



**Product Dev Quality & Project
Management Strategies**

• November 2025

“How things start is how they’ll go...”

- Joseph Tartal, Postmarket and Consumer Branch, U.S.
Food and Drug Administration, 9/30/2025

Small Changes with Big Impacts

- Project Charter
- Project Risk Assessment
- Project Budget
- Market Research Tools
- Affinity Diagram
- Quality Tools
- Project Management Tools

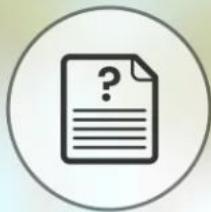


Discussion Question:

- **Think of a time a project felt disorganized.** How could a simple Project Charter or other tools helped bring clarity?

Project Charter

A Project Charter is a living document for an improvement team that outlines the presenting problem, the target and the boundaries of a process improvement effort.



PROBLEM STATEMENT

The problem captured in the form of a measurement



BUSINESS CASE

The business reasons for doing the project



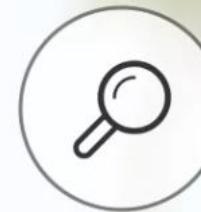
GOAL STATEMENT

The target of the process measurement



TIMELINE

When each project phase will be completed



SCOPE

What's in and what's out of the project



TEAM MEMBERS

The people who will participate in the project

Project Charter

Key Stakeholders	
Name	Title
Tom Trump	Senior Manager (PMO)
Mathew Watson	Project Manger
Allen Parker	Client
Dayna Plummer	Planning Engineer
Varghese Lincoln	Risk Analyst
Key Milestone Schedule	
Description	Due Date
Project Kick-Off	Jan 1, 2021
Planning Completion	Feb 1, 2021
Phase -I Completion	March 1, 2021
Phase -II Completion	April 7, 2021
Complete Project	May 1, 2021
Product Handover	May 7, 2021
The Project Budget	<ul style="list-style-type: none">The project budget is 1,000,000.00 USDContingency Reserve: 50,000 USDManagement Reserve: 50,000 USD
Assumptions	Constraints
<ul style="list-style-type: none">All permits will be provided on time.Political condition will be stable.No adverse climate condition.	<ul style="list-style-type: none">Fix project completion date.Phase-II completion cannot be delayed.Cannot work after 5:00 PM.
Project Risks	<ul style="list-style-type: none">Hot weather condition can stop the work.Final acceptance may delay as it requires a third party inspection and approval.

Project Risk Assessment

Included in Project Risk Assessment:

- Whether or not we will conduct thorough Quality Project Plan (including: FMEA, URRA, and other risk assessments) focused on the product/device.
- Issues that could derail the project
 - What can go wrong with budget and timelines

Risk Category / Event	Probability Criteria	Prob. Score	Impact Criteria	Impact Score	PI Score
Scope	<p>The scope of the project might change.</p> <ul style="list-style-type: none"> • Product scope well defined, only minor changes expected (Low) • Product scope somewhat defined, but at a high level, a few changes to product scope expected (Med) • Product scope very vague, large changes in product scope expected (High) 	3	<p>Minor changes added via change control (Low)</p> <p>Moderate changes added with some difficulty (Med)</p> <p>Major changes added with severe impact to other requirements (High)</p>	2	6
	<p>Other projects may be added that will be dependent on this project's scope and work product.</p> <ul style="list-style-type: none"> • There will be no overlap in scope definition with other possible projects (Low) • There may be an overlap in scope with other projects (Med) • There will be an overlap in scope with other projects which (High) 	1	<p>Other possible projects will not affect this project's scope. (Low)</p> <p>May require some cross-project coordination (Med)</p> <p>May require detailed cross-project coordination (High)</p>	1	1
Team	<p>Team members may leave the project.</p> <p>Current staff attrition is:</p> <ul style="list-style-type: none"> • Less than 20% (Low) • 20-40% (Med) • Over 40% (High) 	1	<p>Team is cross-trained and ready for attrition (Low)</p> <p>Key team members can be replaced with appropriate lead time (Med)</p> <p>Some key team members have unique skill sets that cannot be performed by anyone else (High)</p>	2	2
Total Project Risk					3

Project Budget

Included in Budget:

- Estimated cost of all applicable requirements
 - Plastic Molds
 - CNC work
 - Testing
 - Licensing
 - Patents
 - Regulatory Requirements
 - PDAC/HCPCs
 - Staff Hours dedicated to the project (hours not days)
 - Sample costs, including shipping
 - First order cost

Other considerations are project budget risk assessment, lower and upper range for project delivery. Rough estimates okay to create benchmarks for future projects.

Project Budget

How to Budget

- Estimate lower and upper range/tolerance for each cost on the left
- Use these methods to estimate:
 - Expert Judgment - common sense
 - Analogous Estimation - prior costs of similar projects as indicators of future costs
 - Parametric estimation - used when costs are set, e.g., BOMs when material cost and amount of material needed is known, hours dedicated to the project are known because developers have set pay/salary or hourly rates
 - Three-point estimation - factor in the other three methods and follow a formula
 - $\text{Estimate} = (\text{Optimistic} + \text{Likely} + \text{Pessimistic}) / 3$
 - Or
 - $\text{Estimate} = (\text{Optimistic} + (4 \times \text{Likely}) + \text{Pessimistic}) / 6$
 - This forces you to consider the lower, most likely, and worst case scenarios and offers a framework to derive reasonable quantifiable estimates.
- Factor in time as a cost
 - Estimate time to complete project in hours, because the team is working on more than one project at a time. Days to complete is abstract when it is dependent on workload of other projects that vary in complexity and duration. Hours per project assigns specific estimates and later accurate estimates to each project, then with basic calculations we can estimate time to complete each project in days/months with greater accuracy.

Voice Of the Customer (VoC)

Vive Gait Belt (300lbs) Transfer Belt with Handles - Medical Nursing Safety Patient Assist - Bariatric, Elderly, Handicap, Physical Therapy - PT Gate Strap Quick Release Metal Buckle, Grabbing Teeth



ASIN
B01PYNQT4

FNSKU
B01PYNQT4

SKU
RHB1011N-UPC

[See on Amazon.com](#)

Return Badge Displayed
At risk ▲
[Learn more](#)

Short term return rate
10.7% ▲
For the last three months

Long term return rate
10.54%
For the last twelve months

Suggested short term return rate
< 6.76%
To avoid frequently returned badge

Top Reported Customer Issue ②

Performance or quality not adequate	64.3%	110 complaints
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Top complaint drivers:		Count of drivers	Rate of drivers
1.	Fit Issue	40	35.4%
2.	Unspecific Quality Issue	24	21.2%
3.	Poor Product Performance	17	15%
4.	Hard to use	8	7.1%
5.	Safety Concerns	7	6.2%
6.	Build Quality Issue	5	4.4%
7.	Misleading Product Information	4	3.5%
8.	Random Wrong item	2	1.8%
9.	Missing Issue	1	0.9%
10.	Related Wrong Item	1	0.9%
11.	Material Issue	1	0.9%
12.	Product Packaging Issue	1	0.9%
13.	Authenticity Concern	1	0.9%
14.	Opened Condition	1	0.9%

Other sources ②

Order ID: 113-1514689-4942632
Belt delivered had a metal buckle instead of plastic buckle
Order ID: 114-5503020-0949817
Product is not helping
Order ID: 111-3670305-6558617
Item delivered was used
Order ID: 111-0500193-6087461
Not the right fit for what I need.
Order ID: 112-3842993-8278655
Nothing happened with the item

Returns

Order ID: 114-6006576-1813857	Return authorized date: 9/26/2025
transfer belt that doesn't work for what we need; plz refund. thanks	
Order ID: 112-5072952-6105857	Return authorized date: 9/27/2025
Two large, could not use.	
Order ID: 112-4781751-9025860	Return authorized date: 9/27/2025
Doesn't work right to hard to use	
Order ID: 113-3425085-1781007	Return authorized date: 9/27/2025
Does not fit comfortably	
Order ID: 111-3950224-0861802	Return authorized date: 9/26/2025
It did not work for us	



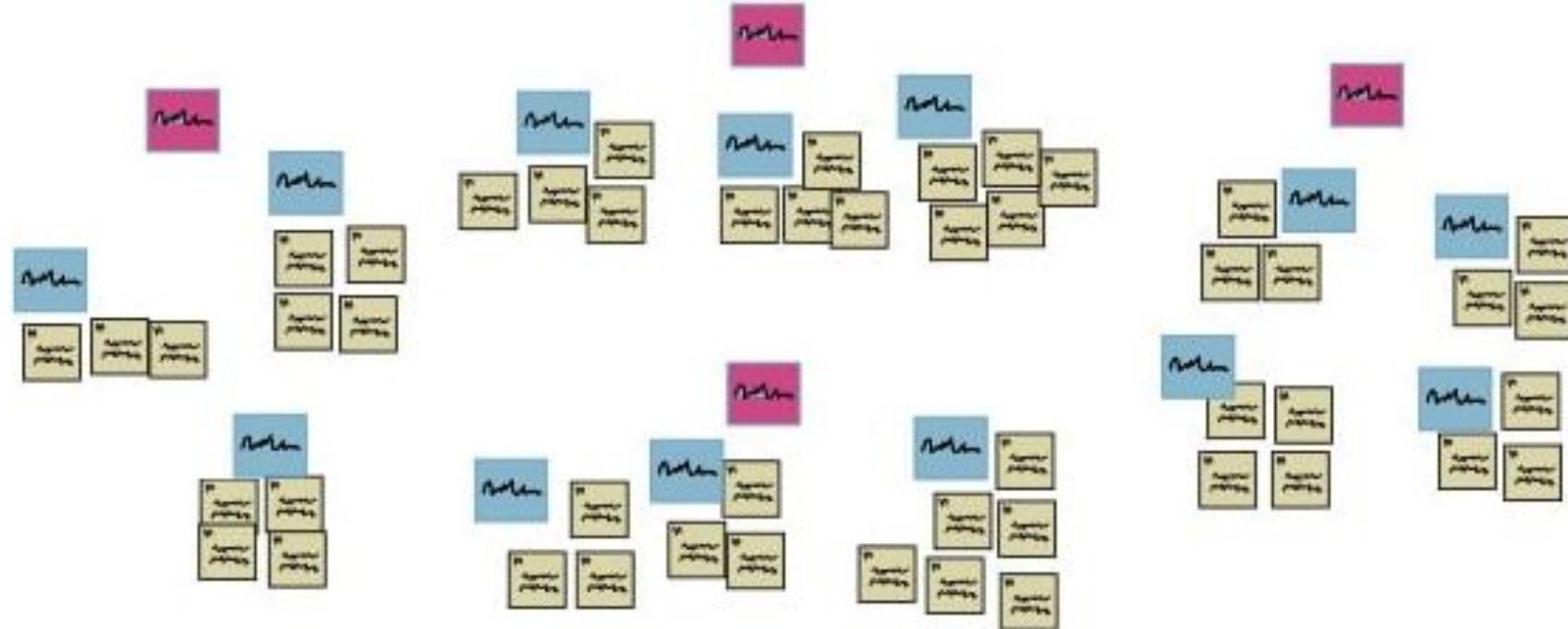
Voice Of the Customer (VoC)

For B2B/Coretech products:

- Feedback needs to be collected directly from sales reps and sales managers
- Use existing feedback documentation tools when available, but pair it with discussions with sales
- Listen in to sales calls or recordings about existing similar products
- What else?



Affinity Diagram



From "What" to "Why"

- **Discussion Question:** Why is it risky for a team to rely only on its own assumptions about what customers will find valuable?
- **Once you know *what* the problems are, you need to find out *why* they're happening.**
The **Fishbone Diagram** is a fantastic tool for this. You put the problem like 'discomfort' at the head of the fish, and you brainstorm potential causes along the 'bones,' like man, materials, methods, environment, or machinery. This can be done pre production and on existing products.
- Example: **The marketing guy wanted to add Bluetooth speakers and Gucci logos**, a 'wow' factor. But before they invested time and money, the product team told the market guy to try the **Kano Analysis**. This model helps you understand what customers actually value. They discovered that breathable fabric was a basic expectation, and better padding was a performance feature. This tool prevents you from wasting resources on things customers don't care about.

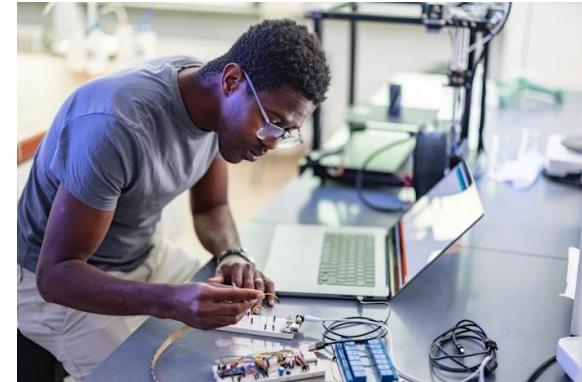
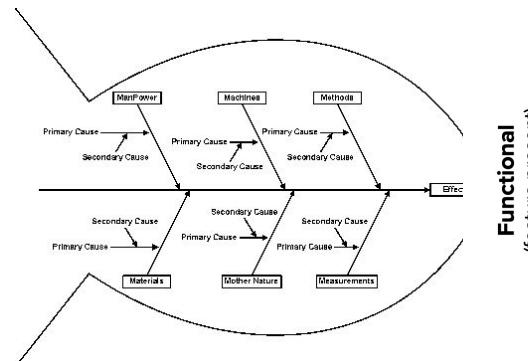


From "What" to "Why"

Fishbone Diagram A root cause analysis tool to trace a problem to its source by exploring categories like materials, methods, and machinery.

Kano Analysis Prioritizes features by sorting them to ensure you build what customers value.

- **Basic Needs:** Expected basic features (e.g., breathable fabric).
 - *Need to have.*
- **Performance Add-Ons:** Is more better? (e.g., more padding).
 - *Nice to have.*
- **Delighters/Extras:** “Wow” factors.
 - *Not expected to have.*
- **“Disappointers”:** Adds no value, increases cost.

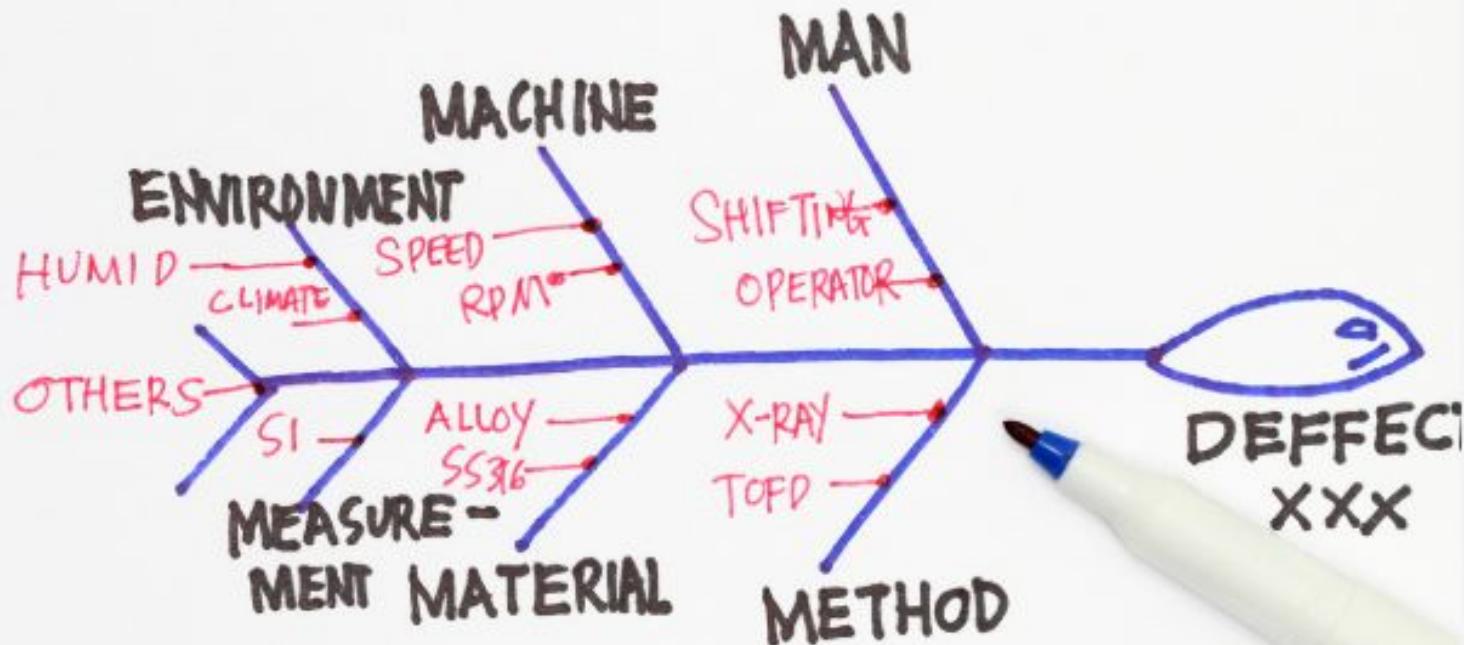


Dysfunctional
(feature absent)

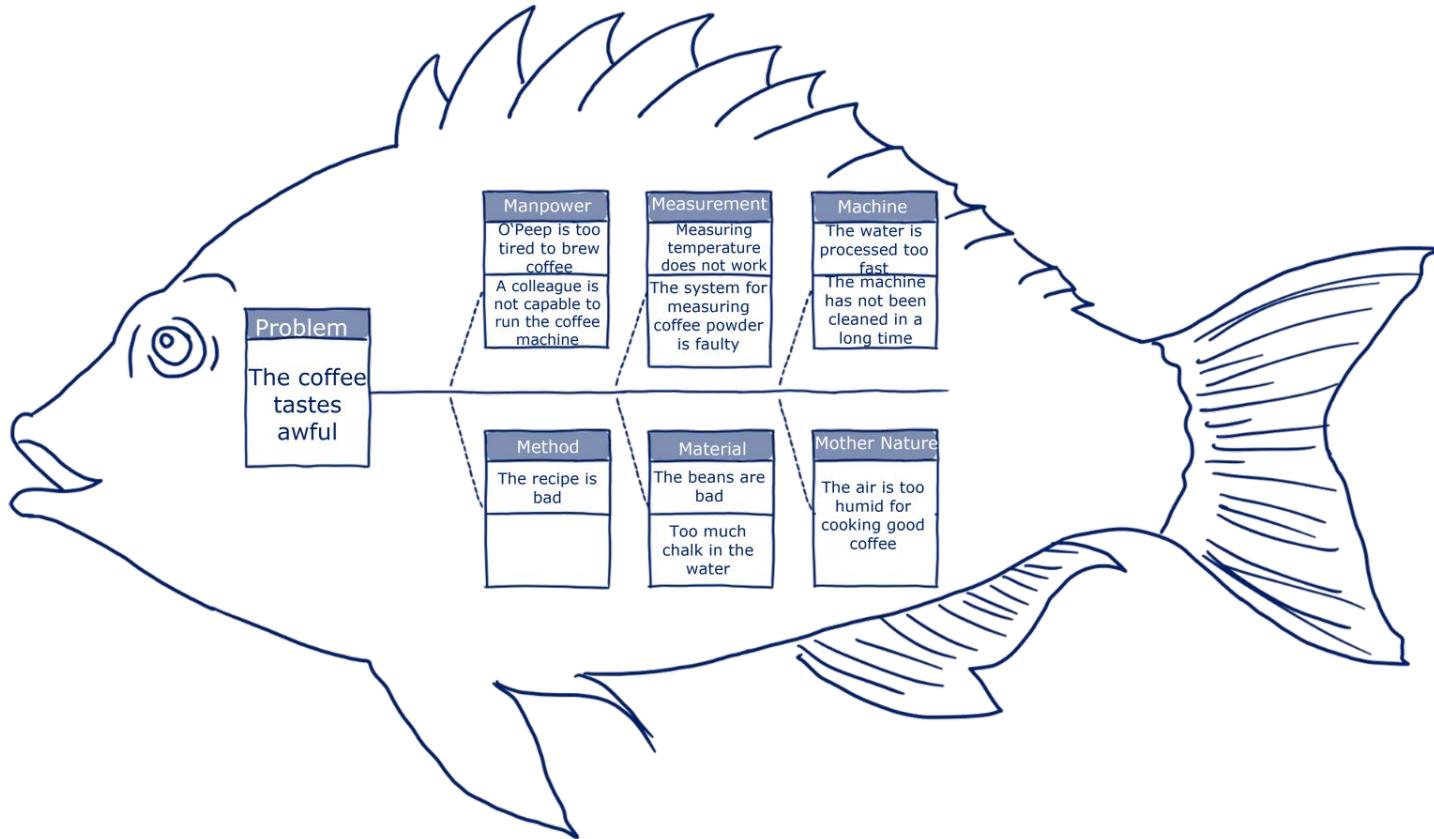
	Like it	Expect it	Don't Care	Live With	Dislike
Like it	Q	A	A	A	P
Expect it	R	I	I	I	M
Don't Care	R	I	I	I	M
Live With	R	I	I	I	M
Dislike	R	R	R	R	Q

vive health

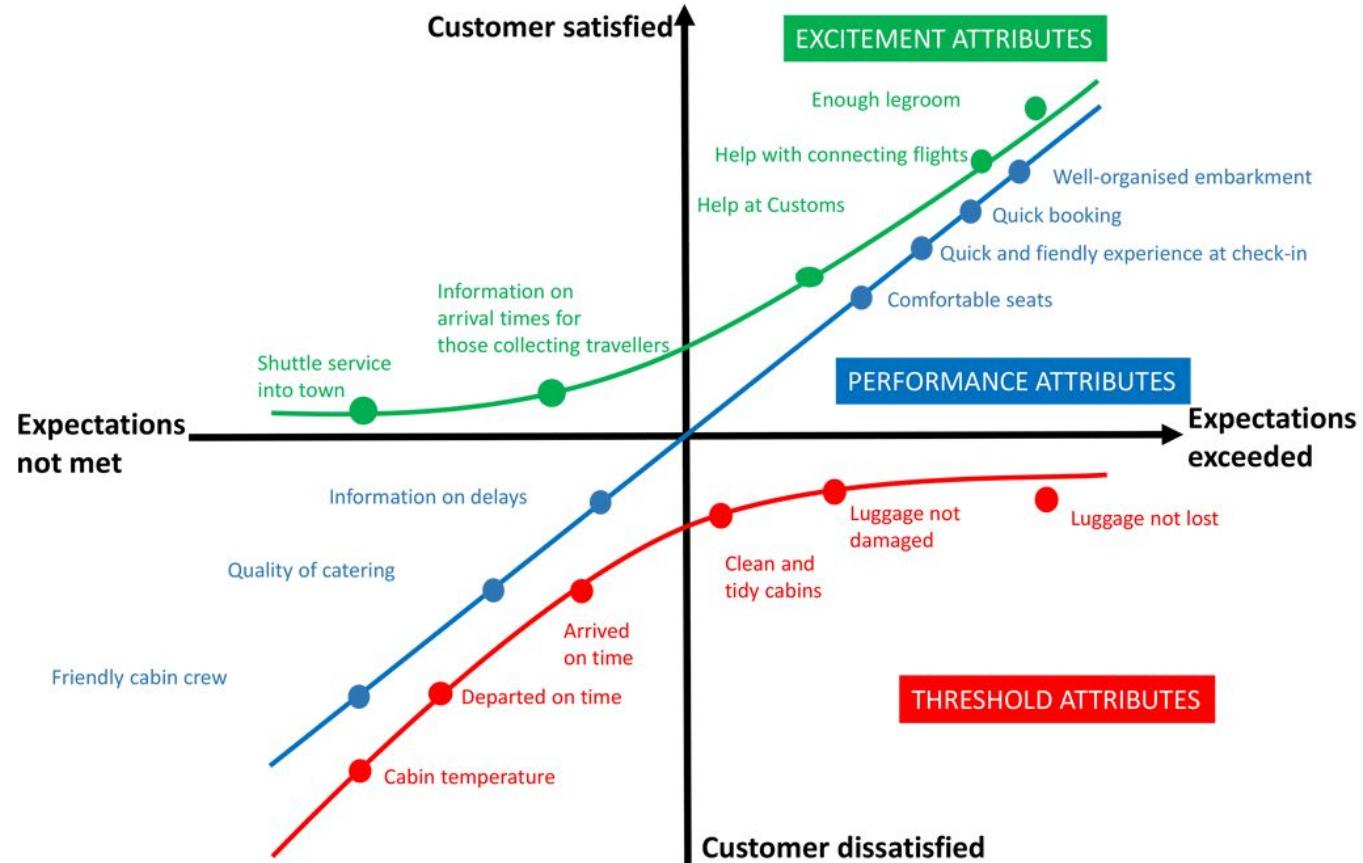
Fishbone Diagram / Ishikawa



Fishbone Diagram / Ishikawa

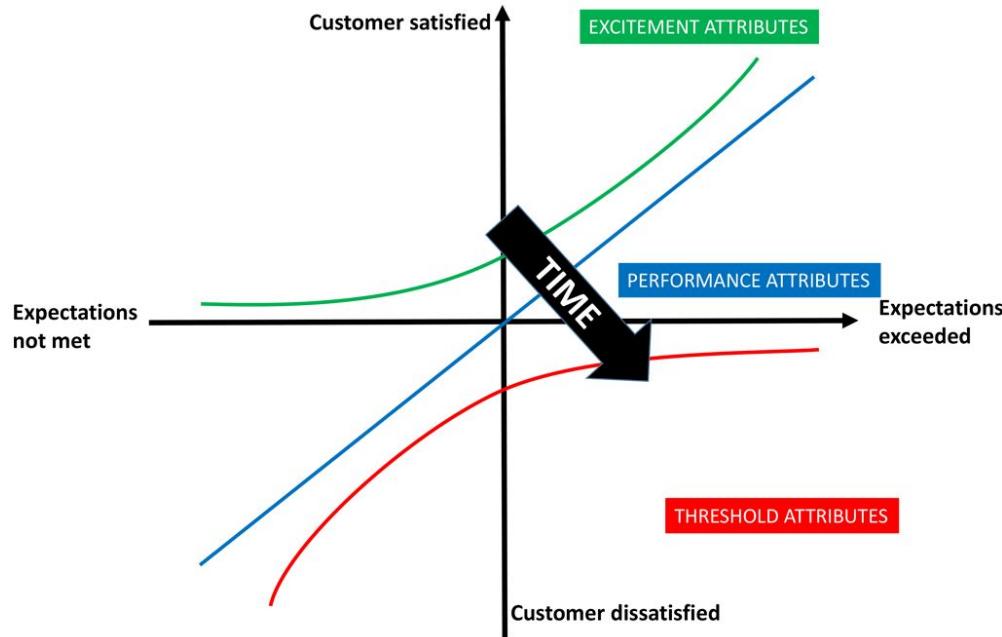


Kano Model



Kano Model (cont.)

- The classification of attributes in the Kano model changes over time.
- Something which excites customers today can already have become an explicit expectation tomorrow. Soon, it may well become something which are taken as given.
- This can be illustrated with a car's airbag. When originally introduced by Mercedes Benz, it was an excitement attribute and showed that you had a higher range car.
- Nowadays, airbags are a threshold attribute, included as standard in even cars in the lowest price class. In fact, every car manufactured after 1999 is required to have an airbag safety system.
- What was once an exciting feature may eventually become required by law, the bare minimum to enter/remain in the market.



Designing & Managing the Work

RACI Matrix

Responsible

Accountable

Consulted

Informed

FMEA (Failure Mode and Effects Analysis)

Proactive

Identifies Potential Problems

Failure Modes & Effects

House of Quality (QFD)

Customer Needs → Design

What Becomes How

Voice to Specs

Connecting Outputs to
Inputs

Define roles, prevent failures, and translate customer needs into design specs.

vive health

RACI Matrix

Roles

- **Responsible (R):** The person who actually performs the task or makes the decision.
- **Accountable (A):** The person who is ultimately answerable for the task's successful completion. There should only be one accountable person per task.
- **Consulted (C):** Individuals who provide input or expert judgment before a decision is made or the task is completed.
- **Informed (I):** Individuals who are kept up-to-date on the progress or decisions of a task.

How to Create a RACI Matrix

- **Identify Tasks:** List all the tasks and activities involved in the project.
- **List Roles:** Identify the roles or individuals within the team.
- **Assign Roles:** For each task, assign the appropriate RACI role (R, A, C, or I) to each individual or department.
- **Review and Refine:** Review the completed matrix with the team to ensure clarity and alignment.

Process / Procedure	Alex Popoff	Carolina Silva	Jessica Marshall	Product Team
Product Development				
New Product Risk Analysis (ISO 14971)	AC	C	C	R
DHF Management & Review	AC	I	C	R
Regulatory & Compliance				
CE Mark Technical File Compilation	RACI	CI	CI	R
UDI / UPC / PDAC Management	I	I	R	ACI
Post-Market Surveillance				
Customer Complaint Data Review	RACI	R	I	CI
Complaint Handling & Investigation	RACI	R	CI	I

Failure Mode and Effects Analysis is a structured process to identify and prevent potential problems *before* they happen.

- 1. Identify Failure Modes:** Brainstorm every possible way the product could fail.

Kneemesis Example: "Gel pad leaks," "Strap material frays," "Hinge lock slips."

2. Assign Risk Scores (Scale of 1-10):

- Severity (S):** How serious is the impact on the customer? (1 = Minor inconvenience, 10 = Severe safety hazard).
- Occurrence (O):** How likely is this failure to happen? (1 = Extremely unlikely, 10 = Almost certain).
- Detection (D):** How likely are we to detect the problem *before* it reaches the customer? (1 = Certain to be caught, 10 = Undetectable).

3. Calculate the RPN (Risk Priority Number):

- Formula:** Severity (S) × Occurrence (O) × Detection (D) = RPN
- Score:** The RPN quantifies the overall risk of each failure mode. A higher number indicates a higher risk.
- Kneemesis Example:** A gel pad leak that is a **severe** skin irritant (S=9), happens **occasionally** (O=4), and is **hard to detect** in QC (D=7) would have an RPN of: $9 \times 4 \times 7 = 252$ (252 out of 1000 RPN)

4. Prioritize & Mitigate:

- Rank all failure modes by their RPN score, from highest to lowest.
- Address the highest RPNs first by creating and implementing a mitigation plan to lower the Severity, Occurrence, or Detection score.

Sample FMEA form

Design failure mode and effects analysis (DFMEA)

Product description: _____

Design engineer: _____

Project name: _____

Project number: _____

DFMEA team: _____

Items	Function(s) and requirements	Potential failure mode(s)	Potential effects of failure	Severity	Potential cause(s)/ mechanisms of failure	Prevention controls	Occurrence	Criticality	Detection controls	Detection	RPN	Actions (anticipated/actual)										
												Recommended actions	Tar- geted controls		Responsibility	Target completion date	Actions taken	Effective date	Severity	Occurrence	Detection	RPN
												Prevention	Detection									
																		0				
																		0				

FMEA = failure mode and effects analysis

RPN = risk priority number

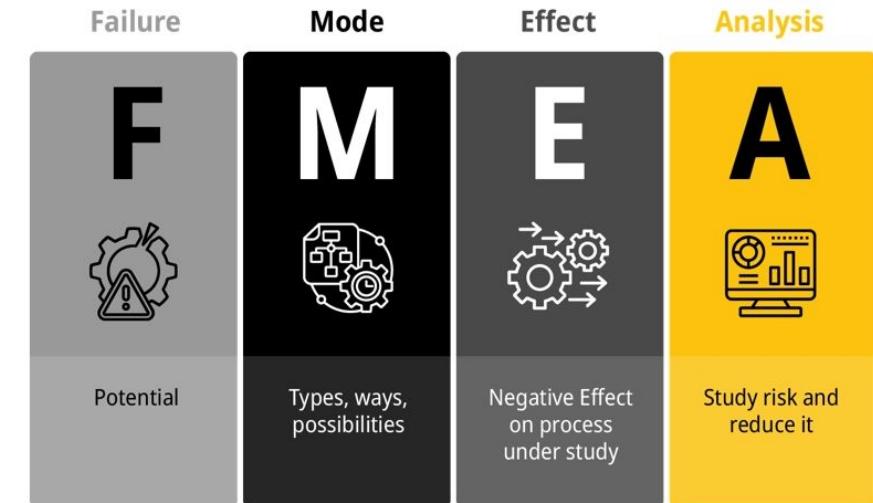
FMEA

Before we commit to a design, we need to manage risk. That's where FMEA comes in. Think of it as a team brainstorming session where we try to imagine everything that could possibly go wrong. For each potential failure, we assign three numbers. How **Severe** is it? How likely is it to **Occur**? And how easy is it to **Detect**?

We then multiply those three numbers together to get the **RPN**, or Risk Priority Number.

This score isn't magic, but it's a powerful tool. It instantly shows us where our biggest risks are. The failures with the highest RPNs are the ones we must tackle first, creating a plan to either design the problem out, change our process to prevent it, or improve our quality control to catch it.

It's about solving problems on the whiteboard, not on Amazon or B2B, not via rework and redesigns - not with new plastic molds, or other costly areas of improvement.



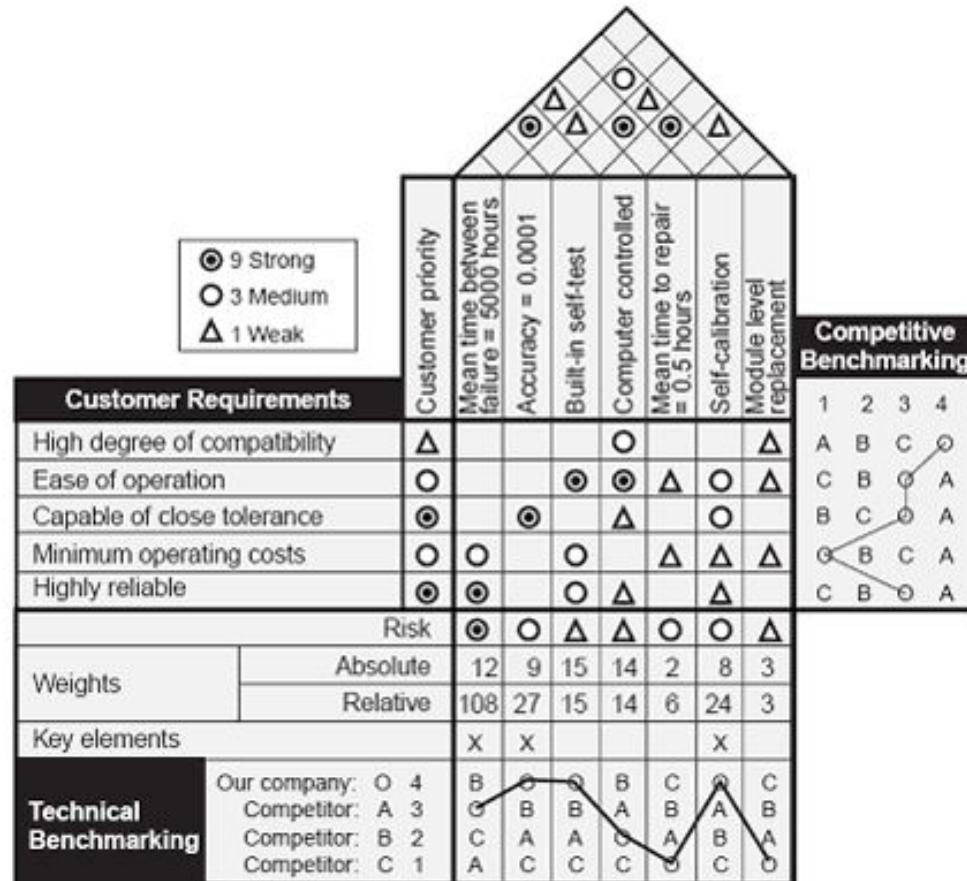
"An ounce of prevention
is worth a pound of cure."
Benjamin Franklin

House of Quality & QFD

House of Quality & Quality Function Deployment (QFD) are a (complex) matrix used to translate customer requirements (the "Whats") directly into engineering specifications (the "Hows").

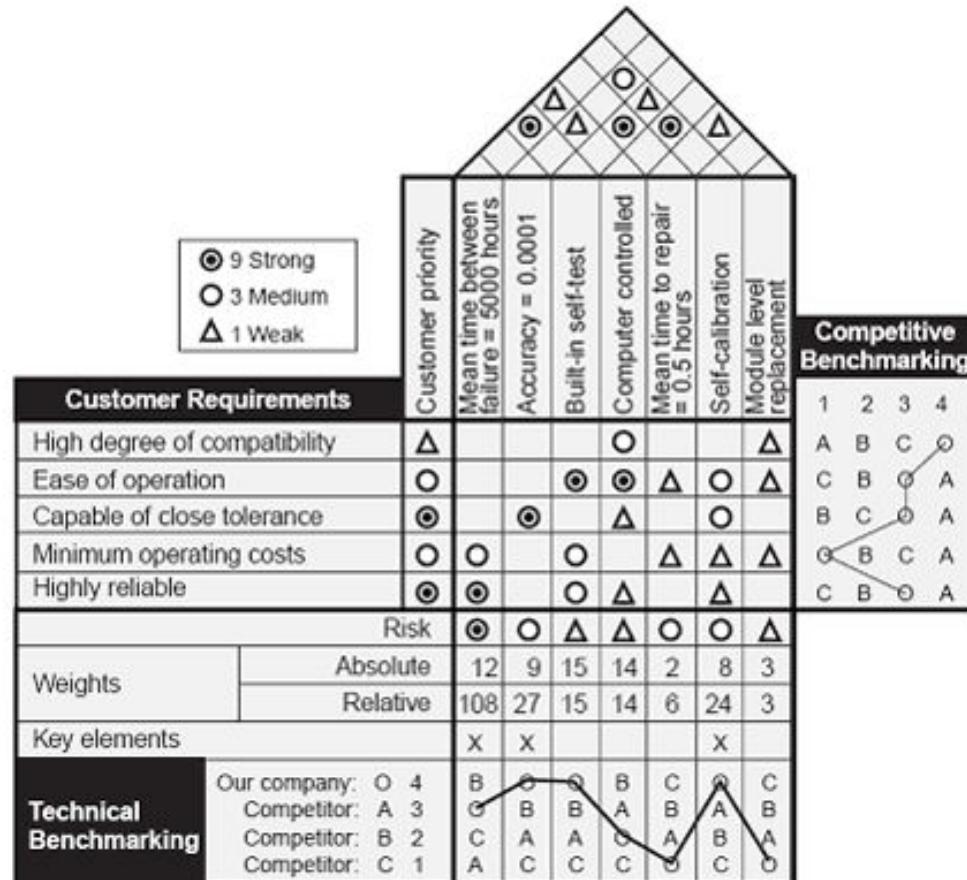
It ensures that the final product design is focused on what the customer truly needs and values.

This process can be watered-down to a more approachable concept, versus a rigid matrix.



House of Quality & QFD (cont.)

- 1. Customer "Whats" (Left Wall):** Lists customer needs in their own words.
 - Kneemesis Example:* "Comfortable," "Not sweaty," "Doesn't pinch during movement."
- 2. Engineering "Hows" (Ceiling):** Lists the measurable, technical characteristics of the product.
 - Kneemesis Example:* "Gel padding thickness (mm)," "Fabric breathability rating," "Strap material elasticity."
- 3. Relationship Matrix (Main Room):** The core of the house, where the team determines the strength of the relationship between each "What" and each "How."
- 4. Technical Correlations (Roof):** Shows how the engineering characteristics relate to each other (e.g., increasing padding thickness might negatively impact breathability).
- 5. Targets (Basement):** Defines the specific, measurable target values for the engineering "Hows."
 - Kneemesis Example:* Target: 5mm gel padding, Target: 85% breathability rating.



What It Is (For Us)

A simple "translation map" that connects customer needs directly to our design specs.

It's not the complex matrix; it's a *forced conversation* to keep us aligned.

It ensures we build what customers *actually* asked for, not what we *think* they want.

The goal is to prevent the "lost in translation" gap between Product, Marketing, and Engineering.

Simple Example:

A customer "**Want**" is "brace must be comfortable all day."

Our "**Hows**" are "Fabric Type," "Stitching Method," and "Velcro Strength."

The team agrees "Fabric Type" *strongly* impacts all-day comfort. Now we know "Fabric Type" is a critical spec to get right.

When & How to Use It

WHEN: Early in the design phase. Use it *after* you have your VOC/Affinity data, but *before* you finalize specs or order samples.

HOW: In one meeting, map your top 3-5 "Customer Wants" (Whats) to your "Engineering Specs" (Hows) to find what matters most.

Quality Requirements

💡 What Are They?

- ✓ Clear, measurable, and testable targets for our product's design.
- ✓ They translate vague customer wishes (like "durable" or "easy to use") into specific engineering goals.
- ✓ This is our "Definition of Done" for quality. If the product passes these tests, we've met the customer's need.
- ✓ They are the primary *output* of the HOQ Lite exercise.

✅ When & How to Use Them

- 📅 **WHEN:** Immediately *after* the HOQ Lite meeting. These are the action items from that meeting.
- 🔧 **HOW:** For each critical "How" (spec) from the HOQ, define a target, a tolerance, and a test method.

Simple Example:

A customer **"Want"** is "brace must be comfortable all day." The **"Critical How"** (from HOQ) is "Fabric Breathability." The **"Quality Requirement"** is: "Fabric must have an air permeability of at least 100 CFM, as measured by ASTM D737."

When to Apply these Tools

Tool	Project Plan Integration Point
Project Charter, Budget, Sign Offs, & Project Risk Assessment	Before and During "Company Kickoff Interdepartmental" to align the team.
Quality Requirements	During or after initial kickoff, again before production
VOC & Affinity Diagram	Enhance "Market Research", Shulex, Amz VoC, B2B Feedback, Categorize/Quantify.
House of Quality (QFD)	Before "Initial Quotes & Sample Review" to translate customer needs into specs.
FMEA	During "Final Development Updates" to proactively identify and mitigate risks.
RACI Matrix	When you "Meet With Departments" to clarify roles and responsibilities.
Design Validation and Pre Production Sign offs	Add a user testing step after "Golden Sample" - Confirm testing completed. Complete Before production
Project Retrospective	Add a 90 day post-launch meeting to capture lessons learned for future projects.

Applying These Strategies

Identify One 'Dumpster Fire': What is one current project or product that is suffering from vague feedback or a lack of clear direction? Let's apply the **Project Charter** framework.

Deepen Your VOC: Where can we get better, more systematic customer feedback? Let's review our current VOC sources and see where we can improve our data collection.

Pick One High-Risk Feature: For an upcoming product launch, let's identify the most complex or riskiest new feature and conduct a *simplified FMEA* on it.

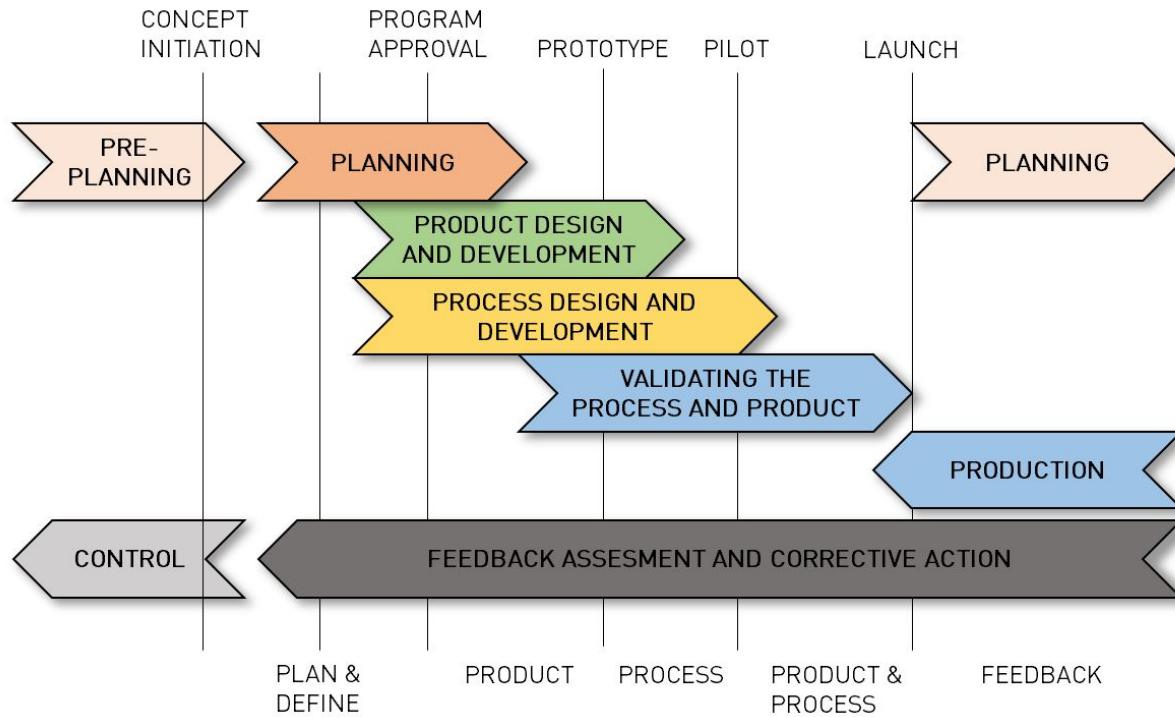
Open Discussion:

- Which of these tools seems most useful for our team right now?
- What is the biggest barrier to implementing one of these strategies, and how can we overcome it?

Summary

- **Design Verification**
 - **What it is:** An internal process to confirm the product was built correctly according to its design specifications.
 - **Remember it as:** "Did we build it **RIGHT?**" (Lab Testing)
- **Design Validation**
 - **What it is:** An external process to confirm the product solves the user's actual problem.
 - **Remember it as:** "Did we build the **RIGHT thing?**" (User Testing)

- **Project Retrospective**
 - **What it is:** A meeting held after a project to discuss what went well, what didn't, and what can be improved for the next project.
 - **Remember it as:** "How Did We Do?" – It turns lessons learned into future improvements.



- Advanced Product Quality Planning (APQP)

What it does:

- Forces us to find and fix problems, before launch
- Aligns Product, Quality, Supply Chain, Sales, Marketing, and Leadership on one plan
- Moves us from 'reactive' to 'proactive'



The benefits:

- Fewer failures
- Lower costs
- Happier Customers
- Happier sales team and leadership
- More profit!

QUALITY WARS

Areas of Improvement

Tools, Tech, & Infrastructure

- Lack of data & reporting tools
- Leaning on in-house development
- No eQMS
- Inefficient Part Request and Returns Processing

Training

- Difficulty training other departments due to our and other team's schedules
 - Can mitigate via emails and videos, but less engagement than in person

Tribal Knowledge

- Lack of structure and documentation within our and other departments
 - SOPs only partially mitigate
 - Challenging but worthwhile for continuity of business

Training

- Difficulty training other departments due to our and other team's schedules
 - Can mitigate via emails and videos, but less engagement than in person

Team

- Over 2000 SKUs and only 1 Quality Manager + 1 Quality Analyst
 - QC/Inspectors properly staffed, QA/Analysis and engineering is not
- KS Warehouse has several quality-related functions but does not have adequate staffing or training to support
- My own lack of experience
 - Mitigated by tenured peers, OJT, education and growing experience

Big Picture

Planning: The Comfort Trap

- **What it is:** A list of activities the company is "going to do," a set of initiatives that sound good, like "open a new warehouse" or "reduce return rates".
- **Why it's "Comfortable":** It focuses on things **you control**. You control your costs, your hiring, and your project timelines.
- **The Trap:** It has no "internal coherence" or "theory" of how these activities will collectively achieve a goal. As Roger Martin from HBR says, "Most strategic planning has **nothing** to do with strategy... If you [only] plan, that's a way to guarantee losing".

Strategy: The Path to Winning

- **What it is:** An "integrative set of choices" that positions you on a playing field in a way that **you win**. It's a coherent theory of *how* you will be better than anyone else at serving your target customer.
- **Why it Causes "Angst":** It specifies a competitive outcome you **don't control**. You don't control your customers; they *decide* if your theory is right. You cannot prove it will succeed in advance.
- **The Outcome:** It gives your organization "the best possible chance of winning" by forcing you to make clear choices about where to play and how to win.

"If you do strategy, it gives you the best possible chance of winning." - Roger Martin, HBR

Why, What, and How

Philosophy (The "Why")

- **This is our core belief system and guiding principles.**
- It is our "why," the foundation upon which everything else is built.
- **Examples:**
 - "Ounce of prevention > Pound of cure"
 - "Do it right the first time"
 - "Defects are caused by process failure"
 - "Quality = Meeting or Exceeding Expectations"

Strategy (The "What")

- **This is our "high-level approach to accomplishing [our] mission".**
- It is *what* we will do, in broad terms, to bring our philosophy to life. "Commander's Intent". Reduce defects to improve CX.
- **Examples:**
 - "Build quality into every process/product at the ideation stage"
 - "Lead with intent and enable innovation"
 - Shift from reactive Quality Control (detecting defects) to proactive Quality Assurance (preventing defects)

Plan (The "How")

- **This is the specific, tangible "how" we execute the strategy.**
- It is the set of projects, initiatives, and "rigid list of tasks" that have defined start dates, end dates, and resource needs.
 - i. **Examples:**
 - a. The "ISO 13485" certification project, to be completed by Q2 2026
 - b. The "Return Rate Reduction" long-term initiative
 - c. The "OJT/TQM Training" initiative

Military Leadership

Autonomy is the Delegation of Decision-Making Authority



Military Leadership



Execution

Our Execution Tools (1): Guiding Principles to Execute our Strategy

- **Guiding Philosophies** from: Toyota, Arthrex, others
- **"Genchi Genbutsu"** (Go and see - to the Source: China, KS Warehouse)
- **"Kaizen"** (Using small, continuous improvements as a tool) e.g., contacting vendors about non-conformances and CAPAs.
- **Extreme Ownership** (We own the mission, not just the task)
 - a. **Acknowledge, Learn, Adapt** (Instilling ownership, using mistakes as learning opportunities)
- **ISO 13485** (Our formal framework for building a world-class system) e.g., FDA required starting February 2026, we are pursuing proactively.

Execution

Our Execution Tools (2): Processes & Collaboration

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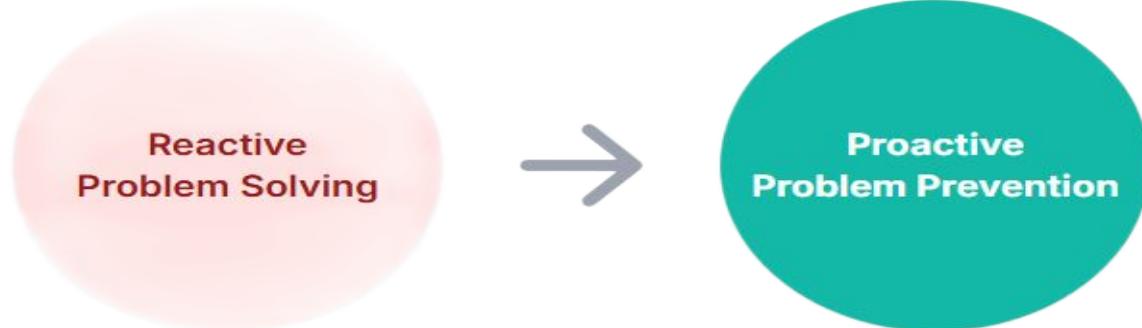
Verification vs. Validation

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Competitor Analysis

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ISO 13485 Certified

McKesson

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Stryker

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Cross-Department Communication

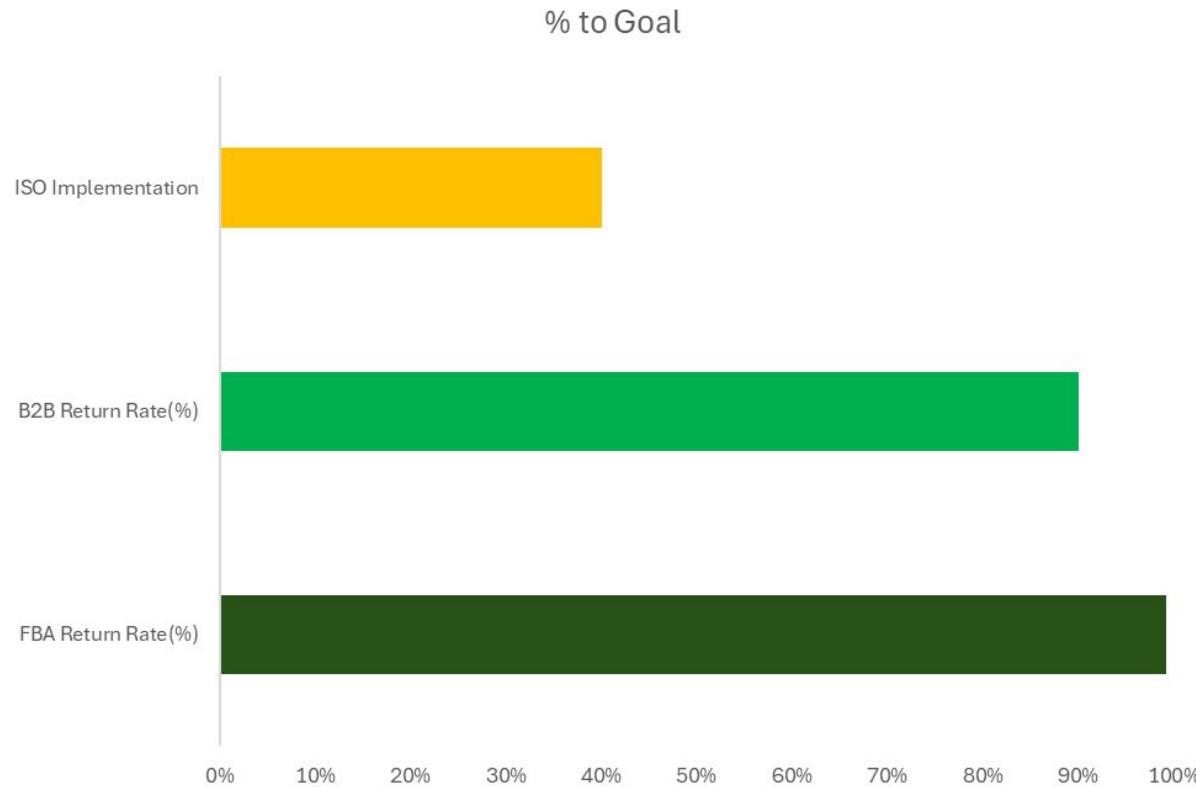
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Proposed Approach (Proactive Comms & QA)

- **The Question:** "Do we change packaging?"
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- **Example:** Customers report products arriving damaged. Quality and product team coordinate to improve packaging to prevent in-transit damage. Net positive for the company as long as it doesn't increase FBA fees or hurt B2B.
- **How:** Cross-department meeting and proper analysis. Doing the analysis upfront prevents knee-jerk changes after damage is already done.

Performance Towards Goals



Target vs. Actual

Goal	Alignment	Target	Actual	% to Goal
FBA Return Rate(%)	Delight the Customer	</= 7.50%	7.41%	101.21%*
B2B Return Rate(%)	Sales Growth	</= 2.00%	2.39%	83.68%
ISO Implementation	Sales Growth	Before Q2 2026	Unknown	~40.00%

*10/30/2025 last 90 days via seller central FBA Return Rate

Active Projects & Initiatives					
Project/Initiative	Start	Projected End	Issues	Needs	Project Health
CE for EU/UK	Q3 2025	Q4 2025	Switched Companies	N/A	Good
ISO 13485	Q2 2025	Q2 2026	Switched Consultants	Product Team Documentation Changes	Fair
Return Rate Reduction	Q1 2025	N/A, Long-term Initiative	Complexity	Support from most departments.	Stable

Active Projects & Initiatives (cont.)					
Project/Initiative	Start	Projected End	Issues	Needs	Project Health
Continuous Process Improvement	Q1 2025	N/A, Long-term Initiative	Breaking habits	Support from all departments.	Fair
OJT/TQM Training	Q1 2025	N/A, Long-term Initiative	Scheduling conflicts	Support from all departments.	Fair
Packaging Optimization	Q1 2025	N/A, Long-term Initiative	Complexity	Support from several departments.	Stable

Strategy & Philosophy

Problem Assessment Matrix

HIGH

HIGH

Severity of Impact

Cost

- I. **Critical (1st Priority)**
- High Impact
- High Frequency
- High Cost

Investigate First, issues in this category need to be solved quickly.

- II. **Important (2nd Priority)**
- High Impact
- High Frequency
- Low Cost

Consider reviewing quickly as proactive measure before costs rise. *Safety risk correlates with cost and reg. reqs.*

III. Costly (3rd Priority)

- High Cost
- Low Frequency
- Low Severity

Explore cost saving and issue resolution.
Prioritize if is exorbitant.

VI. Low Priority (4th Priority)

- Low Impact
- Low Cost
- Low Frequency

Delegate or track for escalation to higher priority quadrants.

Frequency

LOW

HIGH

LOW

QUALITY WARS

vive health

Big Picture

Planning: The Comfort Trap

- **What it is:** A list of activities the company is "going to do," a set of initiatives that sound good, like "open a new warehouse" or "reduce return rates".
- **Why it's "Comfortable":** It focuses on things **you control**. You control your costs, your hiring, and your project timelines.
- **The Trap:** It has no "internal coherence" or "theory" of how these activities will collectively achieve a goal. As Roger Martin from HBR says, "Most strategic planning has **nothing** to do with strategy... If you [only] plan, that's a way to guarantee losing".

Strategy: The Path to Winning

- **What it is:** An "integrative set of choices" that positions you on a playing field in a way that **you win**. It's a coherent theory of *how* you will be better than anyone else at serving your target customer.
- **Why it Causes "Angst":** It specifies a competitive outcome you **don't control**. You don't control your customers; they *decide* if your theory is right. You cannot prove it will succeed in advance.
- **The Outcome:** It gives your organization "the best possible chance of winning" by forcing you to make clear choices about where to play and how to win.

"If you do strategy, it gives you the best possible chance of winning." - Roger Martin, HBR

Why, What, and How

Philosophy (The "Why")

- **This is our core belief system and guiding principles.**
- It is our "why," the foundation upon which everything else is built.
- **Examples:**
 - "Ounce of prevention > Pound of cure"
 - "Do it right the first time"
 - "Defects are caused by process failure"
 - "Quality = Meeting or Exceeding Expectations"

Strategy (The "What")

- **This is our "high-level approach to accomplishing [our] mission".**
- It is *what* we will do, in broad terms, to bring our philosophy to life. "Commander's Intent". Reduce defects to improve CX.
- **Examples:**
 - "Build quality into every process/product at the ideation stage"
 - "Lead with intent and enable innovation"
 - Shift from reactive Quality Control (detecting defects) to proactive Quality Assurance (preventing defects)

Plan (The "How")

- **This is the specific, tangible "how" we execute the strategy.**
- It is the set of projects, initiatives, and "rigid list of tasks" that have defined start dates, end dates, and resource needs.
 - i. **Examples:**
 - a. The "ISO 13485" certification project, to be completed by Q2 2026
 - b. The "Return Rate Reduction" long-term initiative
 - c. The "OJT/TQM Training" initiative

Military Leadership

Autonomy is the Delegation of Decision-Making Authority



Military Leadership



Execution

Our Execution Tools (1): Guiding Principles to Execute our Strategy

- **Guiding Philosophies** from: Toyota, Arthrex, others
- **"Genchi Genbutsu"** (Go and see - to the Source: China, KS Warehouse)
- **"Kaizen"** (Using small, continuous improvements as a tool) e.g., contacting vendors about non-conformances and CAPAs.
- **Extreme Ownership** (We own the mission, not just the task)
 - a. **Acknowledge, Learn, Adapt** (Instilling ownership, using mistakes as learning opportunities)
- **ISO 13485** (Our formal framework for building a world-class system) e.g., FDA required starting February 2026, we are pursuing proactively.

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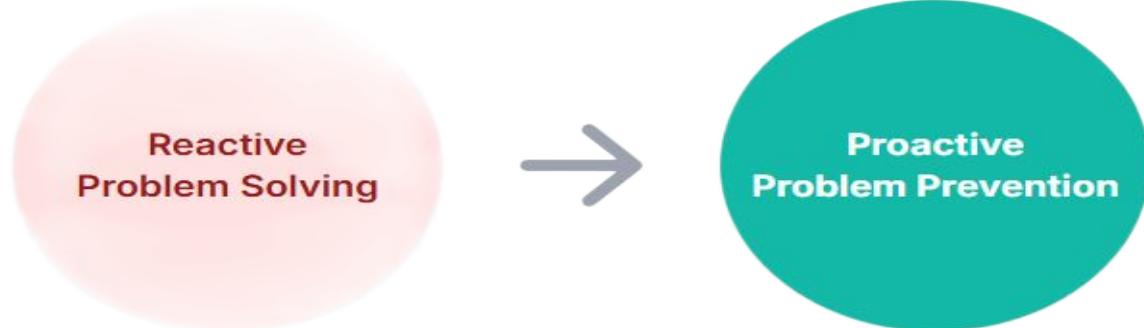
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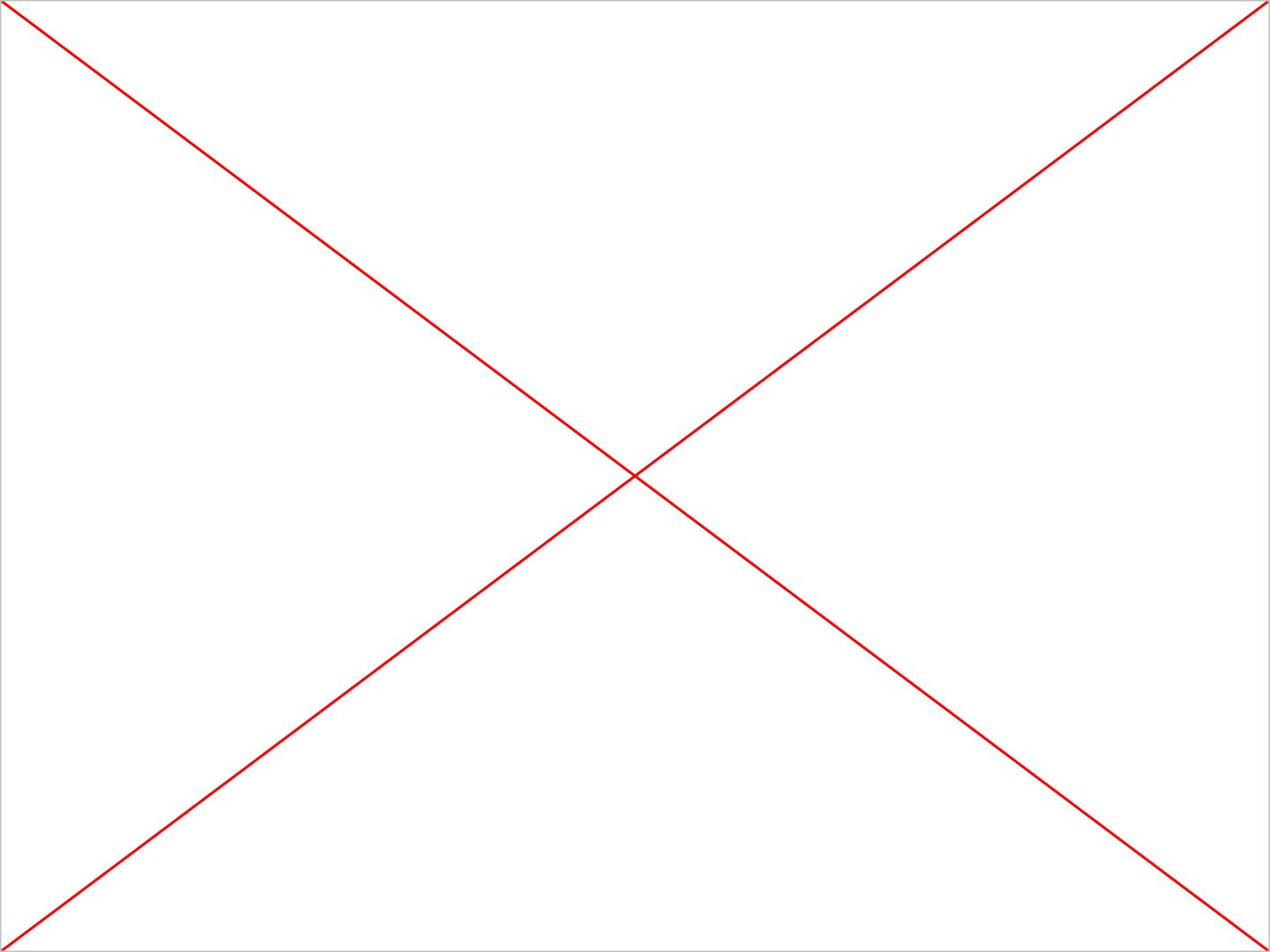
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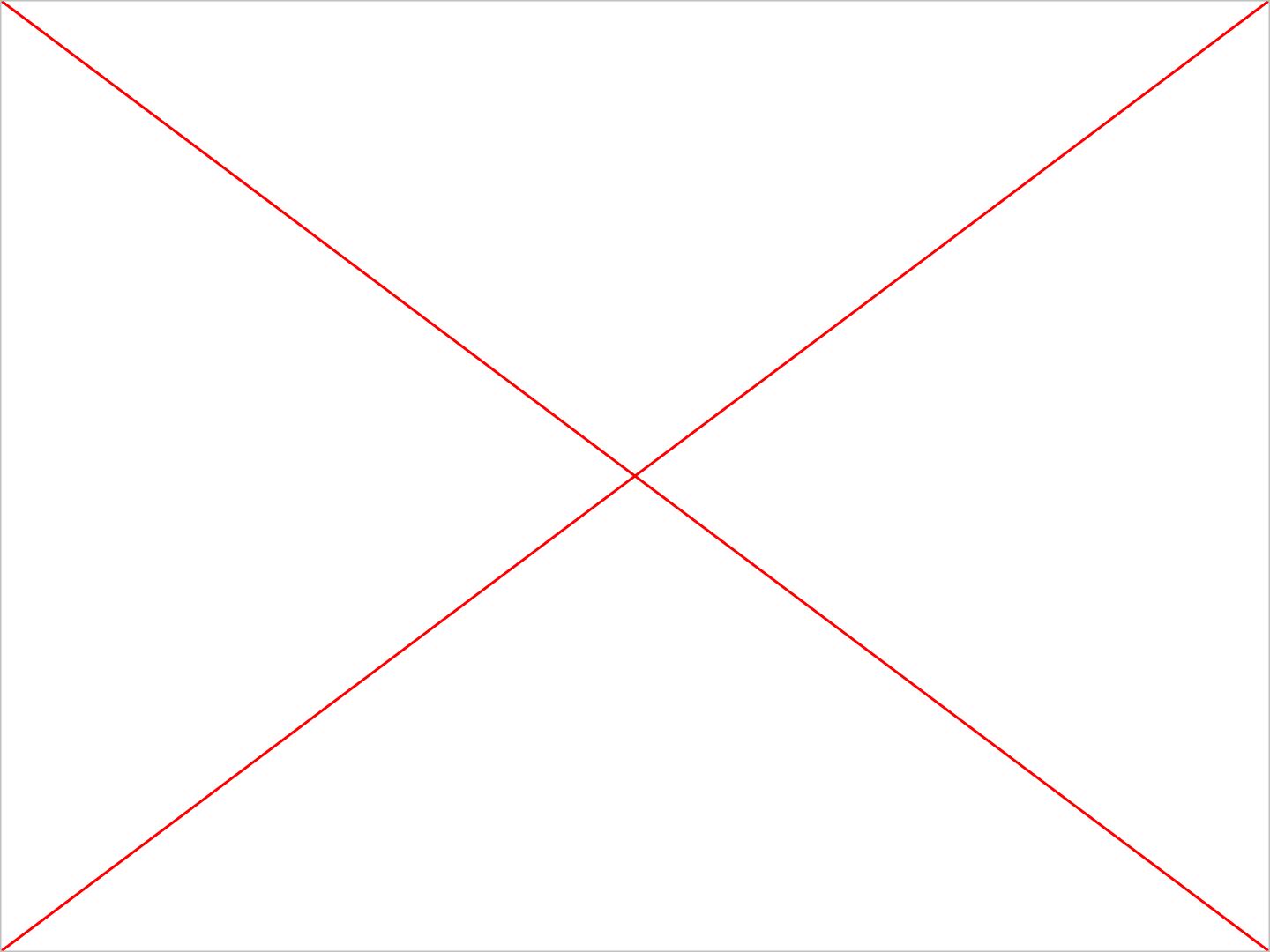
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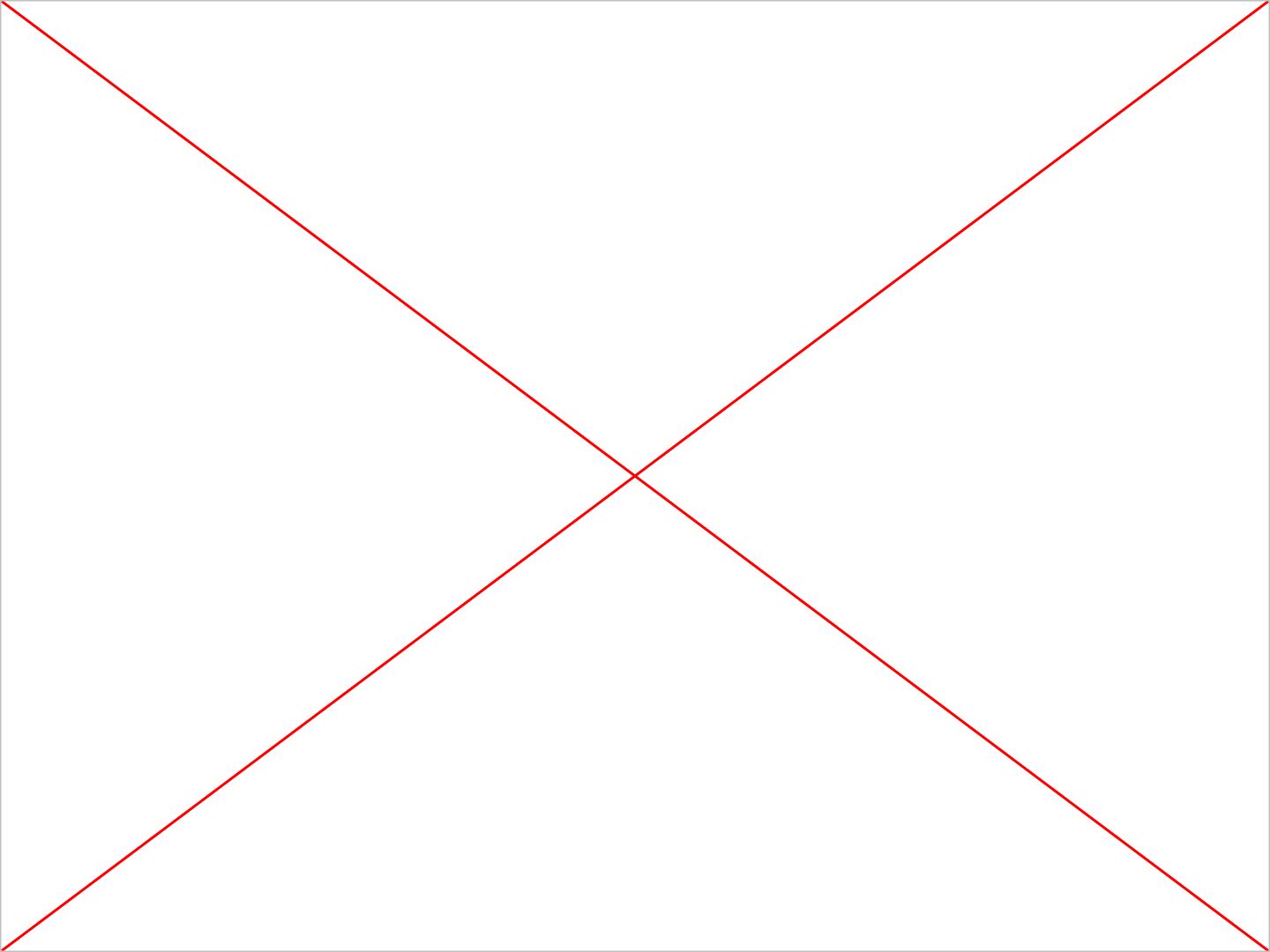
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Key Terminology

- **Quality Control**

Test and inspect components or finished products against approved specifications

Example:

- Does red light appear when you press power button?

- **Quality Assurance**

Manufacture quality into product

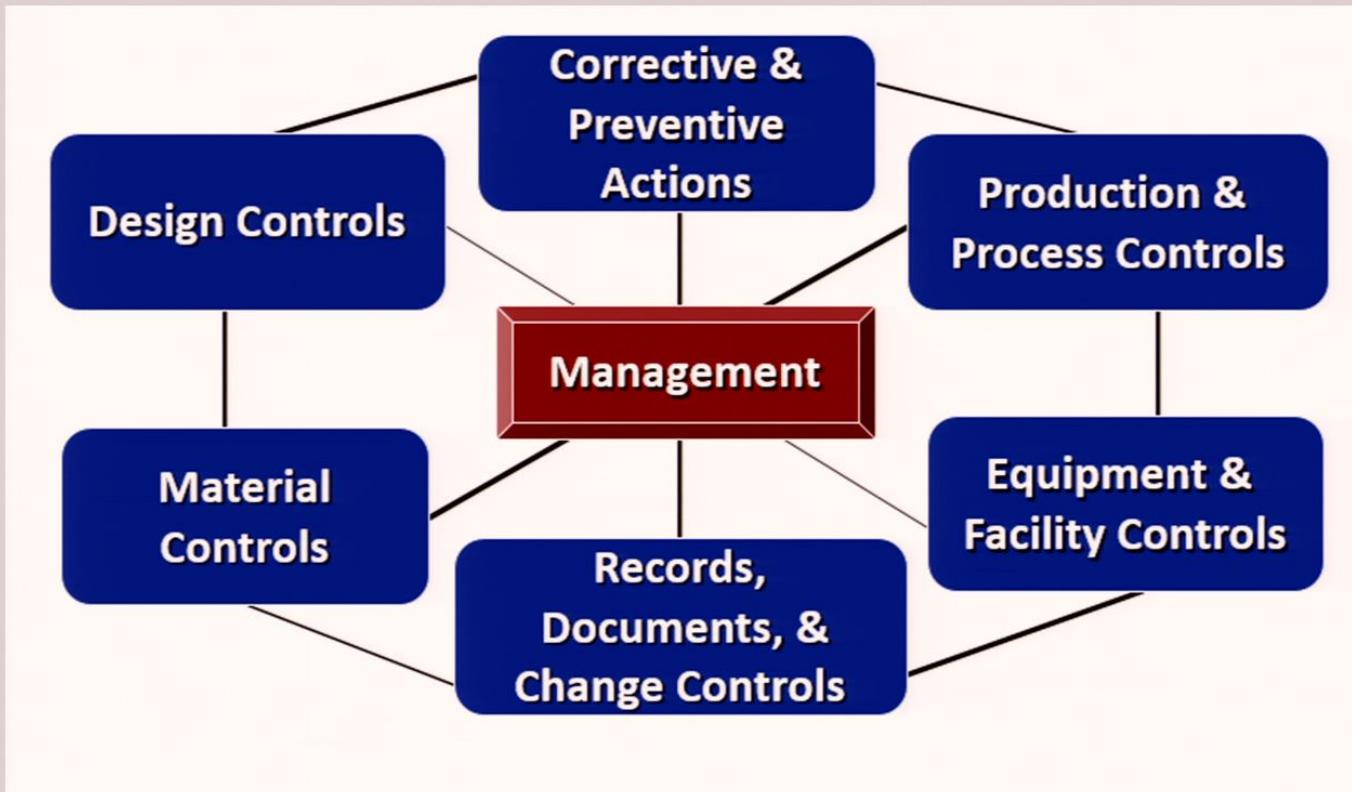
Purpose of Quality System

Governs methods used in, and facilities/controls used for:

- Design
- Manufacture
- Packaging
- Labeling
- Storage
- Installation
- Servicing

of all finished devices intended for humans

7 Subsystems of a Quality System



Quality System

- Management is key to quality system and processes
 - can delegate performance of activity, but not responsibility
 - is ultimately responsible to ensure that QS is implemented and effective
- Subsystems are interrelated and linked

Quality System

- Manufacturers should:
 - PLAN to define and implement effective procedures
 - DO what they say they are going to do
 - CHECK system and make necessary changes
 - corrections, corrective actions, and preventive actions
 - ACT upon changes and ensure they are implemented

Management Controls

- Purpose:
 - Provide adequate resources for operations
 - Monitor quality system
 - Make necessary adjustments
 - Assure quality system is functioning properly
- Quality System monitored through periodic reviews

Design Controls 21 CFR 820.30

Design controls apply to:

- All **Class II** and **Class III** medical devices
- Only these Class I medical devices:
 1. Devices automated with computer software
 2. Tracheobronchial suction catheters
 3. Surgeon's gloves
 4. Protective restraints
 5. Manual radionuclide applicator system
 6. Radionuclide teletherapy source

*Only REQUIRED for Class II, III and special types of Class Is. But recommended for all devices within reason.

Design Controls – Why?

- 44% of voluntary recalls from October 1983 through September 1989 may have been prevented by adequate design controls.

Source: "Device Recalls: A Study of Quality Problems" (see 55 FR 21108, May 22, 1990) and "QS Regulations (Final Rule)" (see 61 FR 52602, October 07, 1996)

- The most frequent causes for recalls are related to Design, Software, and Non-Conforming Materials/Components.

Source: "Medical Recall Report FY2003 to FY2012" (CDRH Office of Compliance, Division of Analysis and Program Operations)