

# A Corporate-Level Process Flow to Ensure Quality and Reliability



March 26, 2019 | Martin Novak



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Ensuring quality and reliability of new product launches requires strategies that work for the organization's internal resource, external resource dependencies and operational structure used to develop then deploy products. This presentation will look at the key process flows which require collaborative interaction to go from product definition to volume deployment. Key elements of those process will be highlighted which can directly impact a product designed for reliability, resulting in a customer's entangled perception of a product's quality and reliability, starting with delivery of the first prototype (e.g. alpha) units onward.

From this presentation you will gain an understanding of the key related high level corporate foundation process flows, the essential collaborative interacting processes, along with the critical elements to ensure the organization's design for reliability efforts results in customers satisfied with the delivered quality and expected life time reliability performance.



## A Corporate-Level Process Flow to Ensure Quality and Reliability

01

Organizations' operational structure and their internal - external resource dependencies

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02

Corporate level foundation processes that ensure quality and reliability

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Collaboration with the foundation process stakeholders

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Reliability Physics based Reliability Engineering Program Example

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DFM, DFT & Mfg. Readiness issues integration with DFR

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Manufacturing and Repair Services Process Requirements Related to Reliability and key analysis tools

# Types and Size of Organizations



## What Type of Organization?



Function Based



Product / Project Based



Cross-Functional



Center of Excellence

## What Size Organization?



Small



Medium



Large

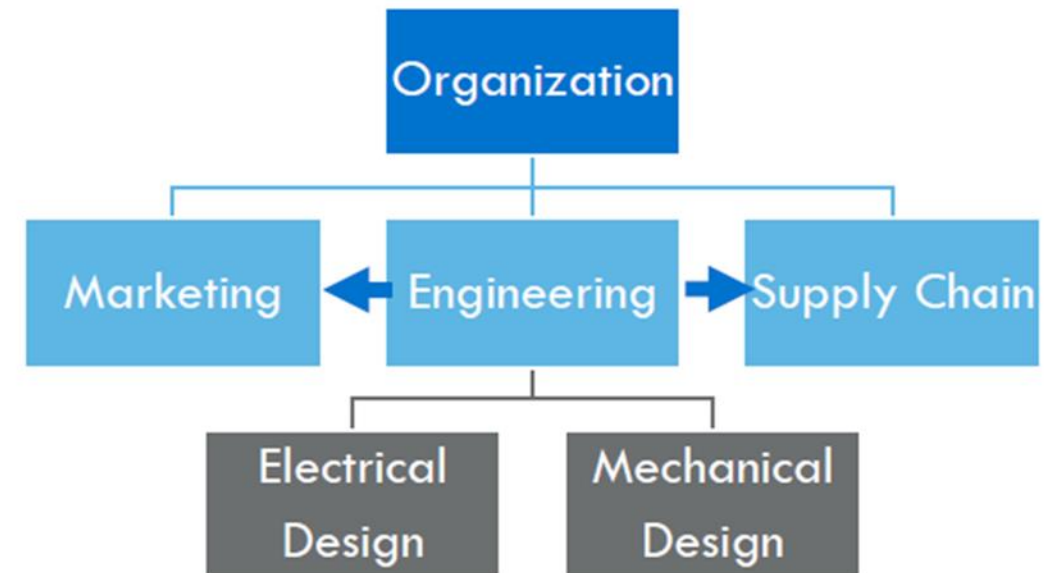
- From “Creating a Reliability Physics-Focused Organization”, Craig Hillman, Jan. 31, 2019

# Small Organizations



## Small / Function Based Organization

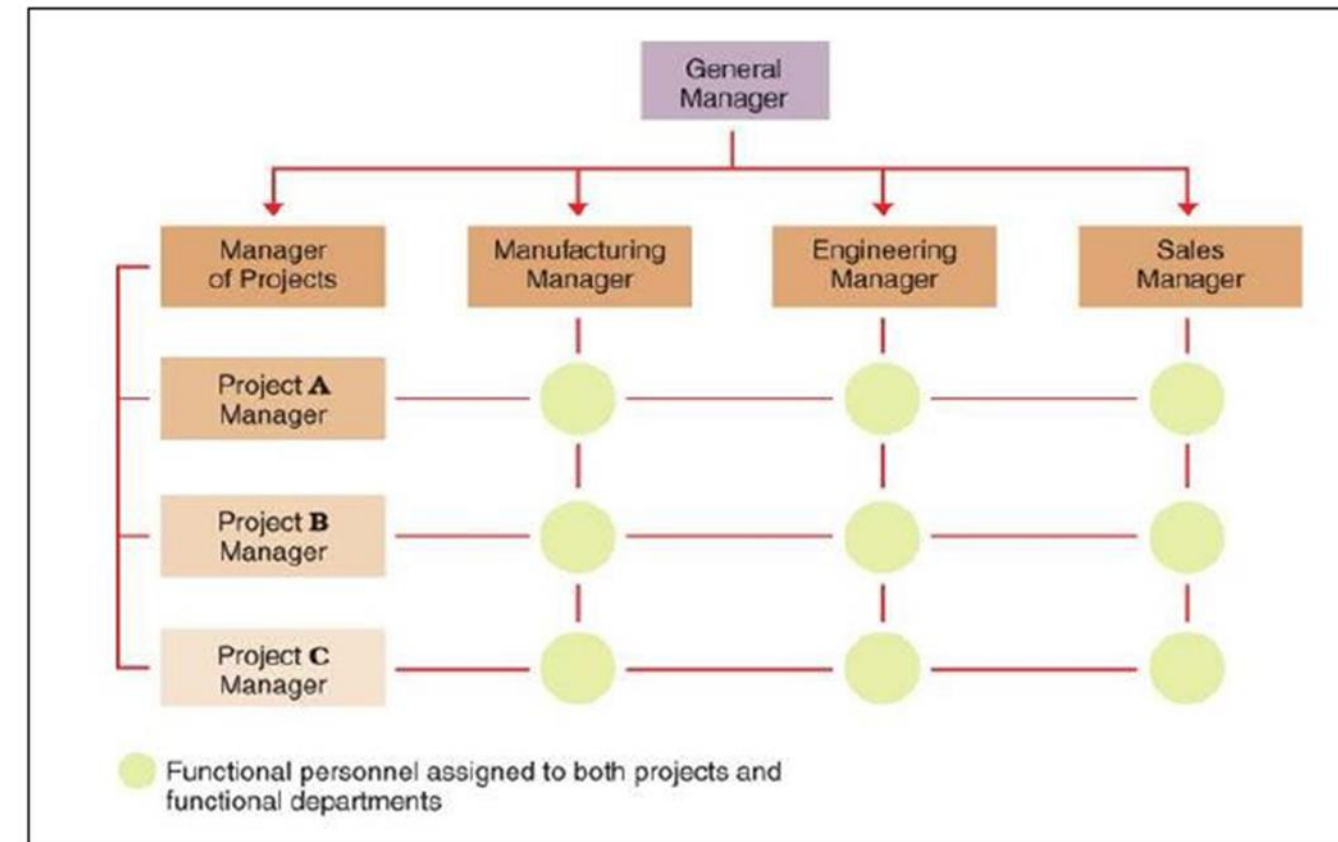
- Start-ups and niche market types
- Tendency towards having people that can cover multiple roles
  - Reliability responsibility could be under engineering or supply chain
    - Person with that responsibility may have a very good or weak background
  - Quality roles & responsibilities (software, customer, business systems, factory, supplier) might be in each function or all under one function
  - Typically involves a combination of internal resources and external outsourcing to cover the work.



# Medium Organizations

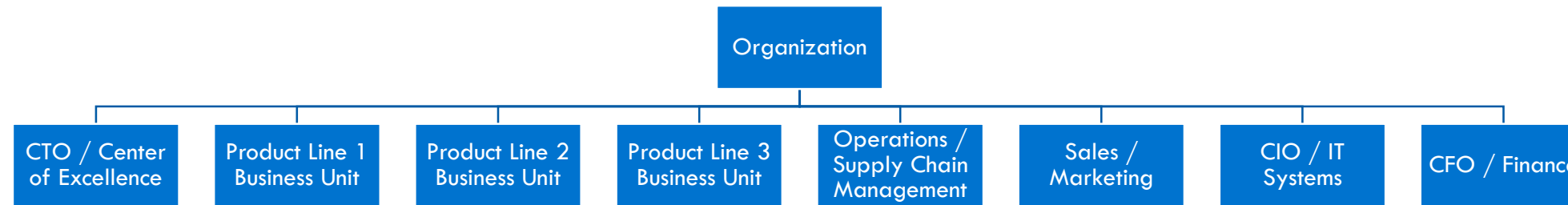
## Medium/Matrix Based Organization

- Post start-up growing business with multiple product lines serving global markets
- Shifts from having people that can cover multiple roles to those people now managing specialists and multi-role team members
- More organization branches and levels form under each executive level
- New projects rely on a support matrix from engineering, supply chain operations/manufacturing, sales/marketing
  - Reliability responsibility could be under engineering or quality
  - Quality roles & responsibilities tend to become more focused
    - Software QA usually found under engineering
    - Customer, business systems, factory, and supplier quality might be all under an independent quality function or still divided under two or three branches
- Still likely to involve a combination of internal resources and external outsourcing to cover the work.
- Product Line and Project Management functions required to coordinate using the matrix based resources





# Large Multi-Business Unit Based Organization



- Combination of organic and acquisitions based business units with multiple product lines within each business serving global markets
- Shifts to each business unit having people now managing more specialists and fewer multi-role team member exists (but are likely now in management roles)
- Each BU has its own engineering, product line management, marketing, project management, manufacturing technical operations
- Supply chain including material procurement, sales ops/fulfillment, contract manufacturer management, and supplier management could still be matrix based supporting the Business Units
  - Quality roles & responsibilities tend to become more focused
    - › Software QA usually found under each BU's engineering
    - › Customer, business systems, factory, and supplier quality might be all under an independent quality function or still divided between each BU, Sales, and Operations/Supply Chain
  - Reliability responsibility could be under each BU's engineering or under the Center of Excellence supporting all the BU's
- Still likely to involve a combination of internal resources and external outsourcing to cover the work.
- Product Line and Project Management functions required to coordinate using the matrix based resources both within their BU and other non-BU organizations

- “The Five Pillars of Organizational Excellence”, by H. James Harington
- Organizational excellence is achieved by focusing on managing the five key pillars. Each of these five organizational pillars is not new by itself. The key to organizational excellence is combining and managing them together.

- The five pillars are:

1. Process management
2. Project management
3. Change management
4. Knowledge management
5. Resource management



The Five Pillars of Organizational Excellence, by H. James Harington  
[https://www.qualitydigest.com/aug06/articles/05\\_article.shtml](https://www.qualitydigest.com/aug06/articles/05_article.shtml)



# Internal - External Resource Dependencies



- Small to large organizations depend on business operations systems, processes, and a product development project management to develop & deploy quality new products meeting customer reliability needs
- A successful value add reliability program must collaborate with those key foundation systems & process owners, input and output stakeholders
- The following can serve as a guide. You just need to find the equivalent “who” in your organization to development partnerships

# Collaboration with the Foundation Process Stakeholders from Product Definition to Volume Deployment

Who	What	Why
Marketing / Sales	Customer requirements for product	Targeted locations and application environment Reliability requirements and expectations
Engineering Project Lead	Development planning, inputs to actions, changes	DFR plan tied to build releases; improvement actions; key partner to align DFR program assessments early in the product lifecycle definition and development phases
Software Engineering and Software QA	Error handling, diagnostics, SW update process, critical to reliability parameter/event monitoring and logging. Test cases used to verify design. Chipset and third party software management	Capability to diagnose and avoid loss or degradation of function. Ability to monitor degradation rate and event drive failures. Test case vs. real life case conditions What is critical to reliability and change control
Component Engineering	Part selection, alternative suppliers, supplier PCNs, supplier reliability data, technology / spec weaknesses	Selection fitness for the application and life requirement Alternatives have specification and fabrication differences Knows supplier's contacts for reliability info details Resource for knowing and finding reliability weaknesses
Configuration Management	Product & Process configuration and change control	Ties assessments to version and improvements to revisions Makes requested changes visible that could impact reliability

# Collaboration with the Foundation Process Stakeholders from Product Definition to Volume Deployment

Who	What	Why
Finance	Warranty, liquidated damage claims cost management and product development costs	Warranty allocation cost per unit shipped, estimate total reliability cost risk and DFR savings opportunity
Supply Chain / Operations	Production Forecasts / Actuals BOM and Manufacturing Value Add costs Factory Readiness Management	Ship dates and Qty by customer Basis for determining warranty costs and improvement savings Reliability impacted by unreliable processes
Supplier Quality Mgmt.	Verify control of critical to reliability items	DFR assessments and improvements depend on it
Factory Quality Mgmt.	Verify control of critical to reliability items and defect/repair failure details reporting system	DFR assessments and improvements depend on it
Field and Repair Services	Repair costs and process readiness  Monitoring, call center/field tech service requests and defect/repair failure details reporting system	Basis for determining warranty costs and improvement savings Reliability impacted by unreliable screen & repair processes  Early warning to rapid containment capability. Infor required to measure DFR effectiveness and improvement feedback
Quality	Quality Management System Customer Quality Management Corrective Action Preventive Action system	Leverage this system so DFR program is key to risk mgmt. Access to what the customer perceives as issues Rapid Containment with effective corrective actions and feedback needed to improve the DFR program

# ASQ/ANSI/ISO 9001:2015 Elements Key to a Successful Reliability Program

2019  
DESIGN FOR RELIABILITY  
CONFERENCE

## Quality Management System

### 8 Operation

- 8.1 Operational planning and control
- 8.2 Requirements for products and services
  - 8.2.1 Customer communication
  - 8.2.2 Determining the requirements for products and services
  - 8.2.3 Review of the requirements for products and services
  - 8.2.4 Changes to requirements for products and services
- 8.3 Design and development of products and services
  - 8.3.1 General
  - 8.3.2 Design and development planning
  - 8.3.3 Design and development inputs
  - 8.3.4 Design and development controls
  - 8.3.5 Design and development outputs
  - 8.3.6 Design and development changes
- 8.4 Control of externally provided processes, products and services
  - 8.4.1 General
  - 8.4.2 Type and extent of control
  - 8.4.3 Information for external providers

### 8.5 Production and service provision

- 8.5.1 Control of production and service provision
- 8.5.2 Identification and traceability
- 8.5.3 Property belonging to customers or external providers
- 8.5.4 Preservation
- 8.5.5 Post-delivery activities
- 8.5.6 Control of changes

### 8.6 Release of products and services

### 8.7 Control of nonconforming outputs

### 9 Performance evaluation

- 9.1 Monitoring, measurement, analysis and evaluation
  - 9.1.1 General
  - 9.1.2 Customer satisfaction
  - 9.1.3 Analysis and evaluation
- 9.2 Internal audit
- 9.3 Management review
  - 9.3.1 General
  - 9.3.2 Management review inputs
  - 9.3.3 Management review outputs

### 10 Improvement

- 10.1 General
- 10.2 Nonconformity and corrective action
- 10.3 Continual improvement



This International Standard employs the process approach, which incorporates the Plan-Do-Check-Act (PDCA) cycle and **risk-based thinking**.

The process approach enables an organization to plan its processes and their interactions.

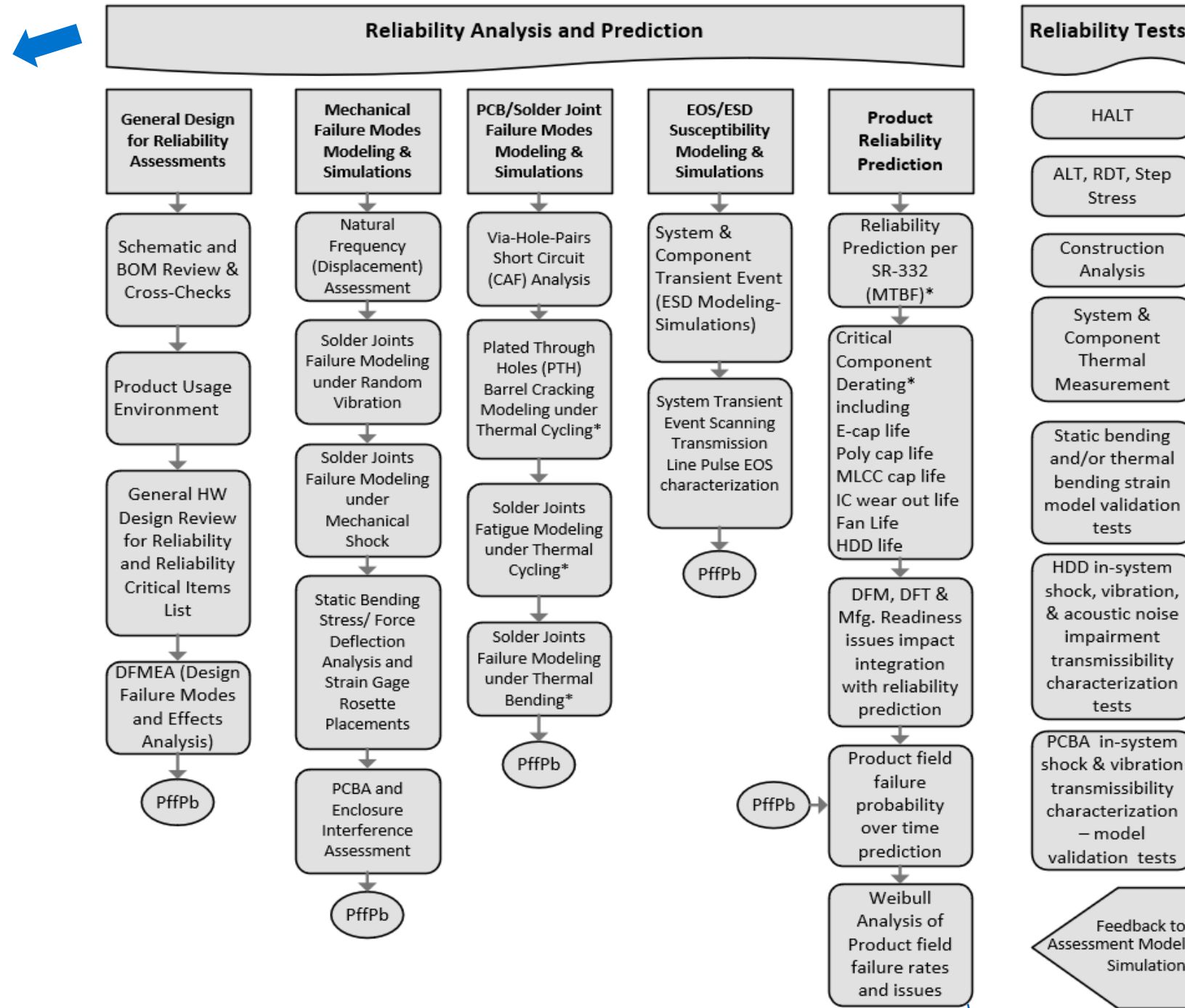
The PDCA cycle enables an organization to ensure that its processes are adequately resourced and managed, and that opportunities for improvement are determined and acted on.

Risk-based thinking enables an organization to determine the factors that could cause its processes and its quality management system to deviate from the planned results, to put in place preventive controls to minimize negative effects and to make maximum use of opportunities as they arise (see Clause A.4).

# Reliability Engineering Program Example

Analysis capability and tools to provide more accurate predictions of new product reliability

- Plans start at the Definition stage of development
- Assessments start with 1<sup>st</sup> engineering drawings and BOM release
- Results from each group of assessments are aggregated to provide a more accurate reliability over time prediction at start of production
- Post launch analysis of field failures rates compared to initial prediction via Weibull analysis method



Reliability Tests → Accelerated Life, Design Margin, Step-stress, Test-to-failure, along with traditional reliability demonstration testing methods when needed.

- Tailored to include measurements required to validate modeling-simulation used in the reliability analysis tools
- When differences are found, the model-simulation used in the analysis tool is adjusted to improve our prediction correlation
- When field results differ from predicted use that analysis to improve the DFR program



# DFM, DFT & Mfg. Readiness issues integration with DFR

## Design for Manufacturability (DFM) Issue Impact

- Filter out the potential DFM issue/ Quality issue that will affect product reliability in a time domain reviewing
- **Open issues**, test coverage, soldering process qualification, i.e., issues that will cause factory escapes of weaker than modeled / predicted assemblies, e.g.,
- **Soldering process behavior & capability analysis (Pp, Ppk, Cp, & Cpk index value differences issues)**
- **Soldering reflow and wave process DoE optimized for a PWI <80%**
- **Strain Gauge Analysis results**
- **C3 or Ion Chromatography results**
- **PFMEA-PQP documents**

## Test Coverage (DFT) Issue Impact

- Analyze the DFT related reports for issues with component test coverage for each test step.
- Filter out the potential DFT issue/ Quality issue that will affect product reliability in a time domain reviewing
- **Open issues**
- **Test coverage limitations**
- **GR&R issues that will cause factory escapes and NTF issues**
- **Process Behavior**
  - **Capability Analysis (Pp, Ppk, Cp, & Cpk index value differences issues)**

## DF Serviceability & Repair Issue Impact

- Analyze component test coverage for each test step. Filter out the potential DFservice issue/ Quality issue that will affect product reliability in a time domain reviewing
- **Open issues**
- **Test coverage limitations**
- **Soldering process qualification for all touch up, removal and replacement steps**
- **GR&R issues that will cause factory escapes and NTF issues**
- **Process Behavior & Capability Analysis (Pp, Ppk, Cp, & Cpk index value differences issues)**
- **Correlation to Factory Acceptance Tests**
- **Strain Gauge Analysis of disassembly, test, repair and reassembly steps**
- **C3 or Ion Chromatography checks**
- **PFMEA-PQP**



## Incoming to staging

- IQC controls check critical parameters on mechanical parts for each assembly lot/batch code
- IQC checks for packaging and labeling compliance to specs for all other components
- PCB warp complies to supplier spec following soldering process
- Programmable device component level programming stations are controlled to supplier and product specs.
- MSL controls comply to supplier's spec; including for controls for partially used trays or reels.
- Traceability for all parts by unit/board level serial numbers
- PCB is serialized prior to solder screen print
- Regulatory and safety critical components traceability / documentation complies to requirements

## Solder screen print to auto placement

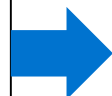
- **Screen printer achieves 80% minimum solder fill for a solder pad based on a stencil aperture with greater than 0.66 for the area ratio and greater than 1.5 for the aspect ratio.**
- Auto and manual cleaning cycles for stencil controlled. Manual cleaning method and material used comply with solder paste suppliers requirements.
  - Controls in-place for determining stencil life / preventive replacement cycles
  - Solder paste inspection controls applied to reliability life risk and/or DFM issue locations
  - Cleaning of defective PCB screen print solder complies to method from solder paste supplier
- Auto-insertion process has controls to prevent loading wrong part on reel or trays; including electrical verification of passive component value on reels.
- Controls to prevent using machine or measurement equipment with less accuracy than what was used to qualify the manufacturing line for GA production.

## Reflow and wave solder

- Reflow, wave and manual solder profiles meet requirements to form compliant solder joints
- Solder paste shelf life and dispensing temperature controls comply to supplier specs
- **Solder profiles comply to all component supplier's spec**
- **IPC610 compliant**
- **Solder joint IMC layer  $\geq 1\mu\text{m}$  avg thickness  $\leq 5\mu\text{m}$**
- **QFN devices have 2.5 to 3 mils thick solder bond line e.g., a 4 mil stencil with a step up to 6 mils should deliver a volume of solder paste that will turn into a reflowed thickness of 2.5 to 3 mils thick. (Rule of Thumb is that you divide the stencil thickness by 2 to get the resultant reflowed solder joint thickness) This presumes the print speed is correct and the paste is properly pressed through the apertures.**
- **BGA/LGA voids  $< 15\%$  on outer ball and  $< 20\%$  inner ball. Void must not be near upper and lower side of ball or change ball shape or within 20% of edge if in IMC layer**
- **Process Window Index  $< 80\%$  for SMT and Wave soldering processes optimized using designed experiments method**
- **Flux amount & solder/pot, application method/controls, and solder temp profile for wave solder complies to flux and solder supplier's specifications**

## • Assembly

- Press fit connector applied force controlled to supplier spec and monitored for compliance
- Manual, Auto & Robotic torque drivers controlled to comply with the product assembly step specs.
- Adhesives, thermal compounds, thermal pad installation comply to specifications
- Bending/flex strain applied to solder joint by a handling event, assembly or test step, or a cyclic stress will be less than the limits defined by finite element analysis
- General workmanship complies to IPC610 standards
- Programmed equipment parameters and limits have restricted access controls



## • ESD, EOS and Cleanliness

- ESD controls comply to level needed based on most sensitive device spec limits for CDM levels
- EOS prevention & controls
- Cleanroom particle controls levels comply to specification on all workstations with exposed susceptible to particle contamination components
- Temperature, humidity and volatile gases controls in factory / stations comply to requirements
- Halides and/or WOAs level or C3-conductivity level comply to spec at PCBA level Ion Chromatography test or at specific component location for C3-conductivity test (e.g. QFN or devices susceptible to trapping active flux residue)
- Optical connectors comply to cleanliness specs after final test

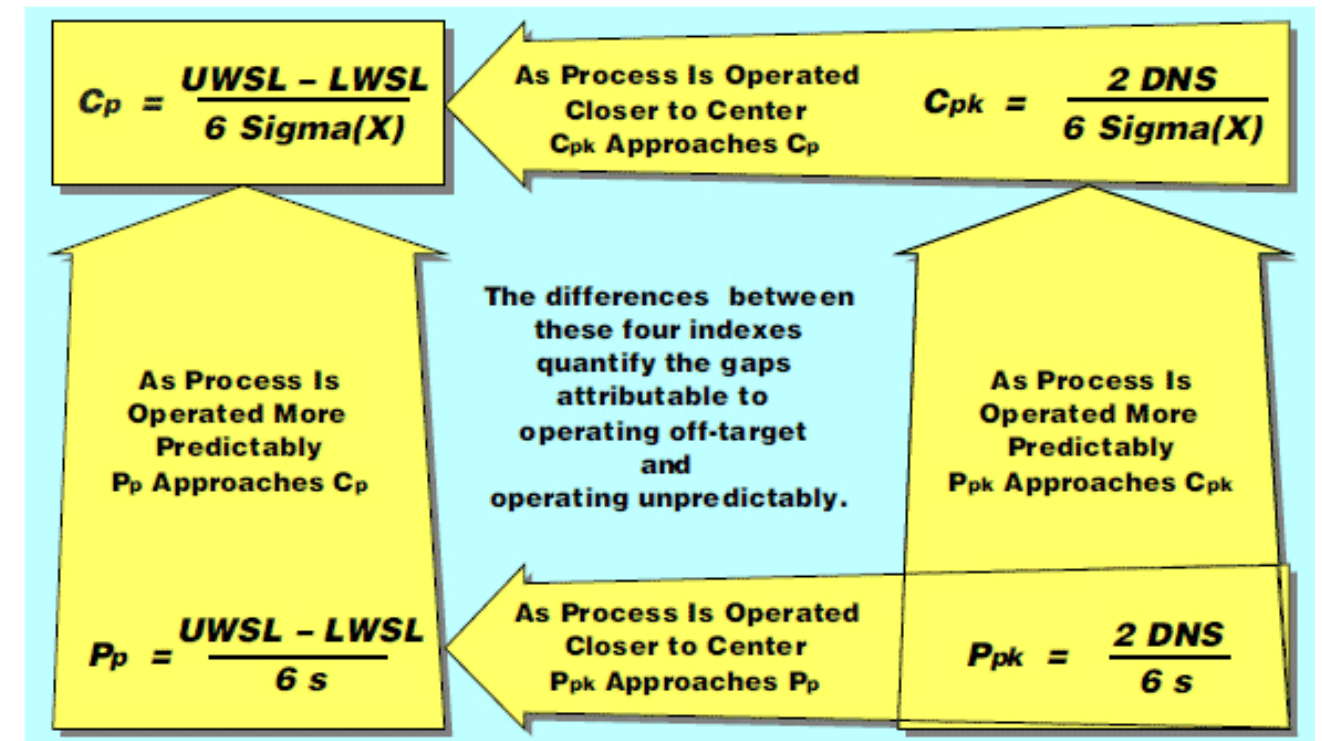


## Testing, Routing Control and Maintenance

- Shop floor controls prevent retest only based passing decision and sets alarm for stations with 3 failures of same type in a row or (n) failures within 1-4 hour window or for process with I-MR or XbarR monitoring failing any of the 1<sup>st</sup> four out-of-control rules
- Shop floor routing controls prevent failed items from progressing without debug/ repair check-in and repair pass/check-out validation
- Measured parameter passing units have >2 probable errors of measurement margin to customer's spec limit
  - If product requires a burn-in or thermal cycle stress in manufacturing the time or cycles provide >95% confidence for time, cycle or stress needed
- Maintenance and cleaning controls comply to equipment supplier requirements or tighter based on factory maintainability program specs. Applies to all equipment, work surfaces, hand tools, fixtures, lighting, ionizers, filters, nozzles, power sources, etc.
- MSD procedures operating in accordance with manufacturers specifications

## Relationship between the four indexes $P_p$ , $P_{pk}$ , $C_p$ , & $C_{pk}$

- The capability ratio uses the difference between the watershed specifications to define the space available and compares this with the generic space required by any process that is operated with minimum variance.
- When a process is operated predictably and on target, the four indexes will be four estimates of the same thing.
  - This will result in the four indexes being close to each other. (Since the indexes are all statistics, they will rarely be exactly the same.)
- As a process is operated unpredictably, the two performance indexes will become smaller than the two capability indexes. The interpretation of what each index represents will depend upon the behavior of the underlying process
- By comparing the four capability and performance indexes you can quickly and easily get some idea about how a process is being operated and whether or not it is likely to possess a sufficient capability to guarantee conforming product.
- ***But the only way to guarantee conforming product requires the active use of process behavior charts to achieve and maintain a predictable and on-target process..***



Reference: "The Keys to Quality Assurance", Quality Digest, 03/04/2019, by Dr. Donald Wheeler, Fellow of both the American Statistical Association and the American Society for Quality, and is the recipient of the 2010 Deming Medal. As the author of 25 books and hundreds of articles, he is one of the leading authorities on statistical process control and applied data analysis  
<https://www.qualitydigest.com/inside/standards-column/keys-quality-assurance-030419.html>

# Process Behavior Analysis



## Process Behavior

- The first rule is to make sure the process is stable (in-control over a period of time or batches or lots or shifts, etc.,)
- To verify the first rule we use Process Behavior Charts (XbarR, XbarS, or ImR) to see if the process is stable.
- Six factors generally regarded as causing variation in process parameter measurements
  - Machine (e.g. degree of wear and choice of tooling);
  - Measurement (e.g. resolution and spread of measuring instrument);
  - Operator (e.g. how experienced and careful he/she is);
  - Material (e.g. variations in surface smoothness and hardness);
  - Environment (e.g. variations in temperature, humidity and voltage);
  - Method (e.g. type of machining operation).

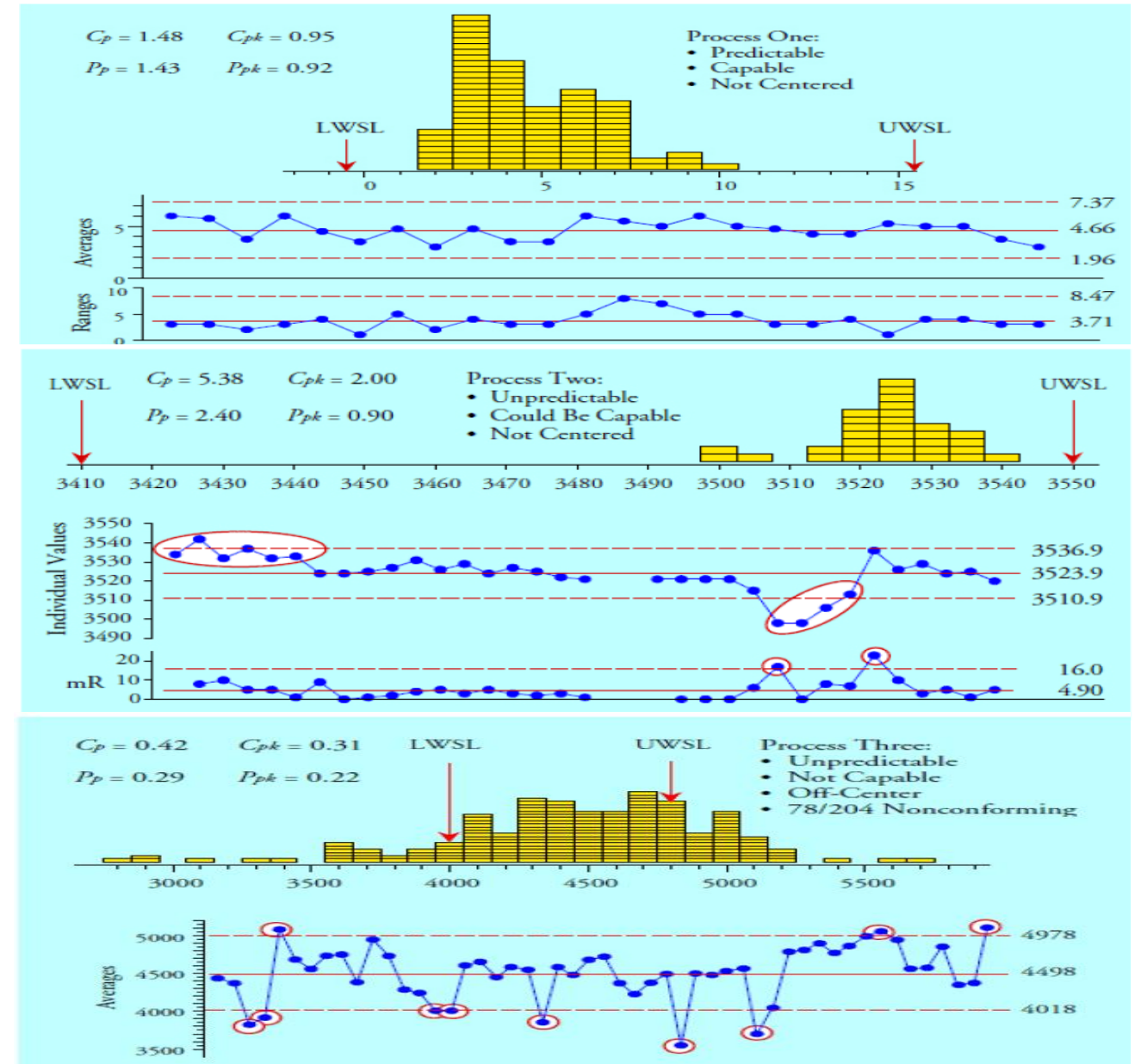
“Any analysis of observational data that does not begin with a process behavior chart is fundamentally flawed.”

Dr. Donald Wheeler

Walter Shewhart (inventor of the process behavior charts) wrote in 1943,

“Classical statistics start with the assumption that a statistical universe exists, whereas [SPC] starts with the assumption that a statistical universe does not exist.” and also, “... measurements of phenomena in both social and natural science for the most part obey neither deterministic nor statistical laws until assignable causes of variability have been found and removed.”

## Process Behavior vs. Capability Examples





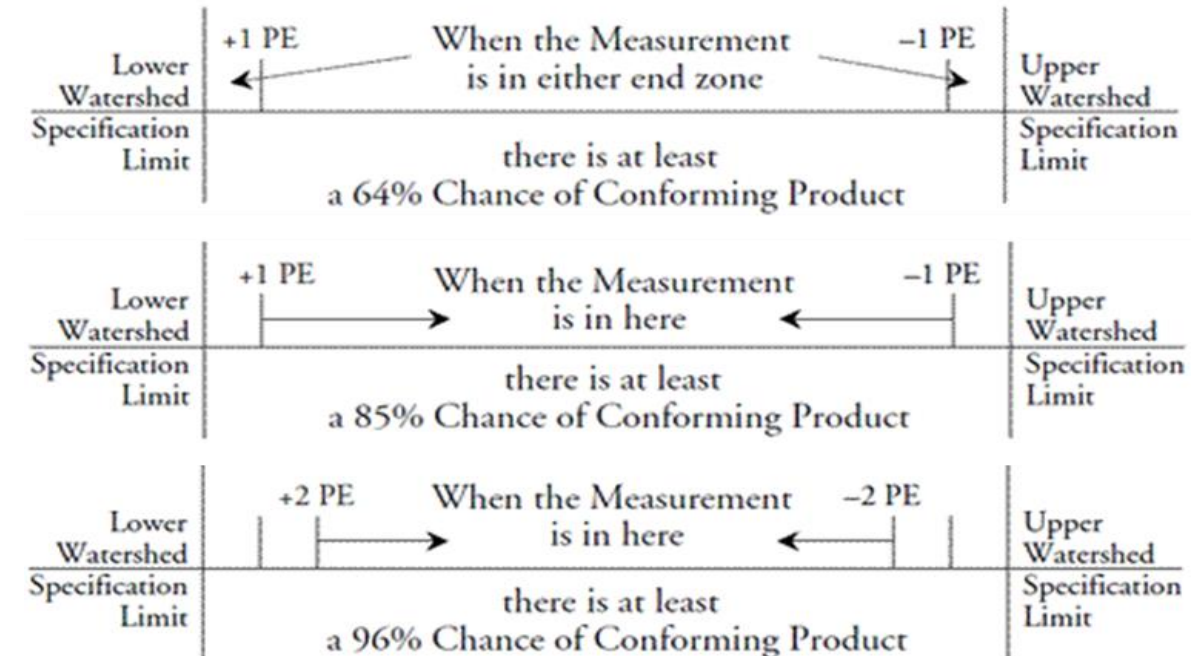
# GR&R Impact on Reliability

- Probable Error is one of the most useful values determined from an **ANOVA based GR&R** study and is derived from the Total Gage R&R StdDev (test-retest standard deviation estimated from the data) = 0.63
- If a unit passed the test with a value of “n.nn”, the next time it is measured the probabilities of the measurement being different are best determined and explained using the Probable Error value:
- In 1818 Wilhelm Bessel came up with the “probable error” value, which is simply 0.675 times the standard deviation of test-retest error.
- It defines the median amount by which a measurement will err: Half the time measurements of a known standard will differ from the accepted value by more than one probable error, and half the time these measurements will differ from the accepted value by less than one probable error (PE).
- The probable error defines the effective resolution of the measurement, so there is no value in attempting the measured value differences more precisely than plus or minus 1 probable error
- When you have a test with units taking a yield hit at one or both parametric based limits, this tool is key to determining the potential reliability impact for both escapes to the field and false rejects requiring unnecessary rework

Gage R&R

Source	VarComp	%Contribution (of VarComp)
Total Gage R&R	0.40269	12.13
Repeatability	0.29432	8.87
Reproducibility	0.10838	3.27
Operator	0.10838	3.27
Part-To-Part	2.91625	87.87
Total Variation	3.31894	100.00

Source	StdDev (SD)	Study Var (6 × SD)
Total Gage R&R	0.63458	3.8075
Repeatability	0.54251	3.2551
Reproducibility	0.32921	1.9753
Operator	0.32921	1.9753
Part-To-Part	1.70770	10.2462



References: Dr. Donald Wheeler, Quality Digest,  
<https://www.qualitydigest.com/inside/twitter-ed/problems-gauge-rr-studies.html>  
<https://www.qualitydigest.com/inside/twitter-ed/part-spec.html>  
<https://www.qualitydigest.com/inside/twitter-ed/where-do-manufacturing-specifications-come.html>



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# Speaker Bio



**Martin Novak**

Sr. Director of Reliability Engineering at ARRIS International plc with 35+ years' experience implementing quality systems and reliability programs for a variety of electronics based companies. Implementing or tailoring product lifecycle management processes to ensure quality and reliability improvements get into new products starting from their concept through volume production. Low and high volume businesses covering industrial and computer numerical controls systems; aerospace communication systems; hard disk drives and network attached storage systems; electronics manufacturing services advanced development; test engineering; repair services; cable and telecommunications central office headend, outdoor plant access transport, and customer premise wired and wireless product development and manufacturing. Identified, evaluated, qualified and implemented successful systems that drove product quality, reliability, time to market, reduced total costs, cemented strong customer relationships and resulting in "Best in Class" quality rankings by our customers.

## Contact



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