

Quality is Everyone's Responsibility

Digital Workflows for Quality Management Excellence

May 25, 2023

Kris Gorrepati and Manish Mathur

KaizenKit

Designed by

Cambrian Lab

Agenda

- ❑ Introductions
- ❑ Cross-functional Quality Management and Challenges
- ❑ Workflow Based Approach to Cross-functional Quality Management
- ❑ Case Study#1 - Quality Hold due to Issue
- ❑ Case Study#2 - Deviation Process
- ❑ Demo
- ❑ Q&A

About Cambrian Lab

Team

Supply Chain, New Product Introduction, and Technology Experts from SAP, Samsung, Siemens, GM, Ford, Applied Materials

Expertise

- New Product Development/Introduction, Supplier Development, and Quality Management
- Enterprise and Supply Chain Technology (ERP, SCM, Manufacturing, CRM, Sourcing, Finance)

Industries

Automotive, High-tech, Semiconductor Equipment, Medical Devices, Consumer Products
(From Fortune 100 to Start-ups)

Locations

SF Bay Area, Detroit, Boston, Houston

Our Mission

To Make

Quality is everyone's responsibility
- W. Edwards Deming

A Reality in the Organization and the Supply Chain

Panelists Today

Kris Gorrepati

- 20+ years experience in New Product Development and Introduction and Supply Chain Manufacturing
- SAP, Samsung, Ford, Caterpillar
- Auto, High-tech, Software
- Michigan Tech (Mech Engg.), UCLA

Manish Mathur

- 20+ years experience in PLM, Business Analytics, Software Engineering
- GM, Ford, Siemens PLM, Cap Gemini
- Auto, High-tech, Software
- Michigan Tech (Elec Engg), Walsh College

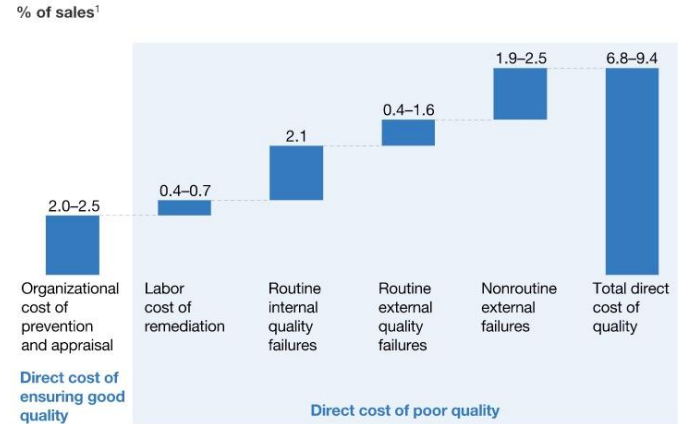
Cost of Poor Quality >>>> Cost of Achieving Good Quality

Cost of Quality			
Cost of Good Quality		Cost of Poor Quality	
Prevention costs	Appraisal costs	Internal failure costs	External failure costs
<ul style="list-style-type: none">• Planning• Process Control• Quality Audits• Maintenance• Supplier Evaluation• Training• Design Review• Risk Assessment• FMEA	<ul style="list-style-type: none">• Inspection• FAT• Document Review• Quality Audits• Calibration• Test Materials• Test product	<ul style="list-style-type: none">• Scrap• Rework• Missing documents• Problem solving• Retest• Redesign• Downgrading• Variation• Downtime	<ul style="list-style-type: none">• Warranty charges• Complaints• Returned Materials• Late Delivery Penalties• Rework After Installation• Lost Opportunities

Cost of Poor Quality

For the first nine months of 2020, Ford's warranty costs totaled \$3.87 billion, while GM's were \$1.68 billion, according to regulatory filings.

The direct cost of quality in the medical device industry is \$26 billion to \$36 billion annually.



¹Estimated annual sales of \$380 billion.

McKinsey&Company | Source: Health Research International; McKinsey analysis

paperwork, often slowing down efforts to address issues. The result: Today's CAPA process consumes significant resources— case studies of participating organizations have indicated that it could be around 1% of a company's revenues!

Most Common Findings/Root Causes of Poor Quality

FDA Inspection Database (483s)

Short Description	Frequency
Lack of or inadequate procedures	165
Lack of or inadequate complaint procedures	139
Lack of Written MDR Procedures	68
Purchasing controls, Lack of or inadequate procedures	62
Nonconforming product, Lack of or inadequate procedures	59
Lack of or inadequate process validation	49
Quality audits - Lack of or inadequate procedures	40
Documentation	32
Training - Lack of or inadequate procedures	30
DMR - not or inadequately maintained	29

Devices

Develop FSVP	514
Hazard Analysis - Identification of Hazard	104
Pest Control	98
Manufacturing, Processing, Packing, Holding - Controls	95
Personnel	87
Sanitation monitoring	81
Sanitary Operations - Plant Maintenance	80
Plant Construction and Design	71
Equipment and Utensils - Design and Maintenance	70
HACCP plan implementation	65
Sanitary Operations - Plant Sanitation	58
Sanitary Facilities and Control	58
Supplier approval - document	55

Drugs

Develop FSVP	514
Hazard Analysis - Identification of Hazard	104
Pest Control	98
Manufacturing, Processing, Packing, Holding - Controls	95
Personnel	87
Sanitation monitoring	81
Sanitary Operations - Plant Maintenance	80
Plant Construction and Design	71
Equipment and Utensils - Design and Maintenance	70
HACCP plan implementation	65
Sanitary Operations - Plant Sanitation	58
Sanitary Facilities and Control	58
Supplier approval - document	55

Food

Not Uncommon to feel

- Designing Quality is Documentation Exercise
- Quality Assurance is Data Collection Exercise
- Quality Issues/Events fall through the cracks and are forgotten

"The only real mistake is the one from which we learn nothing."

- Henry Ford

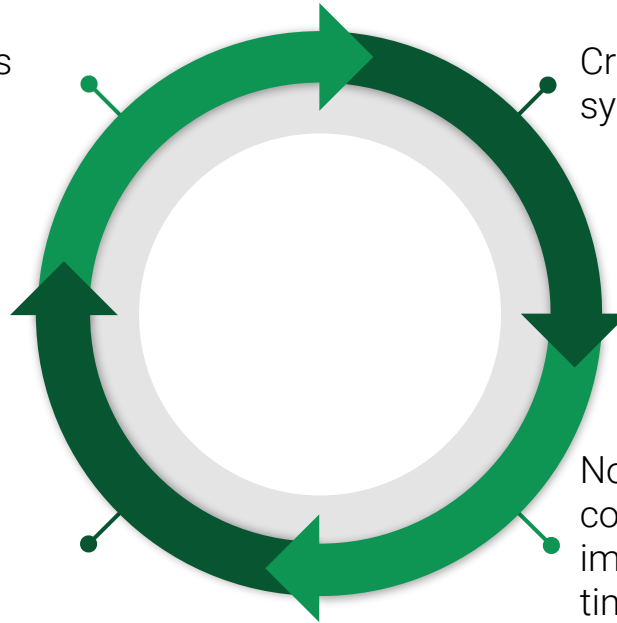
Why Making “Quality is Everyone’s Responsibility” Remains a Challenge

To “Do What is Documented” as QMS Procedures is Hard

Cross-functional teams and systems are disconnected

Involving Supply Chain (Suppliers/Customers/External Partners) is Difficult

No guarantee that corrective/preventive actions are implemented effectively and in a timely manner

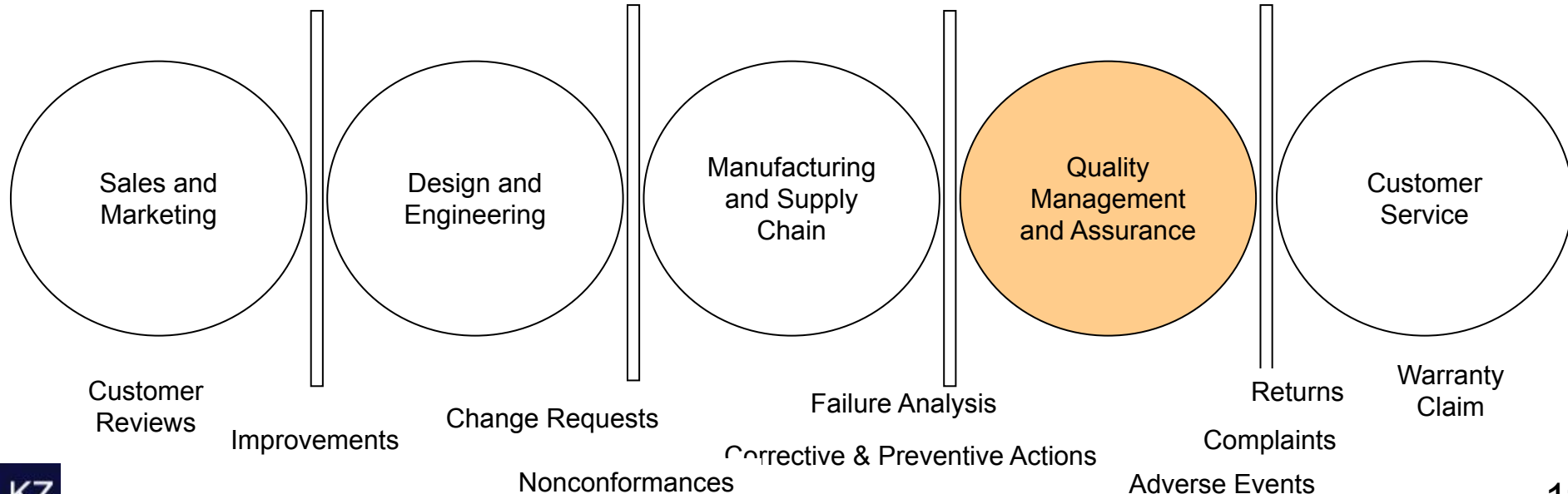


Process and Information Silos Are Obstacles to Making “Quality is Everyone’s Responsibility”

Requirements, Quality
Deployment, Specifications

FMEA, Validation, Prototyping, Product and Process Characteristics,
Process Plan, Control Plans, SOPs, Training, Audits..

Systems Design



Quality Events can get Lost in Disparate and Disconnected systems

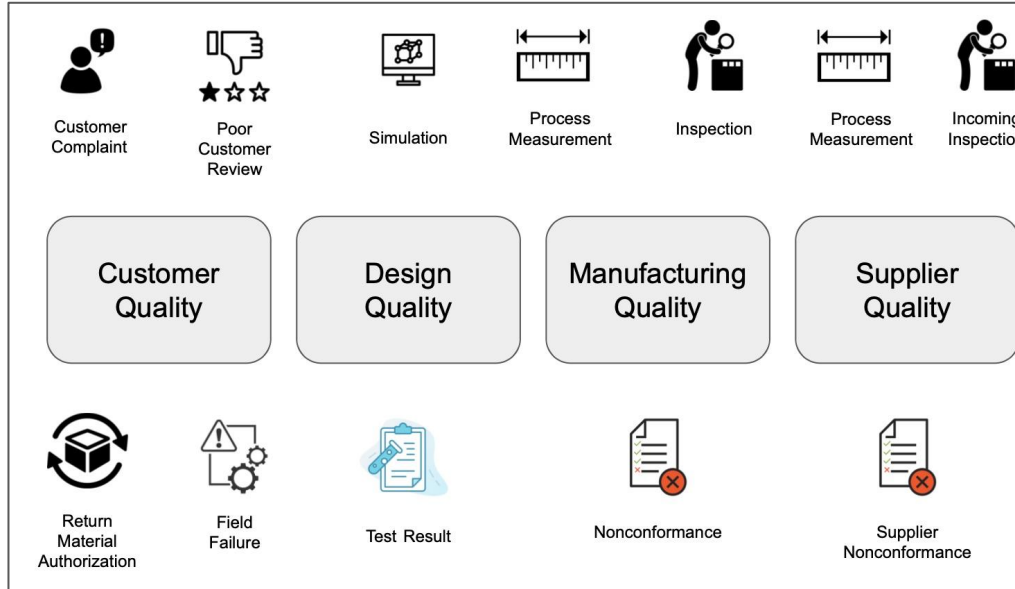
CRM
Systems

E-commerce

Testing
Systems

LIMS

Inspection
Systems



ERP
Systems

Supply Chain
Systems

The Answer - Cross-functional Workflow Approach to making “Quality is Everyone’s Responsibility” a Reality

Quality Workflows that be started by anyone and any system

Quality Workflows connected to ERP, MES, PLM, Supply Chain systems

Flexible and Adaptable

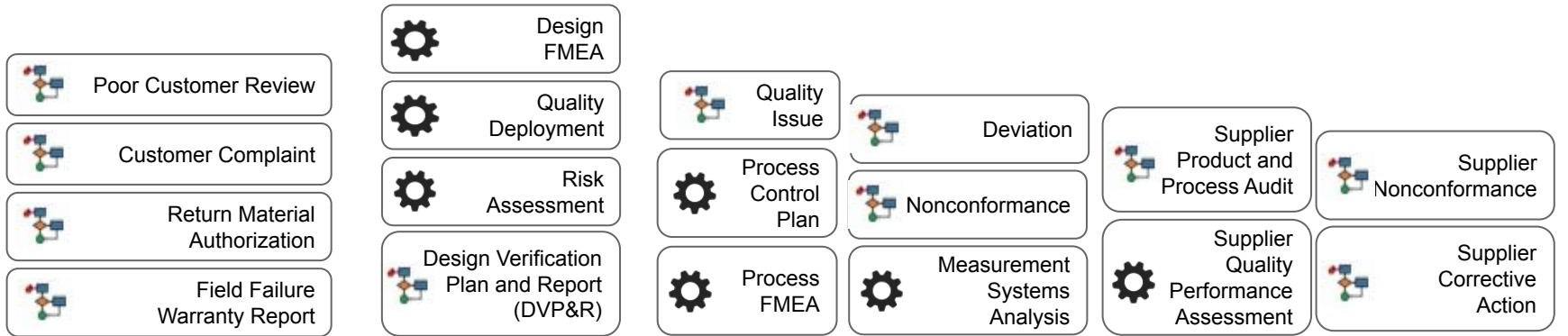


Proactively Involve Right People at the Right Time

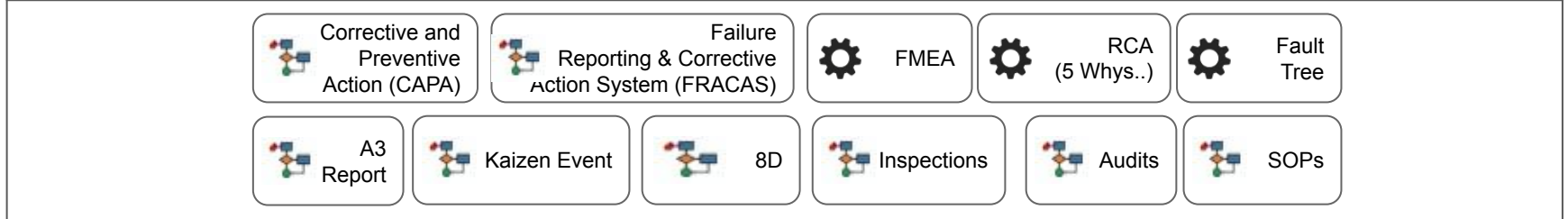
Include Supply Chain

Integrate quality tools and techniques into workflows

Quality is Everyone's Responsibility



Cross-functional Quality and Continuous Improvement Tools

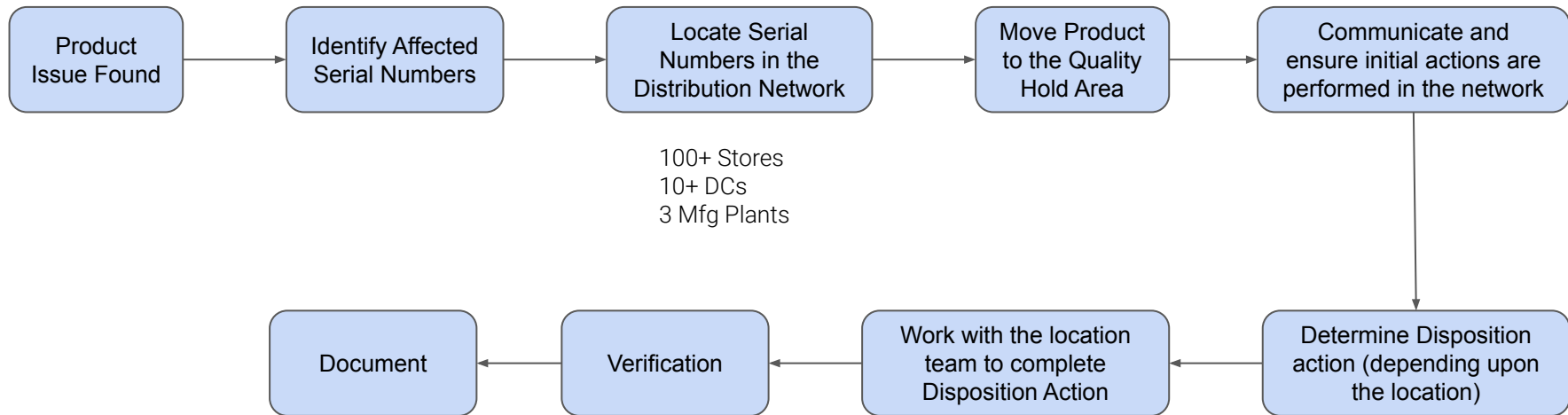


Agenda

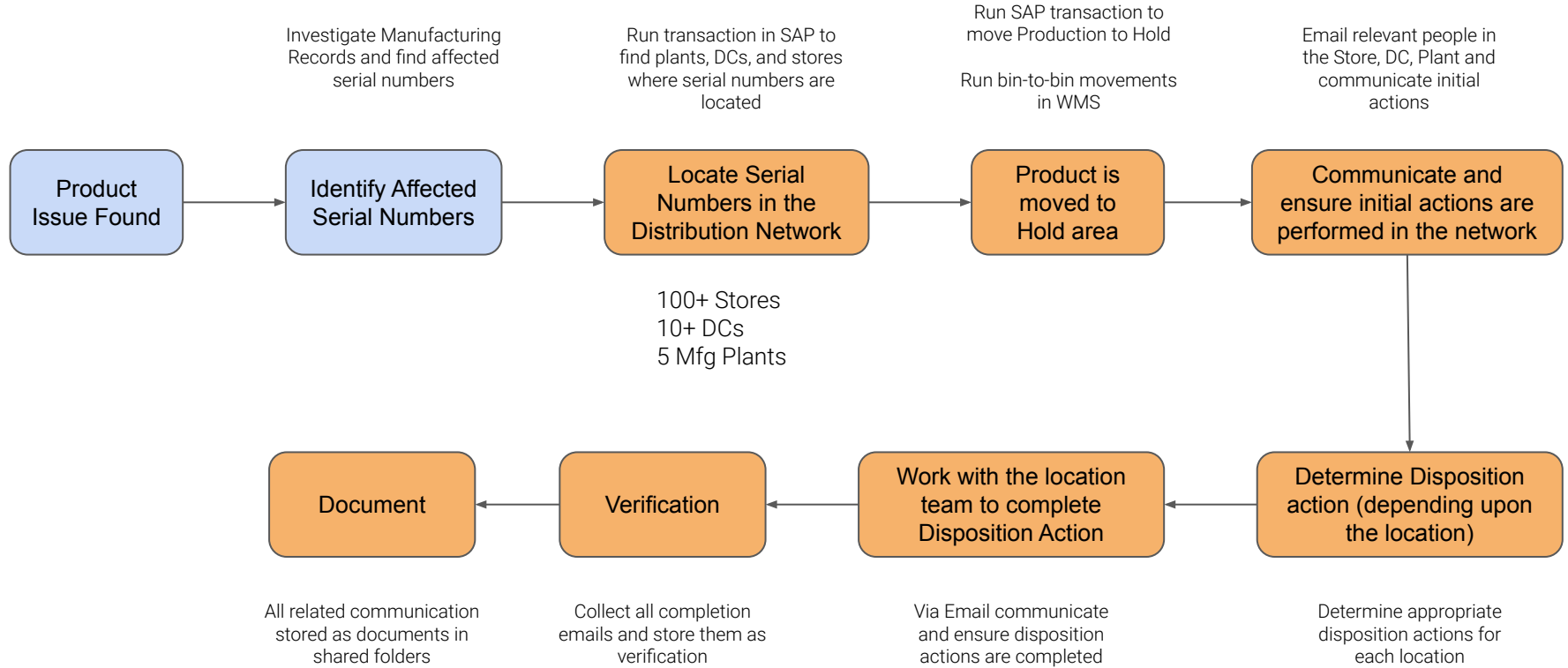
- ❑ Introductions
- ❑ Cross-functional Quality Management and Challenges
- ❑ Workflow Based Approach to Cross-functional Quality Management
- ❑ **Case Study#1 - Quality Hold due to Issue**
- ❑ Case Study#2 - Deviation Process
- ❑ Demo
- ❑ Q&A

Case Study Overview

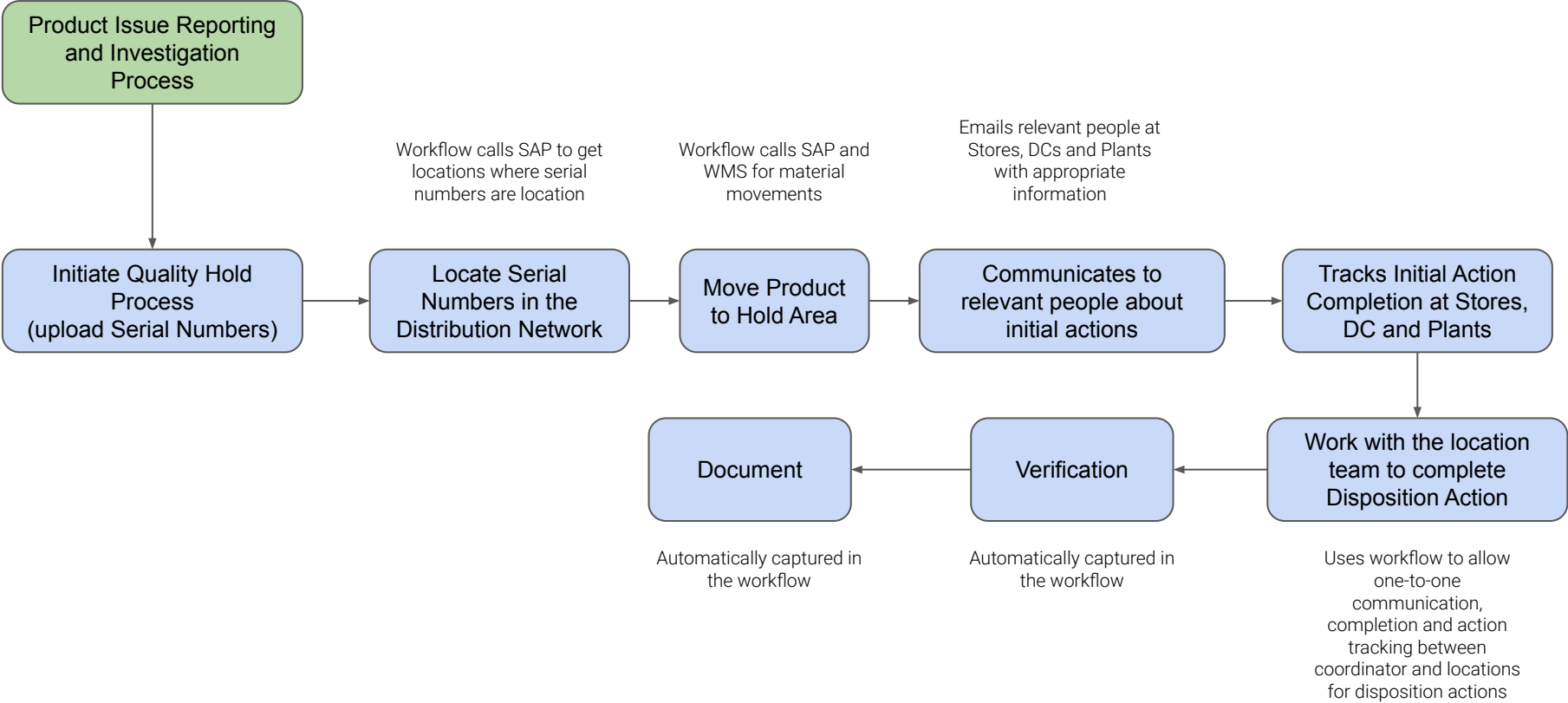
Manufacturer needs to act fast to move non-conforming product (so that it does not end up with customers) from various distribution nodes (Stores, DCs, and Manufacturing Plants) to support immediate actions, fixes and eventual disposition



AS-IS Standard Operating Procedure



Digital Workflow Based Standard Operating Procedure



Initiate Product Hold

Launch Pad Administration ▾ Data Maintenance ▾ Repository Reports Search

Product Hold - [redacted] [user icon]

Info **Current Activity** Data Members Roles WorkFlow Log Graph Process Report

Current Activity: Wait for Plant Action Completion (Current Status: Activity restarted) You are Acting for the Performer Performers: [redacted]

[▶ Complete](#) [▶ Resend Notifications](#)

Primary Facility: [redacted] ▾

Reporting Store/DC/Facility : [redacted] ▾

Reference ID: [redacted]

Issue Description: [redacted]
Wiring Issue

Initial Action Instructions: [redacted]
Put these items in hold
Disposition Plan - FTC's will visit for rework - Please respond Back when complete

Current Scope*: [redacted] ▾

Last Update: [redacted] 2023/05/04 14:00

Serial Number

#	Serial Number
<input type="checkbox"/> 1	[redacted] 254
<input type="checkbox"/> 2	[redacted] 255
<input type="checkbox"/> 3	[redacted] 256
<input type="checkbox"/> 4	[redacted] 257
<input type="checkbox"/> 5	[redacted] 258
<input type="checkbox"/> 6	[redacted] 280
<input type="checkbox"/> 7	[redacted] 291
<input type="checkbox"/> 8	[redacted] 292
<input type="checkbox"/> 9	[redacted] 293
<input type="checkbox"/> 10	[redacted] 294


Workflow connects to SAP, gets Locations of Serial Numbers, and initiates movement to Quality Hold Area in WMS

#	Material Number	Equipment Number	Description	Serial Number	Plant	Current S Loc	Customer	Impacted Quantity
<input type="checkbox"/> 1				38	A12	0001		
<input type="checkbox"/> 2				8	A12	0001		
<input type="checkbox"/> 3				20	A12	0001		
<input type="checkbox"/> 4				38	A12	0001		
<input type="checkbox"/> 5				38	A12	0001		
<input type="checkbox"/> 6				3	A2	0001		
<input type="checkbox"/> 7				4	A2	0001		
<input type="checkbox"/> 8				2	A2	0001		
<input type="checkbox"/> 9					A2	0001		
<input type="checkbox"/> 10					A4	0001		
<input type="checkbox"/> 11	105000410	105000410	CV25-10/24-85-20 Coil/STON/CA50	1102000	A4	0001		

Workflow Identifies and Communicates with Relevant Stakeholders at Impacted Locations

#	Comments	Plant	Email Distribution List	Initial Action Completed?	Initial Action Response	Initial Action Completed By (USER ID)	Disposition Completed?	Disposition Actions
1			A1	Yes	Put on hold		Yes	FTC reworked the wiring
2			A2	Yes	Moved to hold in		Yes	FTC visit 5.4.23
3			A4	Yes	Moved all the		Yes	Held in HOLD Area - Will confirm once rewor

Workflow Allows bidirectional communication and coordination of initial actions, fixes and eventual disposition

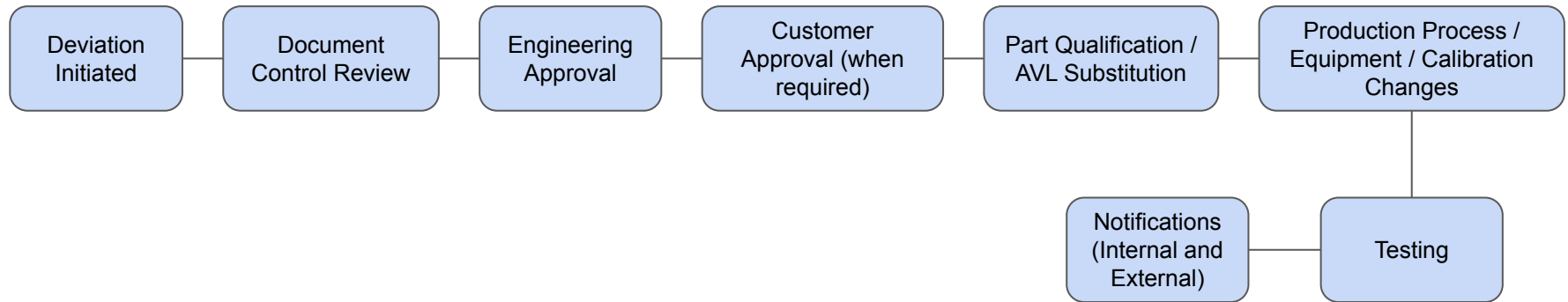
Initial Action Instructions:	Put these items in hold Disposition Plan - FTC's will visit for rework - Please respond Back when complete	Disposition Instructions:	12S87
Current Scope:	Disposition	Creation Date:	2023/05/04 14:06:56
Last Update:	2023/05/04 14:22:31		
Plant			
Plant:		Email Distribution List:	
Initial Action Completed?:	Yes	Initial Action Response:	Moved all the serial numbers to HOLD area
Initial Action Completed By (USER ID):		Initial Action Date:	2023/05/04
Impacted Quantity Summary:	Qty: 10 Qty: 15 Qty: 75 Qty: 90 Qty: 110	Disposition Completed?:	Yes
Disposition Actions:	Held in HOLD Area - Will confirm once reworked	Disposition Completed By (USER ID):	
Disposition Date:	2023/05/04		
Attachments			
 <input type="button" value="CHOOSE FILE"/> No file chosen			

Agenda

- ❑ Introductions
- ❑ Cross-functional Quality Management and Challenges
- ❑ Workflow Based Approach to Cross-functional Quality Management
- ❑ Case Study#1 - Quality Hold Due to Issue
- ❑ **Case Study#2 - Deviation Process**
- ❑ Demo
- ❑ Q&A

Case Study Overview

High-tech Manufacturer uses Deviation Process to handle non-standard, but acceptable changes. The deviation process is highly cross-functional and depending upon the deviation category can involve testing, process changes at the plant, internal approvals, and customer communication.



100s of deviations a month due to supply chain issues

Initiate Deviation Order

Launch Pad Administration Data Maintenance Repository Reports Search

Manufacturing Deviation Order - MDO000

Back to Search results..

Process Info Current Step Process Data Members Roles Workflow Process Log Process Graph Process Report

Reset Email Status Archive Activities Export to Excel Re-Open Obsolete Process Copy Process Link

Process ID: MDO000 Process State: Closed - Complete Process Owner: [Redacted]

Result: Approved Result By: [Redacted] Whole Process Complete (ManufacturingDeviationOrder # : MDO000616)

Description: Manufacturing Deviation Order

Current Activity: None - Process has been Completed

MDO Description*: Approval to purchase [Redacted] material to support qualification build

Special Instructions: Planning to provide Batch Number. Approval to purchase is attached.

Change Description*: Approval to purchase [Redacted] with AVL status Z005 (Under Qualification / Buy with approved deviation only).

Effectivity Date*: 2023/02/28 Expiration Date (Not more than 90 days)*: 2023/03/31

SW/FW Impact: Add To BOM:

Customer: PO Number:

Workflow Path based on Deviation Category

Launch Pad Administration Data Maintenance Repository Reports Search

Manufacturing Deviation Order - [Redacted]

Process Info **Current Step** Process Data Members Roles Workflow Process Log Process Graph Process Report

Current Activity: **Data preparation** Current Status: Activity started

[Submit](#) [Cancel](#) You are Acting for the Performer Performers:

Instructions: Please enter data in the form below and save or add files to the process then click to continue process.

Deviation Details

Facility*: [Redacted] Product Line*: [Redacted]

Deviation Category*: **Component Change or Substitution (all components except PCB)**

MDO Description*: [Redacted]

Special Instructions: [Redacted]

Change/Reason Description*: [Redacted]

Effectivity Date*: [Redacted]

SW/FW impact: [Redacted]

Customer: [Redacted]

Expiration Date (Not more than 90 days)*: 2021/07/30

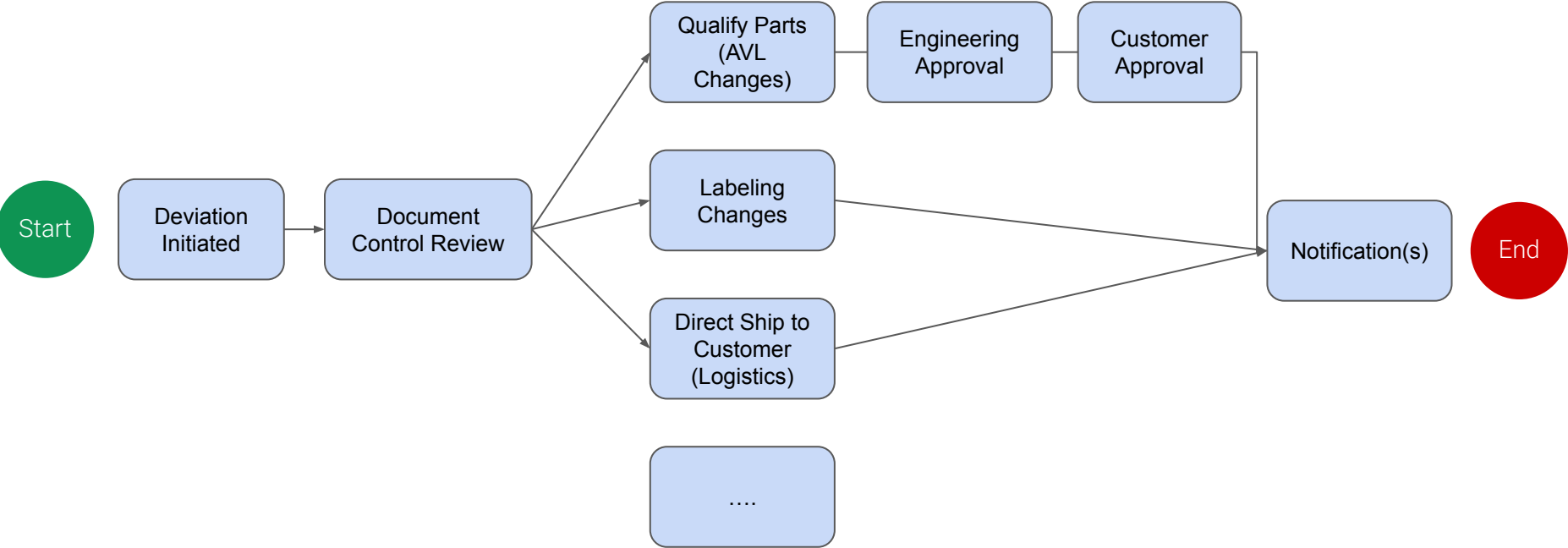
Add To BOM: [- Select -]

PO Number: [Redacted]

[Save Changes](#) [Reset Form](#) [Ed](#)

[Help](#)

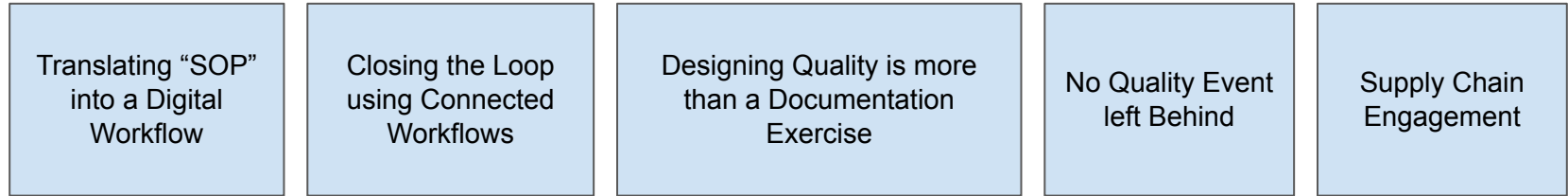
Different Workflow Paths for Different Categories of Deviations



Agenda

- ❑ Introductions
- ❑ Cross-functional Quality Management and Challenges
- ❑ Workflow Based Approach to Cross-functional Quality Management
- ❑ Case Study#1 - Quality Hold due to Issue
- ❑ Case Study#2 - Deviation Process
- ❑ **Demo**
- ❑ Q&A

Demo



Demo



Case for Quality: CAPA Process Improvement

A Whitepaper Recasting the CAPA Process by the Case for Quality CAPA Working Group of the Medical Device Innovation Consortium (MDIC)

December 3, 2019

© 2019 Medical Device Innovation Consortium

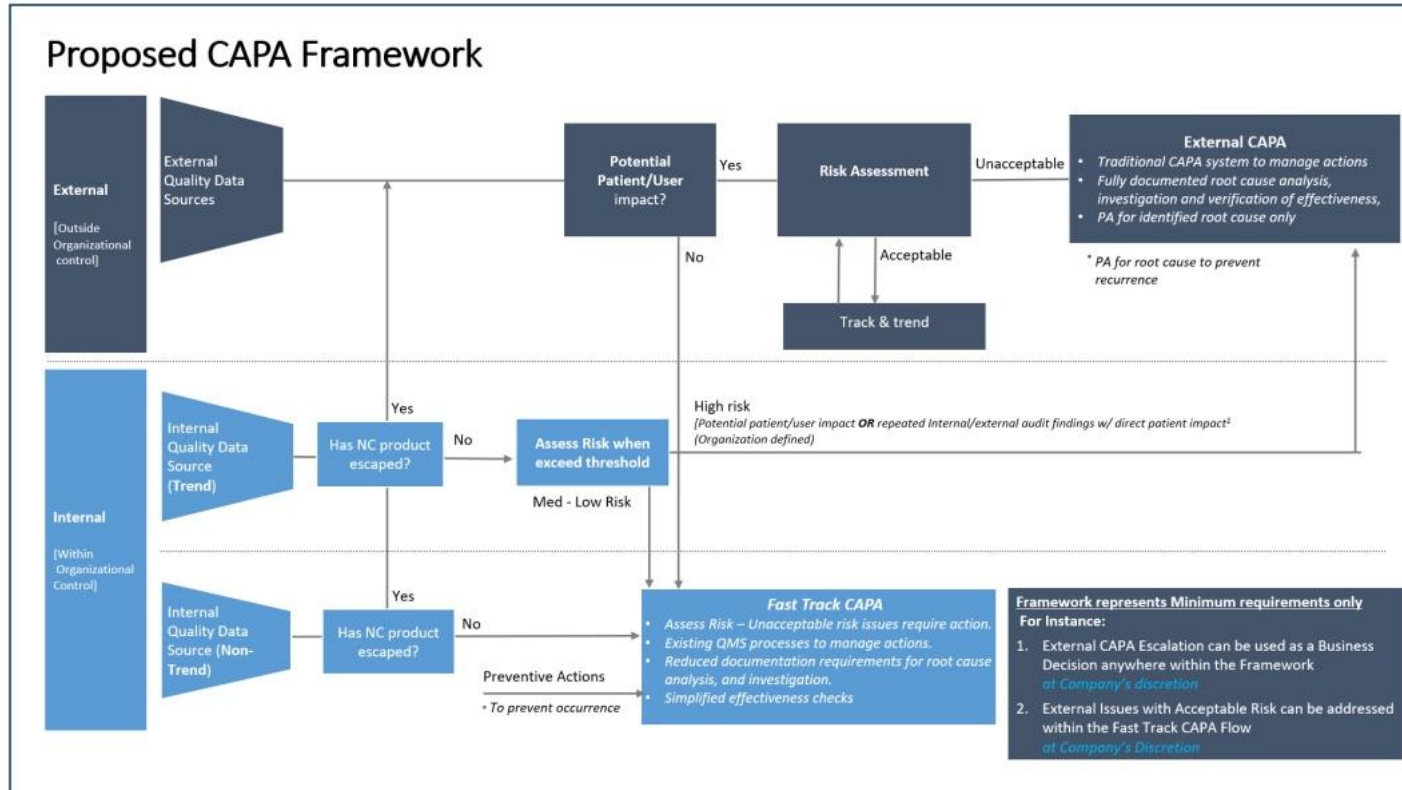
paperwork, often slowing down efforts to address issues. The result: Today's CAPA process consumes significant resources— case studies of participating organizations have indicated that it could be around 1% of a company's revenues!

"Our staff dreads being assigned a CAPA. It is burdensome and is seen as a punishment instead of an improvement opportunity"

"Our CAPA system is bloated and is focused creating documents instead of resolving issues"

Demo

PROPOSED RISK-BASED IMPROVEMENT FRAMEWORK

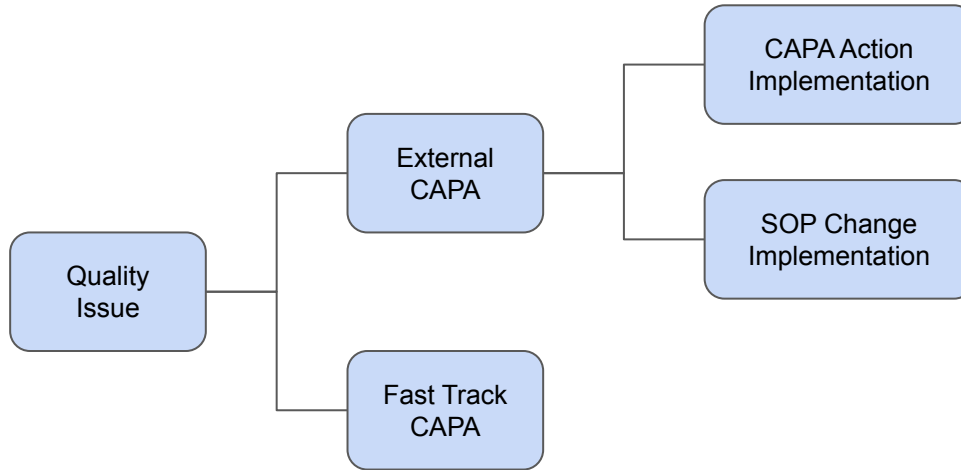


Objective of Proposed Framework

To make today's CAPA process more effective, efficient, and user friendly—while still meeting the intent of the regulations.

the framework acknowledges that **all issues are not created equal**. As a result, an in-depth improvement process is not warranted for every issue, and **some corrective actions can appropriately be handled quickly and compliantly** through other quality system processes and identified governance controls. The framework outlines **interconnected workflows that allow organizations to triage issues and improvement opportunities** based on the risk to users:

Demo



Ready to Use Cross-functional Quality Workflows, Tools, and Techniques

KZ Launch Pad Administration ▾ Data Maintenance ▾ Repository Reports New Search ZFlow Admin ▾

Launch Pad for Administrator

Crossfunctional Quality

- Corrective Action Request
List | Find | Insights | New
- Failure Report
List | Find | Insights | New
- Custom Corrective Action Report
List | Find | Insights | New
- Nonconformance Report
List | Find | Insights
- Quality Issue
List | Find | Insights | New

Continuous Improvement

- A3 Report
List | Find | Insights | New
- 8D Problem Solving Process
List | Find | Insights | New
- Kaizen Event
List | Find | Insights | New

Manufacturing Quality

- Inspection Report
List | Find | Insights | New
- Control Plan
List | Find | Insights
- Measurement Sys Analysis
List | Find | Insights
- Process FMEA
List | Find | Insights
- Process Plan
List | Find | Insights

Design Quality

- NPI Review
List | Find | New
- APQP Program
List | Find | Insights | New
- First Article Inspection Report
List | Find | Insights | New
- Medical Device NPI
List | Find | Insights | New
- Supplier PPAP
List | Find | Insights
- DFMEA
List | Find | Insights
- Design Verification Plan
List | Find | Insights
- Part/Assembly
List | Find | Insights
- QFD
List | Find | Insights
- Requirement
List | Find | Insights
- Risk Assessment
List | Find | Insights
- Traceability Matrix
List | Find | Insights

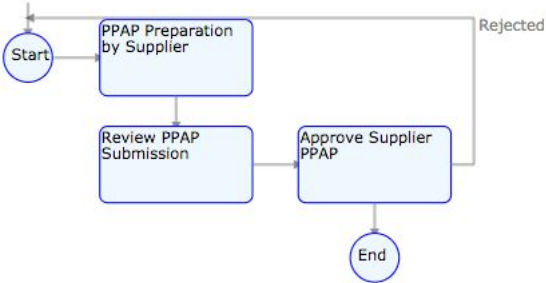
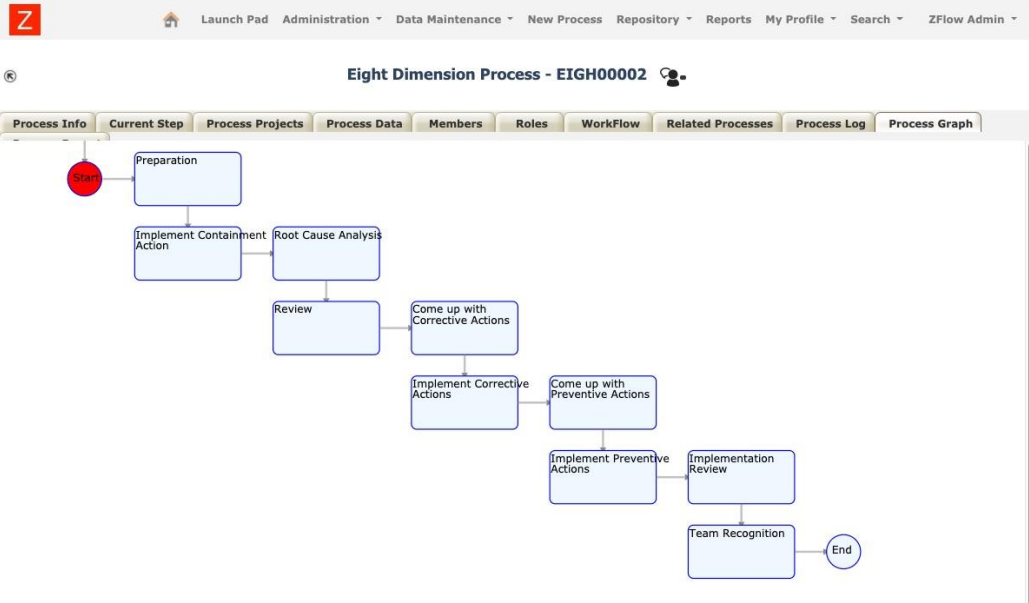
Supplier Quality

- Supplier Performance
List | Find | New
- Supplier Risk Assessment
List | Find | New
- Supplier Audit
List | Find | Insights | New
- Supplier Corrective Action
List | Find | Insights | New
- Supplier Performance Report
List | Find | Insights | New
- Vendor Assessment
List | Find | Insights | New
- Supplier Profile
List | Find | Insights

Customer Quality

- Customer Review Assessment
List | Find | Insights | New
- Field Failure Report
List | Find | Insights
- MedWatch Report
List | Find | Insights | New
- Return Material Authorization
List | Find | Insights | New
- Warranty Claim Analysis
List | Find | Insights

Powerful Do-it-yourself Workflow Design and Execution



Integrated and Effective Techniques as part of Quality Workflows

Design FMEA - Delta Eclipse XZ

Show Spreadsheet
 Attachments
 Show Attachment Tree
 Reports
 Close
 Comments
 Action Items

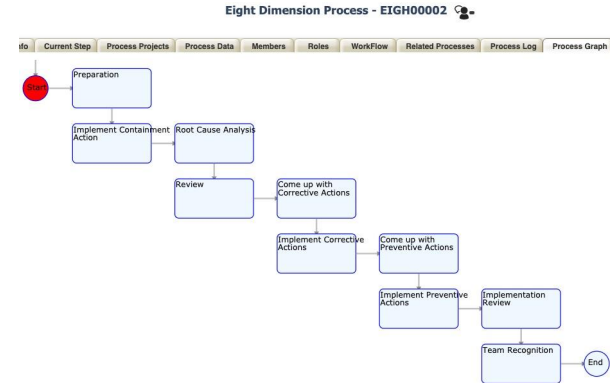
Design FMEA
 Delta Eclipse XZ
 Maintains designed level of low pressure
 Desired vacuum level not maintained
 Contamination of test environment
 Leak due to o-ring failure
 Continuous measurement
 New o-ring
 Vacuum system failure
 Continuous measurement
 Controls movement of IC test beds
 Maintains temperature

Form Identifier: Delta Eclipse XZ DFMEA
 Part Number: Delta Eclipse XZ
 Description: Delta Eclipse XZ DFMEA
Status: Work In Process
 Rev.: A
 Rev. Status: Pending
Created By: admin@zflow.io
 Creation Date: 2020/12/14 8:37:54
 Updated By: admin@zflow.io
Last Update: 2020/12/14 8:37:54

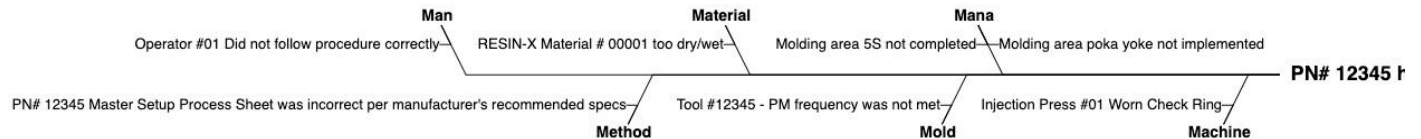
Design FMEA Function

#	System	System Interface
<input type="checkbox"/> 1	Vacuum Chamber	
<input type="checkbox"/> 2	Motion Controller	
<input type="checkbox"/> 3	Thermal Controller	

FMEA




8D





Fishbone


Cross-functional Team Collaboration

Z
Roles - Supplier PPAP
✕


New


Edit


Delete



Update Processes


Role Name	Description	From Org	Privileges
<input type="radio"/> Participant			
<input type="radio"/> Design Engineer		No	
<input type="radio"/> Process Admin			
<input type="radio"/> Purchasing Lead		No	
<input type="radio"/> Supplier Representative		No	


Z
Menu


- Administration ▾
- Data Maintenance ▾
- New Process
- Repository ▾
- Reports
- My Profile ▾
- Search ▾
- ZFlow Admin ▾


Organization Structure - Root



Edit



Add Organization



Add Position



Add New User



Export



Rename



Delete



Delete All



Expand All












Users


Open Org


Report

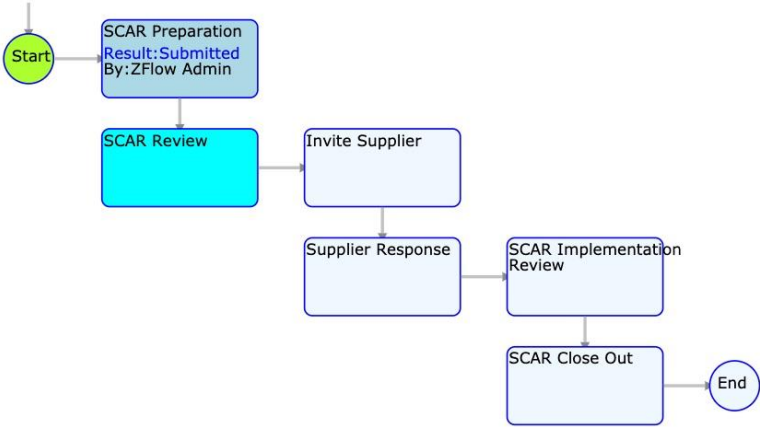

Download


Back

Entity	Type	Person Assigned	Reports To Position
<input type="radio"/>  Root	Organization		
<input checked="" type="radio"/>  ZZ Corp	Company		
<input type="radio"/>  Tezla	Organization		
<input type="radio"/>  CEO	Position	zflow-ceo@mailinator.com	
<input type="radio"/>  VP of Finance	Position	zflow-vp-finance@mailinator.com	
<input type="radio"/>  VP of Manufacturing	Position		
<input type="radio"/>  Fremont Plant	Division		
<input type="radio"/>  Plant Manager	Position		
<input type="radio"/>  Giga Factory	Division		
<input type="radio"/>  Z Lab	Organization		

Easy and Secure Supplier/Customer/External Partner Collaboration

Business Name	Supplier ID	Supplier Relationship Status	Supplier Maturity Level	Supplier Category
<input type="checkbox"/> Avioq Inc.	SAVIOQ	Active	Advanced	Strategic
<input type="checkbox"/> Bosch Sensortec	SBOSCH	Qualified	Advanced	Non -strategic
<input type="checkbox"/> Broadcom	SBRCM	Active	Advanced	Strategic
<input type="checkbox"/> Carrier UTC	Carrier			
<input type="checkbox"/> Cirrus Logic	SCIRRUS			
<input type="checkbox"/> Genco Contractors	Genco			
<input type="checkbox"/> Generac	Generac			
<input type="checkbox"/> Honeywell	Honeywell			
<input type="checkbox"/> Huizhou Desay	SHUIZHOU		Basic	Non -strategic
<input type="checkbox"/> Intel Corp	SINTC	Preferred	Integrated	Strategic
<input type="checkbox"/> Jabil	Jabil	Preferred	Integrated	Strategic
<input type="checkbox"/> Lattice Semiconductor	SLATTICE	Qualified	Advanced	Non -strategic
<input type="checkbox"/> Lennox International	Lennox			
<input type="checkbox"/> MetalDyne	MetalDyne	Active	Basic	
<input type="checkbox"/> Murata Manufacturing	MURATA	Active	Advanced	Routine
<input type="checkbox"/> Northern Tool and Equipment	NorthernTE			
<input type="checkbox"/> NXP Semiconductor	NXPSEMI	Preferred	Advanced	Non -strategic
<input type="checkbox"/> Qorvo Inc	QORVO	Qualified	Advanced	Non -strategic
<input type="checkbox"/> Qualcomm Inc.	QCOM	Restricted	Advanced	Strategic
<input type="checkbox"/> Skyworks Inc.	SKYWORKS	Active	Advanced	
<input type="checkbox"/> TDK Corp	TDKCORP			

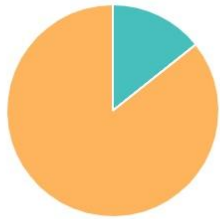


Quality Workflow Status Visibility and Metrics

Supplier Corrective Action - Processes - Total Records: 6

Approval Status ▾

Completed Rejected Approved Other



Process Status ▾

Not Submitted Running - Work In Process



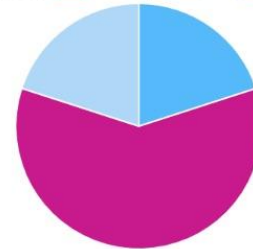
Issue Type

Field Failure Nonconformance Return Customer Complaint Poor Quality



Recommended CAR Type

Design Change Process Change Training Inspection

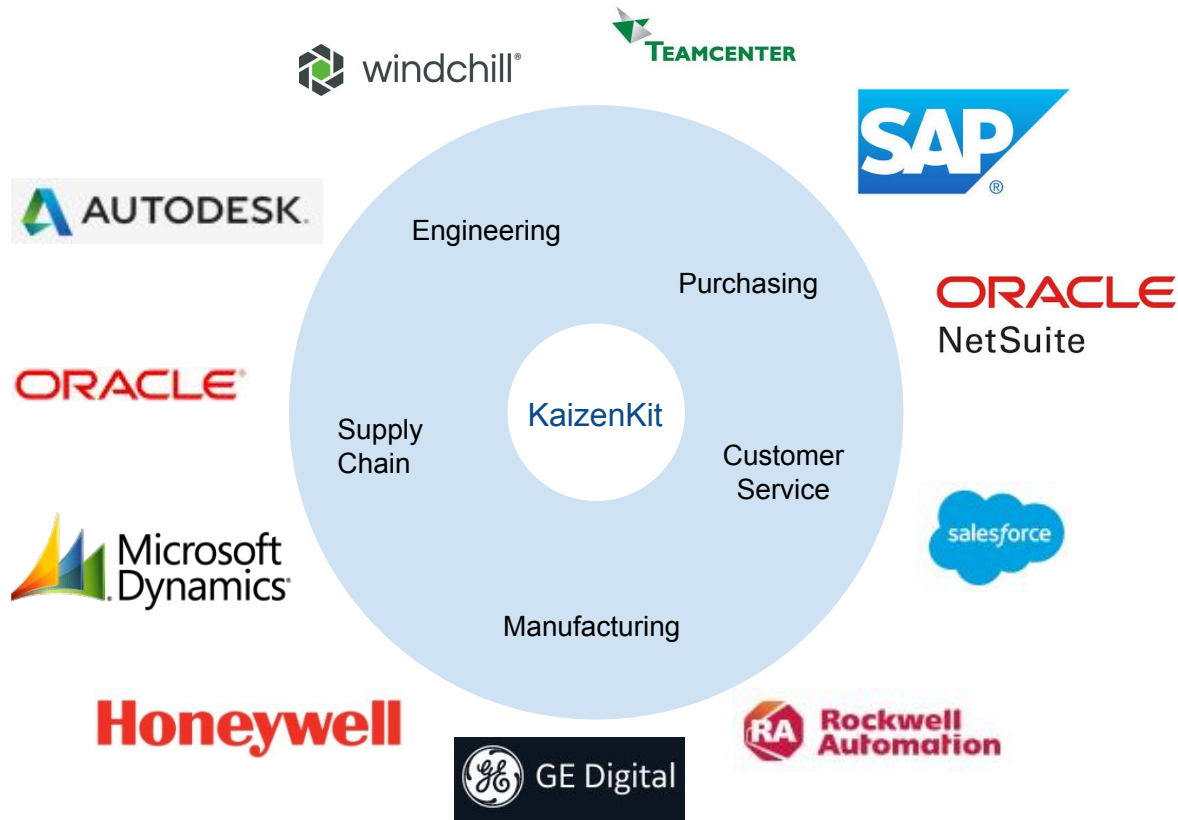


Root Cause Type

Part Process Training Quality Control



Rich Capabilities for Integrating to ERP, Engineering, Manufacturing and Supply Chain Applications



Summary

- ❑ *Proven success in many industries*
- ❑ *Easy to adopt and loved by users*
- ❑ *Easy to get started*

[Free Trial](#)

[Free Pilot](#)

For More Information

<https://www.kaizenkit.io>

Kris Gorrepati

Cambrian Lab

+1-408-569-3744

Kris.gorrepati@cambrianlab.net

