

Quality is Everyone's Responsibility

Digital Workflows for Quality Management Excellence

Kris Gorrepati and Manish Mathur

KaizenKit

Designed by

Cambrian Lab

Our Mission

To Make

Quality is everyone's responsibility
- W. Edwards Deming

A Reality in the Organization and the Supply Chain

Agenda

- ❑ Introductions
- ❑ Cross-functional Quality Management and Challenges
- ❑ Workflow Based Approach to Cross-functional Quality Management
- ❑ 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

Panelists Today

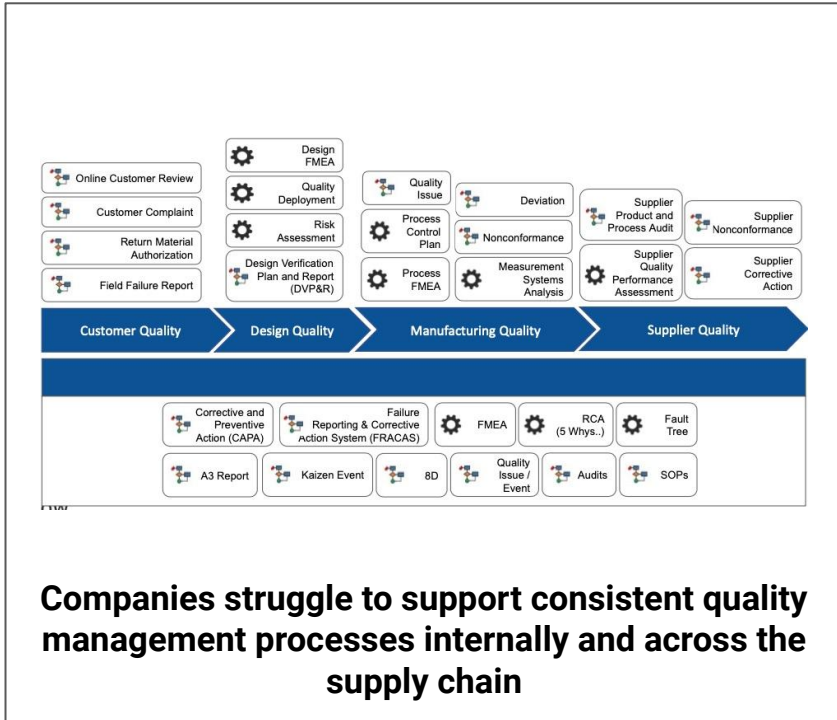
Kris Gorrepati

- 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

Making Quality Everyone's Responsibility is a Challenge



Root cause

- Quality is the responsibility of only quality department
 - No support for cross-functional quality management processes
 - Quality processes are disconnected from key business and supply chain processes
- Cross-functional Quality workflows are poorly supported**

Effect

- | | | |
|----------------------------------|---------------------|-------------------------|
| Poor product and service quality | Reputational damage | High warranty cost |
| Non-compliance | Customer returns | Supply Chain Disruption |
- Uniformly bad consequences**

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

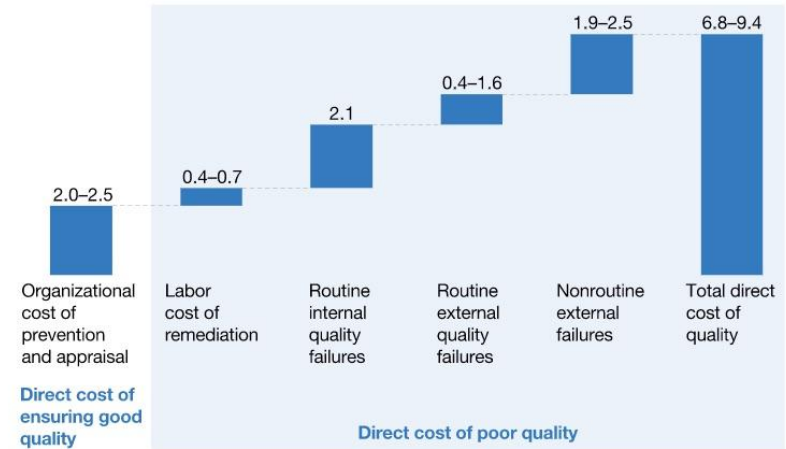
Cost of Quality			
Cost of Good Quality		Cost of Poor Quality	
Prevention costs	Appraisal costs	Internal failure costs	External failure costs
<ul style="list-style-type: none">• Planning• Process Control• Quality Audits• Maintenance• Supplier Evaluation• Training• Design Review• Risk Assessment• FMEA	<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.

% of sales¹



¹Estimated annual sales of \$380 billion.

“Quality Assurance” is neither Easy nor Cost-effective

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

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
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Supplier approval - document	55

Food

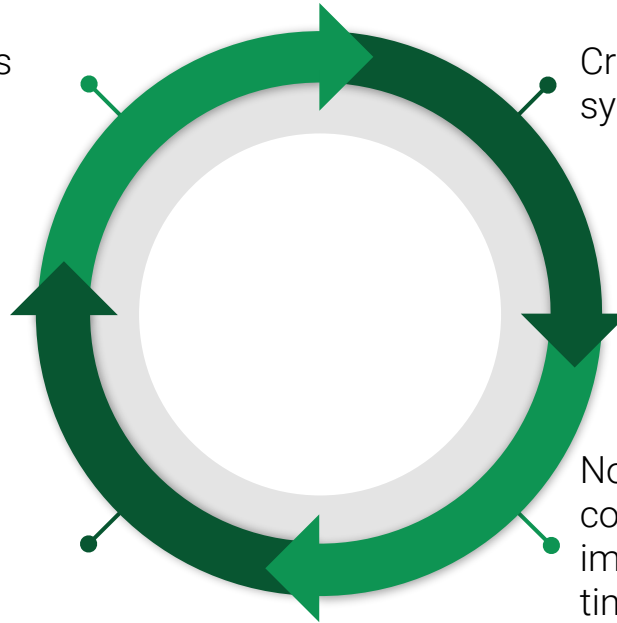
Why Making “Quality is Everyone’s Responsibility” Remains a Challenge

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

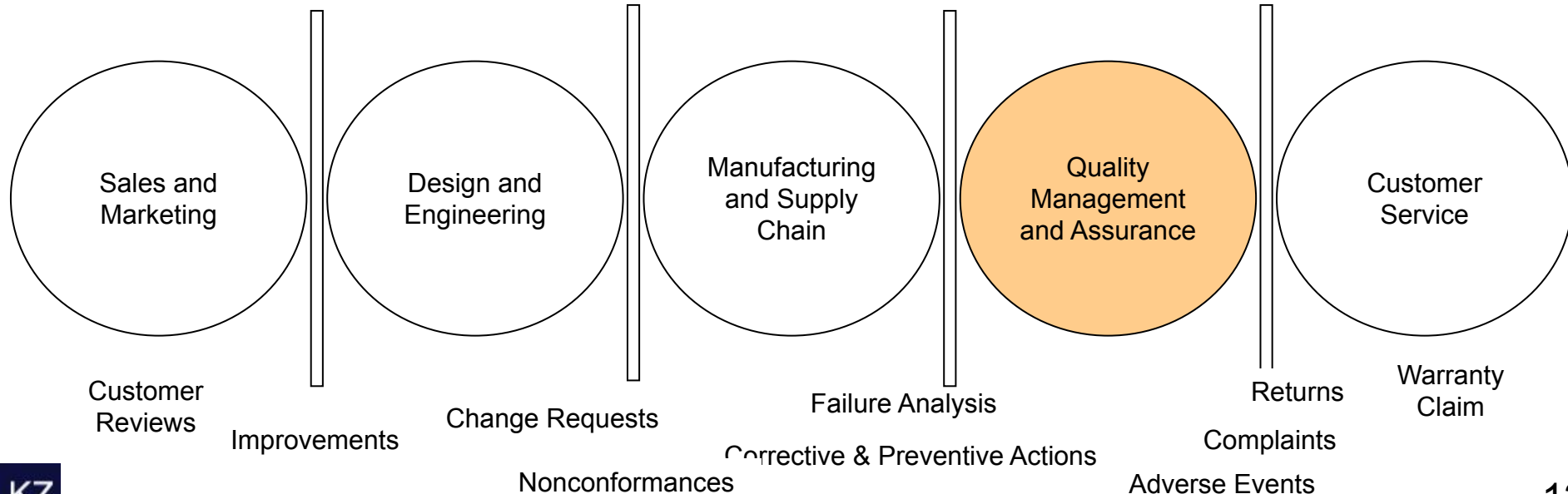


Process and Information Silos Are Obstacles to Making “Quality is Everyone’s Responsibility”

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

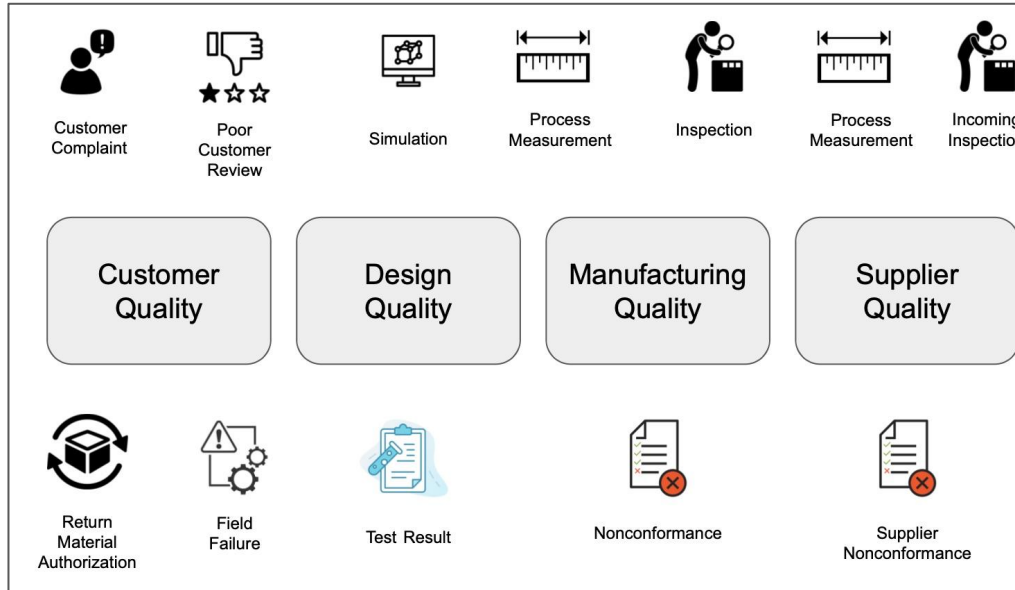
CRM
Systems

E-commerce

Testing
Systems

LIMS

Inspection
Systems



ERP
Systems

Supply Chain
Systems

The Answer - Quality Management Workflows that Make “Quality is Everyone’s Responsibility” a Reality

Quality Workflows that can include and be started by anyone and system

Out-of-the-box Integration to ERP, MES, PLM, Supply Chain systems

Zero-code

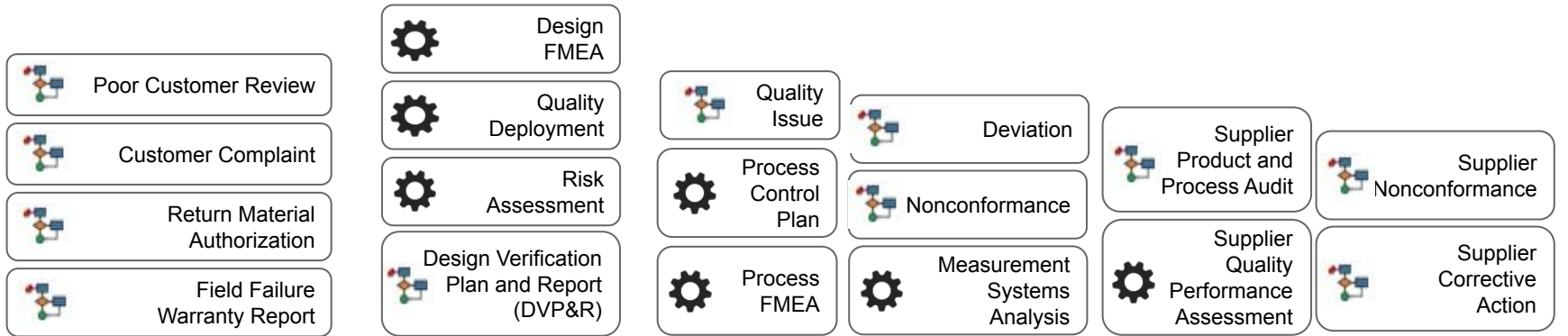


Proactively Involve Right People at the Right Time

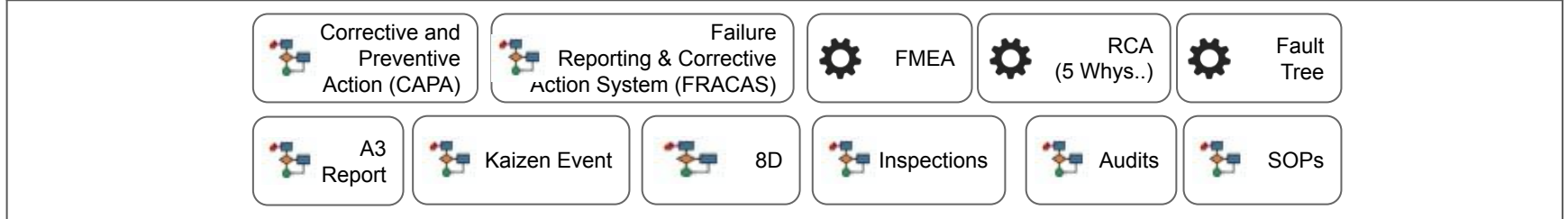
Supply Chain Ready

Integrated and effective quality tools and techniques

Quality is Everyone's Responsibility



Cross-functional Quality and Continuous Improvement Tools



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

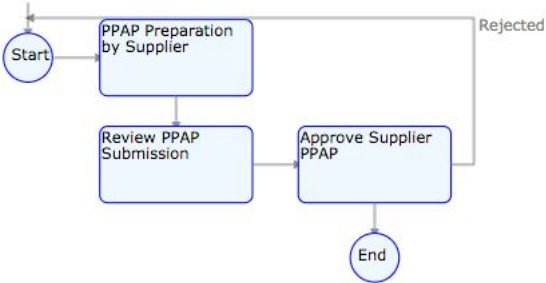
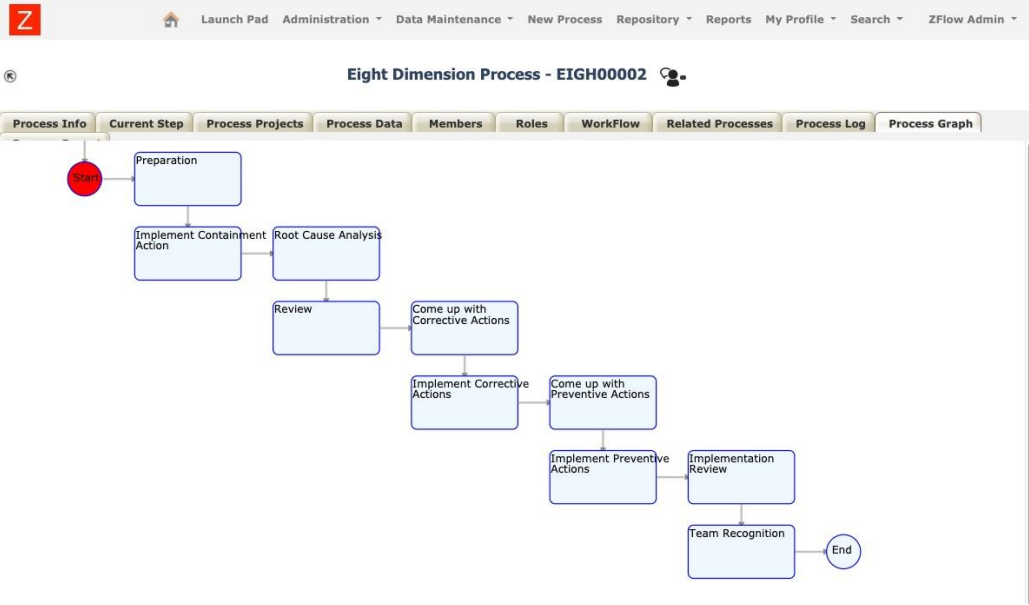
Supplier Quality

- 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

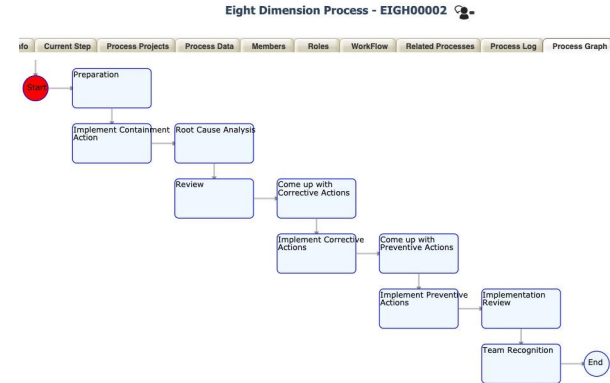
Created By: admin@zflow.io **Creation Date:** 2020/12/14 8:37:54 **Updated By:** admin@zflow.io

Last Update: 2020/12/14 8:37:54

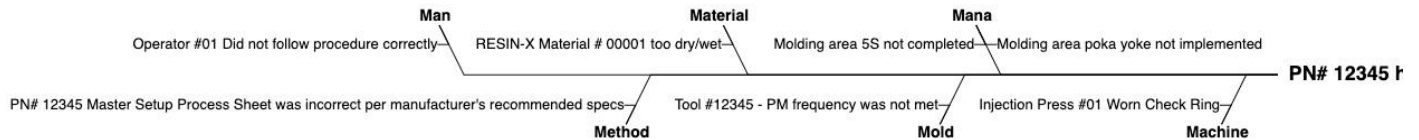
Design FMEA Function

#	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


Participant


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


Design Engineer No


Organization Structure - Root



Edit



Add Organization



Add Position



Add New User



Export



Rename



Delete



Delete All



Expand All












Users


Open Org


Report

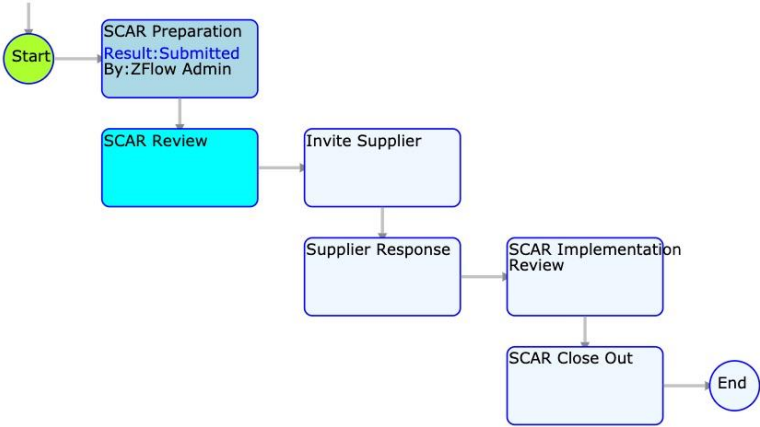

Download


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



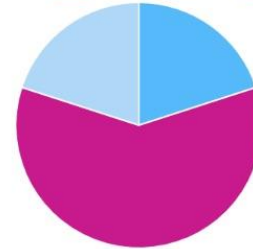
Issue Type

Field Failure Nonconformance Return Customer Complaint Poor Quality



Recommended CAR Type

Design Change Process Change Training Inspection

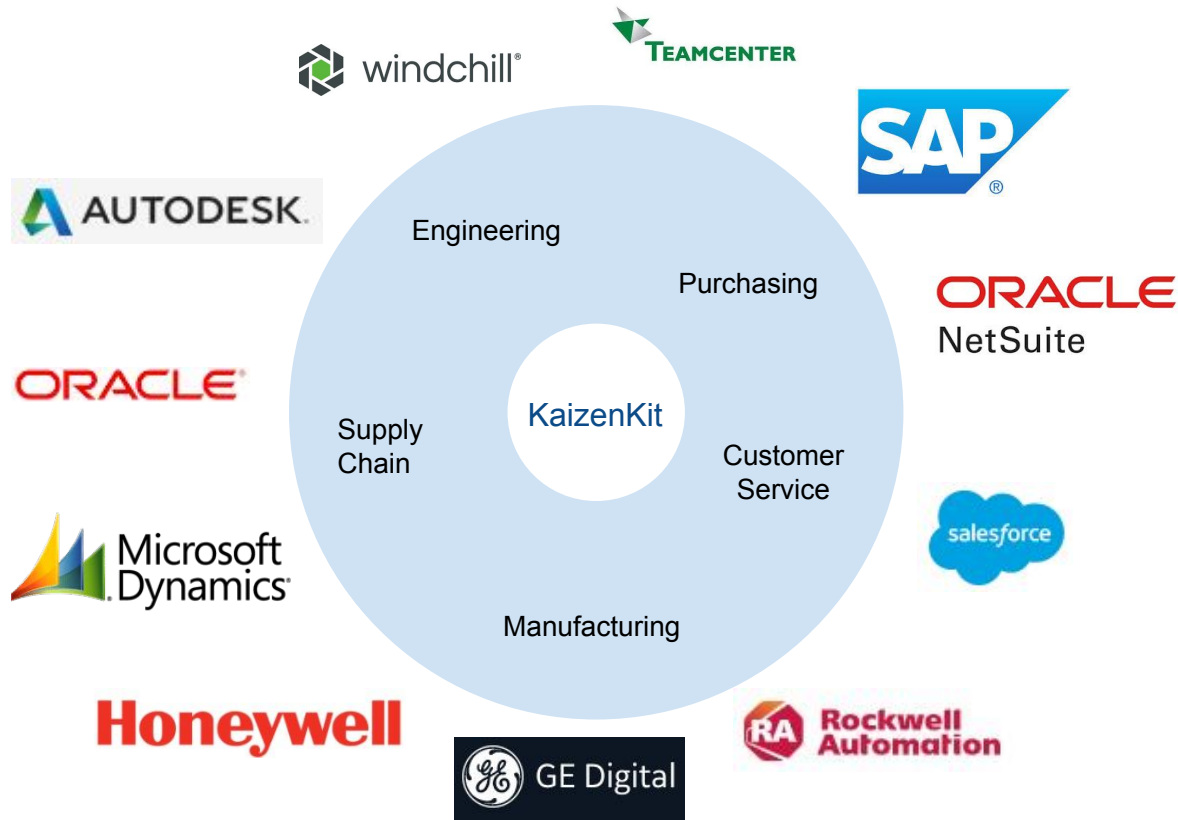


Root Cause Type

Part Process Training Quality Control



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



Demo

Doing “What is Documented” proactively as a Digital Workflow

Closing the Loop using Connected Workflows

Integrating to other Systems (ERP, Manufacturing, Supply Chain, Maintenance, Customer Service..)

Visibility and Traceability

Process Metrics and Improvement Opportunities

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>

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