foundation (2021). https://wikimediafoundation.org/. Accessed 12 Nov 2021
25. Google. Google Knowledge Graph Search API. Google Developers (2021). https://developers.google.com/knowledge-graph?hl=de. Accessed 12 Nov 2021
26. Samuel, A.L.: Machine learning. Technol. Rev. **62**(1), 42–45 (1959)
27. Christensen, K., Nørskov, S., Frederiksen, L., Scholderer, J.: In search of new product ideas: identifying ideas in online communities by machine learning and text mining. Creat. Innov. Manag. **26**(1), 17–30 (2017)
28. Wang,Y., Zhang, J.: Bridging the semantic gap in customer needs elicitation: a machine learning perspective. In: DS 87–4 Proceedings of the 21st International Conference on Engineering Design (ICED 2017), vol 4: Design Methods and Tools, Vancouver, Canada, 21–25 August 2017, pp. 643–652 (2017)

29. Hein, A.M., Condat, H.: Can machines design? an artificial general intelligence approach. In: Artificial General Intelligence, Cham, pp. 87–99 (2018)
30. Liu, H., Huang, Y., Ng, W.K., Song, B., Li, X., Lu, W.F.: Deriving configuration knowledge and evaluating product variants through intelligent techniques. In: 2007 6th International Conference on Information, Communications Signal Processing, pp. 1–5 (2007)
31. Bertoni, A., Larsson, T., Larsson, J., Elfsberg, J.: Mining data to design value: a demonstrator in early design. In: DS 87–7 Proceedings of the 21st International Conference on Engineering Design (ICED 17), vol 7: Design Theory and Research Methodology, Vancouver, Canada, 21–25 August 2017, pp. 021–029 (2017)
32. Mahesh, B.: Machine learning algorithms-a review. Int. J. Sci. Res. (IJSR) **9**, 381–386 (2020)
33. Cook, D.J., Holder, L.B.: Mining Graph Data. John Wiley & Sons, Hoboken (2006)
34. The Neo4j Graph Data Science Library Manual v2.0 - Neo4j Graph Data Science. Neo4j Graph Data Platform. https://neo4j.com/docs/graph-data-science/2.0/. Accessed 30 Mar 2022
35. Brin, S., Page, L.: The anatomy of a large-scale hypertextual Web search engine. Comput. Netw. ISDN Syst. **30**(1), 107–117 (1998)
36. Schweitzer, G.M., Bitzer, M., Vielhaber, M.: Produktentwicklung: KI-ready? Zeitschrift für wirtschaftlichen Fabrikbetrieb **115**(12), 873–876 (2020)
37. Schweitzer, G.M., Mörsdorf, S., Bitzer, M., Vielhaber, M.: Detection of cause-effect relationships in life cycle sustainability assessment based on an engineering graph. In: DESIGN 2022 (2022)