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ENGINEERING PHARMACEUTICAL INNOVATION

ISPE

Design for Six Sigma

The Key to Efficient Innovation

Presented by the North Haven Group, LLC
Philip J. Ramsey, Ph.D. – pramsey@northhavengroup.com
Marie A. Gaudard, Ph.D. – mgaudard@northhavengroup.com
Mia L. Stephens, M.S. – mstephens@northhavengroup.com

What is DFSS?

- A structured approach for designing new products, processes and/or services, or for redesigning existing products, processes and/or services;
- An approach for building quality into the product during development;
- A toolbox, containing engineering and statistical tools;
- A method for ensuring that customer expectations are understood and are met or exceeded.

What is DFSS?

- The basic algorithm for DFSS is known as **IDOV**. We discuss the details shortly.
- Traditional Six Sigma for continuous improvement almost universally uses the **DMAIC** algorithm as a basis for organizing project work.
- Design for Six Sigma or DFSS does not have a consensus among practitioners as to a best algorithm.
- Countless variants to IDOV exist, but all share a core set of concepts and tools.

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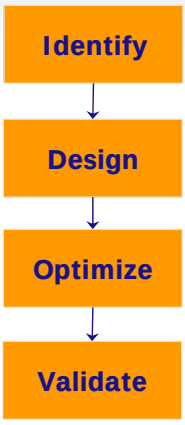
The IDOV Process

The primary deliverables of IDOV are:

- **Identify** the voice of the customer (VOC), translate customer needs into functional responses (CTCs), and prioritize CTCs.
- Translate functional responses into product **design** characteristics and process variables, and develop transfer functions
- Predict process capability, **optimize** the design, and develop tolerances
- **Validate** performance, address gaps in capability, and implement process controls



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The IDOV Process

Key activities are summarized in the IDOV checklist:

Identify	*Design*	*Optimize*	*Validate*
Review initial project charter	Develop design concepts	Apply robust design	Finalize design details
Form team and identify necessary training	Evaluate design concepts, and select the best concept	Define tolerances, and determine if they are acceptable	Develop process map or value stream map
Develop project milestones, a project plan, and a communication plan	Use DFMEA to analyze design and idenfity risks, and apply mistake-proofing	Use transfer functions and simulation to determine ability to meet functional requirements	Use cause and effect diagrams, and QFD 4, and FMEA to identify critical process controls
Identify customer requirements (VOC)	Develop design validation test plan (DVP)	Use QFD 3 to identify critical process variables	Develop process control plan
Use QFD House 1 to translate customer requirements into funtional responses (CTCs)	Use QFD 2 to translate CTCs into design characteristics.	Apply design for manufacturing (DFM)	Complete the design validation plan (DVP)
Prioritize CTCs, add specs and targets	Begin to develop transfer functions	Use process FMEA to identify and mitigate risks	Perform gap analysis
Populate performance scorecard	Update scorecard	Update scorecards	Update scorecards
Gate Review - Go/Kill	Gate Review - Go/Kill	Gate Review - Go/Kill	Gate Review - Go/Kill

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Lean Six Sigma

Whereas DFSS is used for design or redesign, Lean6Sigma is used to improve existing processes. Lean6Sigma is:

- A **business strategy** for continuous improvement, integrating lean and 6 sigma tools and methods
- A **fact-based, data-driven problem solving** methodology (DMAIC):
  - Define
  - Measure
  - Analyze
  - Improve
  - Control

A toolkit, providing a variety of problem solving, project management, lean and statistical tools.

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The DMAIC Process

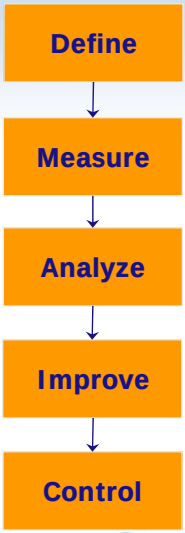
The process is **defined**, and key process inputs and outputs are identified.

Key characteristics are **measured**, measurement systems are evaluated, a baseline is established, and process capability is assessed.

Root causes of problems are identified using analytic and statistical tools, and opportunities for improvement are identified.

Potential solutions are identified, evaluated, tested, and implemented.

The **process is monitored and controls are implemented**, and new methods and processes are standardized.



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Transactional Six Sigma

Six Sigma was originally developed at Motorola in the 1980's by an engineer named Bill Smith.

The original focus of Six Sigma was on improving yields of manufacturing processes.

In recent years there has been a recognition that large gains in business performance can be made in non-manufacturing areas.

A version of Lean6Sigma referred to as Transactional Six Sigma has evolved to achieve continuous improvement in these non-manufacturing areas.

Transactional Six Sigma uses the DMAIC process, however, the emphases and tools differ from the manufacturing version.

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Visual Six Sigma

An innovative and “leaner” approach to Six Sigma is evolving which relies on the powerful and dynamic visualization capabilities of modern statistical software.

The goal of Visual Six Sigma (VSS) is to reduce the amount of time needed to achieve results in a Six Sigma project.

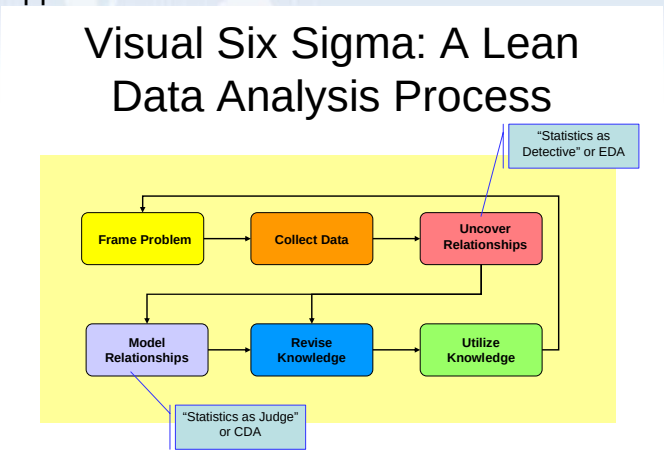
VSS uses visualization on existing or newly generated databases to explore relationships among variables and generate causal hypotheses, which may be confirmed in several ways.

We will be publishing a case study oriented book, based upon the JMP® statistical software, on VSS in the first half of 2009.

The next slide contains a VSS project roadmap.

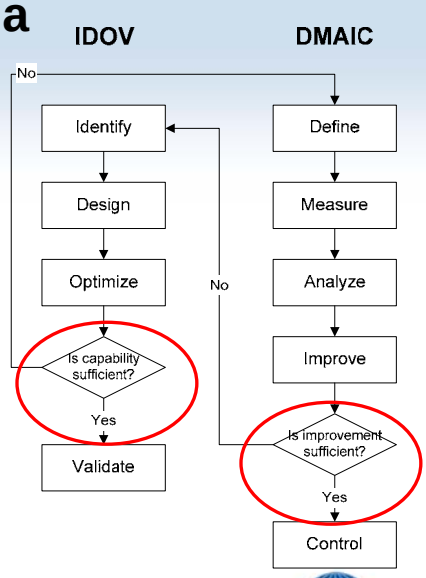
Visual Six Sigma

The VSS approach:



DFSS and Lean6Sigma

- Design for Six Sigma and Lean6Sigma are linked:
- DFSS may be used for redesign if it is determined that the product or process, even after improvements, will never meet customer expectations.
- Lean6Sigma may be used to reduce variation when process capability is insufficient.



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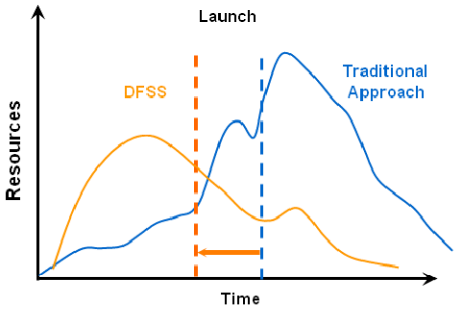
Why DFSS?

Up to 80% of overall costs are established during the design phase. The remaining 20% are fixed during or after launch.

DFSS invests time and resources early in the product development cycle to:

- Lower development and overall product cost;
- Speed time to market;
- Efficiently utilize resources (rather than fire fighting);
- Produce robust product designs;
- Satisfy customer needs.



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Why DFSS?

The DFSS Vision

- From reactive design …
- Changing requirements, multiple design iterations
- Supplier or process capability issues after launch
- Multiple build-test performance evaluation cycles
- Performance issues addressed after product launch
- 'Tested-in' quality

- ... to predictive design
- Disciplined requirements flow-down
- Capability estimates factored into design analysis
- Product performance modeled and simulated
- Robust design and Design for Manufacturing (DFM), issues addressed prior to launch
- 'Designed-in' quality

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DFSS Tools

On the following slides, we will introduce some common tools used by DFSS teams.

These include:

- VOC, Conjoint Analysis, Data mining
- Quality Function Deployment
- Transfer Functions
- Scorecards
- FMEA
- Design Validation Test Plans
- Communication Plans
- Designed of Experiments (DOE)
- Robust Design
- Tolerance Design
- Control Plans

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Tools: Conjoint Analysis

Voice of the customer or **VOC** is critical to designing a product or process that meets or exceeds customer requirements.

Much literature exists on VOC, however a more quantitative approach is known as **Conjoint Analysis**.

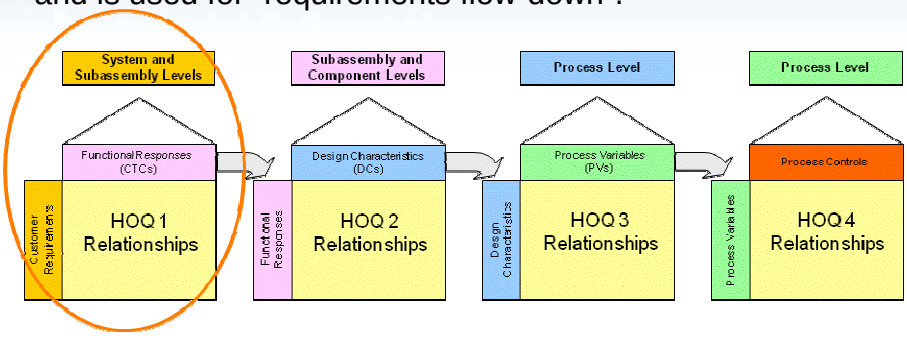
Conjoint Analysis is a cousin of design of experiments. It allows designers to uncover important characteristics to the customer as well as important interactions among those characteristics.

For example, a customer may be more likely to purchase a more expensive cell phone only if it is bright red and has a larger keypad.

Conjoint Analysis allows one to develop statistical models to predict customer preferences and associated cost models.

Tools: Quality Function Deployment

Quality Function Deployment (QFD) consists of four "houses", and is used for "requirements flow-down".

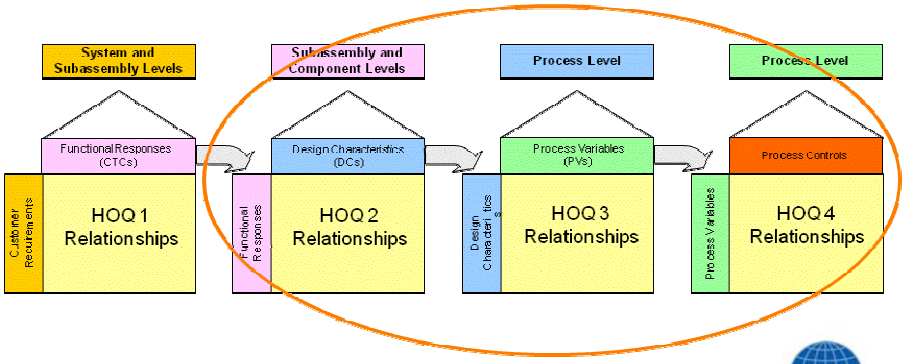


House 1, which is perhaps the most important, translates customer requirements (VOC) to **measurable** system level functional responses (CTC's).

Tools: Quality Function Deployment

House 2 relates the functional responses to design characteristics.

Houses 3 and 4 relate the design characteristics to process variables and manufacturing controls, respectively.



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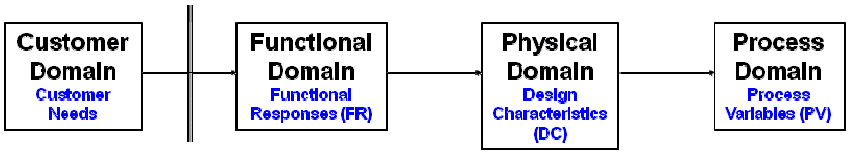
Tools: Transfer Functions

There are three “domains” of interest in design:

- The functional domain
- The physical domain, and
- The process domain

This following schematic shows the design flow, in terms of “domains”.



For a complex part, each of these domains will have a hierarchical structure.

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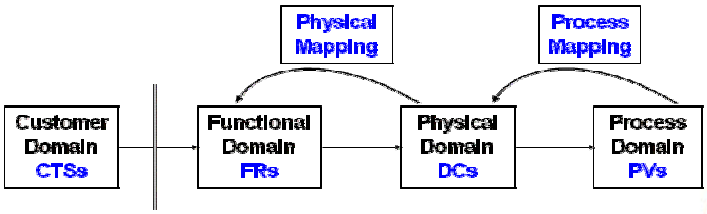
Tools: Transfer Functions

A transfer function is a function that relates one set of variables to another.

Two transfer functions are of major interest in DFSS projects.

- The Physical Mapping relates the design characteristics to the functional responses.
- The Process Mapping relates the process variables to the design characteristics



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Tools: Score Cards

Scorecards are living documents used to track and summarize performance across the functional, physical, and process domains.

The probability of system conformance, as well as yield based on DPU, are computed from the individual scorecards.

Below, we see an example of a Part/Component scorecard, and the resulting Product summary information.

Part/Component Scorecard

Row Number	Characteristics	Component	Number Required for Assembly	Continuous or Nominal	Source of DPU Estimate	Stability Bas ed on Control Chart?	Sample Size	If Continuous: Unit of Measure	Spec Type	Target	LSL	USL	Mean	St Dev	If Nominal: Actual No. Defective	ST or LT Sample Cpk	If From Other Source: Estimated Cpk	Estimated Prop Defective	Cpk Value	Prop Defective Value	Contribution to DPU Value (Need "Number Requ Red")
1	Width	Tire	2	Continuous	ST Sample	Yes	20	Inches	Two-Sided	1.50	1.48	1.52	1.494	0.002		1.555556			1.555556	0.000015306	0.000030613
2	Diameter	Wheel	2	Continuous	ST Sample	Yes	25	Inches	Two-Sided	26.00	25.95	26.05	26.00	0.02		0.222222			0.222222	0.256329181	0.512658362
3	Weight	Rim	2	Continuous	LT Sample	Yes	100	Grams	LSL Only	395.00	395		470	2.5		2.000000			2.000000	0.000000010	0.000000020
4	Weight	Rear Strailer	1	Continuous	LT Sample	Yes	100	Grams	Two-Sided	280.00	275	285	283	1.2		0.555556			0.555556	0.047790353	0.047790353

Summary Scorecard

	Number of Components/ Steps/FRs	Capability Growth Index	DPU Sum	Prob of Conformance for System	System Cpk	Normalized Cpk	Yield Based on DPU
Performance							
Product	7	54.17%	0.560439250	0.5266232700	0.0222614	0.1705280	0.5709582154
Process							

Tools: FMEA

FMEAs are living documents used to uncover problems in designs, or in the manufacture of product, that could result in product failures or safety risks

- **Design FMEAs** (**DFMEA**) are used during the Design phase
- **Process FMEAs** (**PFMEA**) are used during the Design and Optimize phases.

Process/Product FMEA Form

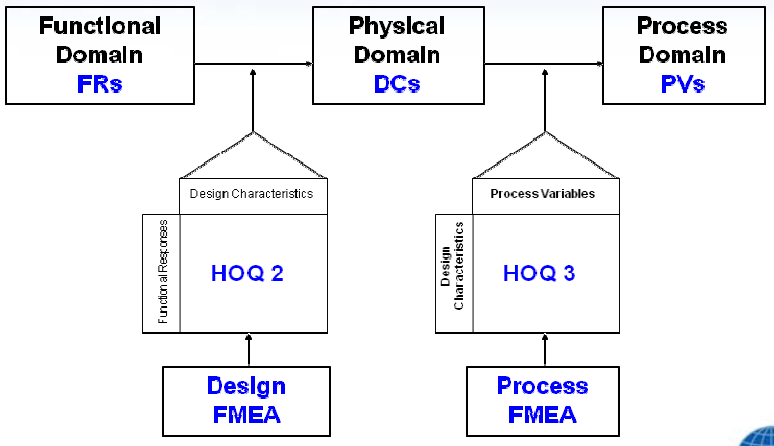
Process or Product Name _____ Date: _____

Prepared By: _____ Page ____ of ____

Step/Function	Potential Failure Mode	Potential Effects	Sever	Potential Causes	Occur	Current Control	Detect	RPN	Recommended Actions	Resp	Action and Results

Tools: FMEA

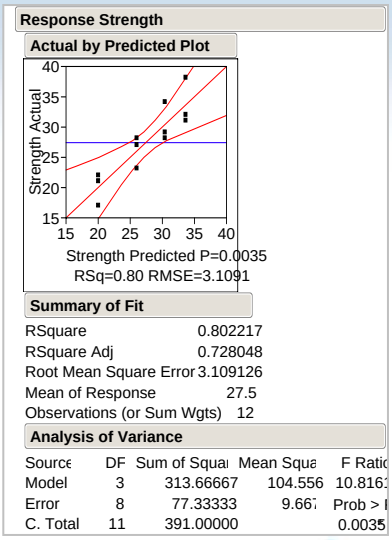
DFMEAs and PFMEAs are related to HOQs 2 and 3, as shown in the schematic below.



Tools: Design of Experiments

DOE is a structured, efficient approach in which factors are systematically changed and the effects on the response(s) are observed. DOEs are used to:

- determine if factors have an effect on the response,
- determine if two or more factors interact in their effect on the response, and to
- model the behavior of the response as a function of the factors.



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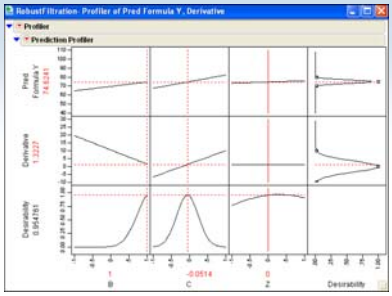
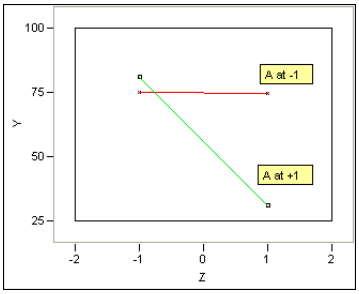
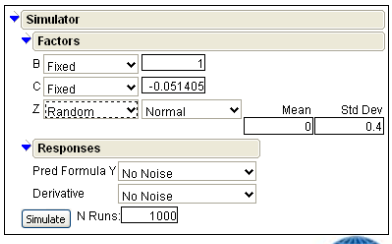
Tools: Robust Design

Robust design is a statistical/ engineering methodology employed to optimize a process or product in terms of its mean performance and variation.







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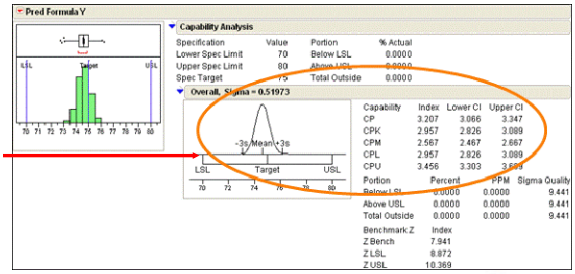
Tools: Robust Design

The goals of robust design are to:

- Find and adjust the fixed settings of the control factors to optimize mean performance,
- Simultaneously make that performance insensitive to variation in the noise factor settings.

Predicted capability based on experimentation (robust design) and simulations



Tools: Tolerance Design

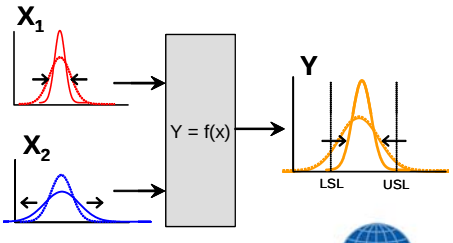
Tolerance Design utilizes analytical and statistical methods to optimize tolerances.

This involves using transfer functions to determine the sensitivity of the output, Y, to the inputs, or Xs.

Suppose that, for the transfer function f, Y is very **sensitive** to variation in X_1, but **robust** to variation in X_2.

Then, as suggested in the diagram, we may be able to optimize the response and minimize cost by:

- reducing variation in X_1, and
- allowing more variation in X_2.



Tools: Control Plans

Process controls are identified using QFD 4 in the validate phase.

A control plan is a summary of the types of process controls that will be used to monitor and control critical process variables (KPOVs and KPIVs).

Process Control Plan - Surface Defects on Cups Project

Operation	Characteristic	Measurement Method	Responsible	Frequency	Type of Control	Signal	Corrective Action	Responsibility
Washing	Water consumption	Observation of reservoir level	Operator	Daily	Pass/fail	more than 10, less than 30	Check supply lines for leaks and valves for correct settings. See WI-027RevA.	Operator
	Bath concentration	10ml sample from tank 4??	Lab technician	Daily	SPC	out of control condition	Add chemicals as directed by lab technician. Sample additional parts and re-wash if required.	Operator
	Product cleanliness	50 piece random sample (pull evenly from available boxes) once	Lab technician	Daily	SPC	out of control condition	Contain suspect production. Notify supervisor and investigate.	Quality?

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DFSS Case Study
Design and Build a Better Bicycle

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Case Study: Build a Better Bicycle

A team has been asked to develop a bicycle that will meet the needs of multiple demographic groups.

Customer requirements for different demographic groups and intended uses were summarized using a VOC Table.

VOC Summary Table for Multi-purpose Bicycle		
Demographic Information	**Intended use of Product or Service**	**Customer Requirement**
Age 18-29, predominantly males	Off road and city, medium to long distances	Fast, lightweight, attractive, rugged
Age 30-50, females	Gentle trails and city, short to medium distances	Comfortable, attractive, easy to use, easy to maintain
Age 30-50, males	Off-road and city, medium to long distances	Fast, lightweight, comfortable, easy to maintain, easy to transport
Age >50, males and females	Gentle trails and city, short to medium distances	Comfortable, easy to use, easy to maintain, rugged, inexpensive

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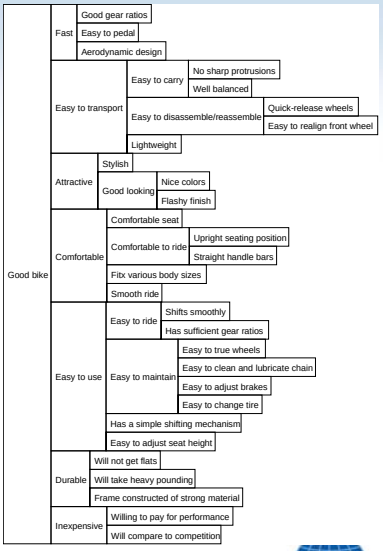
Case Study: Build a Better Bicycle

A **tree diagram** was used to organize and analyze VOC data collected by the team.

Tree diagrams can also be used to help expand ideas, or to fill in gaps or missing thoughts.

Note many approaches exist to organizing and analyzing VOC data.

Other common tools are Affinity Diagrams, KJ Analysis, and Kano Analysis.



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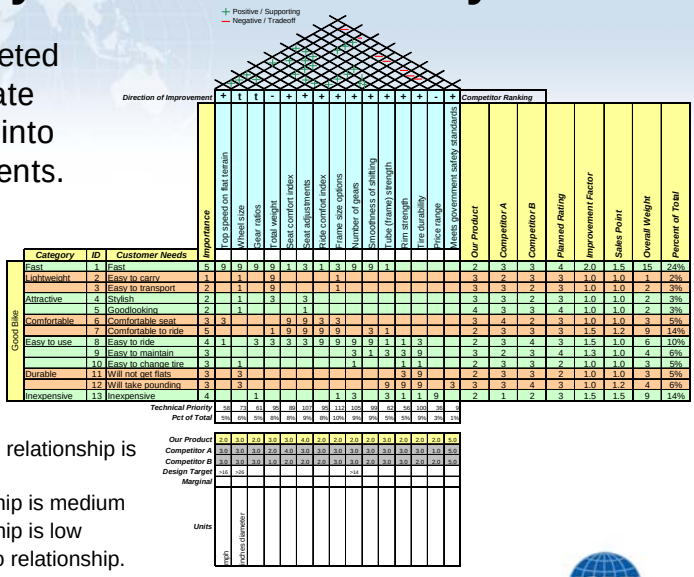
Case Study: Build a Better Bicycle

The team completed **HOQ 1** to translate customer needs into design requirements.



Put a “9” in the box if the relationship is high

Use a “3” if the relationship is medium

Use a “1” if the relationship is low

Leave blank if there is no relationship.

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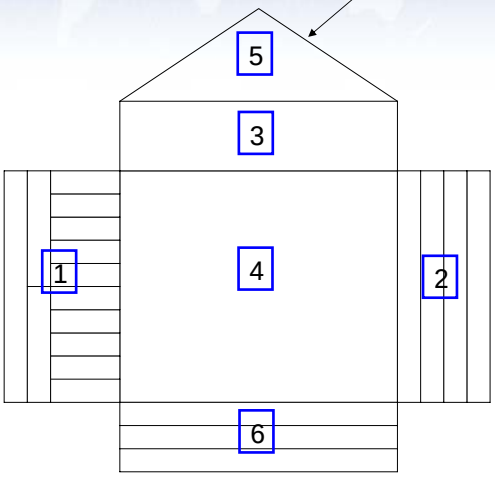
Case Study: Build a Better Bicycle

The QFD Structure

The “roof” of the House of Quality



House 1 is typically filled out in the following order:

1. Customer needs
2. Planning matrix
3. Functional Response
4. Relationships
5. Technical correlations
6. Technical targets, etc.

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Case Study: Build a Better Bicycle

Next, the team used a **design synthesis matrix** to identify solutions to the functional responses from HOQ 1. Combinations of solutions define potential design concepts.

Functional Response	Solution				
Top speed on flat terrain					
Wheels	Off-road tire	Medium wide high pressure slick	Wide high pressure slick	Robust wide touring	Wide slick
Handlebar design	Drop handlebars	Regular handlebars			
Wheel size	26 inch	27 inch	29 inch		
Gear ratios*	Gear Set 1	Gear Set 2	Gear Set 3	Gear Set 4	
Total weight					
Frame weight	Titanium tubing	Aluminum tubing	Carbon fiber	Cast magnesium	
Total wheel weight	3.79 lbs.	2.69 lbs.	2.88 lbs.	3.21 lns.	3.95 lbs.
Drivetrain	5.0 lbs.	5.5 lbs.	6 lbs.		
Seat comfort index					
Shape	Shape1	Shape2	Shape3		
Material	Material1	Material2	Gel		
Construction	Springs	No springs			
Seat adjustments	Height	Tilt	Height and tilt	Height, tilt, springiness	
Ride comfort index	Triangular design	Recumbent			
Frame size options	Male only - 1	Male only - 2	Male only - 3	M/F - 3 sizes	
Number of gears	15	10	12	18	24
Gear range	Lo1 - High1	Lo2 - High2	Lo3 - High3	Lo4 - High4	Lo5 - High5
Smoothness of shifting	Friction shifting	Indexed shifting			
Tubing strength	Steel	Titanium	Aluminum		
Rim strength					
Material	Aluminum alloy	Carbon fiber	Steel		
Construction	Single wall	Double wall			
Tire durability	Brand 1	Brand 2	Brand 3	Brand 4	
Price range	$300-$399	$400-499	$500-599	$600-699	$700-799

* A gear set is a specification of the number of front gears and number of rear gears, and their sizes.

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Case Study: Build a Better Bicycle

The team identified five potential design concepts. The first design concept was used as a baseline, or datum, for comparisons.

Datum	Concept 1	Concept 2	Concept 3	Concept 4
Robust wide touring tires	Medium wide high pressure slick	Wide slick tires	Wide high pressure slick tires	Medium wide high pressure slick tires
Regular handlebars	Regular handlebars	Regular handlebars	Drop handlebars	Drop handlebars
27 inch wheels	26 inch wheels	27 inch wheels	29 inch wheels	27 inch wheels
Gear Set 4	Gear Set 2	Gear Set 2	Gear Set 3	Gear Set 2
Aluminum tubing	Aluminum tubing	Titanium tubing	Carbon fiber	Aluminum tubing
2.88 lbs. wheel weight	2.69 lbs. wheel weight	3.95 lbs. wheel weight	2.88 lbs. wheel weight	2.69 lbs. wheel weight
5.0 lbs. drivetrain weight	5.5 lbs. drivetrain weight	6 lbs. drivetrain weight	6 lbs. drivetrain weight	5.5 lbs. drivetrain weight
Seat shape3	Seat shape2	Seat shape2	Seat shape3	Seat shape2
Seat: Gel	Seat Material2	Seat Material1	Seat: Gel	Seat Material2
No springs in seat	No springs in seat	Springs in seat	No springs in seat	No springs in seat
Height and tilt adj -seat	Height adj -seat	Height and tilt adj -seat	Height and tilt adj - seat	Height adj -seat
Triangular design	Triangular design	Recumbent	Triangular design	Triangular design
Male only - 2	Male only - 2	Male only - 3	M/F - 3 sizes	Male only - 2
15 gears	10 gears	24 gears	12 gears	10 gears
Lo5 - High5	Lo2 - High2	Lo5 - High5	Lo3 - High3	Lo2 - High2
Indexed shifting	Indexed shifting	Indexed shifting	Friction shifting	Friction shifting
Aluminum tubing	Titanium tubing	Steel tubing	Aluminum tubing	Titanium tubing
Aluminum alloy rims	Carbon fiber rims	Aluminum alloy rims	Steel rims	Carbon fiber rims
Single wall rims	Double wall rims	Double wall rims	Double wall rims	Single wall rims
Brand 2 tire material	Brand 2 tire material	Brand 4 tire material	Brand 3 tire material	Brand 2 tire material
$400-499	$400-499	$700-799	$500-599	$400-499

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Case Study: Build a Better Bicycle

The team used a **weighted Pugh Matrix** to compare potential design concepts.

The team wants to know the following:

- Does any one design concept stand out as being the best?
- Do any concepts have a lot of weaknesses compared to the datum?

Pugh Concept Selection Matrix

Functional Responses	Technical Priority	Concepts: Datum	Concept 1	Concept 2	Concept 3	Concept 4
Top speed on flat terrain	58	0	+	-	-	s
Wheel size	73	0	-	s	+	s
Gear ratios	61	0	s	+	+	-
Total weight	95	0	s	+	-	s
Seat comfort index	89	0	s	-	+	-
Seat adjustments	107	0	-	s	s	-
Ride comfort index	95	0	+	s	+	-
Frame size options	112	0	s	+	+	+
Number of gears	105	0	-	+	-	-
Smoothness of shifting	99	0	s	s	-	-
Tube (frame) strength	62	0	+	-	s	+
Rim strength	56	0	+	s	s	+
Tire durability	100	0	s	-	+	s
Price range	36	0	s	-	-	s
Meets government safety standards	9	0	s	s	s	s
Sum of Positives (+)			271	373	530	230
Sum of Negatives (-)			285	345	393	556
Sum of Ss (Sames)			601	439	234	371

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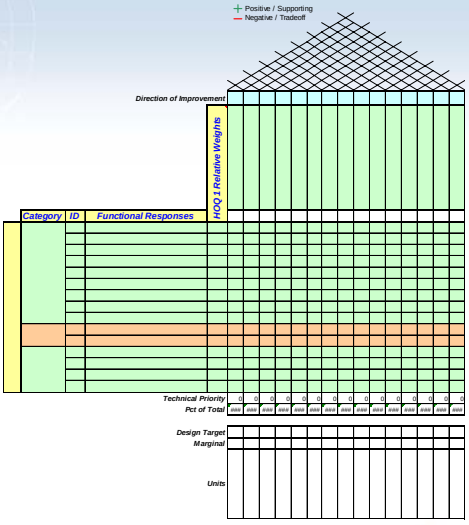
Next, the team used a **Process FMEA** to identify potential problems with the selected design concept.

They also used **HOQ 2** to translate functional responses into design characteristics for the selected design concept.

HOQ 2 is very similar in structure to HOQ 1.



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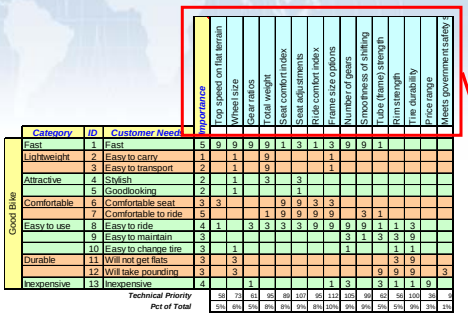
Case Study: Build a Better Bicycle



Category	ID	Customer Need	Importance	Top speed on flat terrain	Wheel size	Gear ratios	Total weight	Seat comfort index	Seat adjustments	Ride comfort index	Frame size options	Number of gears	Smoothness of shifting	Tube (frame) strength	Rim strength	Tire durability	Price range	Meets government safety s
Good Bike																		
Fast	1	Fast	5	9	9	9	9	1	3	1	3	9	9	1				
Lightweight	2	Easy to carry	1		1		9				1							
	3	Easy to transport	2		1		9				1							
Attractive	4	Stylish	2		1		3		3									
	5	Goodlooking	2		1				1									
Comfortable	6	Comfortable seat	3	3				9	9	3	3							
	7	Comfortable to ride	5				1	9	9	9	9		3	1				
Easy to use	8	Easy to ride	4	1		3	3	3	3	9	9	9	9	1	1	3		
	9	Easy to maintain	3									3	1	3	3	9		
	10	Easy to change tire	3		1							1			1	1		
Durable	11	Will not get flats	3		3										3	9		
	12	Will take pounding	3		3									9	9	9		3
Inexpensive	13	Inexpensive	4			1					1	3		3	1	1	9	
		Technical Priority		58	73	61	95	88	107	95	112	105	99	62	58	100	36	9
		Pct of Total		5%	6%	5%	8%	8%	9%	8%	10%	9%	9%	5%	5%	9%	3%	1%

Functional responses from HOQ 1 are inputs to HOQ 2.

Grouped by subassembly where possible

Category	ID	Functional Responses	Importance
Good Bike			
Overall bike	1	Top speed on flat terrain	5%
	2	Total weight	8%
	3	Ride comfort index	8%
	4	Price range	3%
	5	Meets government safety standard	1%
Wheel/Tire	6	Wheel size	6%
	7	Rim strength	5%
	8	Tire durability	9%
Gear System	9	Gear ratios	9%
	10	Number of gears	9%
	11	Smoothness of shifting	9%
Seat	12	Seat comfort index	8%
	13	Seat adjustments	9%
Frame	14	Frame size options	10%
	15	Tube (frame) strength	5%

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A partial list of design requirements for the bicycle has been added.

Separate houses may be built for each subassembly, particularly with “complex” products.

Category	ID	Functional Response	Importance	Tire width	Tire material	Tread design	Handle bar geometry	Wheel diameter	Sprocket size	Number of teeth	Number of front sprockets	Number of back sprockets	Carbon fiber composite	Rim material	Rim weight	Rim design	Number of spokes	Spoke design
Good Bike																		
Overall bike	1	Top speed on flat terrain	5%															
	2	Total weight	8%															
	3	Ride comfort index	8%															
	4	Price range	3%															
	5	Meets government safety stand	1%															
Wheel/Tire	6	Wheel size	6%															
	7	Rim strength	5%															
	8	Tire durability	9%															
Gear System	9	Number of gears	9%															
	10	Smoothness of shifting	9%															
Seat	11	Seat comfort index	8%															
	12	Seat adjustments	9%															
Frame	13	Frame size options	10%															
	14	Tube (frame) strength	5%															

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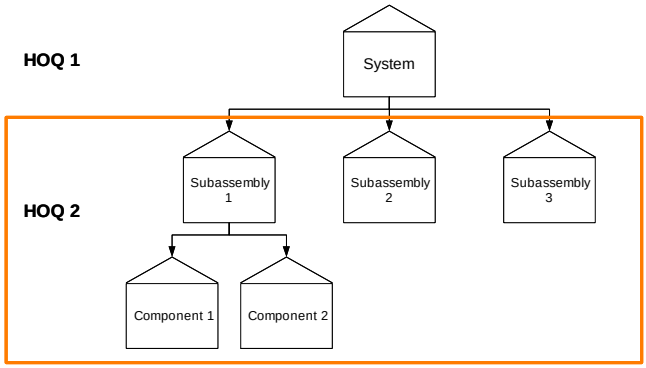
For both subassemblies and components, we use HOQ 2 to identify design characteristics (DCs) to satisfy functional responses (FRs) from HOQ 1.

This information is used to start building transfer functions.



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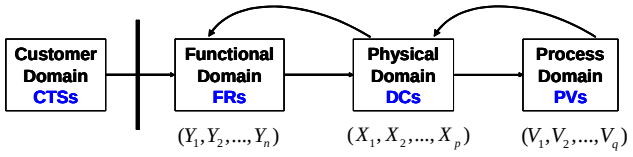
At a conceptual level, one can think of a single transfer function that relates all FRs (Ys) to all DCs (Xs):

$$(Y_1, Y_2, ..., Y_n) = f_{\text{Physical}}(X_1, X_2, ..., X_p)$$

Analogously, a single transfer function may be used to relate all DCs (Xs) to all Process Variables, or PVs (Vs):

$$(X_1, X_2, ..., X_p) = f_{\text{Process}}(V_1, V_2, ..., V_q)$$

By synthesizing these transfer functions, the designer will be able to track the effects of changes across the design to see their effect on the high-level FRs.



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Example. Consider our bicycle example.

A customer requirement is that **the bike rolls easily**.

This desire is translated to a high-level functional requirement for the bicycle assembly, called rolling resistance (or rolling friction): **Y = Rolling Resistance**

Rolling resistance depends on the coefficient of rolling resistance, which is a property of the wheel assembly.

The coefficient of rolling resistance is affected by tire material, tire contact area, flex in sidewalls, level of inflation, tread thickness, size of wheel.

So rolling resistance is affected by the **design of the tire and of the hub, rim, and spokes**.

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For the spoke, hub, and rim subassembly, certain critical parameters that drive rolling resistance include:

- Y_{21} = Rim circumference
- Y_{22} = Rim width
- Y_{23} = Rim geometry
- Y_{24} = Rim width uniformity

These are **high-level design characteristics (DCs) that affect the high-level functional response, Rolling Resistance**.

But these are also FRs at a lower level, namely for the rim subassembly. This is why these are denoted as Ys and why the subscript 2 appears in the notation for these FRs – they are at a second level in the hierarchy.

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One might begin the process of deriving transfer functions by relating each of the four Y_2s to critical design parameters for the spoke, hub, and rim subassembly.

For example, the second-level DCs on the previous slide are:

- X_{21} = Spoke length
- X_{22} = Spoke strength
- X_{23} = Hub geometry
- X_{24} = Rib material

Transfer functions for the Y_2s would include these as arguments (i = 1, 2, 3, 4):

$$Y_{2i} = f_{2i}(X_{21}, X_{22}, ...X_{24})$$

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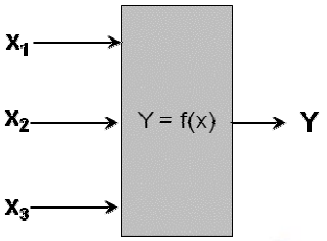
Transfer functions can be used to model both the mean and the variance for the functional responses.

$$Y_1 = f_1(x_1, x_2, ..., x_N)$$
$$Y_2 = f_2(x_1, x_2, ..., x_N)$$
$$Y_3 = f_3(x_1, x_2, ..., x_N)$$

Sources of transfer functions:

- Physical laws
- Engineering relationships
- Functional approximations to physical measurements
- Statistical models

$$Y = b_0 + b_1X_1 + b_2X_2 + b_3X_1X_2$$



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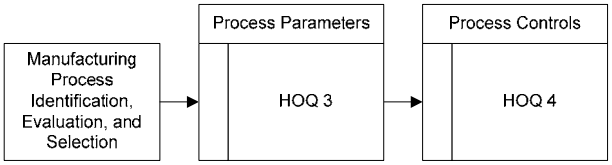
The team also begins to identify the manufacturing approach:

- The manufacturing approach is selected and detailed, and **design for manufacturing** concepts are applied.
- A **process FMEA** is used to evaluate the selected process.
- **HOQ 3** is used to identify key process output variables (KPOVs).
- **HOQ 4** is used to identify key process controls, or key process input variables (KPIVs).



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Tools: Summary of Tools by IDOV Phase

Identify	Concept	Design and Optimize	Validate
Project Charter	Concept Generation	Measurement System Analysis (MSA)	Process Map, VSM
Project Plan	Concept Selection	Regression	Transfer Functions
Communication Plan	QFD House 2	Design of Experiments (DOE)	Statistical Process Control (SPC)
Voice of Customer (VOC)	DFMEA	Transfer Functions	Capability
QFD House 1	Mistake-Proofing	Robust Design	DVP
Functional Responses (CTCs)	Design Validation Plan (DVP)	Response Distribution Analysis (RDA)	Gap Analysis
Performance Scorecard	Transfer Functions	Tolerance Intervals	QFD House 4
	Product Scorecard	Tolerance Design	Control Plans
		QFD Houses 2 and 3	Summary Scorecard
		Design for Mfg (DFM)	
		DVP	
		DFMEA and PFMEA	
		Reliability	
		Product and Process Scorecards	

The key tools used by a design team during the IDOV process are summarized here.

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Are you sure this is what the customer wants???

DFSS assures that a disconnect does not occur between the customers and the designers.

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About NHG

www.northhavengroup.com

North Haven Group (NHG) is a limited liability company registered in the state of New Hampshire, providing comprehensive consulting and training for industry and service organizations.

NHG provides worldwide consulting and support for Six Sigma quality programs to improve manufactured products and business processes.

With over 60 years of combined experience, the partners of NHG provide a unique combination of outstanding academic credentials and expertise in the application of statistical techniques and continuous improvement methods.

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