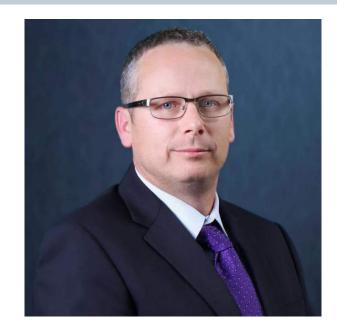




Introduction: Chuck Boots

Chuck Boots: Technical Presales Consultant II

- 20+ years of manufacturing/quality experience
- Bachelor of Science, Business Management
- 5 years as Siemens customer 3 years in current role
- Apollo RCA, Int/Ext/Supplier auditing, Six Sigma



Charles.boots@siemens.com



Introduction: Mary McAtee

Mary V. McAtee: Technical Presales Consultant II QM/FQC/LQC

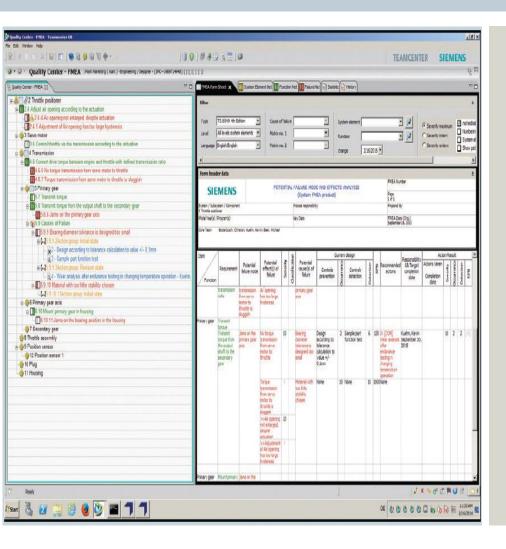
- Mechanical Engineer with 30+ years Quality and Reliability Engineering Experience
- New England Research Center: R&D Infrared Detector Development
- MA/Com Space Center: Leading Provider of High Reliability Microelectronics
- Lead Assessor: ISO 9001, ISO 14001, OHSAS 18000, TS 16949



Mary.mcatee@siemens.com



FMEAs and Risk Management: Not just for the Automotive Industry Anymore



- Failure Modes Effects Analysis (FMEA), both Design FMEAs and Process FMEAs evolved from the defense industry in the late 60s.
- The Automotive Industry embraced the concept for design, manufacturing and safety risk assessment.
- FMEAs have proved their worth and are increasingly becoming the standard in other industries including aviation, medical device and energy.

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Spreadsheets the Historical Tool of Choice



Historically Design and Process FMEAs and Control Plans have been developed in Excel spreadsheet formats which has some inherent drawbacks:

- Spreadsheets are not optimal for collaborative working groups.
- Spreadsheets are limited in providing functionality that supports intelligent reuse and qualification by similarity
- Change Management across the process can be challenging.



Sample Spreadsheet FMEA

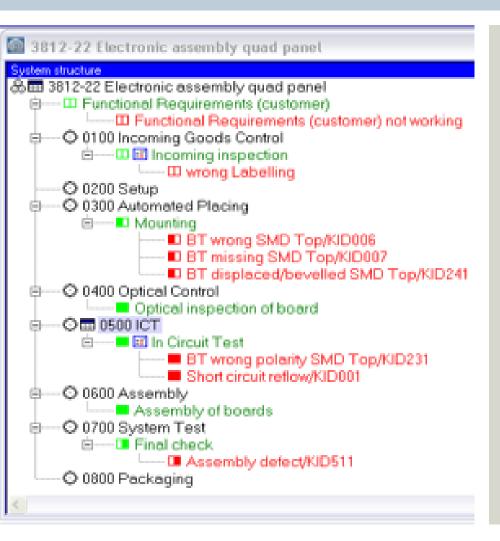
POTENTIAL **FAILURE MODE AND EFFECTS ANALYSIS**

Part Number:		(PROCESS FMEA)	FMEA Number:	116409.02
Part #:	Process Responsibility:		Prepared by:	
Part Description:	Key Date		Date (Orig.)	
Core Team:			Date (Rev.)	

I	Process	Process	Potential Failure	Potential Effect(s) of	(0	0	Potential	0	Current Process Controls	Current Process Controls	D	Ŗ	Recommended	Responsibility & Target	Action I	Kesul	lts	
	Step	Function/Requirements	Mode	Material Failure	Sev	ass	Cause(s)/Mechanism(s) of Failure	ocur	Prevention	Detection	etec	P.N.	Action)s)	Completion Date	Actions Taken	S e v	C	e P. t N.
	1-A	Chemicals Unload and verify freight	Unload wrong quantities	Inventory level incorrect within manufacturing system	1		Receiving Technician error	2	Training on receiving procedures	Visual freight verification to shipment documentation (Packing Slip, Bill of Lading)	8	16	None					
			Damage freight	Unusable product	1		Improper handling techniques	2	Fork-lift Training / Licensed Drivers	Visual freight verification	8	16	None					
,		Input receiving data and forward paperwork	no input or input of wrong quantities or part number	Inventory level incorrect within manufacturing system	1		Receiving Technician error	2	Training on receiving procedures	Cycle count, physical inventories, and visual and operator feedback	8	16	None					
	1-B	Door Beams Unload and verify freight	Unload wrong quantities	Inventory level incorrect within manufacturing system	1		Receiving Technician error	2	Training on receiving procedures	Visual freight verification to shipment documentation (Packing Slip, Bill of Lading)	8	16	None					
			Damage freight	Unusable product	1		Improper handling techniques	2	Fork-lift Training / Licensed Drivers	Visual freight verification	8	16	None			Ш		
	1-C	Brackets Unload and verify freight	Unload wrong quantities	Inventory level incorrect within manufacturing system	1		Receiving Technician error	2	Training on receiving procedures	Visual freight verification to shipment documentation (Packing Slip, Bill of Lading)	8	16	None					
			Damage freight	Unusable product	1		Improper handling techniques	2	Fork-lift Training / Licensed Drivers	Visual freight verification	8	16	None					
		Place freight in storage location	Place in wrong location	Unable to locate material when needed	1		Operator Process Error	2	Delivery address, rack label, visual map, or item number Plant Address/Locator System	Physical Inventory	8	16	None					
		Determine run sequence and quantity	Schedule incorrect quantity or sequence	Parts not available when needed	1		Operator Process Error	3	Daily shop floor schedule/ parts needed list, Kanban red zones	Visual hot boards, Customer ratings, On-time delivery reports	7	21	None					
	2-A	Load Formula Chemicals	Wrong Formula Selected	Out of Spec. Material	3		Operator Error	- 1	Operator Training	Material Performance INS- 2001	5	15	None					
Unrestrict	ed © S	iemens AG 2017	Formula will not load on computer	Machine will not operate	2		Prior weigh-up not discharged	- 1	Operator Training & TPM system	X5 alarm (maximum residue exceeded)	1	2	None			Π		



Tree Structure Design and Process FMEA Advantages

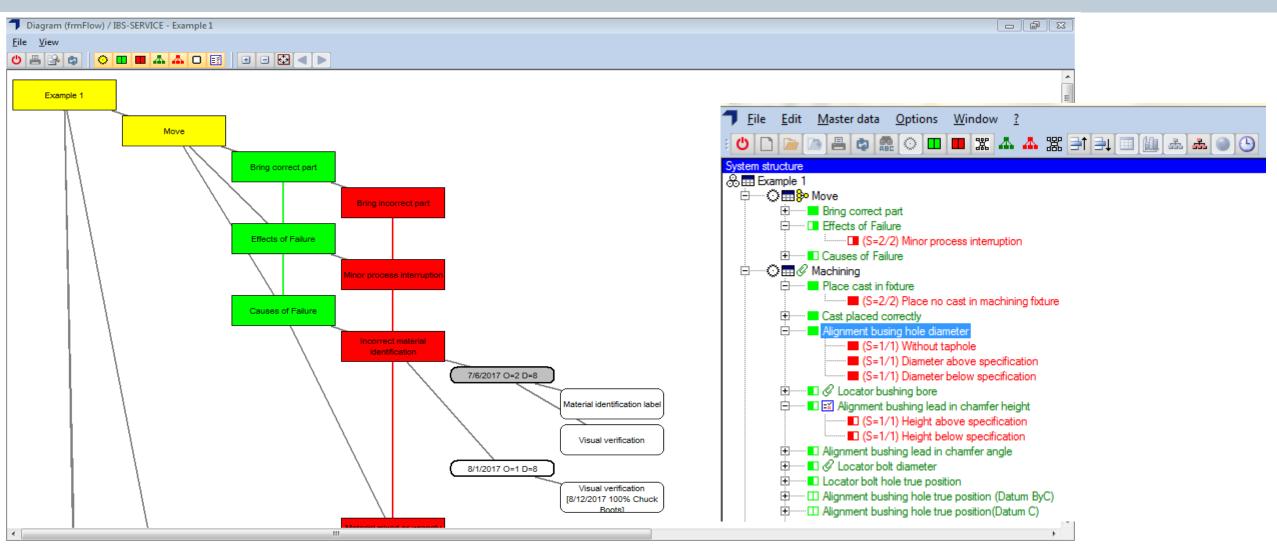


Moving to a tool that utilizes a tree structure methodology provides many advantages:

- Tree structure FMEAs can take in content from block diagrams to form the backbone of the Process FMEA.
- Design & Process FMEAs can seamlessly take in content and updates from Bill of Materials (BOM) and Bill of Process (BOP) data maintained in other systems including ERP and PLM Systems such as SAP and Teamcenter.
- Querying and reusing data is much more straight forward and real time to facilitate collaborative team efforts.
- Output can display in a variety of required regulatory formats including AIAG and VDA.



Tree Structure FMEA and Block Process Flowchart Diagram



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AIAG Example Output Format

Process step/	Requirement	Potential	Potential	S	С	Potential	Controls	0	Controls	D	RPN	Recommended	d F	esponsibility	Actions Taken S	O D RPN					
Function		Failure Mode	Effect(s) of Failure			Cause(s) of Failure	Prevention		Detection			Actions	Со	& Target	Completion Date						
	SIF	MENS		PC	OTE	NTIAL FAILURE N	ODE AND E	FF	ECTS ANAL	YSI	S		FM	EA Number		FMEA000207					
		penuity for life				(Pro	ocess FMEA)					Pa	je		1 of 1					
System Structure Exa	mple 1												Cre	at./modif.date	2017-06-23 (B)	2017 00 00	11				
Item Example 1							Process Respons	sibili	ty				Pre	pared By	Viev	v in action	on list				
Model Year(s) / Progra	m(s)						Key Date					2017-07-0)6 FM	EA Date (Orig.)	2017-06-23 /5	2017-09-06					
Core Team R.Valle, I.I	Duarte, A.Tercero,	J.Valdez, Chuck Boots																			
Process step					E		Cur	rent	Process				T_	d do	Action Resu	lts					
Function	Requirement	Potential Failure Mode	Potential Effect(s) of Failure	Severity	Classification	Potential Cause(s) of Failure	Controls Prevention	Occurrence	Controls Detection	Detection	APN N		d	& Target noletion Date	Actions Taken	stection RPN					
Process 70.01: (1) Move (FMEA000209)	Bring correct part	Bring incorrect part	Minor process interruption	2		Incorrect material identification	Material identification label	2	Visual verification	8	32	r.	System System Part No	element element		4	Dw	Ans.			
						Material mixed or wrongly identified	Material identification label	2	Visual verification	8	32	None	₩ Det	idance actions ection actions d actions	Consolive Action Responsibility	Linu Linu Gentles C Clos		od.dete			
Process 70: (2) Machining	Place cast in fixture	Place no cast in machining fixture	Minor process interruption	2		Process step skipped	Operator training	4	Visual verification	8	64	D: Last —		System element	Possible defects	Possible	Avoidance	Detection	Date/	Responsibility	Sta
(FMEA000208) Documents:	I ALGIO	macriming rocard	I ROTOPHOT				Luning		Verification			detection in leak test	(45)	S/MBR, LH/FH FMEA000280]	Sheet motel materials convex strip	Drawback in designing (SAHER, LHURH)	Add more shipping pot and use more governu springs.	actions	oligidate 19.02.2007 19.02.2003		68
•BLACKBEARPASS2.JP G	Cast placed correctly	Cast misplaced in fixture	Machine crashes	7		Process step skipped	Operator training	4	Visual verification	8	224	P: Standard opetation she	(48)	S/MBR, LH/RH FMEA000280	Bushly not allowed	Enatic reading the position trates as to design income [SAHBR_LHARH]	of Check the disension of position of all holes carefully by designer of		28 82 2807 28 82 2800	Lieu	264
						Fixture allows loading of the part incorrectly	None	8	Visual verification	8	448	P: Install air sensoring on machining fixture		S/MBR, LH/RH FMEA000280	Duality not allowed	Drawback of designing in of tace or chair bead [SAHBR. LHARH]	account		24.02.2007 24.02.2003		100
						Fixture cleanliness, chips in fixture	None	8	Visual verification	8	448	P: Cleaning of the fixture by rinsing,	1540	SAMER, UH/RH PMEA000280	Duality not allowed	Drawback of designing in face or draw bead [SAMER, LHARH]	Se Confirm the correctnes of cushion per position and adjust it.		27 82 2807 27 82 2803		100
AIAG v	3 & v4,	VDA 96 su	ipported																		

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Team Collaboration and Efficient Reuse of Data

Team	Team Awesome
Team no.	5
Color	

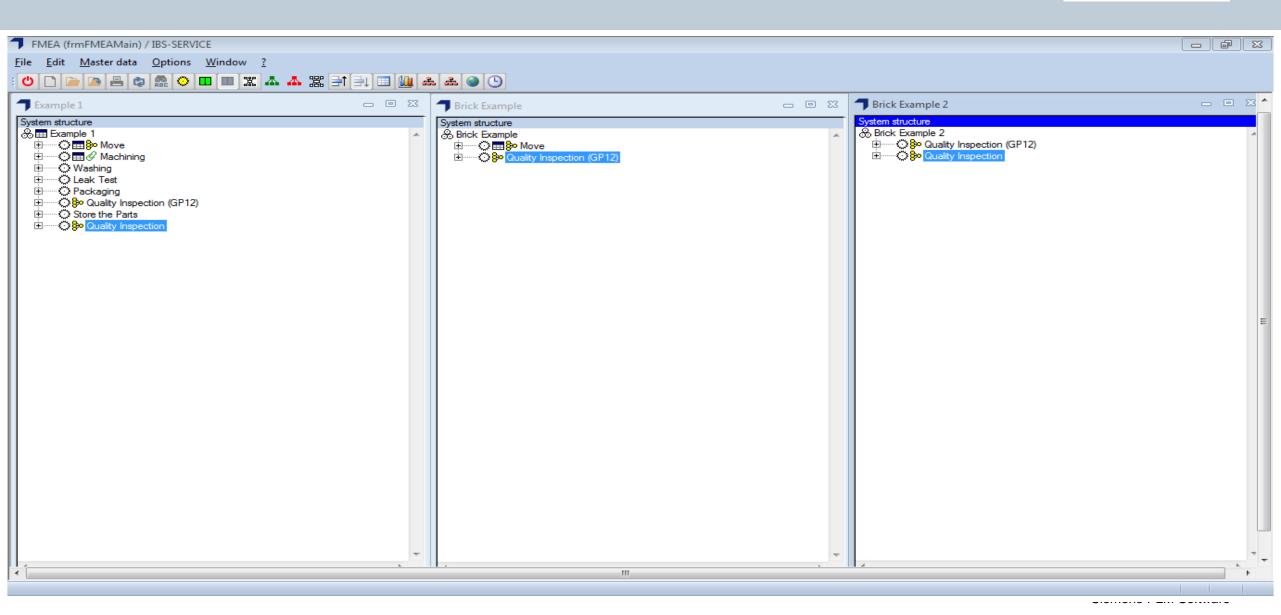
Name	GID no.	Role ID	Department descr.	Role descr.	Email
Chuck Boots	Chuck.Boots	1		Quality Engineerin	charles.boots@siemens.c
Mac Don	Mac.Don	3		Production Super	charles.boots@siemens.c
Test 4	Test.4	6		Planner	
I.Duarte	I.Duarte	2		Manufacturing En	
Test 5	Test 5	7		Machine Operator	
Test 1	Test.1	5		Buyer	

Tree structure FMEAs permit locking lines of the FMEA during editing to assure only appropriate changes are made by the team.

- Revision controls and archive functionality can keep the team oriented and facilitate design by similarity activities.
- Drag and drop of components, subassemblies and assemblies as well as processes and sub processes from one FMEA to another permits easy reuse of data.
- The resulting "where used query net" is extremely valuable when assessing the potential impact of a proposed Engineering Change.

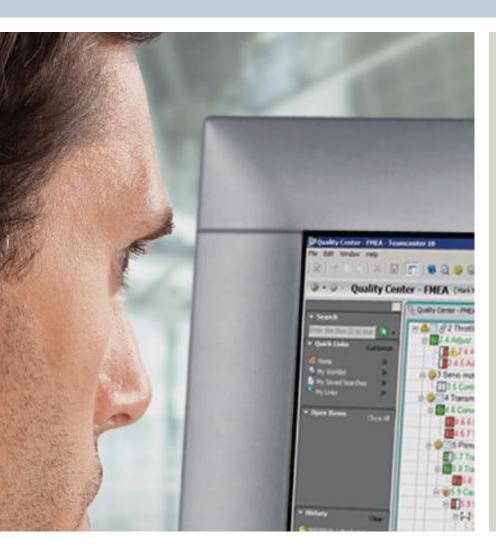


Reusing Data and Lessons Learned through Linkage



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Why Family FMEAs?

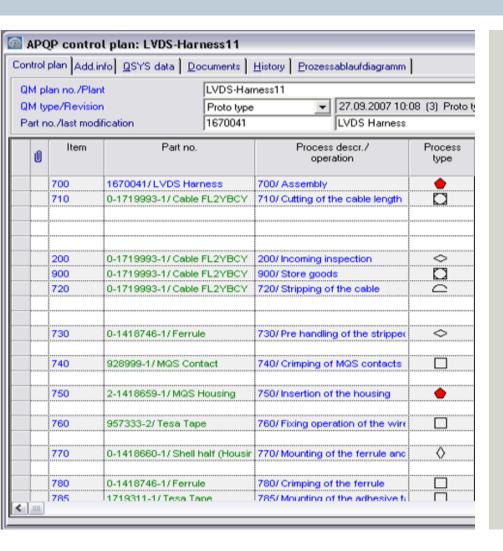


Common Processes that Scale across products such as plating, paint and coatings are good candidates for family FMEAs.

- They can be readily referenced across products and when changed cascade through all the impacted products resulting in:
 - Less errors because a product where the process was changed was missed.
 - Easy queries on these processes can provide useful information when making an environmental or safety assessment of where certain processes and chemicals are used.
 - This is increasingly important with the advent of REACH and RoHS in the EU and other parts of the world.



Inheriting Data



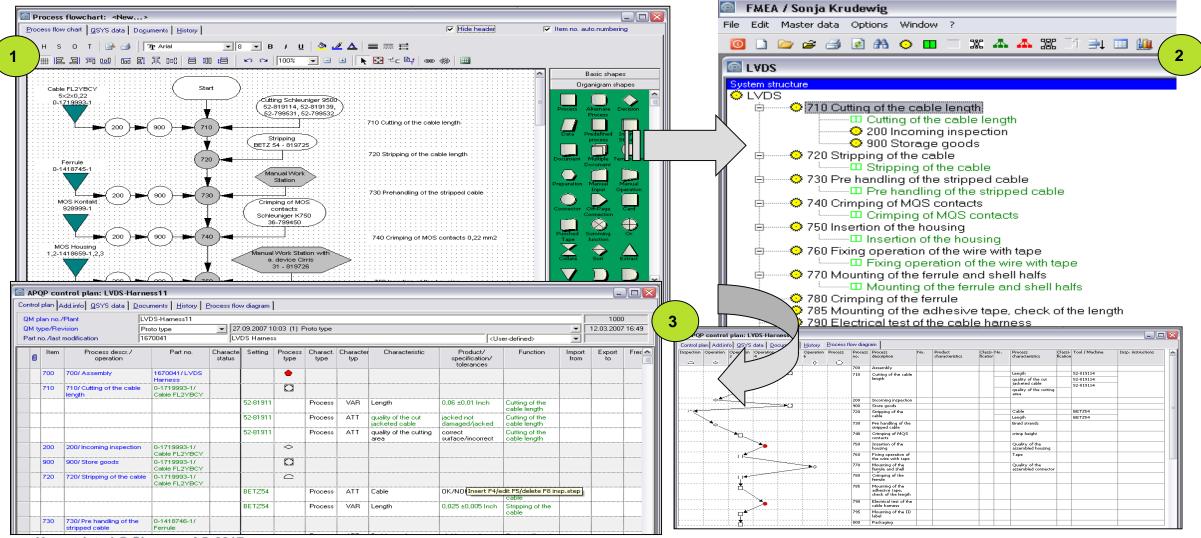
Tree structure approaches to managing FMEAs and Control Plans can leverage the ability to inherit required data from a process FMEA into a Control Plan.

This eliminates redundant data entry and reduces opportunities for errors during the transfer of content.

Data flow from a Design or Process FMEA into a Control Plan can also continue the process further by bringing the data into Inspection Plans.



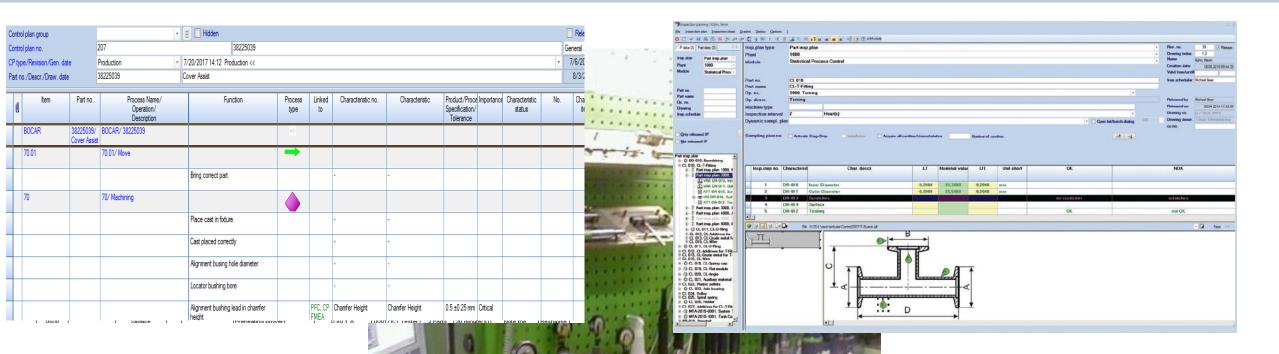
Process Flowchart to FMEA to Control Plan Relationship



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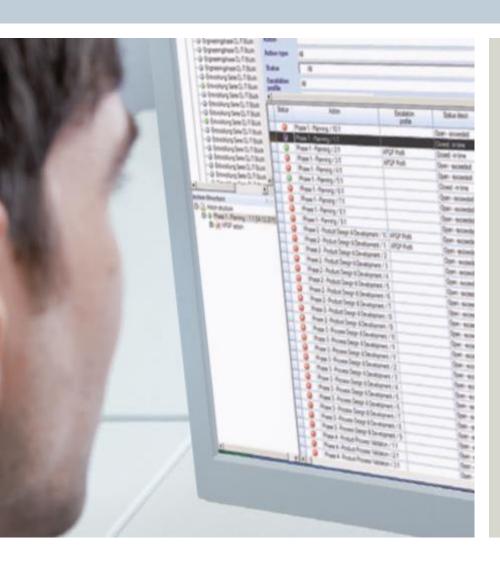


Control Plans to Inspection Plan





Closing the Loop and Change Management

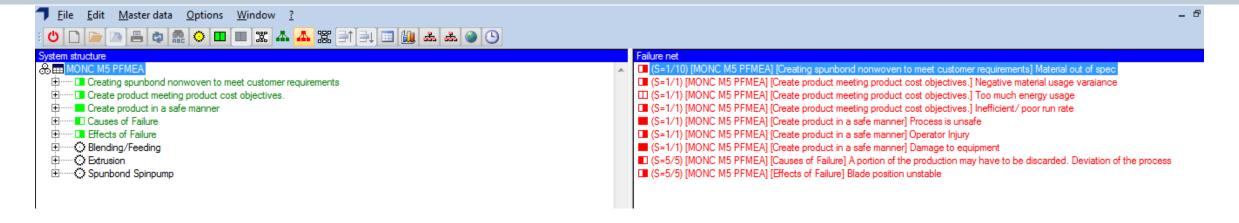


Closed Loop Quality logic expects failures identified during inspection to be communicated back to Engineering closing the loop as lessons learned.

Providing Engineers a fast, reliable means of querying and seeing how failures and defects relate to specific products, and processes permit agile adjustments based on accurate representations of current state of experienced risk



Examples of Failure Feedback from Inspection to FMEAs





Change Management: Faster, Better Communication, and Understanding

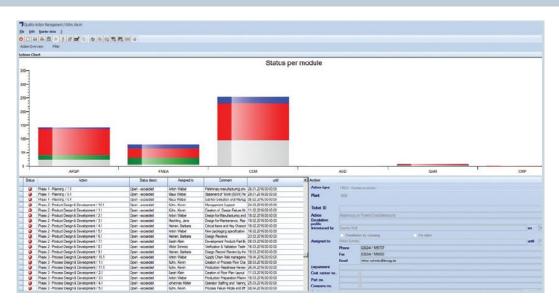


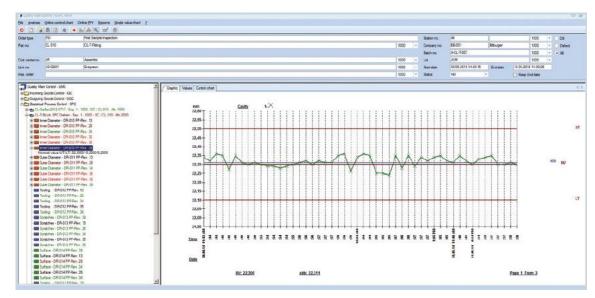
When a Design or Process FMEA is changed:

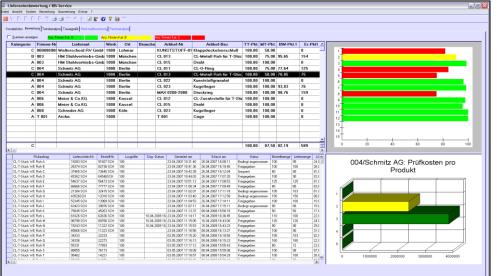
- The entire team is made aware
- The changed FMEA becomes a new revision and the previous one is archived but available for future analysis.
- Data, when properly authorized, can flow into the Control Plan and then into the Inspection Plans.
- These changes are real time and that is crucial in distributed global manufacturing landscapes in place today.



Examples of Communication and Controls









Reporting and Analytics



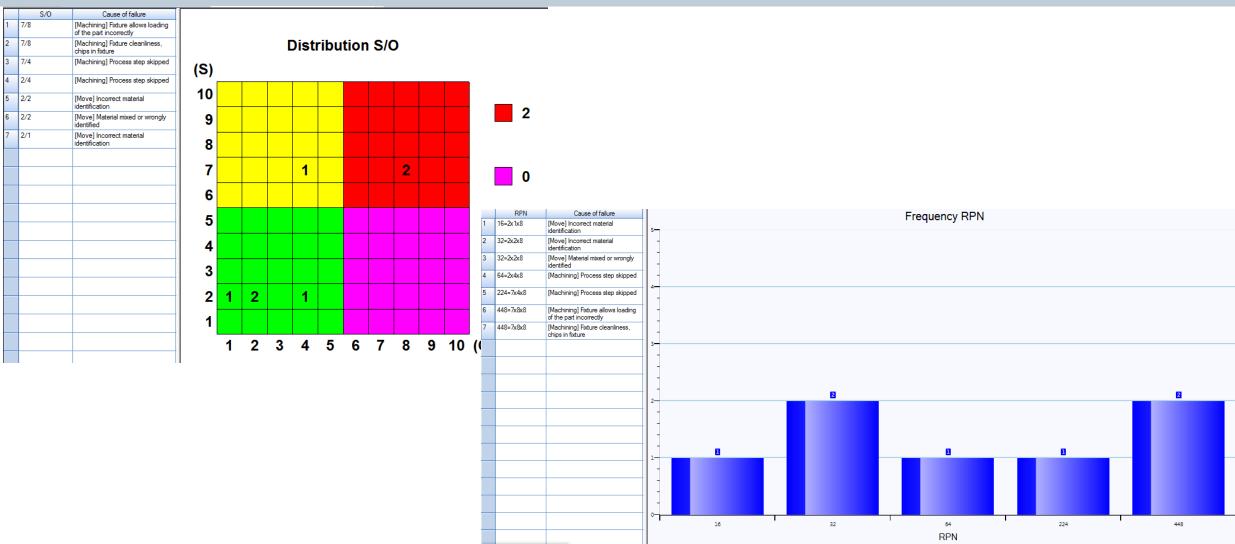
Data is only numbers until it becomes useful information.

Seeing real time tracking of data and information in trending and reports can drive change and confirm validity of risk assumptions and effectiveness of controls.

Sharing Outputs in formats required by customers seamlessly saves time and creates trust and confidence.



Examples of Outputs



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Siemens and End to End Quality



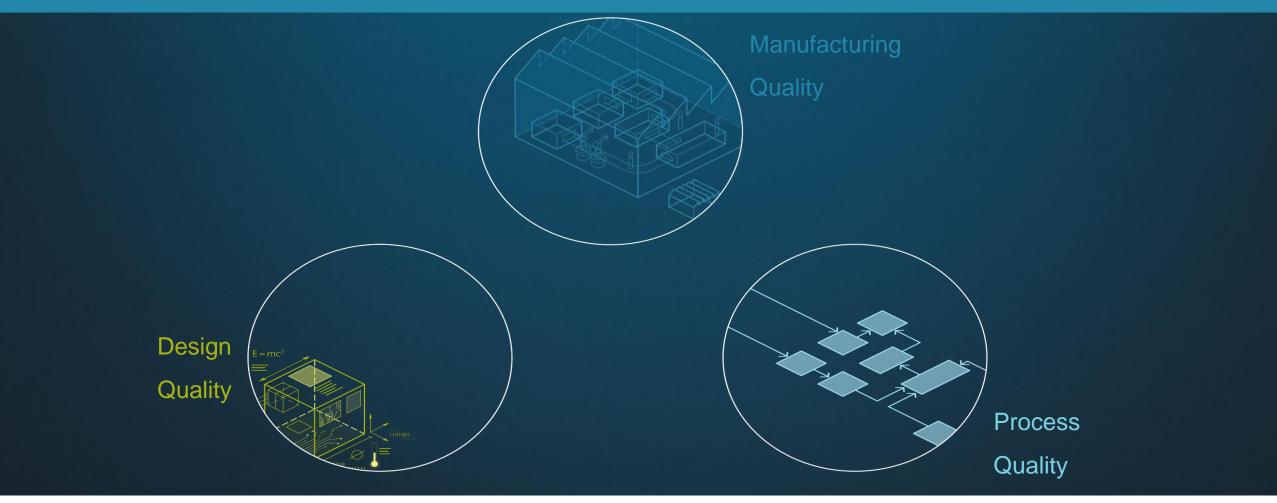
Siemens has invested energy, capital and resources in developing the most comprehensive Design and Quality solutions that scale across both industry sectors and enterprises of all configurations and sizes.

- Product and Application Lifecycle Management for electromechanical and embedded technology designs.
- Design and Process FMEAs and Advanced Product Quality Planning (APQP)
- Inspection, SPC and Supply Chain Management including Production Part Approval (PPAP)
- CAD Design Management

All these systems working together, leveraging the same data sources result in a "single source of truth" with the analytics and reporting to confirm, improve and evolve your business.



Quality Domains connected seamlessly across the Enterprise





Siemens Quality Management Drives



