

# Standardize the Documentation for the Water Analysis for Wastes Elimination in the Raw Material Laboratory

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## Abstract

During the reviewing data of water analysis in the Raw Material Laboratory, the reviewers finds many documentation discrepancies between laboratory analysts, making this task difficult affecting the cycle time due to the waiting of corrections. The plan was create a standardized process for water analysis documentation to improve the documentation procedure to prevent data integrity failure and to establish a new form for the water analysis in the Raw Material Laboratory. The strategy used to reach this goal was support Kaizen method with the PDCA Cycle to standardize a process for the water analysis documentation to monitor and prevent data errors. The results of this project contribute to improve the data integrity, to eliminate wastes and, to create a standardized process to maintain in control the water analysis documentation errors.

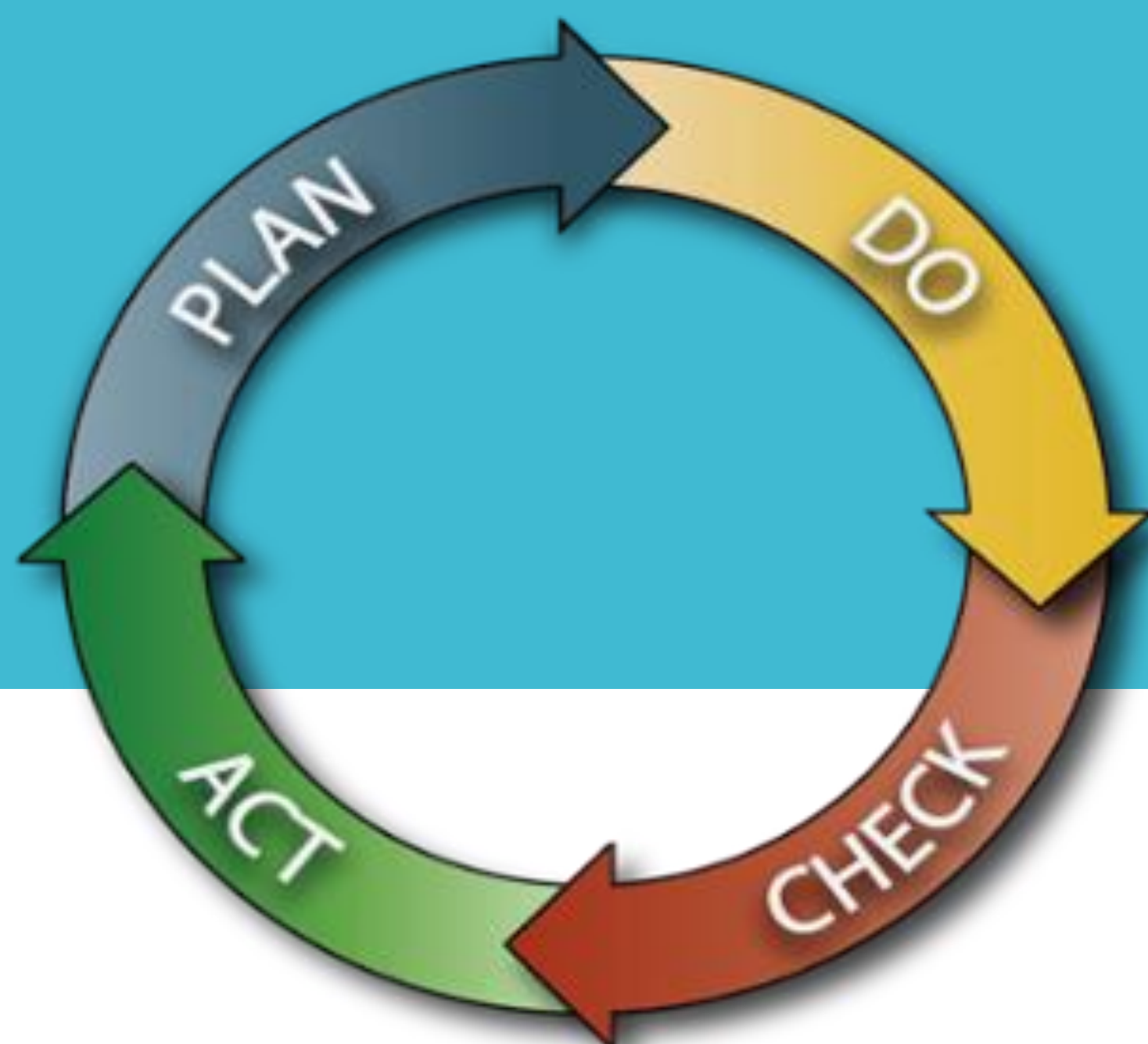
## Project Description

The purpose of this research is to create a standardized process for water analysis documentation. The water analysis in the Raw Material Laboratory has many tests that generate a lot of documentation and discrepancies in documentation between laboratory analysts are found. The importance of this research is to create a standardized process for the water analysis documentation to monitor and prevent data errors that can lead in data integrity failure and cycle time overdue. Data integrity and cycle time are two important components of quality control laboratories' responsibility to ensure the efficacy, safety and quality of drugs.

## Objectives

- The objectives of this research work are:
- To develop a standardized process for the water analysis documentation to prevent data errors by June 2018.
- To improve the documentation procedure to prevent data integrity failure.
- To establish a new form for the water analysis in the Raw Material Laboratory.

## Methodology



## Results and Discussion

The strategy used in this research for executing and support Kaizen method was the PDCA Cycle to standardize a process for the water analysis documentation to monitor and prevent data errors in the Raw Material Laboratory. The PDCA cycle for the research was the following:

### Plan

A meeting was performed with people that know the water analysis in the Raw Material Laboratory, people included were: one analyst, two reviewers, supervisor and documentation specialist. The problem was identified, and it was the following: During the reviewing data of water analysis in the Raw Material Laboratory, the reviewers founded many documentation discrepancies between laboratory analysts, making this task difficult and affecting the cycle time due to the waiting of corrections. In the Raw Material Laboratory, did not exist a standardized process for the water analysis documentation to monitor and prevent data errors

### Do

To get a solution for the documentation errors in the Water Analysis of the Raw Material Laboratory, a meeting was held where the following correction was proposed:

- A standardized process for water analysis documentation. In the Raw Material Laboratory, there is a reconciliation sheet where the analysts write all the information related with the water points and testing done during this day. This reconciliation sheet was modified adding an analyst checklist of the important tasks where analysts must complete the Water Analysis in one day.

After all the recommendations in the meeting, the supervisor review the new changes suggested for the reconciliation sheet and, then they were send to the documentation specialist. The new reconciliation sheet for the water analysis was presented to the documentation specialist, to upload it in the system and to make it official for the benefit of analysts and reviewers.

Figure 1: Old reconciliation sheet 1

Figure 2: Old reconciliation sheet 2

Figure 3: New reconciliation sheet 1

Figure 4: New reconciliation sheet 2

## Check

The documentation specialist made official the new reconciliation sheet in the system. It was proceeded to present the new reconciliation to all the persons that work in the water analysis, to explain the modifications and changes made to new reconciliation sheet. After a week of the implementation of the new reconciliation sheet, a positive feedback was received from analysts and reviewers. They feel more comfortable with the new changes. For analysts the documentation is simpler, and reviewers observed less documentation errors from the analysts.

## Act

As a result of all these changes made to the new reconciliation sheet, a standardized process was created for the water analysis documentation to monitor and prevent data errors. The results of this project contribute to improve the data integrity, to eliminate wastes and, to create a standardized process to maintain in control the water analysis documentation errors. But, it is important to remember that PDCA is a cycle, not a process with a beginning and an end. This means that the improved documentation process becomes the new baseline, and analysts or reviewers can continue to look for ways

## Conclusion

The new reconciliation sheet for the water analysis in the Raw Material Laboratory was a great advantage for the area. This modification helps the reviewers to finds less documentation discrepancies between laboratory analysts; making easy the data review and reducing the chance of affect the cycle time due to the waiting of corrections. Now, in the Raw Material Laboratory exists a standardized process for the water analysis documentation to monitor and prevent data errors. Moreover, with this new documentation procedure, data integrity failure can be prevented.

## Future Work

For future research, the benefit of this standardized process for the water analysis documentation in the Raw Material Laboratory can be quantified. It can be done observing the cycle time of the water analysis documentation. Also, the water analysis area needs a better organization. The 5's concept can be use; it is an important visual tool in any organization. It can help to increase the productivity in the following manner: identification and arrangement easier for benefits of the employees to find the things necessary for the process, easier to catch any problem during the process and working with standardize process.

## References

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