Implementation of a Change Control Process in a Pharmaceutical Industry

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Abstract

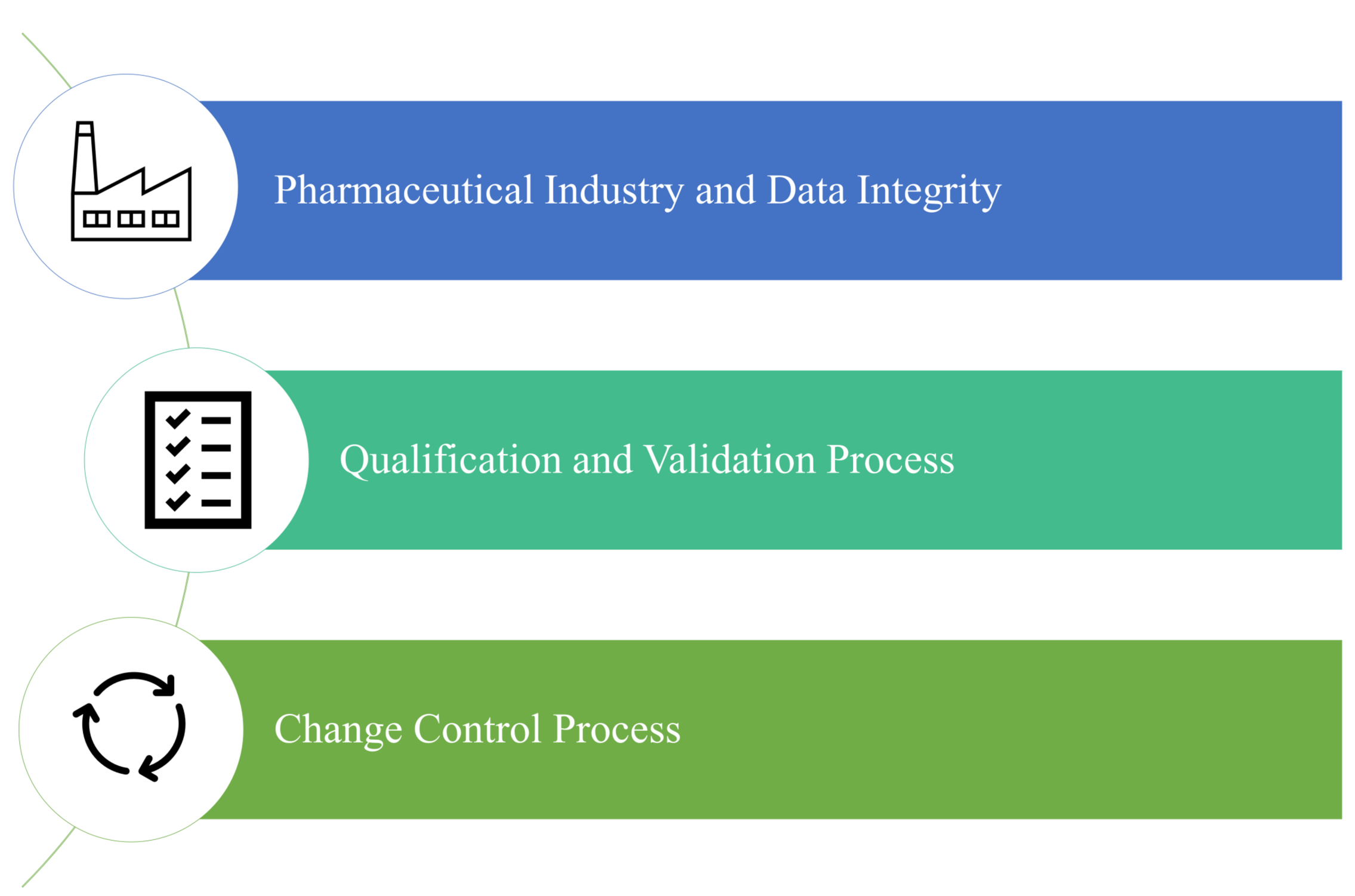
The pharmaceutical industry is monitored by the highest regulatory bodies such as the Food and Drug Administration (FDA) and other agencies to ensure compliance with Good Manufacturing Practices (GMP) and Good Documentation Practices (GDP). The quality of the product is demonstrated through data generated within the process and supporting documentation. The data should demonstrate consistency, accuracy and completeness for data integrity. At the same time the equipment, process and systems should be validated for the intended use. This project focuses on the implementation of a change control in a validated system emphasizing in the required documentation to demonstrate the system has the capacity to function as it is intended and continues to meet regulatory standards. Additionally, the project provides a solution to a problem that has the potential to have data integrity issues.

Key Terms* —*Change Control, Computer System Validation, Pharmaceutical Industry.

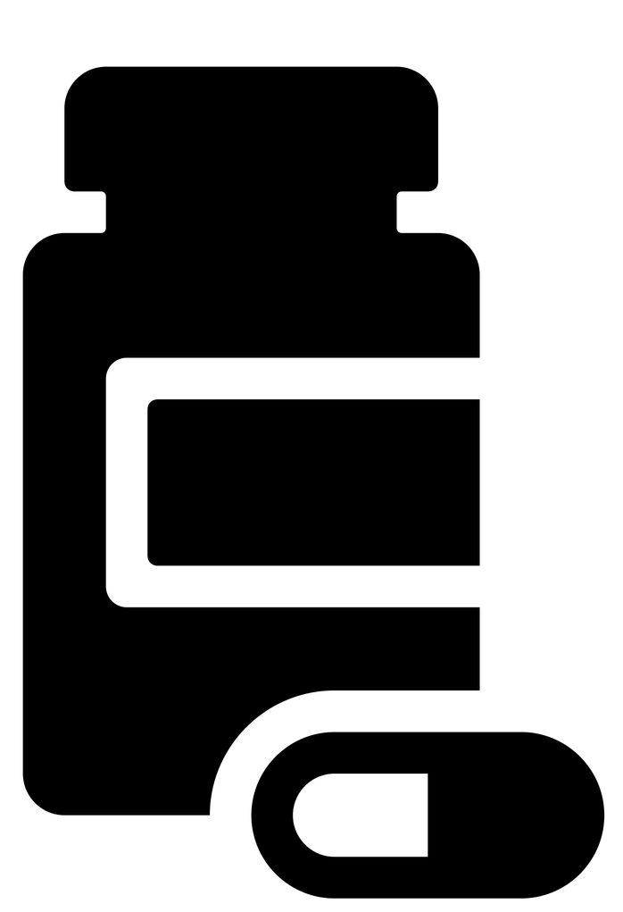
Introduction

The pharmaceutical industries are highly regulatory industries that require documentation for most improvements. Since the improvement to target the problem involves a qualified and validated system, documentation and analysis is required. This research focuses on the regulatory requirements and documentation required to successfully complete the improvements.

Background



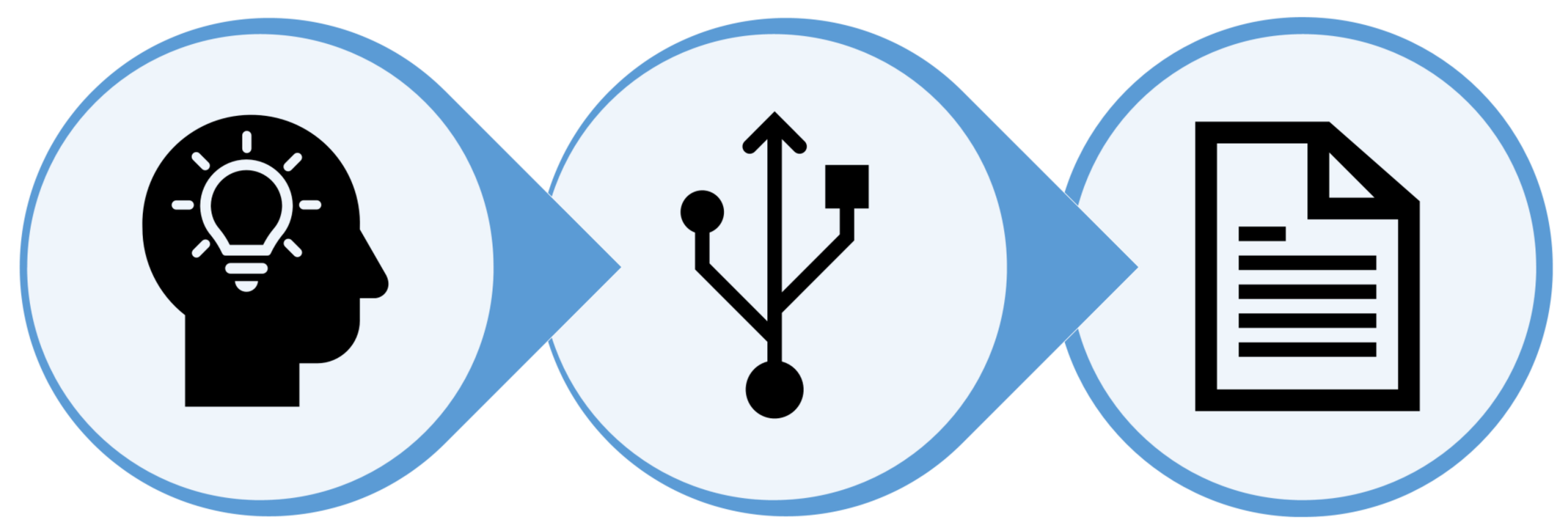
Problem



A Process Team in the pharmaceutical industry was facing instances of power failures on the site. A power failure during the encapsulation process was causing additional documentation such as deviation and incidents, data gathering and reconciliation since a counter of samples was reset to zero and did not store the last value before the power failure. The counter started from zero when the power came back.

Methodology

The strategy to solve the problem and implement the improvement starts with identifying the root cause of the problem. After the complete solution to target the problem is established, the solution is presented to document a change control. The change control will document all the change control requirements to implement the fix.



Results and Discussion

The permanent solution to this problem was to make a software modification on the PLC. For the software fix to work as expected, it was required to replace the existing Uninterruptible Power Supply (UPS) and do a wire modification of the UPS with the PLC.

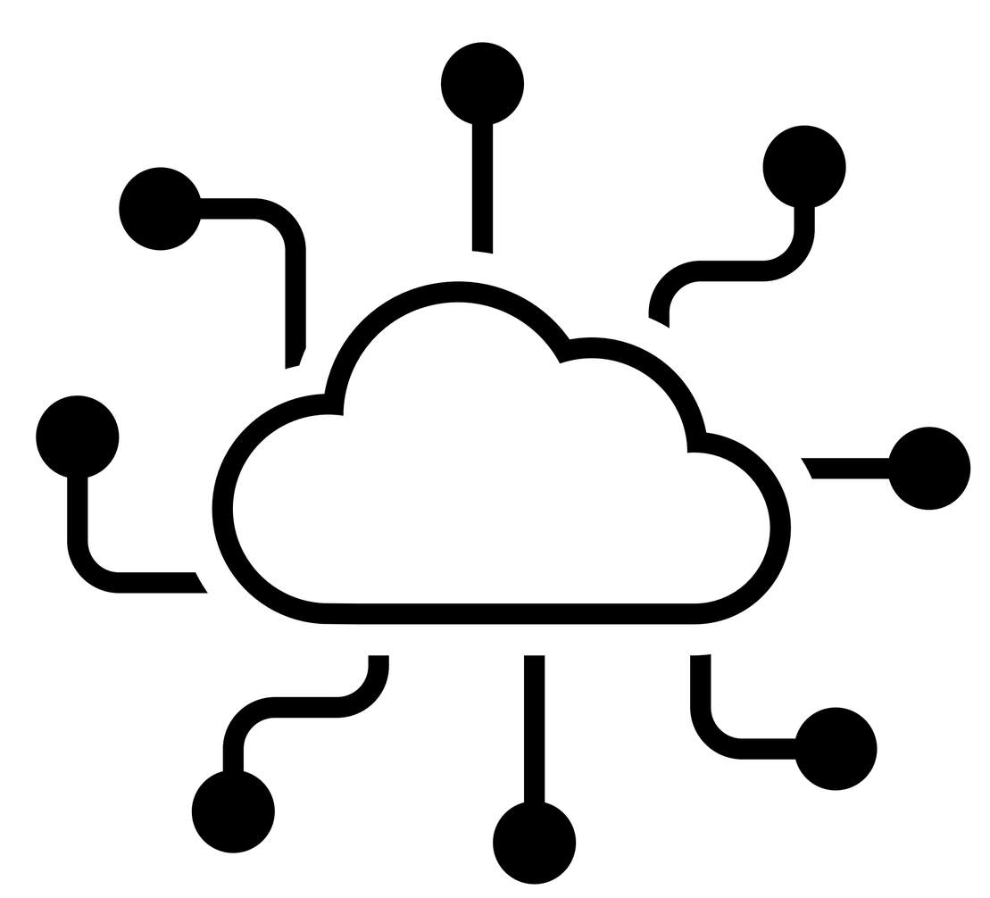


Table 1. Change Control Requirements

Change Control Requirements	
Description	Current State
	Proposed State
	Justification
	Change Control Discussion Meetings
	Risks
Classification	Quality
	Environmental
	Health and Safety
Implementation Steps	Actions
	Action Owner
	Action Completion Criteria
	Due Date

The change control requirements were explained in the different sections that include the change control document.

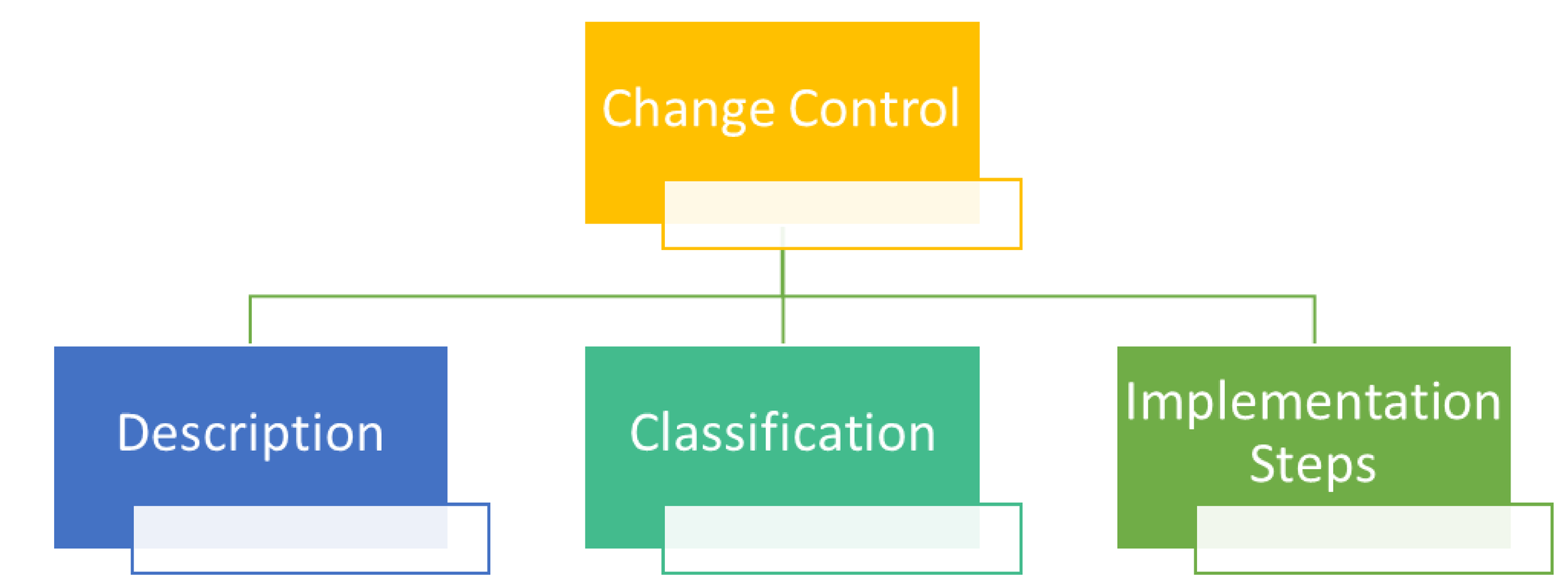


Figure 2. Change Control Main Sections

There were general activities completed during the execution of the change control. Table 2 demonstrates the activities completed for the change control.

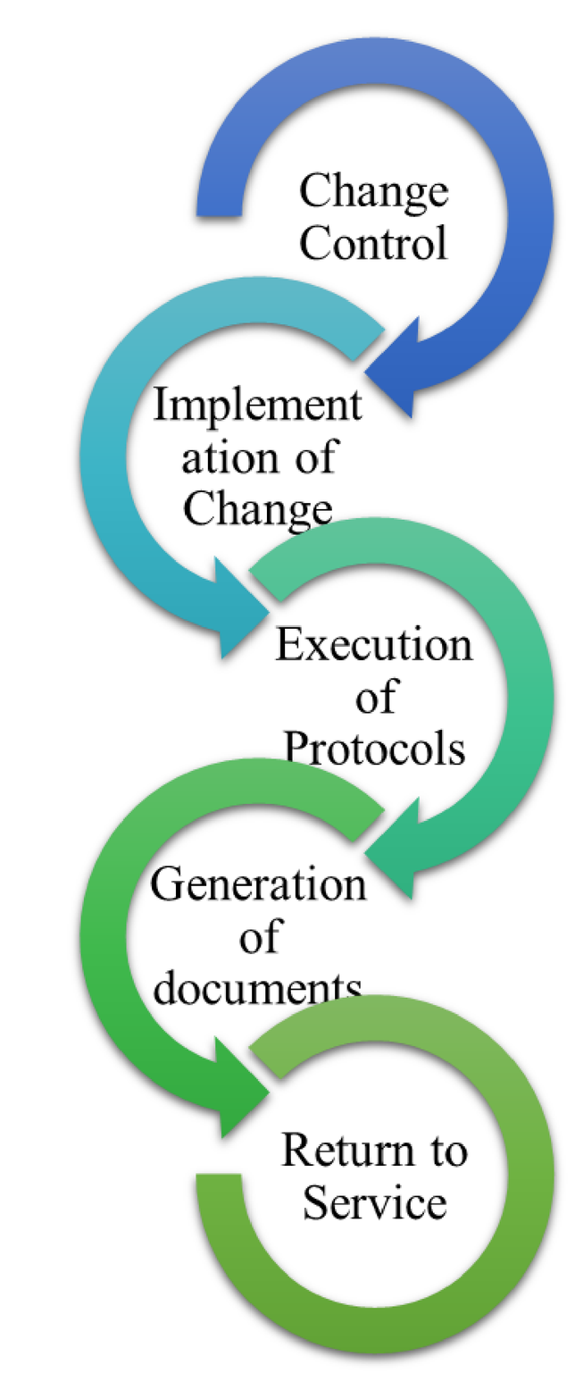


Figure 2. Change Control Activities

The implementation steps were generated based on the requirements of documentation.

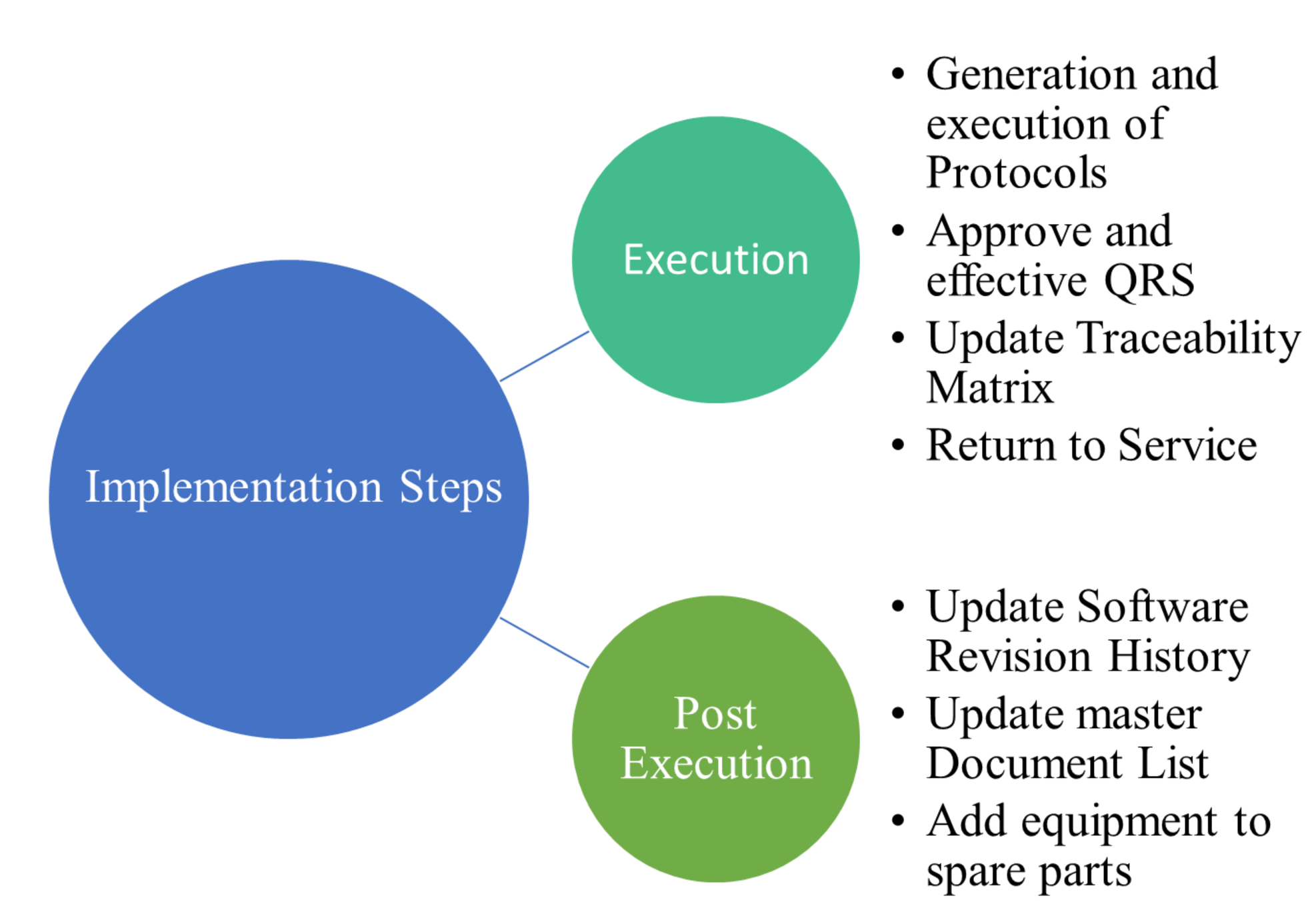


Figure 3. Implementation Steps

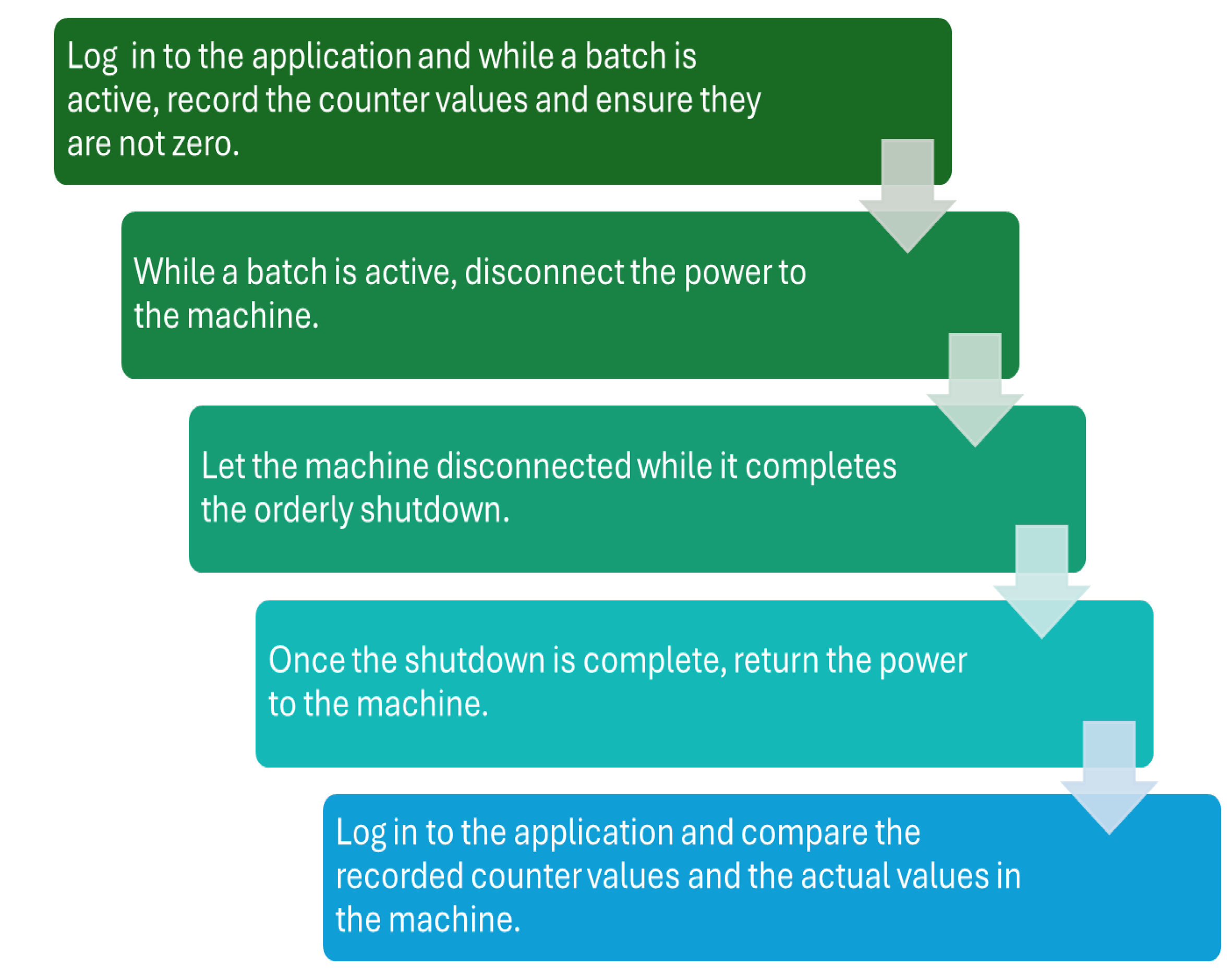


Figure 4. Protocol Steps

Conclusions

The benefits after implementation of the change control process were aligned with the objectives of the research. The first benefit of implementing this change control was that the solution to the problem targets the root cause of a deviation. This eliminates the reoccurrence of deviations related to this problem. Additionally, the implementation of this change control reduces the effort required to document through incidents the correct counter sample values when there were unexpected power failures during a batch. As part of the benefits of this implementation, exposure to regulatory requirements that are present for validated control systems in the pharmaceutical industry. The requirements of a change control were presented and described during the implementation. From the initial presentation of the change control to the documentation and required approvals.

Acknowledgements

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