Final Device Quality Control Unit Operation Optimization

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Abstract *— With the intent of achieving cost reduction initiatives, the Quality Control Unit operation regarding the final device release was identified as a labor cost opportunity. Through kaizen events done across site, it was determined a requirement of 20% total cycle time reduction for the final device packaging and release process and, consequently, eliminate the human interaction from the Quality Control Unit technicians.*

Lean manufacturing principles and DMAIC project methodology was used to develop this project and successfully eliminate the Quality Control Unit operation at the final device release process. With the elimination of the process step, the Unit Record Review was eliminated since it was identified as not required, and the other elements contained on the eliminated step, were moved to the previous step, once this was leaned out.

The implementation of this project achieved its objectives, assuring compliance to the applicable regulation agencies requirements and engagement from the employees.

Key Terms *— DMAIC, Final Device Release, Quality Control, Regulation Agencies.*

PROBLEM STATEMENT

Research Description

As part of cost reduction initiatives, the Final Device Quality Control (QC) operation was identified as a labor productivity opportunity because the verifications completed by the QC inspector at this point are semi-automated, but the human interaction is very time consuming. In addition, inspectors do not feel motivated due to simple repetitive movements and verifications as part of this process.

Research Objectives

- Improve total cycle time of the units by a 20% from last fiscal year average by September 2020.
- Eliminate human interaction on final device QC operation by a 70% by September 2020.

Research Contributions

This project supports the company's overall goal of quality operational excellence with zero customer complaints and observations/warning letters/field alerts from the Federal Drug Administration (FDA) related to the inadequacy within final release documentation of the pharma-medical device.

By automating verifications to final release documentation of the pharma-medical device, the verifications are optimized from being human-dependable, assuring consistency between each unit.

The main contributions of this research will be total cycle time improvement, employee engagement, optimization of quality controls, and reduction of human interaction in a process. In addition, the implementation of this project will reduce process time to complete the final release documentation verifications by the automation of critical verifications and elimination of non-required verifications, and free floor space. By the improvement in process time, this project also yields cost reduction related to inventory and labor.

LITERATURE REVIEW

In the regulated medical device manufacturing industry, it is very common to implement a verification or inspection control to detect any defect or non-conformance produced in the

manufacturing line. This type of quality controls are do-not-ship controls. The lean manufacturing principles suggest moving from implementing do-not-ship controls to a do-not-make control that would eliminate the root cause of the non-conformance. However, in the regulated industry, it is required to have a separate entity, commonly known as a Quality Control unit, that verifies and confirms conformance to certain key requirements of the regulation.

The foundation of high-quality control is a combination of the appropriate training to the workforce and making stable processes capable of meeting customer needs. Therefore, the primary purpose of the implementation of lean manufacturing tools is to easily highlight and make visible problems in a manufacturing process. One key component to this is the people and proper handling of them, such as the proper training [1]. Therefore, it is crucial to understand which is the required and proper training the workforce needs for the corresponding task(s) they complete to assure conformance to the process.

To complete a process improvement project and assure every possible opportunity of the process is identified, the DMAIC Methodology should be used. DMAIC is an acronym that stands for the five (5) major phases the project should have: Define, Measure, Analyze, Improve and Control. Through these phases the team should be able to answer at the Define phase, what is important; at the Measure phase, how are we doing; at the Analyze phase, what is wrong; at the Improve phase, what needs to be done; and at the Control phase, how do we guarantee performance [2]. When analyzing and measuring the current state of the process(es), the most important part of this assessment is to identify: which activities are value-added, that are part of the actual transformation process to the service/product the customer is paying for; which activities are non-value-added, that are pure waste such as rework and un-used information; and which activities are non-value-added, but required, that are required under today's conditions even though it does not add value from the customer perspective, such as inspections and control systems [3].

METHODOLOGY

1. Define Phase:

   1.1. Interview customer, final packaging, and Quality Control unit personnel to understand problem.

   1.2. Confirm Scope and Problem Statement with project champion.

2. Measure Phase:

   2.1. Measure current process cycle time.

   2.2. Complete time measurement sheet.

   2.3. Complete Value Stream Map and include bursts (opportunities).

   2.4. Study the elements of the Final Device QC operation.

3. Analyze Phase:

   3.1. Complete root cause analysis though prioritizing causes on a Fish Bone analysis.

   3.2. Demonstrate effect on the problem of every potential causes prioritized.

   3.3. Analyze each element of the Final Device QC operation to identify which are non-value-added, value-added, or required-non-value-added.

4. Improve Phase:

   4.1. Generate solution ideas and implementation requirements.

   4.2. Forecast benefits.

   4.3. Define and execute implementation plan.

   4.4. Discuss solutions with stakeholders and customer.

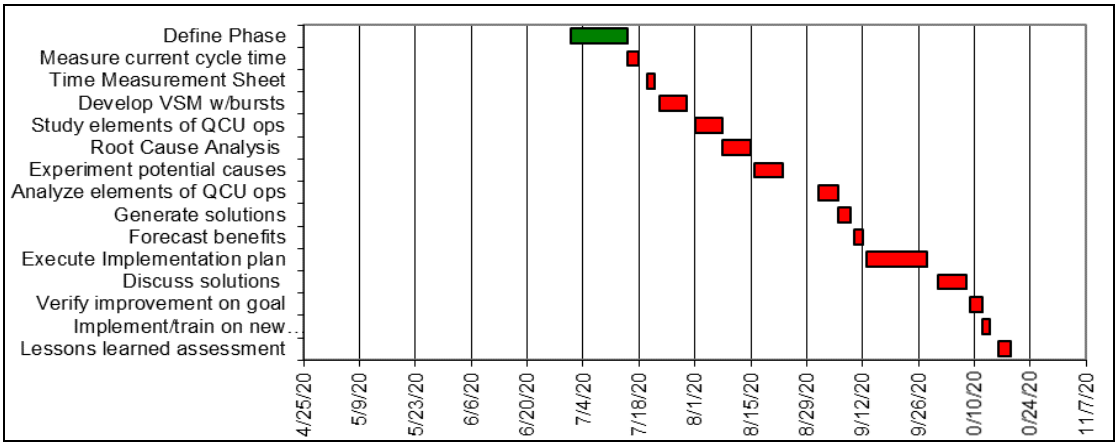
5. Control Phase:

5.1. Verify improvement with the targeted cause on the project goal.

5.2. If required, identify further improvements to achieve project goal.

5.3. Document and train personnel on new standard work.

5.4. Share lessons learned.



RESULTS AND DISCUSSION

The final packaging operations flow, shown in Figure 1, consists of 4 identical final packaging lines that merge on a conveyor that has the capability to feed 2 shrink wrapping machines and, finally, the units undergo the QCU verifications. Due to headcount availability, only 1 shrink wrapping machine is used every day.

Following the Define Project phase documented in the Problem Statement section of this article, the Measure phase follows.

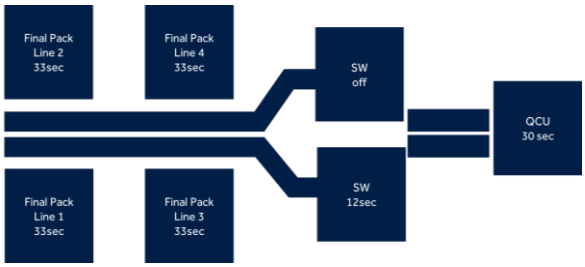


Figure 1

Current final pack and QCU operation flow

Measure Phase

As part of the Measure phase of the project, the current times were measured for the shrink wrap operations and QCU. Per Figure 2, the shrink wrap operation has a total average time of 11.76 seconds/unit, out of which 8 seconds are on scanning and waiting time at the Manufacturing Execution System.

Time Study Sheet: Shrink Wrap		Observations (secs)											Average Time		
#	Elements	1	2	3	4	5	6	7	8	9	10		Average	Std. Dev	Variance
1	The operator wait for the first scan, takes the unit and do a visual inspection (Start scanning)	4.39	4.43	4.95	4.32	5.37	5.91	5.28	3.87	5.8	5.42		4.574	0.7713	0.595
		5.27	3.72	4.16	4.8	4.9	4.25	3.34	4.2	3.6	3.5				
2	Scan the unit twice and place it on the conveyor (Wait FW screen and Close the job and place on conveyour)	7.7	8.42	7.01	8.18	5	7.99	7.88	10.38	8.47	9.34		8.002	1.2758	1.6278
		8.95	7.53	7.19	7.23	8.56	8.83	6.32	10.41	7.46	7.19				
3	Shrink Wrap full, so the opertor takes the units and put in WIP in the rack	6.67	5.15	7.35									6.39	1.1264	1.2688
	Non-Cyclical Element														
4	The operator takes the unit of the rack, put it in the camara for the fisrt scan, takes the unit after the first scan and do a visual inspection	6.09	4.65										5.37	1.0182	1.0368
	Non-Cyclical Element														
											Total Avg. Time:		11.76		

Figure 2

Current time measurement sheet for the Shrink Wrap operation

Time Study Sheet: QCU		Observations (secs)											Average Time		
#	Elements	1	2	3	4	5	6	7	8	9	10		Average	Std. Dev	Variance
1	Track In & Unit Record Review Upload	9.54	7.91	8.51	8.62	9.16	8.86	8.85	11.9	8.39	9.12		9.086	1.088	1.1838
2	Track Out	5.37	5.56	5.47	5.94	5.49	5.62	5.61	5.25	6.06	6.12		5.649	0.2944	0.0867
3	End Processing Report	14.42	15.73	14.97	15.94	15.45	14.87	15.62	13.36	15.99	16.14		15.249	0.8633	0.7452
											Total Avg. Time:		29.984		

Figure 3

Current time measurement sheet for the QCU operation

Moreover, the time measurement assessment was completed for the QCU operation to measure the current state of the operation, refer to Figure 3. The current lead time for the QCU operation was measured to be an average of 29.98 seconds, which is 155% higher than the previous operation time. This is enough evidence that the QCU operation is in fact a bottle-neck operation and improvements are required.

Through the Value Stream Map (VSM) developed and shown in Figure 4, it was easier to see the flow of every step/element of the operations in scope. Most importantly, the discussion of the VSM with the users of the process was fundamental to identify wastes and pains of the current process. The most consistent pain discussed was the waiting time the users encounter throughout the process with the Manufacturing Execution System (MES) used. Therefore, the proposed process improvements go beyond physical stations, but also oversee the transactions required on the MES. Due to the main goal the project has of eliminating the QCU operation, in conjunction of the technician that currently completes it, the elements within the MES process step of the QCU operation will need to be re-located on other steps or eliminated from the overall process.

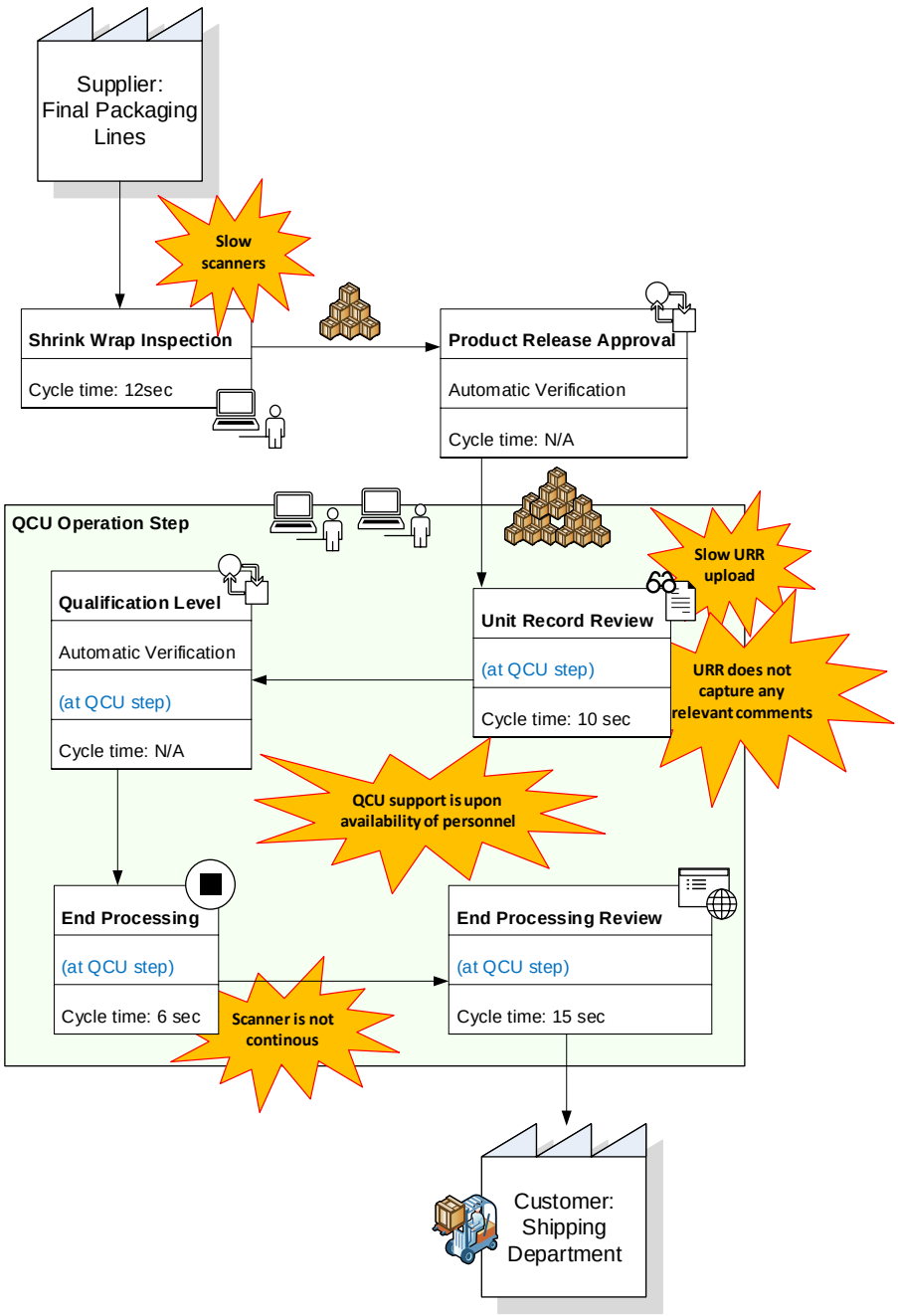


Figure 4

Value stream map for the operations contained in the scope of this project

Analyze Phase

With the intent of identifying potential root causes of the bottle neck and high cycle time of the QCU operation, a cause-and-effect analysis was completed and documented using a Fish Bone diagram, as Figure 5. As part of the Analyze project phase, the potential causes identified in the diagram were prioritized with the scale listed in Table 1.

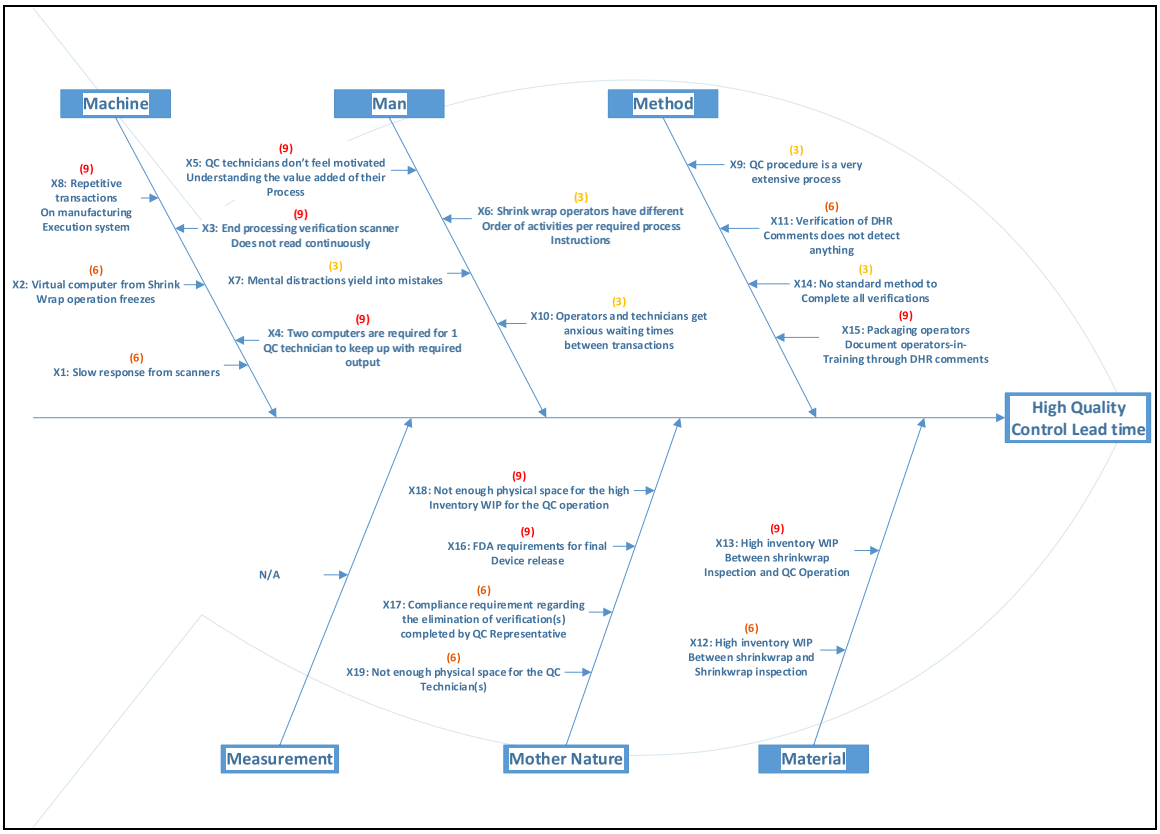


Figure 5

Fish Bone diagram for the Cause-and-Effect analysis

Table 1

Prioritization scale per the effect the cause has on the project Y

Level of effect on project Y	Scale
(3)	Low
(6)	Medium
(9)	High

The causes with higher rating were evaluated through the Analyze project phase, as shown on Table 2. These assessments evaluate each high-ranked cause from the fish-bone analysis and provides the evidence on the evaluation of the effect each of these has on the project Y. Out of the 8 causes brought to the Analyze phase, 5 causes will be taken to the next project phase, Improve, due to the proven effect these have on the project.

Table 2

Analyze assessment for high ranked causes on Fish Bone

Cause	Evidence Source	Proven effect on project Y?
X8: Repetitive transactions on MES	DHR review and Gemba walk	YES
X5: QC techs don't feel motivated	Gemba walk and VOC collection	YES
X3: Issues with scanners	Gemba walk	YES
X4: Two computers are required for 1 QCU tech	Gemba walk	NO
X15: Packaging operators document trainings through DHR comments	DHR Comments Report (developed and validated for the assessment of this X)	YES

Cause	Evidence Source	Proven effect on project Y?
X13: High inventory WIP between shrink wrap and QCU	Gemba walk	NO
X18: Not enough physical space for the high inventory WIP pending QCU	Gemba walk	NO
X16: FDA requirements for final device release	Interviews with Compliance SMEs	YES

Improve Phase:

Through the Improve project phase, each element and transactions were evaluated to understand the value-added of each. In addition, given that the product being packaged and verified is a combination of pharma-medical device, the regulation agencies have strict requirements and understanding these requirements is critical to complete this assessment. Under Table 3, each element of the QCU operation is described and additional identified causes with the proposed improvement.

Table 3

QCU operation elements description and assessment

Element / Cause	Description	Proposed Improvement (If applicable)
Unit Record Report (URR) Generation and Review, X5: QC techs don't feel motivated, X15: Packaging operators document trainings through DHR comments, and X16: FDA requirements for final device release	The URR is generated to review comments documented on Final Pack Device History Record (DHR) of each unit. The report is triggered by the operator through the Manufacturing Execution System (MES). Once generated, the operator reviews the comments listed on the unit's DHR verifying conformance to Good Documentation Practices requirements.	To eliminate the DHR comments at the Final Packaging area, training was provided to the operators on a function the MES must Add users in training in the corresponding DHRs without creating comments. Elimination of the URR is proposed since the Final Pack DHRs did not contain any comments to review. An Engineering Technical Report was developed to demonstrate compliance to the requirements the final device release process has even without the URR.
Qualification Level Verification	An automatic verification at the MES, triggered by the operator, that confirms the unit is under production level. If the unit in not under production level, this verification fails and sends the unit on Hold.	Other than the process step location due to elimination of the QCU process step, no additional changes are being proposed since it is an automatic verification.
End Processing	This is an automatic process as part of the QCU process step that terminates the unit in the MES and creates it as part of the shipping inventory.	Other than the process step location due to elimination of the QCU process step, no additional changes are being proposed since it is an automatic and required process.
End Processing Report Generation and Review	The End Processing Confirmation Report is triggered by the	Train Shrink-wrap operators on the End Processing Confirmation

Element / Cause	Description	Proposed Improvement (If applicable)
	operator on a second computer and from the browser in use. Once the report loads, which is per unit, this is reviewed to confirm and assure that each unit completes the required transactions, including the End Processing, in the MES. A PASS result on this report means the unit is ready for the Shipping process.	Report generation and review.
X8: Repetitive transactions on MES	The repetitive transactions found were related to repetitive user signatures, where the operator/technician is prompted by the MES to enter his/her login ID and password.	Updates on the MES process steps to automize and merge these signatures to eliminate the repetitive waste of the processes.
X3: Issues with scanners	The scanners found in the stations were outdated and did not scanned in continuous manner, requiring the operator/technician to attend the scanner until it is ready to read the unit.	Partnered with Information Technology (IT) team to reconfigure the scanners to continuously scan in an unattended manner.

Control Phase:

Having implemented the improvement plan discussed above, the final VSM and Process Flow yield to be as shown in Figure 6, where the QCU operation as a separate process step is successfully eliminated and, therefore, achieving a reduction in QCU technician head count and overall lead time. The shrink wrap inspection operation transactions on the MES were optimized, providing the space and time for this operator to overtake the End Processing Report, which is generated and reviewed on a separate computer per shrink-wrap operation. As part of the Control project phase, the Standard Operating Procedures (SOPs) for the Shrink-Wrapping process and for the QCU Final Release process were updated to reflect the changes implemented and, consequently, the associates were trained on the new instructions. The area was closely monitored by the project team after the implementation to address doubts and/or questions the associated might have regarding the new process flow and therefore assure business continuity.

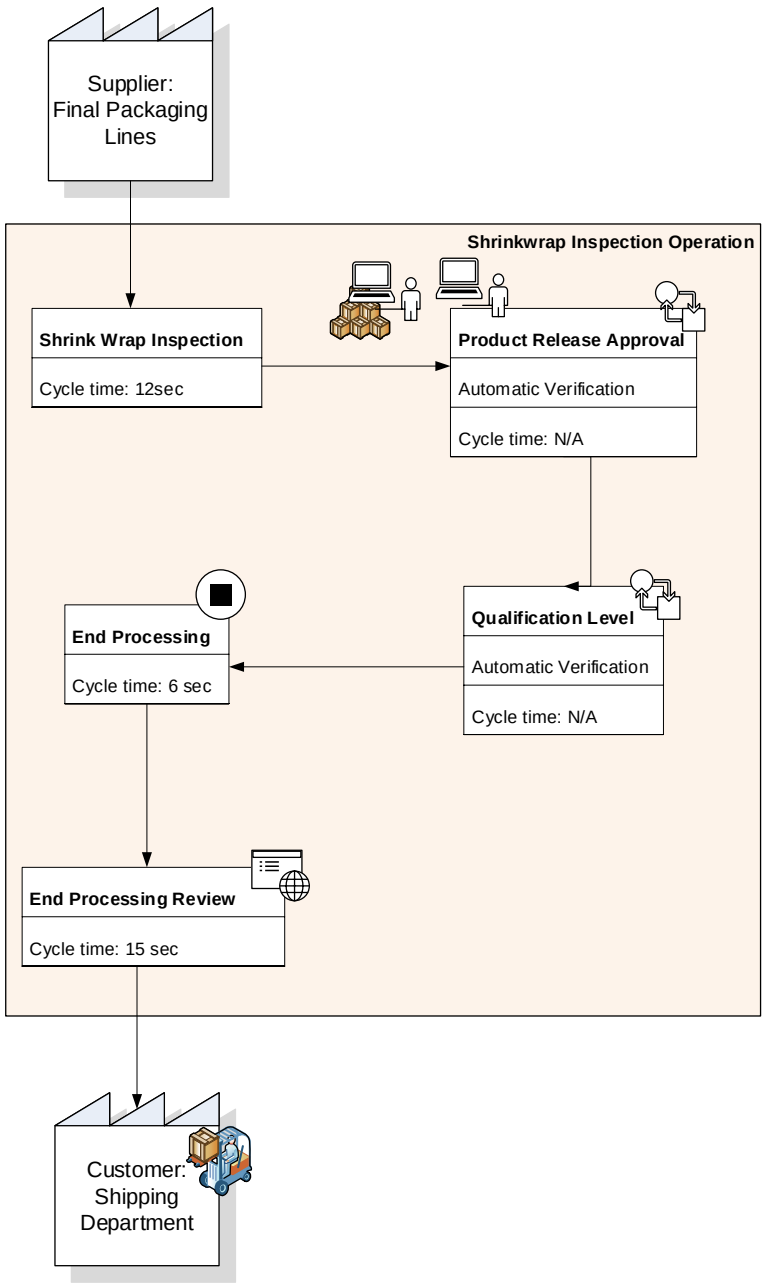


Figure 6

Final Value Stream Map for the operations within scope

CONCLUSIONS

The Final Device Quality Control operation, which was identified as a labor productivity opportunity, has been successfully leaned out. Through the implementation of the Improvement plan of this project, the QCU operation as itself was eliminated since the most time-consuming verification (Unit Record Review) performed through this operation was eliminated. Refer to Figure 7 for the Final Process Flow and Cycle times of the final device packaging and release process.

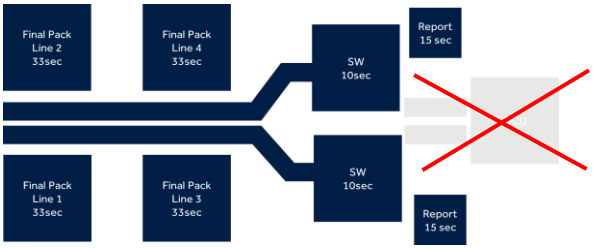


Figure 7

Final Process Flow

With the successful elimination of the physical station of the QCU operation, 15 seconds for the End Processing Report Generation and Review is moved to the previous operation, shrink wrapping inspection. To complete this, the shrink wrap operation transactions were leaned out eliminating repetitive signatures and improving scanners used in the station. After the training sessions and hyper-care support to the area, the improvement in the total cycle time was achieved from 75 seconds per unit down to 58 seconds per unit, which represents an improvement of 22.7%. This exceeds the project objective of improving the time by a 20%. In addition, the reduction of one (1) quality control technician was achieved, and therefore there is no need to open a new position to oversee the increment in volume the plant is having on another areas that require the support from the Quality Control Unit.

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