Design for Assembly (DFA) – Using a DFSS Approach for Cost Reduction of an Existing Product

Living Our Mission and Guiding Principles

G U I D I N G P R I N C I P L E S

TEAM MEMBERS
Respect and show gratitude for the contributions and diverse perspectives of others

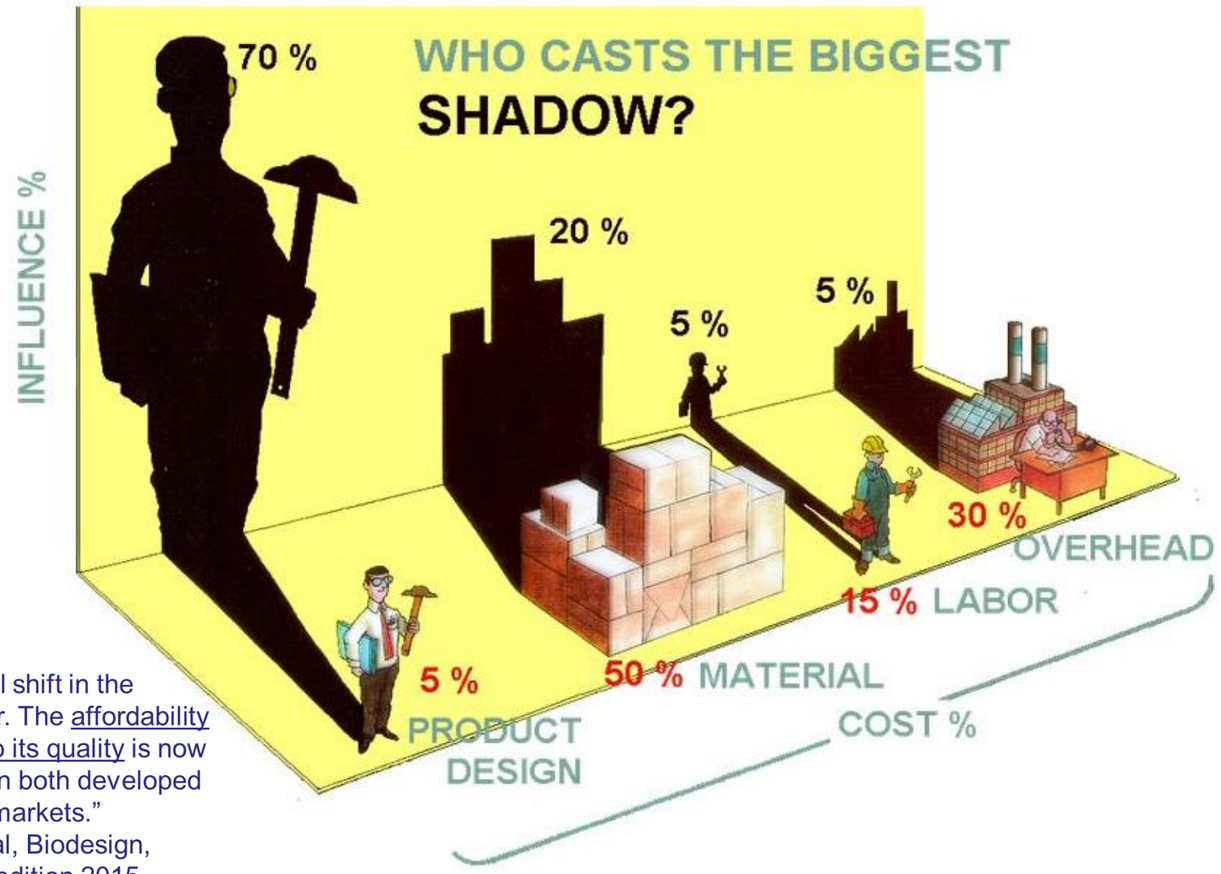
PATIENT SAFETY, QUALITY & INTEGRITY
Commit to the highest standards of patient safety, quality and integrity

FOCUS
Focus our resources in areas where we will make a difference

VALUE
Ensure the company's return is equivalent to the value we provide our customers and patients

GIVING BACK
Give back to our communities and people in need

Why DFSS?
Overall Influence of R&D



Source: Ford Motor Company

"…a fundamental shift in the healthcare sector. The affordability of care relative to its quality is now a primary focus in both developed and developing markets."

- Yock et al, Biodesign, Second edition 2015

- When we launch a New Product– The Design dictates how we build production parts for years to come
- Manufacturing and suppliers will spend years to reduce the Cost of Poor Quality (6σ) and make the Process more efficient (Lean)
- They cannot however change the Design to address poor Quality and Waste without an requalification of the Design.

DFMA for Production Designs can **help identify Potential design changes with min cost, time and risk** to make these **products more Competitive** especially in an inflationary Market.

5% of product's cost influences 70% of quality, manufacturability, serviceability & general acceptance in the marketplace – DFSS allows us to leverage this influence.

Three Rules of Complexity (Design)

1. Eliminate complexity that the customer will not pay for*
   - DFA looks for parts to eliminate / simplify (Waste)
   - Sometimes the part is over-designed and material waste can be removed.

2. Exploit the complexity customers will pay for*
   - DFSS can help preserves key Product Function/Performance Requirements (Strategic)

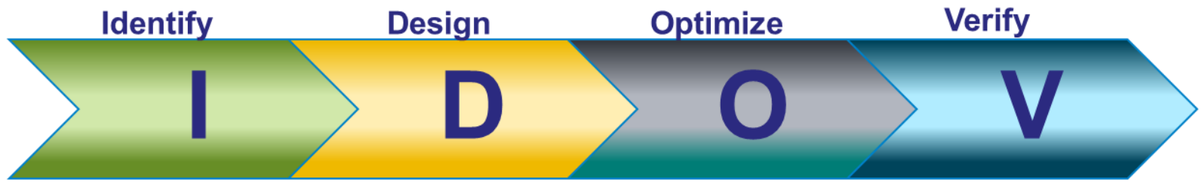
3. Minimize the cost of the complexity you offer*
   - DFA looks to simplify and eliminate potential mistakes, But listing known cost will help you focus on material cost for selection/reduction (Tactical)

*** From the Book "*Conquering Complexity in your Business*" by Michael L. George and Stephen A. Wilson**

Design For Six Sigma:

DFSS What it is?

- A Methodology to enable improvement in the Design and Development of new Products and/or Processes.
- Employs a Strategic and Tactical Systems approach for 1st effective and 2nd efficient Projects
- A way to Implement the Six Sigma methodology early in the product or service life cycle to add value.
- A way to exceed customer expectations and gain market shares
- A proactive strategy to reduce COPQ for designed products or processes.
- Not the same as DMAIC



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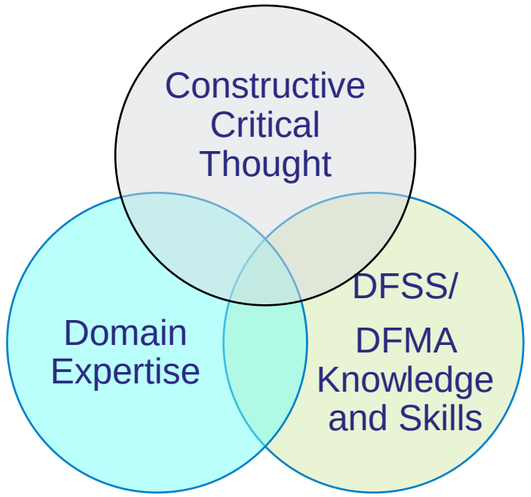
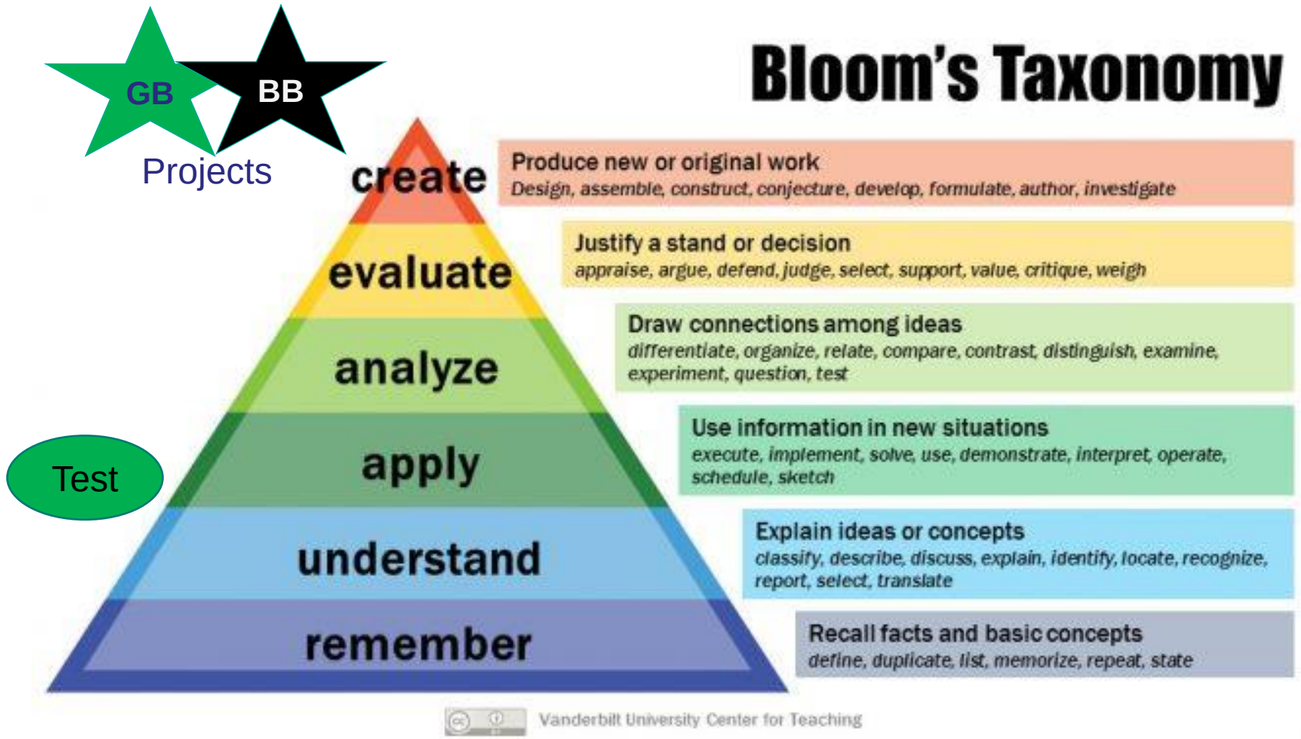
DFSS GB Certification – Performance Expectations

- Successful Integration of DFSS Methods/Tools



Seek wisdom to add value



Your DFSS project will require additional learning outside the classroom

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Critical Thinking – Significant

In January 2016, the World Economic Forum issued a report "The Future of Jobs". It says:

The Fourth Industrial Revolution, which includes developments in previously disjointed fields such as artificial intelligence and machine-learning, robotics, nanotechnology, 3-D printing, and genetics and biotechnology, will cause widespread disruption not only to business models but also to labor markets over the next five years, with enormous change predicted in the skill sets needed to thrive in the new landscape.

Top 10 skills

in 2020	in 2015
1. Complex Problem Solving	1. Complex Problem Solving
2. Critical Thinking	2. Coordinating with Others
3. Creativity	3. People Management
4. People Management	4. Critical Thinking
5. Coordinating with Others	5. Negotiation
6. Emotional Intelligence	6. Quality Control
7. Judgment and Decision Making	7. Service Orientation
8. Service Orientation	8. Judgment and Decision Making
9. Negotiation	9. Active Listening
10. Cognitive Flexibility	10. Creativity

the act or practice of thinking critically (as by applying reason and questioning assumptions) in order to solve problems, evaluate information, discern biases, etc.

the set of skills, methods, etc. involved in critical thinking

A process/framework exist in many Critical thinking approaches to break down a logical flow of gathering / evaluating information

We have many other process examples in

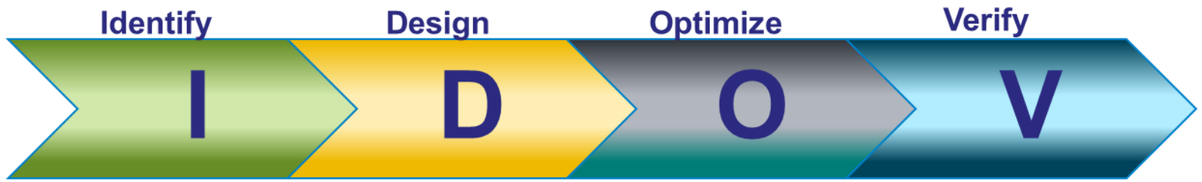
- Problem Solving/Six Sigma - DMAIC process
- Deming's - PDCA cycle
- DFSS - IDOV or DMADV process
- FDA Design Controls
- R&D Product Launch - Stage Gate System

What is unique in Critical Thinking - how we challenge the evidence Understanding **Biases and Fallacies** that can be recognized and removed or compensated for, or using metal models to help guide us All to make **the Right Decision or Judgement**

Design For Six Sigma

Why this approach?

- DFSS integrates with a new product development or a change in an existing Product or Process
- DMAIC is a specific methodology that is more prescriptive in solving a problem or Issue within the parameters of an existing Design/Product.
- DFMA is a tool / approach that is taught as part of the DFSS Methodology for the specific purpose of changing a Design to make it easier to produce.
- For a value-added activity –the IDOV framework adjust to focus of reducing cost while maintaining Quality of the Design Capabilities
- The IDOV workstream reflects the principles of a Stage Gate Process without all the baggage – this allows for a proactive approach to de-risk your Stage Gate and optimize faster.



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IDOV Methodology – Frames a Workstream (Event)

Identify	Design (Measure)	Optimize	Verify (Value)
• Identify the right Program/Focus • Identify the Design and Process. • Communicate to the team	• **Baseline DFA Analysis**	• **Brain Storming DFA issues** • **Focused Facilitation** • **Pugh Matrix**	• **Improved Design - DFA Analysis** • **Prioritize Scope (Value Curve) / Initial plan for Implementation**
What are we working on?	Measure the Baseline Design.	Optimize the Design.	Verify Improvements have Value. Plan next Workstream

Identifying the right Project

Why would we do this?

- Looking for Value - Benefits/Cost and for Design Changes, Time is money

Historically what gives us the most Value?

- Priority of Cost Reductions 1 – Eliminate Waste, 2 – Tactical changes, 3 – Strategic Changes only when necessary (typically these should be rolled into New Products)

What to look for

- Neglected products
  - 1st to market under pressure with no or limited DFMA
  - Product has been in Production for many years with no or limited design revisions
- Product that have a future
  - Design that has 2 years before revision/end of life- need time for V&V and payback
- Matter of Survival
  - Margins are getting Tighter – Due to inflation of cost or market pressures to reduce price
  - Process Improvements have been exhausted – Limit to Leaning out the process without Design

Note ALL selections come with Risk and results can vary

DFA Process

Step 1 – Understand the Design Intent and assembly process – (Identify)

- Product Information: Review *functional /performance requirements , Drawings*
- Functional analysis , P Diagram review
- Process Map of Assembly, Review Quality issues, Actual COGs breakdown

Step 2 – Perform the Initial DFA Analysis– Identify Opportunities for (Design – Measure)

- Part count reduction
- Quality (mistake proofing)
- Handling and Insertion
- Secondary Operations
- Part cost reduction opportunities – No change to fit performance or function.

Step 3 – Create solutions based on analysis (with solution risk ranking) (Optimize - -Improvements)

- Methodically brainstorm ideas based on Opportunities (Line by Line)
- Use additional Creativity Tools for stubborn High Value Opportunities

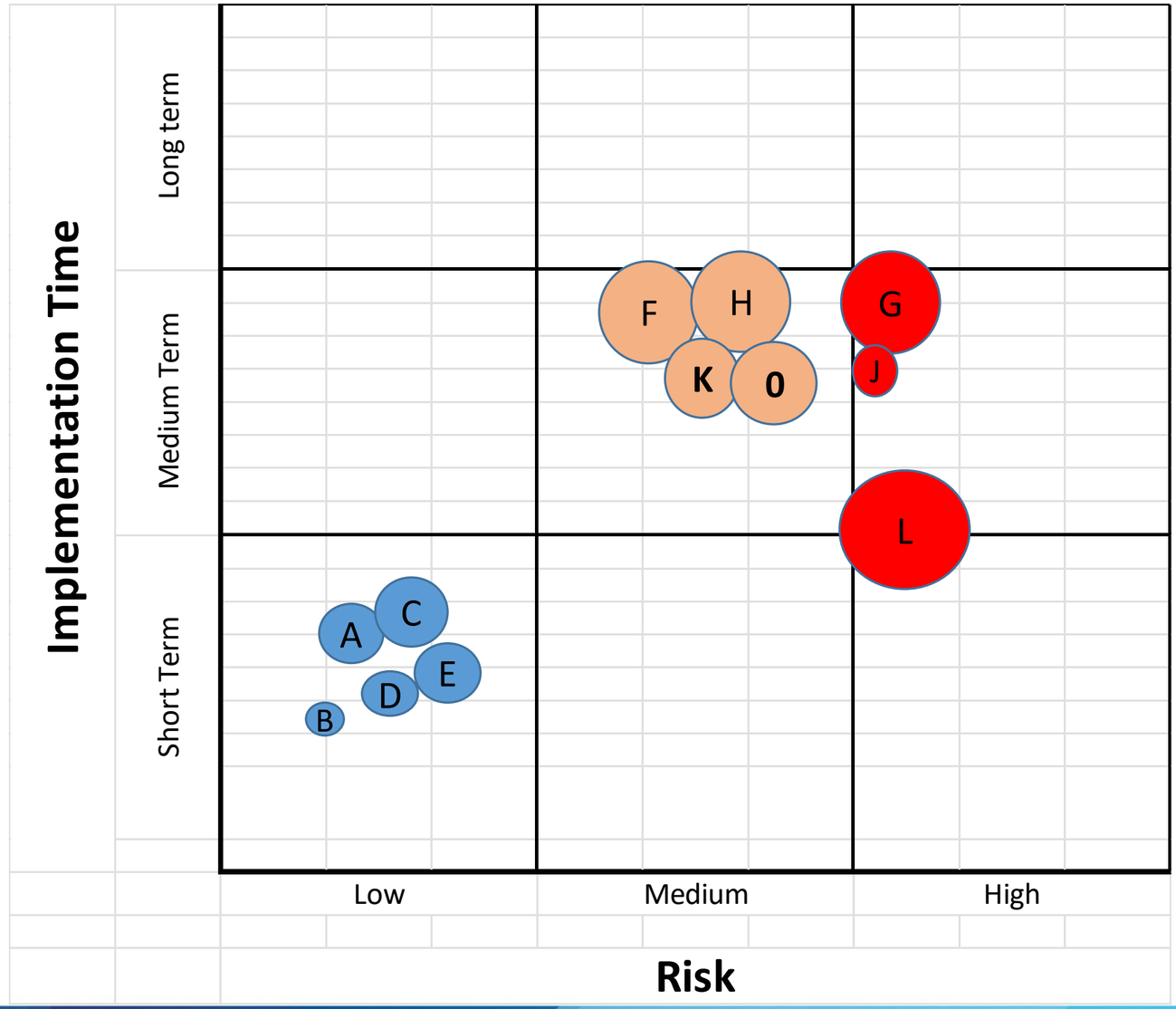
Step 4 - Select Best Solutions with considerations for Risk, Cost and Schedule (Optimize – Selection)

- Use Risk Vs Implementation Time to sort solutions
- Use Pugh Matrix or AHP matrix for difficult decisions

Step 5 - Evaluation of expected results with final DFA Analysis (Verify –Estimated Results)

Step 6 - Implement Solutions and communicate unresolved issue to Manufacturing (Verify – Plan)

DFA Analysis – Initial evaluation of Ideas



Color Coded Grouping help to sort by Risk

DFA – Evaluation - Modified Pugh Matrix

Idea Number (Weight)	Biggest Concern	Risk (technical and project) (6)		Time to Implement (Time to release and Inventory) (6)		Cost Savings %total/year (rough estimation with estimations) (8)		Quality (Customer and internal) (10)		Strategic Alignment (7)		Cost to Implement (Capital and resources) (8)		Overall Score
A-E - Low risk	Still need to send a wwcn to all customer and notified Body for all changes - for approval	No foreseen tech risk	5	TBD - No aging	5	9.6%	4	Only concern is mixing of product	4	No change	3	Mold Modifications (<20K)- Pins only plus V&V test (Supplier cost is 40K) Validation minus lite NPI/CPI)	4	185
F	- Strength of the new/alternate material going to be comparable? - Biocompatibility?	Re-executing design verification protocols to verify functional requirements are still met with new material	3	18 - 24 months Full design verification. Assy verification. Age verification.	3	10.2%	5	- Customer acceptance (stretchy/sticky /cosmetic difference)	3.5			- Engineering support - Samples - Tooling - Validations	4	143
O	- Cutting into sterile pouches when opening outer box?	Customer acceptance? With potential for cutting bags and no small boxes	3	6-12 months	5	4.3%	3	Need marketing / customer feedback	3			Cost for packaging testing	5	142
H	- Age testing required - Biocompatibility required - Adhesive strength vs. stitching??	- New method of fixation - technical concerns on passing	2	18 - 24 months Full design verification. Assy verification. Age verification.	3	9.9%	5	- Messy? - Quantity of adhesive vs. # of stitches	3			- Engineering support - Samples - Tooling - Validations	4	132

DFA Analysis

Design level	Part Count	Poke Yoke Opportunities	# Part with Cost Reductions	Overall % Cost Savings
Baseline	18	15	0	NA
Low Risk	18	15	5	9.6%
Med/High Risk	13	9	3	51.9%

Processing Changes were calculated separately by the supplier ad included Lean workshop results

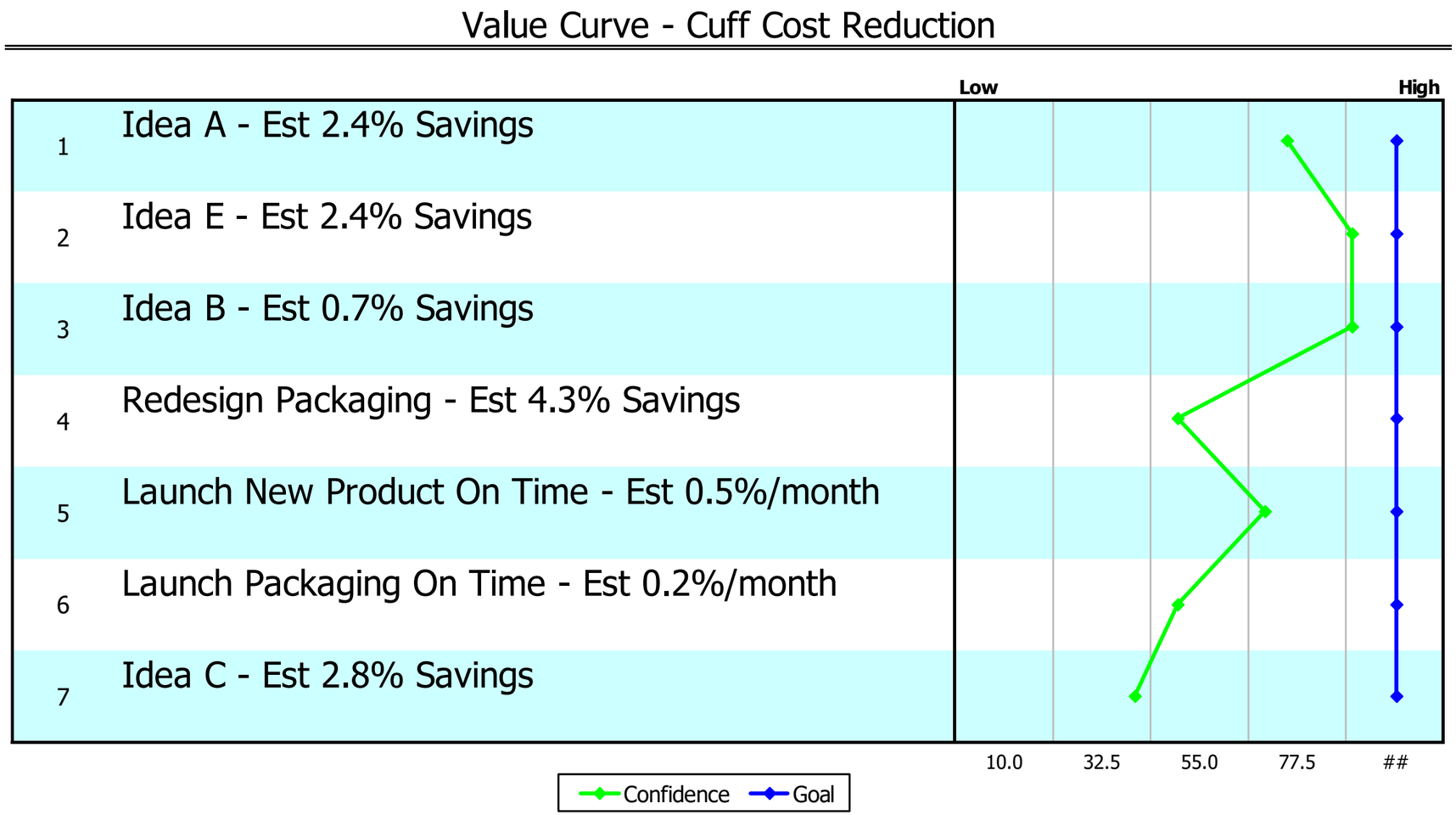
Lesson's Learned

- Gain as much information as possible before the event
- A good Cross functional Approach is very helpful
- Listen – sometimes the best ideas are not expected – Material vs Part count reduction

Next Steps

- Start planning the next steps at the event
- Once agreed to a Value Curve is a great tool to keep priorities in focus

DFA – Change Project Scope - Modified Value Curve



The X Axis was used to indicate Initial confidence

DFA Workshop – Final Thoughts

The (DFA) Event [+]

- Encourages decisions
- Motivates and Challenges People
- Is a Calendar issue
- Is the easier part of this Process

Execute[+] - to Implement the Design Changes

- Encourages Development
- Changes and Matures People
- Is a Culture Issue
- Is the harder part of this Process
- Should verify no changes to Design Quality

[+] Reference : John C Maxwell " 21 Irrefutable Laws of Leadership" Chapter 3 ' " The Law of Process", 1998

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