

Medical Device Failures Analysis: Engineering Management Perspectives

Limpat Salamat

Engineering Management
Faculty of Engineering and IT
University of Melbourne
Melbourne, Australia

lsalamat@student.unimelb.edu.au

Abstract

Medical device develops over time and failure cases persist, resulting in many complications, including deaths. This paper investigates some real-world medical device failures, which are pacemaker, insulin pump, vascular closure device, and ventricular assist device and presents the common causes and implications. This paper will put forward engineering management perspectives from the cases and propose solutions for managing medical device projects. Literature reviews are conducted to figure out the failure causes and areas for improvement to diminish medical device failure in the future. Intense competition, disturbed system engineering and flawed regulation are the common causes identified by this paper. This paper proposes improvements in regulation and guidelines for the medical device industry so that its project management is handled with specific standards and monitored accordingly with particular regulations. In the end, this paper will help all stakeholders in the medical device industry when developing new medical devices.

Keywords

Medical device, Failure cases, Engineering management, Project management.

Biography

Limpat Salamat is currently a Master of Engineering Management student at Faculty of Engineering and IT, University of Melbourne. His previous background was Bachelor of Biomedical Engineering at Faculty of Science and Technology, Airlangga University. He published two journal articles with the focus topic of arm biomechanics and hand prosthetics. Before continuing his study, he was a professional worker at several private medical device companies. He is now interested in engineering and project management in medical device industry focusing on medical device failure.