Paper ID:	1571068061
Paper Title:	Evaluation of Medical Device Data and their Potential Use in Medical Product Development
Authors:	Laura Link (Karlsruhe Institute of Technology (KIT), Germany & IPEK - Institute of Product Engineering, Germany); Katharina Bause (Karlsruhe Institute of Technology (KIT), Germany); Stefan Eric Schwarz (Karlsruhe Institute of Technology (KIT) & IPEK - Institute of Product Engineering at KIT, Germany); Lars Gesmann (Karlsruhe Institute of Technology KIT, Germany); Tobias Düser (Karlsruhe Institute of Technology (KIT) & IPEK - Institute of Product Engineering at KIT, Germany)
Email:	laura.link@kit.edu

Abstract

In the highly regulated field of medical device development, leveraging data offers opportunity to reduce uncertainty and optimize the development process. This work examines the potential of leveraging existing safety and recall data to support and enhance product development activities in the medical industry. This paper provides an overview of three significant data sources and highlights their utility in informing product design and regulatory compliance. Through an example analysis of implantable defibrillator safety notices, the research categorizes failure types, demonstrating the value of data-driven insights for future product iterations and research directions. Based on this, requirements for a knowledge database for product development can be derived, in particular which information must be processed and how the information can be evaluated. The findings underscore the importance of developing automated processes for data analysis and propose further steps to enrich datasets for deeper trend analysis and the identification of innovation opportunities in medical device development.