Chapter 19
Quality Assurance in Medical Devices:
A Bibliometric Analysis

Juliana Shaibun
Universiti Utara Malaysia, Malaysia

ABSTRACT

Quality management system (QMS) is acknowledged as the primary method for any manufacturer, especially medical device manufacturers, in order to sustain the product quality in the competitive advantage in business environment. QMS is an essential requirement for regulatory control in high risk medical devices. Globally, the number of medical device manufacturers certified by ISO 13485 is escalating. Ownership of this certification symbolizes the medical device manufacturer acquired high performance in their QMS. This bibliometric provides a brief review of the quality assurance and how safety plays an important role in medical devices. Bibliometric analysis guided user to summarize the essential part of quality assurance process in medical device. The insights presented in this research assist in building a firm theoretical base and direction for future research.

INTRODUCTION

Healthcare environment grows rapidly days by days which require optimum measurement of the quality of end user medical care. Strict criteria have been generated by The National Quality Forum for the assessment of potential performance measures throughout medical area as acknowledged by Friedman (2016). Quality Management System (QMS) is acknowledged as the primary method for any manufacturer especially medical device manufacturer in order to sustain the product quality in the competitive advantage in business environment. QMS is essential requirements for regulatory control in high risk medical device. Globally, the number of medical device manufacturers certified by ISO 13485 is escalating. Ownership of this certification symbolizes the medical device manufacturer acquired high performance in their QMS.

DOI: 10.4018/978-1-7998-4772-4.ch019

Copyright © 2021, IGI Global. Copying or distributing in print or electronic forms without written permission of IGI Global is prohibited.

ISO 13485 is required to apply the medical device regulatory requirements into QMS. Likewise, ISO 14971 is a standard for Medical Device Risk Management also plays important role. Additionally, ISO 13485:2003 also refers to ISO 14971. Even though it is not compulsory in some of the country, this standard serves as guidance to medical device organizations prior to development of the risk evaluation process (Westgard, 2013).

Medical Device Reprocessing (MDR) is vital for the safety and health of end user guided by the industry service standards (Lorv, Horodyski, Welton, Vail, Simonetto, Jokanovic, Sharma, Mahoney, Savoy-Bird, & Bains, 2017). Past scholars like Lorv et al. (2017) stressed that the establishment of initial structure that form on prominent instructions, consist of service standards, targets and key performance indicators for MDR operations assessment need to be further explored. This structure is still scant in the extant research and vital to uphold healthcare facilities to endure with the current practices, and to empower a platform towards collaboration for better MDR performance management.

Additionally, there is deficiency of clarity in the safety certification process as reported by Mark (2013). When x-rays the worldwide medical related issue, much incident that harm patient were related to medical devices. The regulatory processes were in questioned on their capability to assure patients safety and care adequately from preposterous risk and harm. Garcia and Costa (2008) asserted that in order to maintain the product and service quality, adaptation of an effective QMS is imperative as one of the manufacturer strategies.

More research that delve into facet of consumer behavior in the digital economy is deemed necessary (Ling Chang, Ling Tam, & Suki, 2016; Nathan, Fook Chiun, & Suki, 2016; Suki, 2013; Suki, 2013a; Suki, 2013b; Suki, 2016; Suki & Abang Sulaiman, 2016). The aims of this study are to analyze trends in research on quality assurance in medical device between 2011 and 2020 by using bibliometric analysis. Bibliometric research is referred to "The statistical analysis of books, articles, or other publications… to measure the 'output' of individuals/research teams, institutions, and countries, to identify national and international networks, and to map the development of new (multi-disciplinary) fields of science and technology" (OECD Glossary of Statistical Terms, 2013, para 1-3). In the present study, aspects such as journal distribution, origin country of authors, keywords analysis, and citation analysis were the emphasized in this bibliometric analysis.

The major discovery of the paper is delineated as follows:

1. A detailed bibliometric analysis of mobile device has been executed via Scopus database.
2. The progression of research related to quality assurance in medical device are documented between 2011-2020.
3. The aspects of journal distribution, origin country of authors, keywords analysis, and citation analysis were assessed.

The ensuing section of the paper describes the data collection process and the methodology employed. Section 3 details the description of bibliometric analysis in terms of journal distribution, origin country of authors, keywords analysis, and citation analysis. The final section presents the conclusion and direction for future research.

11 more pages are available in the full version of this document, which may be purchased using the "Add to Cart" button on the publisher's webpage:
www.igi-global.com/chapter/quality-assurance-in-medical-devices/261537

Related Content

Traditional and Complementary Medicine (TCM) Usage vs. Health Technology: Moderating Effect of Races
Dyana M. L. Changand Norazah Mohd Suki (2021). *Handbook of Research on Technology Applications for Effective Customer Engagement (pp. 315-328).*
www.irma-international.org/chapter/traditional-and-complementary-medicine-tcm-usage-vs-health-technology/261538

A Critical Investigation in Measuring the Impact of the Metaverse in Revolutionising the Future of Financial Services
Sanya Sethand Saumya Seth (2022). *Applying Metalytics to Measure Customer Experience in the Metaverse (pp. 1-8).*
www.irma-international.org/chapter/a-critical-investigation-in-measuring-the-impact-of-the-metaverse-in-revolutionising-the-future-of-financial-services/309299

CRM as Antecedent of Electronic Retailing and Online Customer Satisfaction
Joshua Kofi Doeand George Kofi Asamoah (2022). *Building a Brand Image Through Electronic Customer Relationship Management (pp. 169-200).*
www.irma-international.org/chapter/crm-as-antecedent-of-electronic-retailing-and-online-customer-satisfaction/312115

Investigating Quick Response Code Application in Third-Party Logistics Companies
Siti Norida Wahab, Yew Meng Cheeand Dazmin Daud (2021). *Handbook of Research on Technology Applications for Effective Customer Engagement (pp. 234-252).*
www.irma-international.org/chapter/investigating-quick-response-code-application-in-third-party-logistics-companies/261533

Understanding Customer Engagement and Purchase Behavior in Automobiles: The Role of Digital Technology
Krishnadas R. (2021). *Handbook of Research on Technology Applications for Effective Customer Engagement (pp. 1-13).*
www.irma-international.org/chapter/understanding-customer-engagement-and-purchase-behavior-in-automobiles/261519