

Feasibility Study of Statistical Analysis Tool Replacement for Quality Control Process

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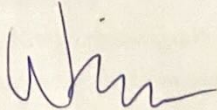
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STATEMENT BY THE AUTHOR

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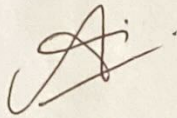


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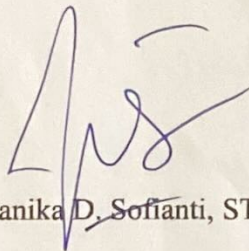
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ABSTRACT

Feasibility Study of Statistical Analysis Tool Replacement for Quality Control Process

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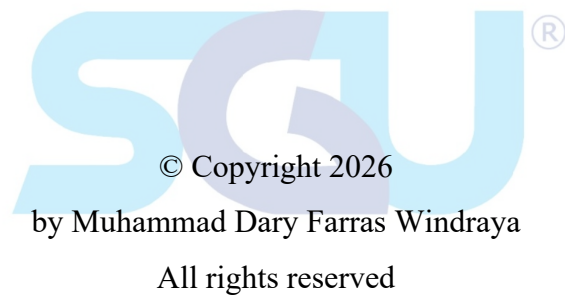
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A pharmaceutical manufacturing company is considering the adoption of MATLAB as a centralized statistical analysis platform to replace its existing software. Pharmaceutical quality control activities are governed by strict regulatory requirements that mandate statistically justified data analysis; however, in practice, statistical workflows are often fragmented across multiple tools, leading to manual data handling and operational inefficiencies. This study evaluates the feasibility of implementing MATLAB for quality control applications using a mixed-method approach based on the TELOS framework (Technical, Economic, Legal, Operational, and Schedule). Technical feasibility was assessed through functional replication testing and prototype demonstrations using identical datasets, while economic feasibility was evaluated using an assumption-based cost-benefit analysis supported by user perception data. Legal feasibility was examined through regulatory analysis with reference to Indonesian Good Manufacturing Practice for Drugs (CPOB) requirements, and operational and schedule feasibility were assessed through Likert-scale user evaluations and expert judgement. The results indicate that MATLAB can replicate the required statistical analyses without altering analytical outcomes, and the economic evaluation suggests that projected efficiency gains outweigh the associated costs under the stated assumptions. Overall, MATLAB is considered feasible for controlled and phased implementation as a centralized statistical analysis platform for pharmaceutical quality control activities.

Keywords: Statistical Tool; MATLAB; Feasibility Study; TELOS framework; Pharmaceutical Quality Control.



DEDICATION

To God, my family, and my friends,
who have given me strength throughout this journey.



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