Abstract

The Master Thesis called "*Process Evaluation for an Electronic Quality Management System in a Digital Health Start-up Company.*" was developed by Catalina Avendano Mejia as part of a Master Thesis research to obtain the title of master's in biomedical engineering as a combined program from the Universität zu Lübeck and the Technische Hochschule Lübeck. This Master Thesis was developed within the start-up Smart4Diagnostics GmbH ("S4DX") located in München/ Germany.

S4DX is a start-up that offers solutions to the pre-analytical phase of clinical laboratories. S4DX is growing and reaching more and more markets. Therefore, the processes and documentation have been growing and need to be carried out efficiently. One of the measures to improve the handling of documentation was the creation of an Integrated Management System (IMS). The Quality Management System (QMS) is part of the IMS. In the past, there was just paper-based documentation without a version tracking system, which led to an unnecessary accumulation of non-updated documents of this IMS and QMS were integrated into a new platform called Confluence from Atlassian to create an electronic Quality Management System (eQMS).

In healthcare, the effective management of quality processes is crucial to ensure the safety and efficacy of product solutions. The purpose of this thesis is to evaluate crucial processes of the QMS such as Incoming Control, Supplier Evaluation, and Nonconformities. And search for improvement opportunities. To achieve these improvements in processes, mixed methods and quality tools have been implemented. On the one hand, some of the methodologies used to collect data for searching for improvement was the use of interviews, questionnaires, and document analysis. On the other hand, several quality tools were used to analyze the data collected, such as histograms, control charts, check sheets, cause-and-effect diagrams, brainstorming, and Pareto analysis. In addition, for a better understanding of the status of the processes before and after this thesis, process mapping and modeling were created. Moreover, for the processes Incoming Control and Supplier Evaluation Processes, Power BI dashboards for KPI tracking were created. And for the nonconformity process, a new system called 8D report was implemented.

In conclusion, this research covers the processes evaluation of Incoming Control, Supplier Evaluation, and Nonconformities process for the digital healthcare company S4DX within an eQMS, which is part of an IMS. This thesis emphasizes quality improvements and enhances a culture of continuous improvement. Furthermore, these processes did not fulfill ISO 9001 requirements therefore solutions needed to be implemented. The improvements in these processes include cross-functional work culture, which was not present in these 3 processes. In addition, the use of KPI Dashboards and data analytics in Power BI is a new measure implemented in S4DX through this thesis as well as the use of automate flows in Power Automate to develop task such automatically inform other teams when a process is finish for control or continuity. One challenge of this thesis was to decide which was the appropriate software to develop the improvements of the processes and which are the KPIs that needed to be measure. Moreover, the development of the thesis was challenging due to the fact that the processes were not appropriate to meet ISO requirements. Another challenge for development of this thesis was the search for a manner on how to implement processes that follows ISO requirements, since it was challenging to pass from the theoretical interpretation of the ISO requirements to the practical part.