Modified Kugel Patch Lot History Record (LHR)

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Project Charter

Project Name:	Modified Kugel Patch Lot History Record (LHR)	Value Stream:	Quality
Company or Organization	Becton Dickinson and Company (BD) - Humacao	Impacted Product Family/ Line:	Mesh documentation from Sewing to Packaging/Shipping
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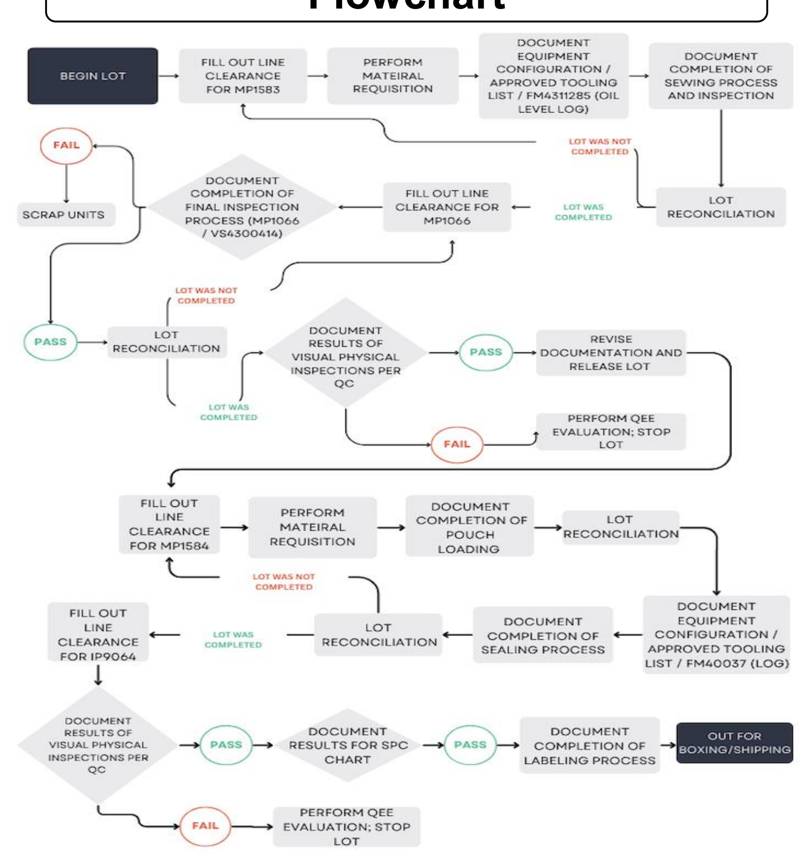
Problem Statement	The Modified Kugel Patch production line has experienced elevated non-conformance and auditor hold rates due to documentation discrepancies. In 2023, the auditor hold rate reached 82% (71 lots), and in 2024, it remained high at 75% (50 lots), with non-conformance rates increasing from 1% to 7%. Each lot requires approximately 445 manual entries in the Lot History Record (LHR), increasing the risk of errors such as missing information, duplicated entries, and GDP violations		
Project Description	The Modified Kugel Patch Lot History Record (LHR) project focuses on enhancing the accuracy, efficiency, and compliance of documentation practices within the Mesh Line at Becton Dickinson and Company. The project was initiated in response to elevated non-conformance and auditor hold rates observed in 2023 and 2024, primarily due to documentation discrepancies and gaps in the Lot History Record (LHR) process. Currently, each lot requires approximately 445 manual entries, significantly increasing the risk of errors such as missing signatures, duplicated information, and violations of Good Documentation Practices (GDP). These issues have led to production delays, increased rework, and reduced audit readiness. The ultimate goal is to reduce documentation-related quality issues, improve compliance, and support operational excellence across the production line.		
Project Scope	This project will focus on improving the documentation process for the Modified Kugel Patch production line within the Mesh Line at Becton Dickinson and Company. The scope includes a comprehensive evaluation of the current Lot History Record (LHR) process, which requires approximately 445 manual entries per lot. The project will identify redundant or error-prone documentation steps, streamline workflows, and verify compliance with Good Documentation Practices (GDP).Operator training and change management will also be integral to the project to ensure successful adoption of improvements. The scope is limited to the Modified Kugel Patch product codes (0115808, 0115810, 0115812, 0115814, 0115816) and does not include changes to product design, manufacturing equipment, or documentation processes for other product lines.		
Expected Business Results:	This project is expected to reduce documentation-related non-conformances and auditor holds by 50%, while increasing overall productivity by 50%. These improvements will enhance product quality, reduce delays, and support compliance with Good Documentation Practices.		
Required Support:	Quality Department, Line Lead, Supervisor, Operators		

Project Metrics and Goals:

Metric	Unit Of Measure	Current State (JOP)	Goal	Expected Project Savings:
Documentation-related Non-Conformances	Reported MRRs	5 lots	0 lots	-Quality Holds Savings : $1,897.00 - Consumptions/Archiving: $300.00 - NCR Savings: $6,960.00 - Lot Release Savings: $43,680.00 - Productivity Increase: $44,000.00 - Error Coorection/Rework: $4,500.00 - Audit Preparation Reduction: $3,000.00 Total Savings: $106,346.50
Documentation-related Auditor Holds	Reported Holds	50 lots	10 lots	
Productivity Increase	minutes/lot	120 min/lot	60 min/lot	

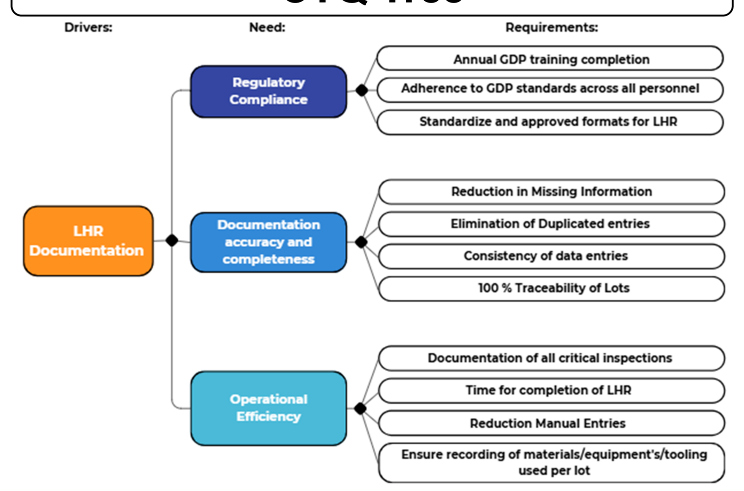
Flowchart



SIPOC

S	I	P	O	C
- Mesh is Cutted in Laser and given shape: Top, Bottom, Strap - Lot History Record is printed and given to Line Lead or Supervisor				
Laser Operator	- 3 types of subassemblies: Top, Bottom, and Strap - Manufacturing Checklist - Line Clearance - Material Requisition - Oil Log	Sewing Process	- Sewn Mesh (3 SA) - Defects Data Sheet - Process completion verification - Lot Reconciliation	Trimming Operator
Sewing Operator	- Line Clearance - Sewn Mesh	Trimming and Final Inspection	- Trimmed mesh ready for Quality verification - Documentation of completion - Completion of visual inspections - Lot Reconciliation	QC Operator
Timming Operator	- Mesh ready for Inspection - Line Clearance	Final Inspection on Kugel Mesh	- Results Visual and Physical Inspections of Mesh - Documentation of Completion of Inspections	Packaging Operator
QC Operator	- Mesh Inspected ready for Packaging - Line Clearance -Mateiral Requisition	Packaging / Sealing	- Completion of Packaging - Lot Reconciliation -Packaged units	Sealing Operator
Packaging Operator	- Packaged Units - Equipment and tooling configuration - Logbook documentation	Sealing / Labeling	-Completion of Sealing -Lot Reconciliation - Label Reconciliation	QC Operator
Sealing Operator	- Sealed Units - Line Clearance - Quality Operator Checklist	Final Packaging Inspection	- Results for Visual and Physical Inspections - Results for SPC Chart - Completion of Inspections -Quality Auditors Checklist -Mesh Ready for Boxing	Boxing Operators
Lot goes out for Boxing with Lot History Record				

CTQ Tree



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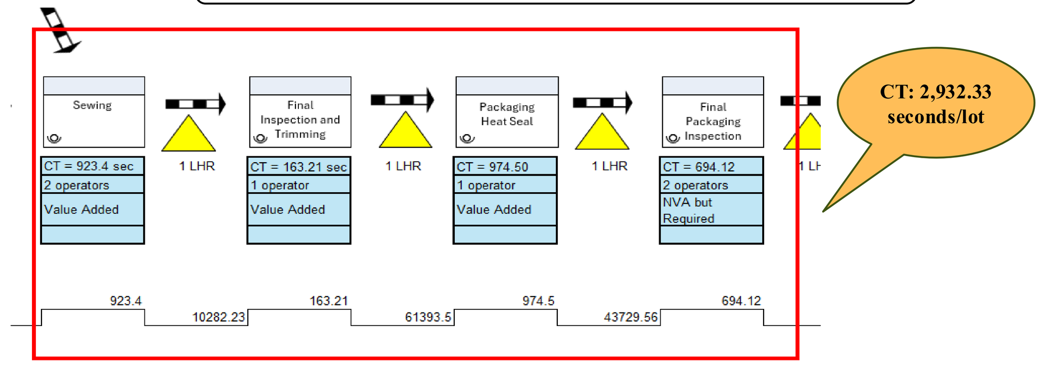
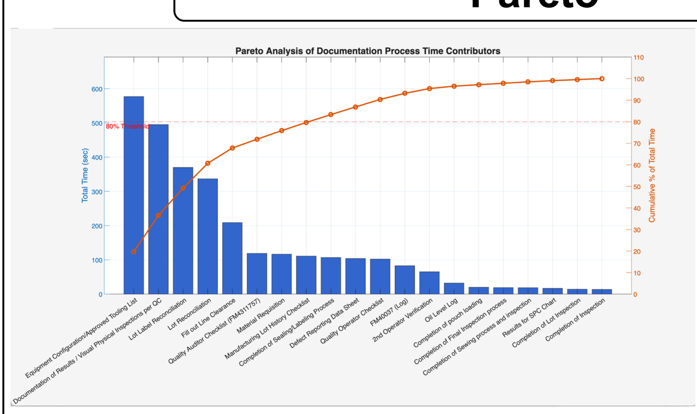
Value Stream Map



Spaghetti Diagram Elements

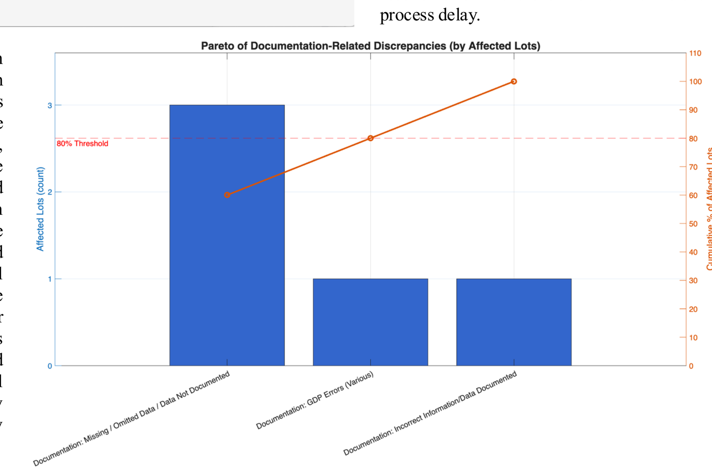
Process Stage	Doc. Page	Element Description	Process Step	Travel Distance (feet)	Travel Time (sec)
MP1583 / Sewing	p37 -38	Manufacturing Lot History Checklist	1-2	5	8.35
	p13	Fill out Line Clearance	2-3	32	53.44
	p13	2nd Operator Verification	3-4	5	8.35
	p1	Completion/Material Requisition	4-3	5	8.35
	p29-32	Equipment Configuration/Approved Tooling List	3-3	0	0.00
	N/A	Oil Level Log	3-3	0	0.00
	p39	Defect Reporting Data Sheet	3-3	0	0.00
	p1	Completion/Material Requisition	3-3	0	0.00
	p16,18	Lot Reconciliation	3-3	0	0.00
MP1066 / Final Inspection and Trimming Procedure	p13-p14	Fill out Line Clearance	3-5	5	8.35
	p13-p14	2nd Operator Verification	5-6	5	8.35
	p1	Completion/Material Requisition	6-5	0	0.00
	p16,18	Lot Reconciliation	5-5	0	0.00
IP4017 Final Inspection Kugel	p14	Fill out Line Clearance	6-7	32	53.44
	p14	2nd Operator Verification	7-8	26	43.42
	p27-p28	Documentation of Reults (Visual Physical Inspections per QC) / Documentation	8-7	26	43.42
	p1	Completion/Material Requisition	7-7	0	0.00
MP1584 / Packaging Heat Seal Kugel	p14	Fill out Line Clearance	7-9	40	66.80
	p14	2nd Operator Verification	9-10	12	20.04
	p2	Material Requisition	10-9	12	20.04
	p1	Completion/Material Requisition	9-9	0	0.00
	p18	Lot Reconciliation	9-9	0	0.00
	p24	Equipment Configuration/Approved Tooling List	9-9	0	0.00
	p24	Equipment Configuration/Approved Tooling List Verification	9-10	12	20.04
	N/A	FM40037 (Log)	10-9	12	20.04
	p25	Completion of Sealing/Labeling Process	9-10	12	20.04
	p18	Lot Reconciliation	10-9	12	20.04
	p51	Lot Label Reconciliation	9-10	12	20.04
IP9064 / Final Packaging Inspection	p14	Fill out Line Clearance	10-11	36	60.12
	p14	2nd Operator Verification	11-12	14	23.38
	p9-p10	Quality Operator Checklist	12-11	14	23.38
	p22-p23	Documentation of Reults (Visual Physical Inspections per QC)	11-11	0	0.00
	p33-p34	Documentation of Reults (Visual Physical Inspections per QC)	11-11	0	0.00
	p35-p36	Results for SPC Chart	11-13	148	247.16
	p3	Completion of Inspection	13-11	148	247.16
	p6-8	Quality Auditor Checklist (FM4311757)	11-14	257	429.19
			TOTAL	882	1472.94

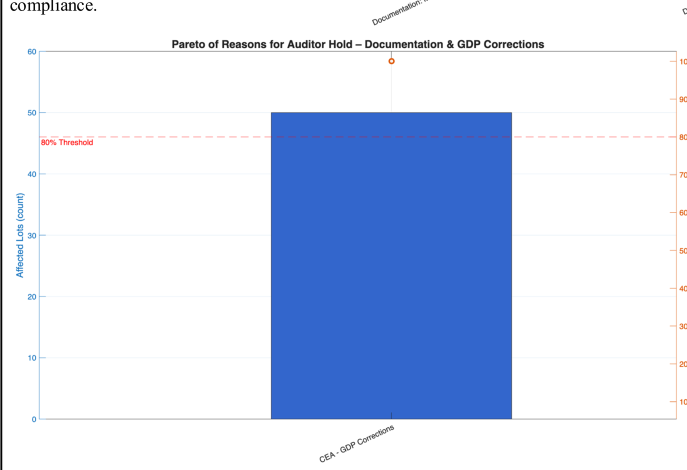
Pareto



The Pareto analysis of the Modified Kugel Patch LHR documentation process shows that the top Equipment Configuration/Approved Tooling List (577.12 sec, 19.68%), Documentation of Results/Visual Inspections per QC (495.15 sec, 16.9%), Lot Label Reconciliation (370.03 sec, 12.6%), Lot Reconciliation (336.87 sec, 11.5%), and Line Clearance (209.03 sec, 7.1%), collectively represent 67.8% of the total time, reaching nearly 80% when additional verification steps are included. These high-impact steps primarily involve manual documentation and validation activities, confirming that equipment setup, inspection recording, and reconciliation tasks are the main drivers of process delay.

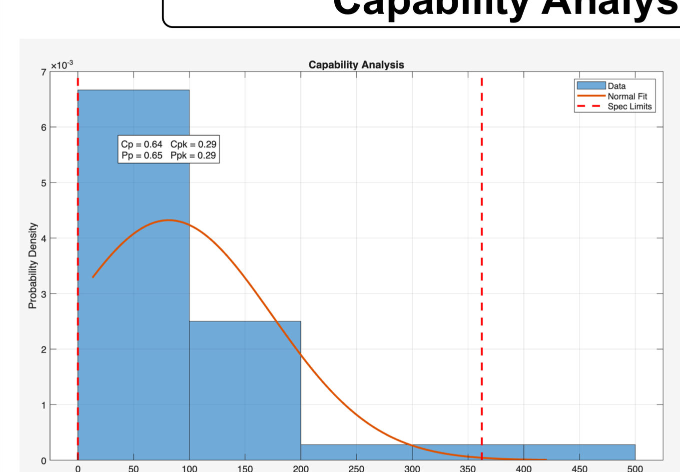
The Pareto analysis of documentation discrepancies in the Modified Kugel Patch LHR process identified five affected lots distributed across three main categories. The largest contributor, "Missing/Omitted Data", (60%), making incomplete documentation the primary source of defects. "GDP Errors" and "Incorrect Information Documented" each represented 20% each, affecting compliance and data accuracy. Together, missing data and GDP errors account for 80% of total discrepancies, confirming that most issues are from incomplete entries and improper documentation practices. These findings indicate that reinforcing GDP training and implementing standardized or digital documentation controls would significantly reduce errors and strengthen regulatory compliance.





The Pareto analysis of auditor hold reasons reveals that 50 affected lots were placed on hold due to CEA GDP Corrections, making documentation quality the cause of release delays in the Modified Kugel Patch LHR process. All issues rooted from Good Documentation Practice violations such as missing initials, incorrect dates, or improper corrections. This concentration of holds within a single category highlights a systemic weakness in documentation consistency and operator compliance. Since GDP corrections account for the entire cumulative percentage of affected lots, strengthening GDP training, standardizing templates, and implementing verification controls would directly eliminate the primary root cause of auditor holds, improve lot release time, and enhance overall audit readiness.

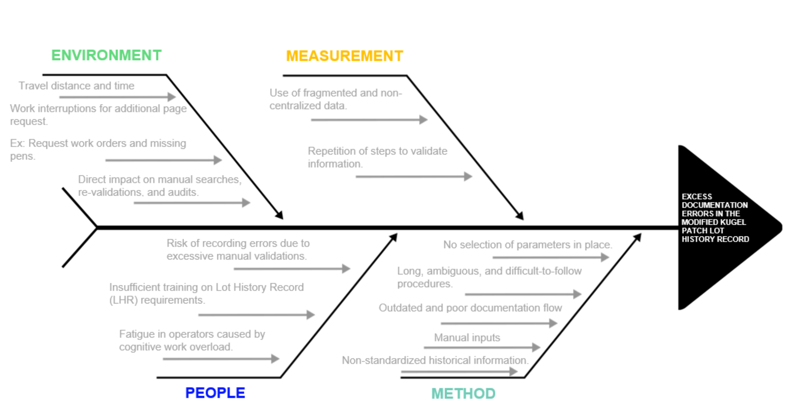
Capability Analysis



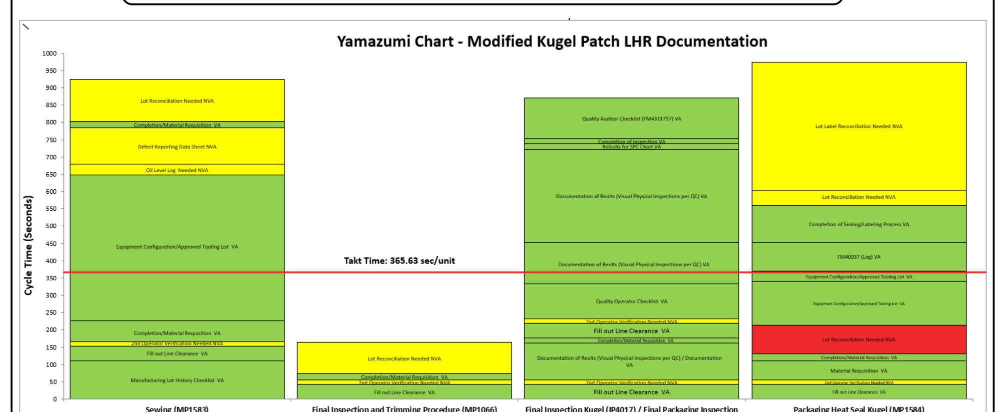
A capability analysis revealed a mean documentation time of 81.45 seconds with a within standard deviation of 93.63 seconds and an overall standard deviation of 92.32 seconds. With specification limits set at 0 seconds (LSL) and 362.33 seconds (USL), the calculated capability indices were Cp = 0.645, Cpk = 0.290, Pp = 0.654, and Ppk = 0.294, all below acceptable benchmarks, indicating the process is not capable. Although most documentation times fall below 150 seconds, several outliers extend near 400 seconds, including extreme values of 420.705 and 370.03 seconds. The small difference between Cpk (0.290) and Ppk (0.294) shows consistent variation, but the widespread relative to specification limits confirms excessive variability, particularly in complex forms such as equipment configuration and lot reconciliation records.

A

Fishbone Diagram



Yamazumi Chart



5 Why's

PROBLEM The Modified Kugel Patch Lot History Record documentation process shows high frequency of GDP errors, missing/incomplete information, variation and long documentation times

01 Operators record information manually and inconsistently, leading to omissions, multiple formats and handwriting styles. Operators struggle with complex, lengthy, repetitive documentation step.

02 The current documentation process does not have a sequence of operations, and does not clearly define fields that need to be documented . Documentation process requires multiple manual entries, duplicated fields, and unnecessary information that increases the workload and cognitive burden.

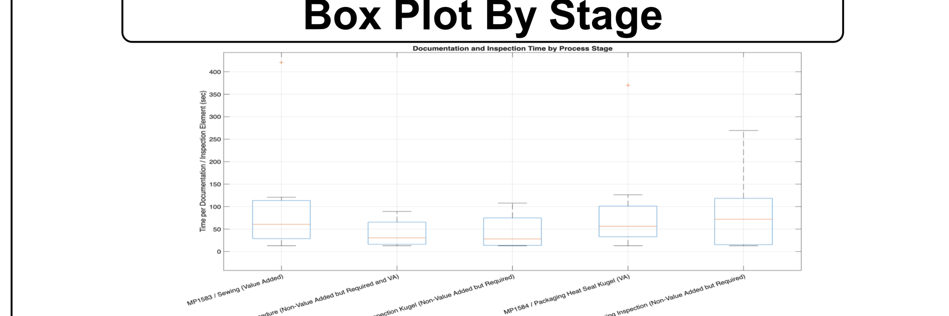
03 Existing LHR does not have an integrated/ standardized template and uniform instructions because LHR was developed over time without streamlining, consolidation, or removal or redundant steps.

04 There is no centralized governance and there is no standardization process. Each change owner edits their own portion, resulting in inconsistent layout, and repeated fields. There is no structured documentation simplification initiative/plan

05 The organization lacks a standardized, simplified documentation model that guides all process stages

ROOT CAUSE The documentation process has become complex due to redundant entries, manual recording, unclear instructions, and inconsistent formatting because of the absence of streamlined, standardized and simplified LHR. This drives operator confusion, increase GDP errors, rework, inflates process time and auditor holds.

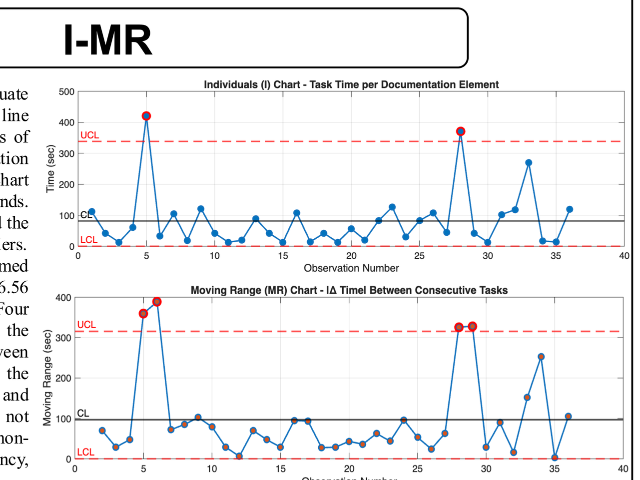
Box Plot By Stage



The box plot by stage highlights the variation in documentation time across the main stages of the Modified Kugel Patch LHR process. MP1583 (Sewing – Value Added) shows the highest average time at 102.6 seconds and the greatest variability, with values reaching up to 420.7 seconds, indicating significant inconsistency in this stage. In contrast, MP1066 (Final Inspection and Trimming) and IP4017 (Final Inspection Kugel) show lower and more consistent mean times of 40.8 and 44.3 seconds, reflecting more standardized documentation practices. For packaging operations, MP1584 (Packaging Heat Seal Kugel) and IP9064 (Final Packaging Inspection) have moderate mean times of 88.6 and 86.8 seconds, respectively. Although more structured than sewing, these stages still exhibit occasional high values due to rechecks or incomplete entries. Overall, value-added stages such as sewing and packaging require the most documentation time and show the highest variability, highlighting clear opportunities for standardization and potential digitalization to improve efficiency while maintaining compliance.

I-MR

An I-MR control chart was developed to evaluate the statistical stability of the Modified Kugel line documentation process using 36 observations of documentation time. The average documentation time was 81.45 seconds, with an Individuals chart UCL of 338.26 seconds and LCL of 0 seconds. Two observations (indices 5 and 28) exceeded the upper control limit, indicating significant outliers. The Moving Range chart further confirmed instability, with a mean moving range of 96.56 seconds and a UCL of 315.46 seconds. Four transition points (5, 6, 28, and 29) exceeded the control limits, showing abrupt variability between consecutive documentation steps. Overall, the presence of multiple out-of-control points and large variability confirms that the process is not statistically stable and is likely affected by non-standardized procedures, operator inconsistency, and documentation inefficiencies.



I

SCAMPER

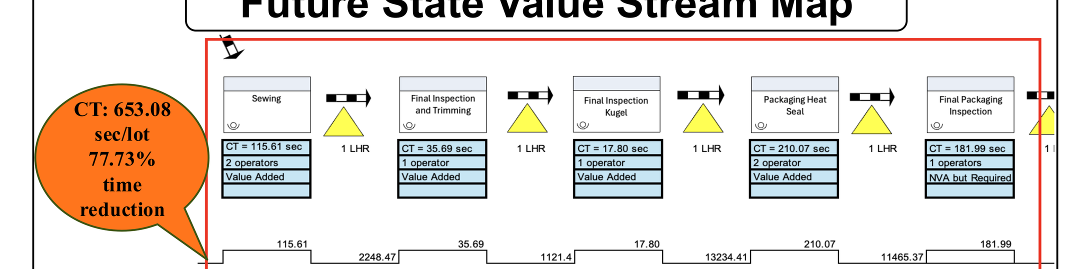
SCAMPER – Modified Kugel Patch Lot History Record	
Substitute	Manual handwritten obliteration and critical data entries for tooling and equipment can be substituted with pre-filled checkboxes or dropdown menus if electronic. This substitution reduces manual writing, improves legibility, and minimizes GDP-related documentation errors.
Combine	Multiple verification steps and signatures for the same process can be combined into a single consolidates section to reduce duplicated signatures and redundant entries across manufacturing steps.
Adapt	Documentation standards from other manufacturing lines with lower documentation error rates can be adapted, including standardized layouts, visual cues, and built-in error-proofing prompts, to improve consistency and usability of the LHR.
Modify	Documentation steps can be modified by minimizing non-value added but required entries and maximizing clarity though clear instructions and consistent formation. Page layout and process flow can be modified to follow the actual manufacturing sequence, reducing backtracking, confusion, and variability.
Put to other uses	Time study and documentation data can be repurposed for operator training, continuous improvement tracking, and audit readiness metrics, supporting long-term process control and performance monitoring.
Eliminate/Erase	Redundant signatures, repeated data fields, and duplicate checks across manufacturing stages can be eliminated. Documentation steps that do not add compliance value can be removed after risk assessment, reducing overall documentation time and variability
Reverse/Rearrange	Rearranging documentation steps so that the critical data is captured in the actual sequence of operations can reduce omissions, auditor holds and rework by ensuring information is recorded at the point of execution.

Future State Spaghetti Diagram Elements

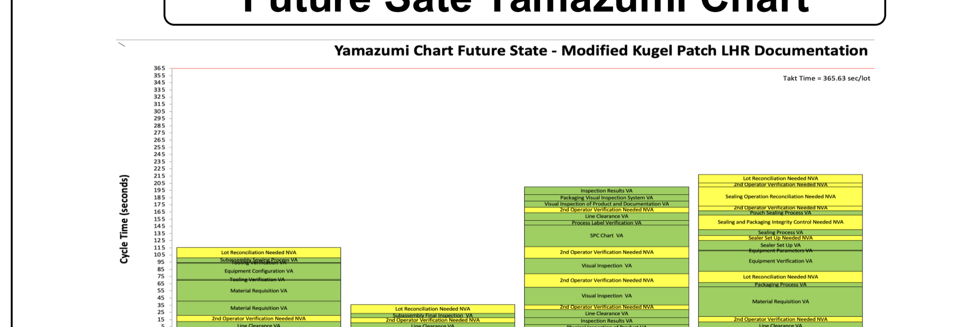
Process Stage	Doc. Page	Element Description	Process Step	Travel Distance (feet)	Travel Time (sec)
MP1583 Sewing	p3	Line Clearance	1-2	5	8.35
	p3	2nd Operator Verification	2-1	5	8.35
	p4	Material Requisition	1-1	0	0.00
	p5	Material Requisition	1-1	0	0.00
	p6	Tooling Verification	1-1	0	0.00
	p6	Equipment Configuration	1-1	0	0.00
	p7	Tooling Verification	1-1	0	0.00
	p7	Subassembly Sewing Process	1-1	0	0.00
	p7	Lot Reconciliation	1-1	0	0.00
MP1066 / Final Inspection and Trimming Procedure	p8	Line Clearance	1-2	5	8.35
	p8	2nd Operator Verification	2-1	5	8.35
	p8	Subassembly Final Inspection	1-2	5	8.35
	p9	Lot Reconciliation	2-2	0	0.00
IP4017 Final Inspection Kugel	p10	Physical Inspection of Product	2-3	26	43.42
	p11	Inspection Results	3-3	0	0.00
MP1584 / Packaging Heat Seal Kugel	p12	Line Clearance	3-4	40	66.80
	p12	2nd Operator Verification	4-5	12	20.04
	p13	Material Requisition	5-4	12	20.04
	p14	Packaging Process	4-4	0	0.00
	p14	Lot Reconciliation	4-4	0	0.00
	p15	Equipment Verification	4-5	12	20.04
	p16	Equipment Parameters	5-5	0	0.00
	p16	Sealer Set Up	5-5	0	0.00
	p16	Sealer Set Up	5-5	0	0.00
	p17	Sealing Process	5-5	0	0.00
	p18	Sealing and Packaging Integrity Control	5-5	0	0.00
	p19	Pouch Sealing Process	5-5	0	0.00
	p19	2nd Operator Verification	5-4	12	20.04
	p20	Sealing Operation Reconciliation	4-5	12	20.04
	p20	2nd Operator Verification	5-4	12	20.04
	p21	Lot Reconciliation	4-5	12	20.04
IP9064 / Final Packaging Inspection	p22	Line Clearance	5-6	28	46.76
	p22	2nd Operator Verification	6-7	5	8.35
	p23	Visual Inspection	7-6	5	8.35
	p23	2nd Operator Verification	6-7	5	8.35
	p24	Visual Inspection	7-6	5	8.35
	p24	2nd Operator Verification	6-7	5	8.35
	p26 - p27	SPC Chart	7-6	5	8.35
	p28	Process Label Verification	6-6	0	0.00
	p31	Line Clearance	6-7	5	8.35
	p31	2nd Operator Verification	7-6	5	8.35
	p32	Visual Inspection of Product and Documentation	6-6	0	0.00
	p33	Packaging Visual Inspection System	6-6	0	0.00
	p34	Inspection Results	6-6	0	0.00
			TOTAL	243	405.81

Travel Distnce and Time Improvement: 72.45% reduction

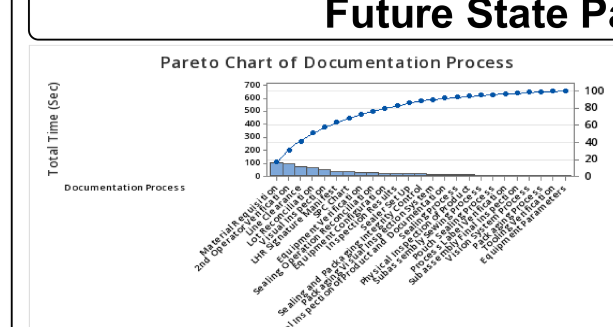
Future State Value Stream Map



Future Sate Yamazumi Chart

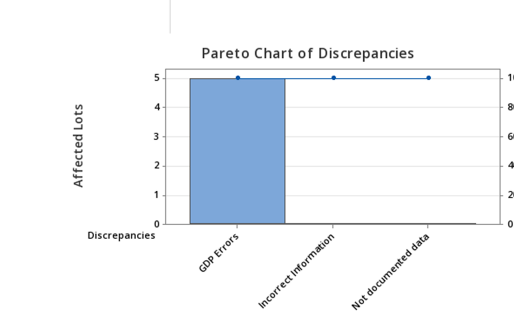


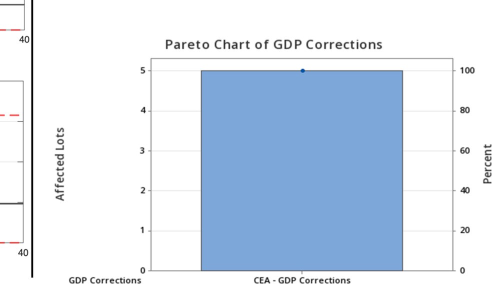
Future State Pareto



The first 4 documentation activities account for approximately 50–60% of the total documentation time (650 seconds). The cumulative curve shows that most of the workload is concentrated in a small number of steps, while the remaining processes contribute minimally. This confirms that targeted improvements in the top contributors generate the greatest impact on overall documentation efficiency.

All affected lots (5 out of 5; 100%) were related to GDP Errors, while no discrepancies were attributed to incorrect information or undocumented data. This indicates that documentation issues are fully concentrated in GDP compliance, allowing focused corrective actions.





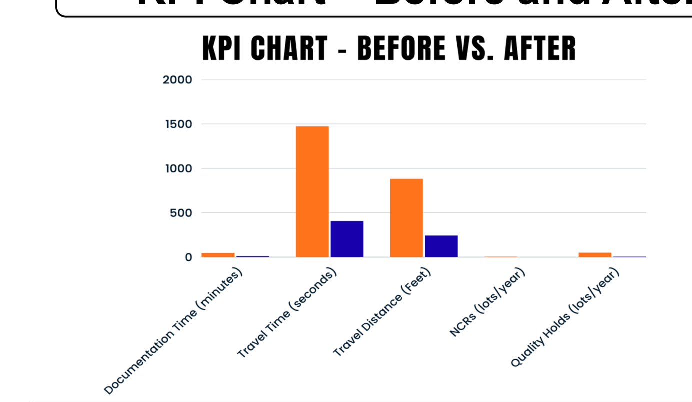
All affected lots (5 out of 5; 100%) were related to CEA – GDP Corrections, with no additional correction categories identified. Compared to the previous state, where 50 lots were affected, the total number of impacted lots decreased significantly to 5, representing a substantial reduction in documentation-related auditor holds.This demonstrates improved documentation control and standardization, while confirming that remaining issues are concentrated in a single, clearly defined compliance area for targeted improvement.

C

Financial Analysis

Proposed State Financial Analysis (Cost vs. Benefit)				
Item	Before	After	Benefit	Cost
Productivity Saving for LHR Documentation	48.87 min/lot 882 ft (travel distance)	10.88 min/lot 243 ft (travel distance)	$44,000	$1,599.00 for operator retraining + learning curve impact
NCR Savings	5 lots x 6 hrs x 4 days	0 lots	$6,960.00	$0.00
Product Release Delay	Delayed Release	No delay	$43,680.00	$0.00
GDP Error / Rework	2 lots per year	0 lots per year	$4,500.00	$0.00
Quality Holds	50 lots, 2.5 hrs per lot	5 lots, 1 hr per lot	$1,897.50	$0.00
Lot Release	1 day per week delay	Reduced lot delays	$2,000.00	$0.00
Storage / Archiving	High paper & storage usage	Less printer toner, paper consumption, physical storage, low administrative cost	$300.00	$0.00
Audit Prep	10 hrs per audit	Fewer observation, less backtracking data	$3,000.00	$0.00
Paper Savings	64 pages	34 pages	$9.00	$0.00

KPI Chart – Before and After



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1. Sort — Remove Unessary Documentation: All LHR forms, attachments, logs, and verification steps were reviewed to identify redundant, obsolete, or non–value-added documentation elements. Duplicate data entries, outdated forms, and unnecessary verification signatures were eliminated. Non-critical logs that did not directly support regulatory, quality, or traceability requirements were either removed or consolidated.

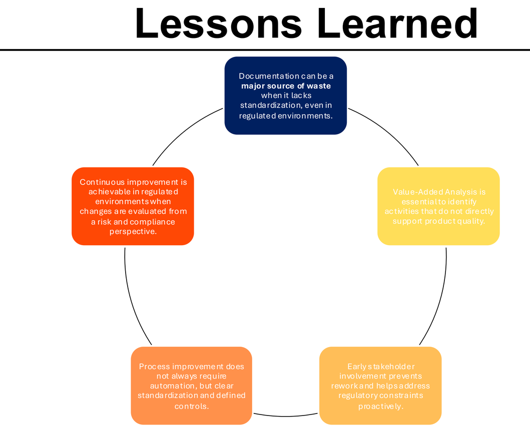
2. Set In Order — Optimize Documentation Flow: The physical and informational flow of the LHR was redesigned to match the manufacturing sequence. Documentation was reorganized so that forms were completed in the exact order of operations, minimizing backtracking and unnecessary movement.

3. Shine — Improve Clarity and Document Quality: Forms were updated to include clearer instructions, standardized formats, and defined data fields to ensure consistent entries. Visual cues and formatting improvements were implemented to guide operators and reduce interpretation errors.

4. Standardize — Establish Consistent Documentation Practices: Establish Consistent Documentation Roles and responsibilities for documentation completion and verification were clearly defined. Standard completion practices were reinforced through operator and quality training. Standardization was achieved by implementing an approved LHR Template for the Mesh Manufacturing Area

5. Sustain — Maintain Improvements Over Time: controls were established to monitor documentation performance and ensure continued compliance. Refresher training and audit feedback loops were incorporated to prevent regression. A structured feedback loop was implemented to capture documentation errors, near-misses, and improvement opportunities. When errors are identified, immediate corrective actions are taken.

Lessons Learned



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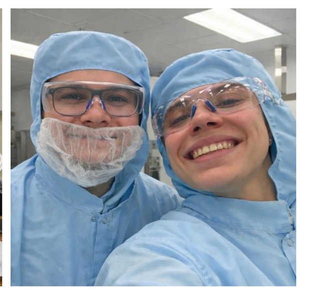
We would like to express our sincere appreciation to our project sponsor, Orlando Rivera, for his guidance, support, and valuable insights throughout the development of this Capstone project. We also extend our gratitude to our professor, Dr. Carlos González Miranda, for his mentorship, academic guidance, and continuous support during the Capstone process. Their contributions were instrumental in the successful completion of this project.