
Transforming Medical Device Data into Product Development Insights with AI

Laura Link*

Karlsruhe Institute of Technology (KIT), IPEK – Institute of Product Engineering, Kaiserstr. 10, 76131 Karlsruhe, Germany
E-mail: laura.link@kit.edu

Katharina Bause

Karlsruhe Institute of Technology (KIT), IPEK – Institute of Product Engineering, Kaiserstr. 10, 76131 Karlsruhe, Germany
E-Mail: katharina.bause@kit.edu

Tobias Düser

Karlsruhe Institute of Technology (KIT), IPEK – Institute of Product Engineering, Kaiserstr. 10, 76131 Karlsruhe, Germany
E-Mail: tobias.düser@kit.edu

* Corresponding author

Abstract: This contribution shows how unstructured medical device safety data can be transformed into actionable knowledge to support early-stage product development. Focusing on national recall and safety reports from the German Federal Institute for Drugs and Medical Devices (BfArM), the authors developed a structured approach for extracting, analysing, and applying real-world failure data. Using Large Language Models (LLMs), unstructured reports were converted into a searchable, categorized dataset highlighting root causes and common failure patterns. To evaluate the practical value of this structured data for future product development of medical devices, a live lab study was conducted. The participants used the data to model product profiles and assessed the usefulness of the database. Results show that the data has potential to support the generation of specific product profile elements. The research demonstrates that regulatory safety data, when properly processed, can offer value in guiding product development actions.

Keywords: Medical Devices; Product Development; Data Analysis; AI; LLM, Risk Mitigation; Innovation; Product Profile

1 Introduction

Medical devices are subject to strict regulations to ensure product reliability and therefore patient safety. Despite these safety measures, devices occasionally fail after enter the market what can lead to serious consequences for the patients' lives as well as for the responsible manufacturers of medical devices – ranging from reputational damage to costly recalls. (Thirumalai and Sinha, 2011)

To trace and prevent these failures, regulatory frameworks, especially under the new European Medical Device Regulation (MDR) require extensive documentation, such as safety and recall information, which can build barriers when it comes to development of new devices. (Bretthauer *et al.*, 2023) (Joshi, Zhu and Xu, 2019) While this generates vast amounts of data and requires lots of resources, this can be seen as a chance to use the knowledge documented for future development processes. Currently there is no uniform way of documenting these failures since different national authorities have different processes. For example, the U.S. MAUDE database managed by the FDA (Food and Drug Administration) contains reports of adverse events, malfunctions, and other issues related to medical devices categorized using specific codes that are not used in other systems. (*Manufacturer and User Facility Device Experience (MAUDE) Database*, 2024) When looking at the German BfArM (Federal Institute for Drugs and Medical Devices), the format of the publicly available recall and safety reports are highly inconsistent in format. They often appear as non-standardized entries – including free-text fields, scanned documents and bad-quality pictures – which makes them difficult to analyse systematically. (BfArM, 2024) Nevertheless, these reports contain critical information with potential to be integrated in future development processes when analysed systematically. (Liebel *et al.*, 2020) Properly processed, the data can help identify common failure mechanisms and support risk mitigation strategies. (Erdman, Keefe and Schiestl, 2013) More specifically, especially in the decision making of early product development processes, this data has the potential to support in defining test cases, prioritizing development objectives and shaping product profiles for future iterations of medical devices. (Link *et al.*, 2024) Product Profiles, as described by Albers *et al.*, are used to capture and document the essential features, functions and characteristics of a product, as well as stakeholder needs and expectations to guide decision making in the product development process. (Albers *et al.*, 2018)

This paper explores how such unstructured safety and recall data can be transformed into actionable development insights. By converting fragmented recall data into structured formats, we aim to bridge the gap between regulatory documentation and practical product development of medical devices, offering an approach to integrate real-world safety data into innovation processes in the MedTech sector.

2 Current Understanding

With the further development of Artificial Intelligence (AI), data-driven approaches in product development are becoming more relevant, wherever useful data is available (Zhan *et al.*, 2018) To contextualise the use of medical devices data, this section reviews

the current understanding of how regulatory safety data and structured development methods contribute to early-stage development activities.

2.1 Supporting Innovation with Regulatory Data

The development of medical devices is time-consuming, costly, and tightly regulated. The high complexity of regulatory compliance is a major challenge for manufacturers, especially in early development phases where design decisions are still fluid and uncertainty is high. (Amaral *et al.*, 2024) Over the past years, increasing attention has been paid to the potential of data-driven approaches in managing these challenges. Among the most underutilized yet promising sources are regulatory safety and recall reports that document real-world device failures, including root causes and corrective actions. While valuable, these data are often unstructured and difficult to analyse due to inconsistencies in format, language, and structure across countries and institutions. (Erdman, Keefe and Schiestl, 2013)

Recent advancements in AI, particularly Large Language Models (LLMs), open up new possibilities for analysing these data at scale. By extracting and clustering relevant information from heterogeneous sources, LLMs can reveal patterns in failure mechanisms and highlight recurring issues in specific device categories. (Link *et al.*, 2024) Building on this foundation, our research seeks to operationalize these insights for practical use in product development.

2.2 Product Profiles and Their Role in Product Development

One of the key challenges in early product development is to translate stakeholder needs into clear, actionable design objectives. Product profiles serve as a tool to meet this challenge with capturing customer and provider expectations, including use cases, benefits, requirements, and boundary conditions (Figure 1). They form a central reference point for interdisciplinary development teams and help align technical design decisions with user value. (Albers *et al.*, 2018)

However, the development of valid product profiles necessitates structured and relevant information, which is frequently insufficient or unavailable in the early stages of projects. By systematically analysing existing safety and recall data, developers can derive concrete indications of what went wrong in previous device generations. These insights can support the generation of use cases, anticipate critical test scenarios, and help define product-specific claims and constraints.

In this context, we explore whether regulatory safety data can effectively contribute to modelling product profiles, thereby enabling a more data-informed and risk-aware approach to innovation in the MedTech domain.

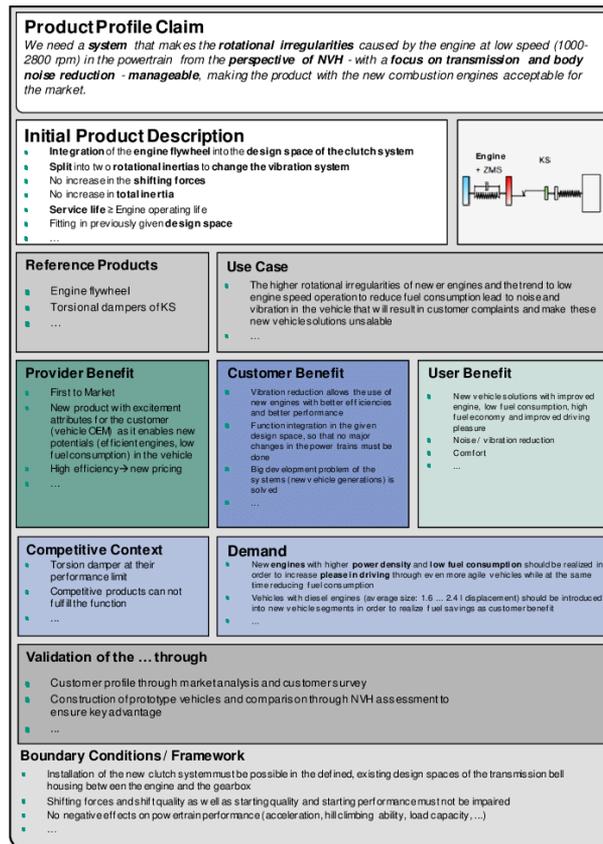


Figure 1: Example of a filled product profile scheme in the field of automotive engineering (Albers *et al.*, 2018)

2.3 System Generation Engineering (SGE)

In addition to product profiles, another established approach relevant to innovation management is the SGE (System Generation Engineering) model, which emphasizes the systematic use of reference systems. In the context of new product development, the core premise of SGE is that existing references—such as predecessor systems, competitor products, or even innovations from other industries and research—form the basis for developing new solutions. A key strength of the SGE model lies in its ability to harness insights from earlier system generations. This historical knowledge helps identify innovation opportunities and assess development risks. By systematically analysing past successes and failures, one can make better-informed decisions, anticipate technical and organizational challenges, and avoid costly errors. (Albers and Rapp, 2022)

However, one of the main obstacles within the SGE framework is accessing and utilizing this knowledge effectively. Information about previous systems is often fragmented, undocumented, or confined to specific departments within a company. These limitations hinder the full potential of SGE, particularly when critical insights remain siloed or are not shared across teams. In this context, the integration of structured

regulatory safety data can be viewed as a means of operationalizing the principles of SGE, by systematically capturing and utilizing external reference knowledge to inform and de-risk the development of next-generation medical devices.

3 Research Aim

The aim of this research is to demonstrate how unstructured safety and recall data from medical devices can be processed and applied to support early-stage product development. In addition, it investigates which specific activities within the product profile modelling process are best supported by the structured data.

The research focuses on three main aspects: (1) the technical preparation and structuring of raw data, (2) the practical application of this structured data in modelling product profiles, and (3) the evaluation of the data's usability in a controlled educational live lab setting. Based on these objectives, the following research questions guide this study:

- RQ1: How can unstructured safety and recall data from the MedTech sector be prepared for systematic analysis? (Chapter 4.1)
- RQ2: How can these analytical results be transformed into practical insights for product development processes? (Chapter 4.2)
- RQ3: To what extent does the structured data support the modelling of product profiles? (Chapter 5)
- RQ4 (Outlook): What are potential future applications of this data-driven approach in product development? (Chapter 7)

4 Research Design

To systematically examine the feasibility and practical value of using structured safety data in product development, this research follows a research design combining data processing, AI-supported analysis, and empirical evaluation.

4.1 Data Source and Preparation

The primary data source is a collection of national recall and safety notifications from the BfArM, covering entries from 2004 to the first quarter of 2024. In Figure 2, the structure of the BfArM safety notifications is shown.

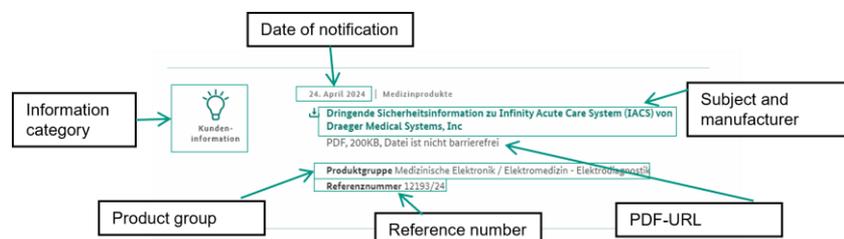


Figure 2: Structure of BfArM Safety Notice Entry

The dataset includes a variety of formats, ranging from text-based PDFs to scanned documents with low image quality. These documents often contain inconsistent structures, complex tables, and mixed content, making automated extraction challenging.

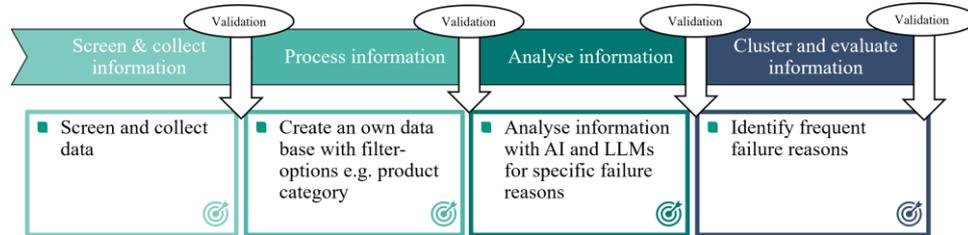


Figure 3: General approach to analyse safety and recall information

To address these issues, LLMs were tested and employed to parse and process the documents. After converting the PDFs into machine-readable text, the LLMs were used to extract and summarize relevant sections describing the causes of reported incidents. The challenge hereby was the right prompting and to choose a LLM that is able to generate robust and compact descriptions of the safety notices. In this case the GPT-4o Model was used based on accessibility, the quality and the robustness of the results. These textual summaries were then categorized and clustered in a next step by the LLM, based on recurring failure mechanisms, forming a structured dataset (Figure 3). The output was stored in a searchable, tagged format to enable targeted access to specific types of failure causes and device categories (Table 1).

Table 1 Excerpt from the Live-Lab data base – Product Group Cardiac Pacemaker

<i>Date</i>	<i>Subject</i>	<i>Manufacturer</i>	<i>Product Category</i>	<i>Root Cause</i>	<i>Failure Category</i>
10/11/2023	Urgent safety notice for Assurity, Endurity by Abbott Sylmar	Abbott	Active implantable medical devices - pacemakers	The central issue of the safety communication concerns a potential malfunction in a limited subset of Assurity™ and Endurity™ pacemakers caused by a manufacturing issue. These malfunctions may result in loss of pacing, shortened battery life, switch to back-up mode, loss of telemetry/communication and/or shortened time between recommended replacement time and end of life.	Production and material quality

4.2 Evaluation in a Live-Lab Setting

The structured dataset was then evaluated in an educational Live-Lab involving ten participants with backgrounds in product development. All participants were familiar with the product profile template but had no prior experience in medical technology. Participants were introduced to the context and received a short tutorial on how to use the database. They were then assigned three fictional product categories and asked to work in pairs to create product profiles based on the available data.

The goal was not to assess the quality of the resulting profiles, but to evaluate whether and how the structured safety data could support the modelling process. After a 45-minute working session, each group presented their results and completed a standardized questionnaire. The questionnaire used a 5-point Likert scale (from -2 = strongly disagree to +2 = strongly agree) to assess the perceived usefulness, sufficiency, and relevance of the data in supporting the generation of product profile elements such as use cases, customer benefits, boundary conditions, and validation strategies. Free-text comments were also collected for qualitative insights.

5 Results

The primary outcome of this research is the demonstration of how unstructured medical device data – more specifically recall and safety reports – can be transformed into support for early product development activities, such as modelling product profiles. This approach was evaluated through a Live-Lab study. The participants were asked to use the newly created database, which contains processed and clustered safety report data from the BfArM to derive product profiles for three pre-selected product categories. The evaluation was conducted using a standardized questionnaire based on a 5-point Likert scale, assessing the usability and relevance of the information provided in the database for modelling product profiles.

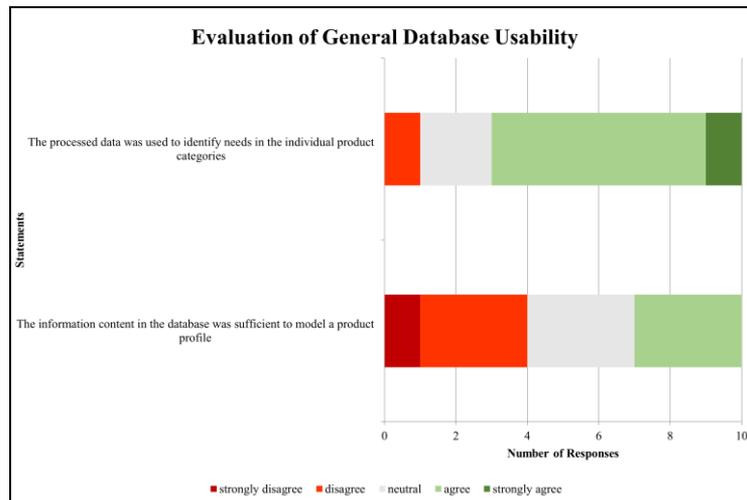


Figure 4: General evaluation results of using the data base

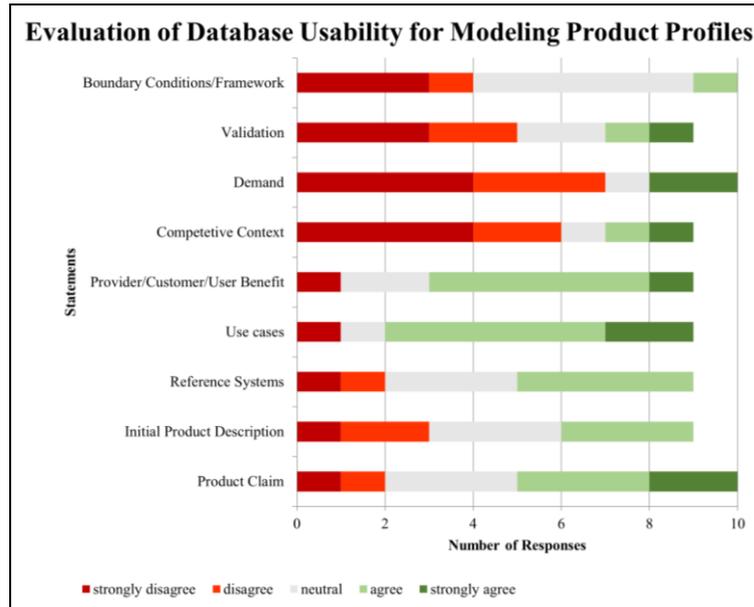


Figure 5: Evaluation results of using the data base for modelling product profiles in a Live-Lab Study

The evaluation results indicate a generally positive reception of the structured database, with varying degrees of agreement across different aspects of the product profile modelling process (Figure 4). Participants mostly agreed that the processed data helped identify needs within the product categories (Figure 3). Similarly, statements relating to the generation of concrete elements such as Provider/Customer/User Benefit and Use Cases positively rated, suggesting that participants were able to extract valuable insights from the data to support the creation of these components.

In contrast, certain elements of the product profile were perceived as more difficult to derive. For example, validation and boundary conditions received lower and more mixed evaluations, indicating uncertainty or lack of clarity in the data for these categories. The statement regarding the overall sufficiency of the information for modelling a product profile suggests a neutral to slightly critical perception regarding the completeness of the database content.

In addition to the quantitative ratings, qualitative feedback provided valuable insights into participants' experiences with the structured database. Several participants expressed the need for more detailed and technically specific information, particularly regarding root causes of failures. Comments such as "the root cause was too generic", "I missed the technical background", and "the problem descriptions lacked depth" indicate that while the overall structure of the data was appreciated, its content was at times perceived as superficial. Participants also highlighted that clearer differentiation between device categories and more context around the reported incidents would enhance usability. Despite these limitations, the structured format and the categorization of failure mechanisms were generally seen as helpful. The feedback suggests that while the database serves as a useful entry point for modelling product profiles, particularly for

elements like use cases and stakeholder benefits, further refinement is needed to support technically demanding aspects such as validation or regulatory considerations.

6 Discussion

The findings of this study demonstrate that regulatory safety data—when properly processed and structured—can indeed support early product development processes, particularly in the modelling of product profiles. However, the evaluation results also reveal important nuances and limitations that need to be considered when interpreting the data and generalizing the approach.

One of the main challenges encountered during the data preparation phase was the heterogeneity and poor quality of source documents. Many of the original safety reports were unstructured, scanned, or formatted inconsistently, making data extraction highly complex. While LLMs provided valuable support in parsing and clustering textual content, the quality of the output remained heavily dependent on the initial input format. In some cases, relevant technical details were not extractable or were too generic to offer concrete value for specific product categories.

These limitations were also reflected in the evaluation phase. While participants generally agreed that the database supported the generation of elements such as product claims, use cases, and stakeholder benefits, more abstract or technically demanding categories—such as validation strategies or boundary conditions—received mixed or even critical ratings. This suggests that certain elements of the product profile require either more detailed data or additional contextual knowledge that goes beyond what can be extracted from safety reports alone.

Another important aspect is the user group itself. The evaluation involved only a small number of participants with no prior experience in medical technology. While this helped to assess the general usability of the data, it may have also limited their ability to interpret complex or highly specific failure scenarios. Future evaluations involving domain experts could provide deeper insights into the relevance and completeness of the structured data and its potential for different use cases.

Furthermore, while the scope of this study was limited to safety data from BfArM, the underlying approach can potentially be adapted to other regulatory sources and industries. However, this requires further validation and may involve adjustments to account for different document structures, languages, and regulatory frameworks.

Overall, this study confirms the value of data-driven approaches in innovation management but also highlights the importance of data quality, user context, and technical domain knowledge as well as a methodological approach when integrating AI-supported analysis into product development workflows.

7 Summary and Outlook

This paper presents a data-driven approach to support early-stage medical device development by leveraging unstructured safety and recall data. Using safety reports from the German BfArM as a case example, we demonstrated how such data can be processed and structured with the help of LLMs to extract root causes and failure patterns. The

resulting database was evaluated in a controlled live lab environment, where participants used the information to model product profiles.

The results show that structured safety data can meaningfully contribute to the generation of key elements such as product claims, use cases, and stakeholder benefits. However, the approach also revealed limitations—particularly in supporting more abstract or technically demanding components of the product profile, such as validation strategies and framework conditions. These limitations are mainly due to data quality issues and the lack of domain-specific interpretation.

Beyond the modelling of product profiles, the structured safety data approach introduced in this study holds potential for broader application in medical product development. For instance, the extracted failure patterns could support the creation of more realistic test scenarios in validation planning, or help prioritize requirements based on known weaknesses of previous product generations. Additionally, integrating this data into early risk assessments or design control documentation could improve regulatory readiness and streamline compliance processes. As regulatory data becomes more accessible and AI tools more sophisticated, this approach could evolve into a scalable component of product development processes.

Looking forward, the approach introduced in this study holds promise for broader application. To enhance its effectiveness, future research should focus on improving data preprocessing, expanding the semantic tagging of extracted content, and integrating domain expert feedback into the evaluation process of a methodological support. Additionally, adapting the system to multilingual and multinational datasets could further increase its scalability and impact.

In conclusion, this research contributes to the ongoing integration of AI into innovation management by demonstrating how regulatory data can be transformed from a compliance burden into a strategic asset for product development.

References and Notes

Albers, A. *et al.* (2018) ‘Product Profiles: Modelling customer benefits as a foundation to bring inventions to innovations’, *Procedia CIRP*, 70, pp. 253–258. Available at: <https://doi.org/10.1016/j.procir.2018.02.044>.

Albers, A. and Rapp, S. (2022) ‘Model of SGE: System Generation Engineering as Basis for Structured Planning and Management of Development’, in D. Krause and E. Heyden (eds) *Design Methodology for Future Products: Data Driven, Agile and Flexible*. Cham: Springer International Publishing, pp. 27–46. Available at: https://doi.org/10.1007/978-3-030-78368-6_2.

Amaral, C. *et al.* (2024) ‘Global Regulatory Challenges for Medical Devices: Impact on Innovation and Market Access’, *Applied Sciences*, 14(20), p. 9304. Available at: <https://doi.org/10.3390/app14209304>.

Bretthauer, M. *et al.* (2023) ‘The New European Medical Device Regulation: Balancing Innovation and Patient Safety’, *Annals of Internal Medicine*, 176(6), pp. 844–848. Available at: <https://doi.org/10.7326/M23-0454>.

Erdman, A.G., Keefe, D.F. and Schiestl, R. (2013) 'Grand Challenge: Applying Regulatory Science and Big Data to Improve Medical Device Innovation', *IEEE Transactions on Biomedical Engineering*, 60(3), pp. 700–706. Available at: <https://doi.org/10.1109/TBME.2013.2244600>.

Joshi, A., Zhu, B.Z. and Xu, L. (2019) *Trends in Medical Device Recalls*, *MedTech Intelligence*. Available at: https://medtechintelligence.com/feature_article/trends-in-medical-device-recalls/ (Accessed: 6 August 2024).

Liebel, T.C. *et al.* (2020) 'Analysis: Using the FDA MAUDE and Medical Device Recall Databases to Design Better Devices', *Biomedical Instrumentation & Technology*, 54(3), pp. 178–188. Available at: <https://doi.org/10.2345/0899-8205-54.3.178>.

Link, L. *et al.* (2024) 'Evaluation of Medical Device Data and their Potential Use in Medical Product Development', *The 2024 Biomedical Engineering International Conference (IEEE)* [Preprint], (16). Available at: <https://doi.org/in press>.

Manufacturer and User Facility Device Experience (MAUDE) Database (2024). Available at: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm> (Accessed: 13 August 2024).

Thirumalai, S. and Sinha, K.K. (2011) 'Product Recalls in the Medical Device Industry: An Empirical Exploration of the Sources and Financial Consequences', *Management Science*, 57(2), pp. 376–392. Available at: <https://doi.org/10.1287/mnsc.1100.1267>.

Zhan, Y. *et al.* (2018) 'Unlocking the power of big data in new product development', *Annals of Operations Research*, 270(1–2), pp. 577–595. Available at: <https://doi.org/10.1007/s10479-016-2379-x>.