

ENGINEERING PHARMACEUTICAL INNOVATION



Design for Six Sigma The Key to Efficient Innovation

Presented by the North Haven Group, LLC

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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?

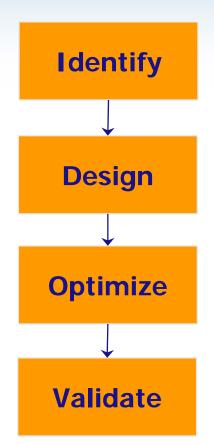
- The basic algorithm for DFSS is known as IDOV. We discuss the details shortly.
- Traditional Six Sigma for continuous improvement almost universally uses the **DMAIC** algorithm as a basis for organizing project work.
- Design for Six Sigma or DFSS does not have a consensus among practitioners as to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



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





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

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.

The DMAIC Process

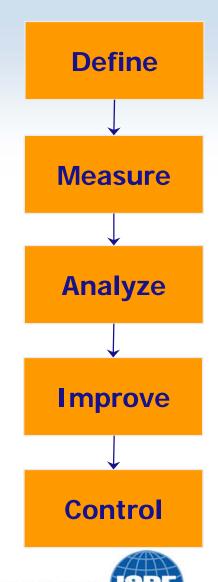
The process is **defined**, and key process inputs and outputs are identified.

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.



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.

Visual Six Sigma

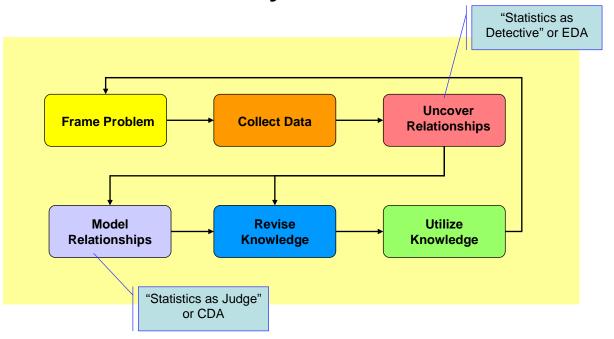
- An innovative and "leaner" approach to Six Sigma is evolving which relies on the powerful and dynamic visualization capabilities of modern statistical software.
- The goal of Visual Six Sigma (VSS) is to reduce the amount of time needed to achieve results in a Six Sigma project.
- VSS uses visualization 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

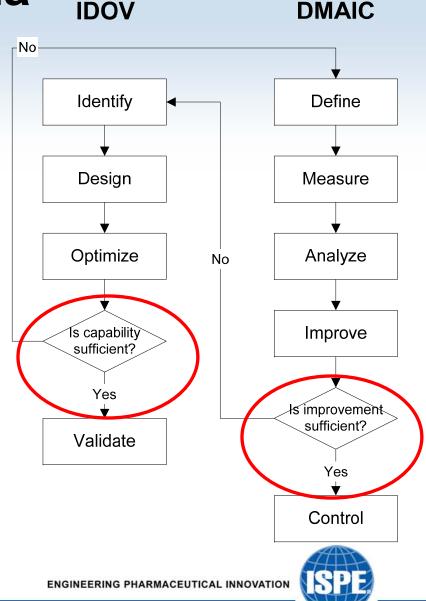
The VSS approach:

Visual Six Sigma: A Lean Data Analysis Process



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.



Why DFSS?

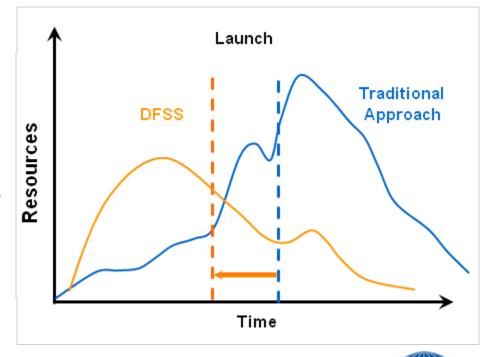
Up to 80% of overall costs are established during the design phase. The remaining 20% are fixed during or after launch.

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.



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 flowdown
- 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



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



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**.

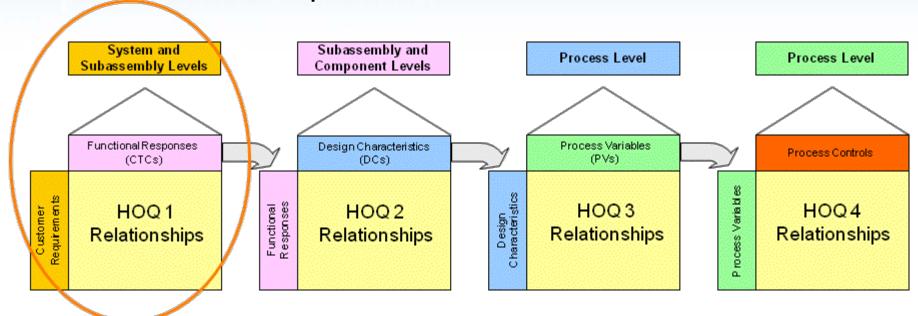
Conjoint Analysis is a cousin of design of experiments. It allows designers to uncover important characteristics to the customer as well as important interactions among those characteristics.

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".

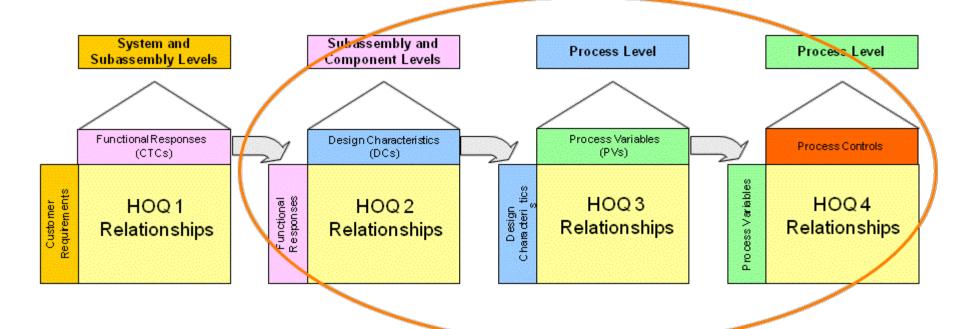


House 1, which is perhaps the most important, translates customer requirements (VOC) to **measurable** system level functional responses (CTC's).

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.

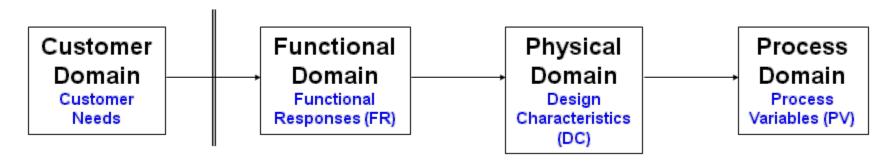


Tools: Transfer Functions

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".



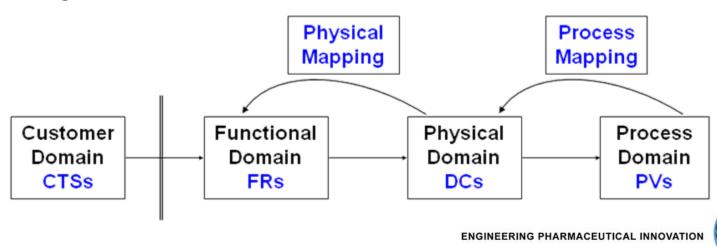
For a complex part, each of these domains will have a hierarchical structure.

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



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																								
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		S	ummary	S	corecard						
	Number of Components/ Steps/FRs	Capability Growth Index	DPU Sum		Prob of Conformance for System	s	ystem Cpk	Normalized Cpk	Yield Based on DPU		
Performance		839003000000000000000000000000000000000	100000000000000000000000000000000000000		100000000000000000000000000000000000000		140000040000000	5666666666666	Avus (Allularen distric		
Product	7	54.17%	0.56043925	0	0.5266232700		0.0222614	0.1705280	0.5709582154		
Process		200000000000000000000000000000000000000						000000000000000000000000000000000000000	STATE OF THE STATE		

Tools: FMEA

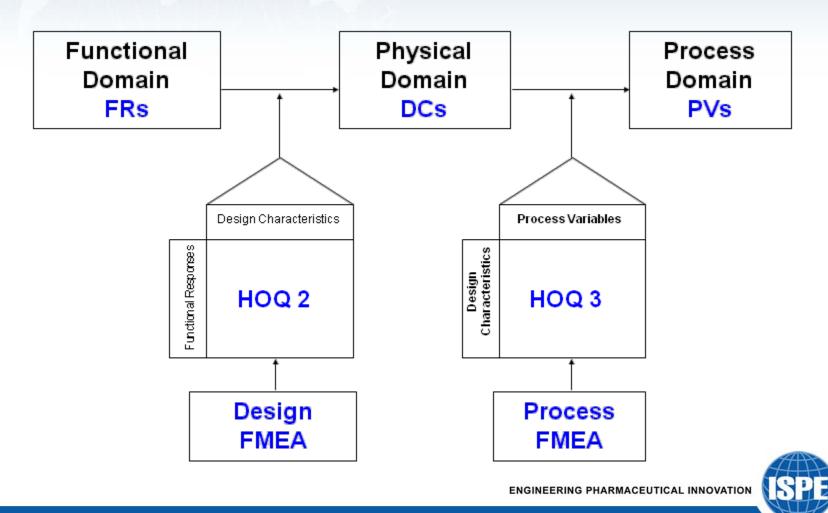
FMEAs are living documents used to uncover problems in designs, or in the manufacture of product, that could result in product failures or safety risks

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

			P	rocess/Pi	odu	ıct FMEA	For	m			
Process or P	roduct Name									Date:_	
Prepared By:										I	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

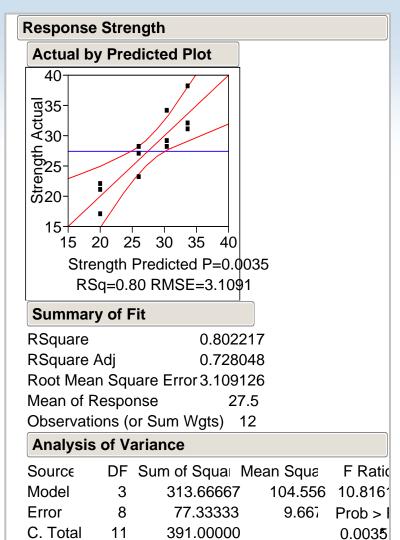
DFMEAs and PFMEAs are related to HOQs 2 and 3, as shown in the schematic below.



Tools: Design of Experiments

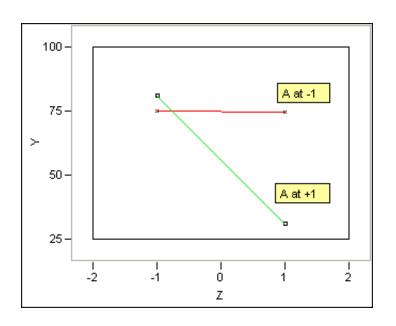
DOE is a structured, efficient approach in which factors are systematically changed and the effects on the response(s) are observed. DOEs are used to:

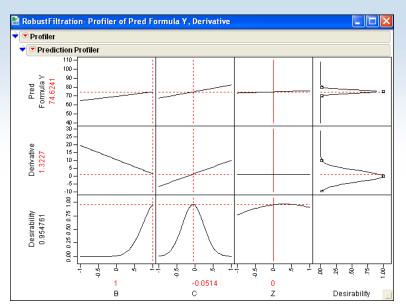
- determine if factors have an effect on the response,
- determine if two or more factors interact in their effect on the response, and to
- model the behavior of the response as a function of the factors.



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.





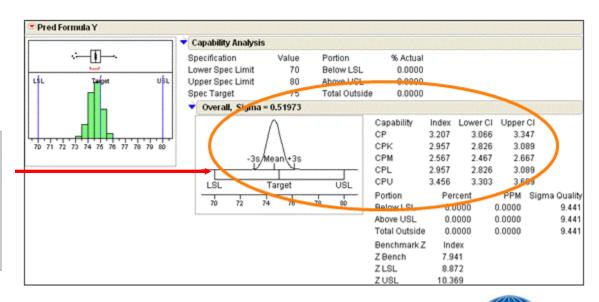
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B Fixed ✔	1			
C Fixed ✓ -0.05	1405			
Z Random 🕶 Norm	al 🕶	Me	an	Std Dev
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Responses				
Pred Formula Y No Noise		~		
Derivative No Noise		~		
Simulate N Runs: 1000				

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

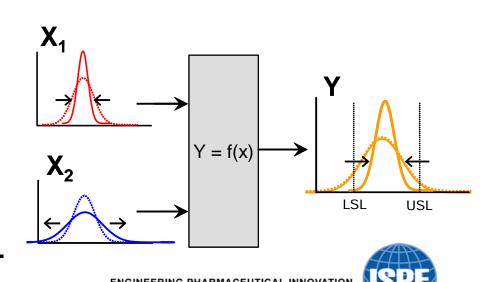
Tolerance Design utilizes analytical and statistical methods to optimize tolerances.

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 X₁, and
- allowing more variation in X₂.



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?					

DFSS Case Study Design and 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.

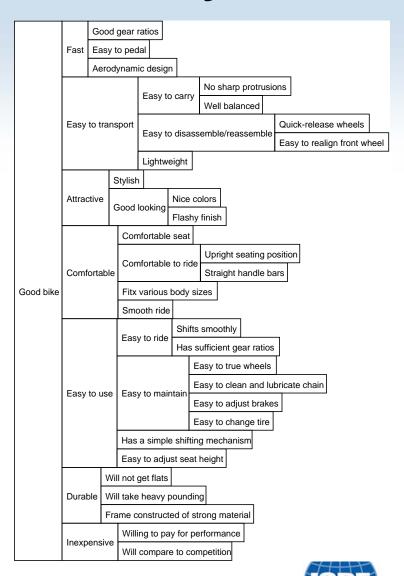
VOC Summary Table for Multi-purpose Bicycle										
Demographic Information	Intended use of Product or Service	Customer Requirement								
Age 18-29, predominantly males	Off road and city, medium to long distances	Fast, lightweight, attractive, rugged								
Age 30-50, females	Gentle trails and city,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

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.



Negative / Tradeoff

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

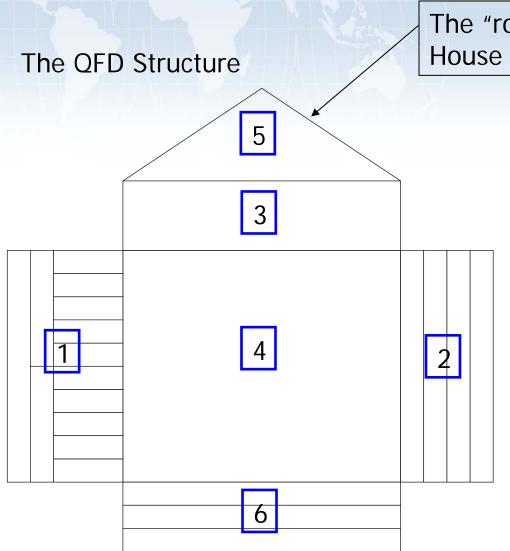
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		Importance	Top speed on flat terrain	Wheel size	Gear ratios	Total weight	Seat comfort index	Seat adjustments	Ride comfort index	Frame size options	Number of gears	Smoothness of shifting	Tube (frame) strength	Rim strength	Tire durability	Price range	Meets government safety standards	Product	Competitor A	Competitor B	Planned Rating	Improvement Factor	s Point	Overall Weight	Percent of Total
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0 1 2 3	Fast Easy to carry Easy to transport Stylish Goodlooking Comfortable seat Comfortable to ride Easy to ride Easy to maintain Easy to change tire Will not get flats	5 1 2 2 2 3 5 4 3 3 3	9	9 1 1 1 1 1 1 3	9	9 9 9 3	9 9	3 3 1 9 9	3 9	1 1 3 9	9 3	3 9	1 1 3	3 1 3	9 1 9	9	3	2 3 3 3 4 3 2 2 2 3 2 2	3 2 3 3 3 4 3 3 2 3 3	3 3 2 2 3 2 3 4 3 3 3	4 3 3 3 4 3 3 4 2 2	2.0 1.0 1.0 1.0 1.0 1.5 1.5 1.3 1.0	1.5 1.0 1.0 1.0 1.0 1.0 1.0 1.0 1.0 1.0	15 1 2 2 2 2 3 9 6 4 3 3	24% 2% 3% 3% 3% 5% 14% 10% 6% 5%
0 1 2 3	Fast Easy to carry Easy to transport Stylish Goodlooking Comfortable seat Comfortable to ride Easy to ride Easy to maintain Easy to change tire Will not get flats Will take pounding	5 1 2 2 2 3 5 4 3 3 3 4	9	9 1 1 1 1 1 1 3	3	9 9 9 3	9 9	3 1 9 9 3 3	3 9	1 1 3 9 9	9 3 1	3 9	1 1 3 9	3 1 3 9	9 1 9	9	3	2 3 3 3 4 3 2 2 2 3 2 2	3 2 3 3 3 4 3 3 2 3 3 3 3	3 3 2 2 3 2 3 4 3 3 4 3	4 3 3 3 4 3 3 4 2 2	2.0 1.0 1.0 1.0 1.0 1.5 1.5 1.3 1.0	1.5 1.0 1.0 1.0 1.0 1.0 1.2 1.0 1.0 1.0 1.0	15 1 2 2 2 2 3 9 6 4 3 3	24% 2% 3% 3% 5% 14% 10% 6% 5% 5%

Put a "9" in the box if the relationship is high

Durable

Use a "3" if the relationship is medium Use a "1" if the relationship is low Leave blank if there is no relationship.

	-														
Our Product	2.0	3.0	2.0	3.0	3.0	4.0	2.0	2.0	2.0	2.0	3.0	2.0	2.0	2.0	5.0
Competitor A	3.0	3.0	3.0	2.0	4.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	1.0	5.0
Competitor B	3.0	3.0	3.0	1.0	2.0	2.0	2.0	3.0	3.0	2.0	3.0	3.0	2.0	2.0	5.0
Design Target	>16	>26							>14						
Marginal															
Units	ydw	inches diameter													



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.



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		S	olution		
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

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

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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

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?

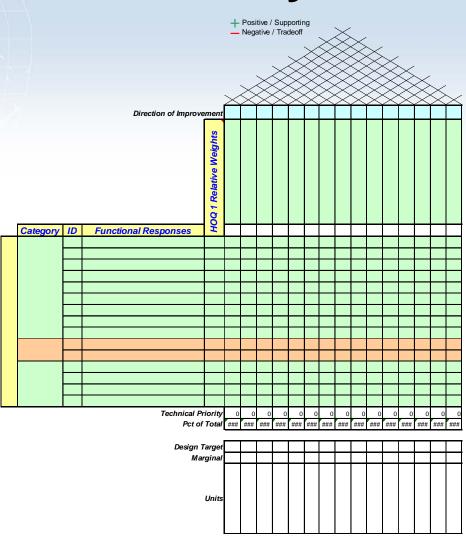
Pugh Concept Selection Matrix						
	>	Concepts				
Functional Responses	Technical Priority	Datum	Concept 1	Concept 2	Concept 3	Concept 4
Top speed on flat terrain	58	0	+	-	-	S
Wheel size	73	0	-	S	+	S
Gear ratios	61	0	s	+	+	-
Total weight	95	0	S	+	-	S
Seat comfort index	89	0	S	-	+	-
Seat adjustments	107	0	-	S	S	-
Ride comfort index	95	0	+	S	+	-
Frame size options	112	0	S	+	+	+
Number of gears	105	0	ı	+	-	-
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

Next, the team used a

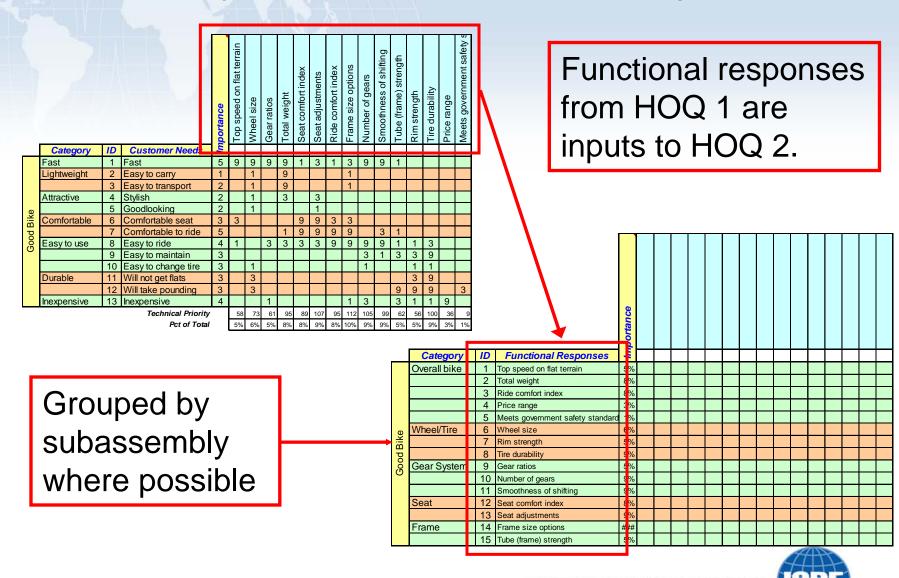
Process FMEA to
identify potential
problems with the
selected design concept.

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.







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

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

				Import	Tire	Tire	Trea	Hand	Whe	Spro	Num	Num	Num	Carb	Rim	Rim	Rim	Num	Spok
	Category	ID	Functional Response	щ															
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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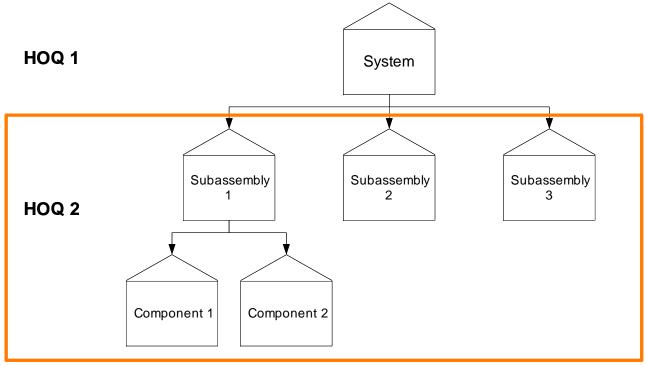
e bar geometry

design

aterial

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.



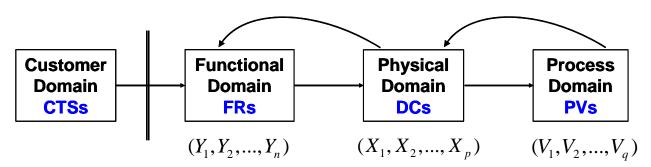
At a conceptual level, one can think of a single transfer function that relates all FRs (Ys) to all DCs (Xs):

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

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.



ENGINEERING PHARMACEUTICAL INNOVATION

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.

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.

NGINEERING PHARMACEUTICAL INNOVATION

One might begin the process of deriving transfer functions by relating each of the four Y₂s 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
- X₂₂ = Spoke strength
- X_{23} = Hub geometry
- X₂₄ = Rib material

Transfer functions for the Y_2 s would include these as arguments (i = 1, 2, 3, 4):

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



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

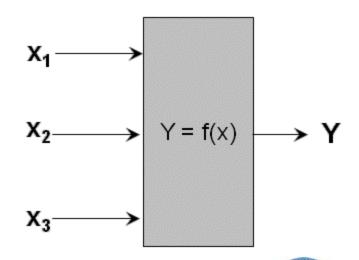
Sources of transfer functions:

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

$$Y_1 = f_1(x_1, x_2, ..., x_N)$$

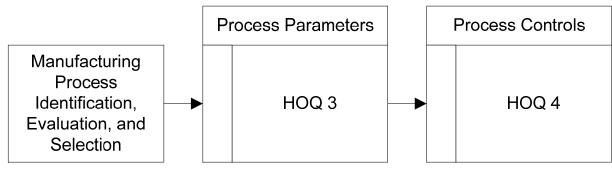
 $Y_2 = f_2(x_1, x_2, ..., x_N)$
 $Y_3 = f_3(x_1, x_2, ..., x_N)$

$$Y = b_0 + b_1 X_1 + b_2 X_2 + b_3 X_1 X_2$$



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).



Tools: Summary of Tools by IDOV Phase

Identify

Concept

Design and Optimize

Validate

Project Charter

Project Plan

Communication Plan

Voice of Customer (VOC)

QFD House 1

Functional Responses (CTCs)

Performance Scorecard

Concept Generation

Concept Selection

QFD House 2

DFMEA

Mistake-Proofing

Design Validation Plan (DVP)

Transfer Functions

Product Scorecard

Measurement System Analysis (MSA)

Regression

Design of Experiments (DOE)

Transfer Functions

Robust Design

Response Distribution Analysis (RDA)

Tolerance Intervals

Tolerance Design

QFD Houses 2 and 3

Design for Mfg (DFM)

DVP

DFMEA and PFMEA

Reliability

Product and Process

Scorecards

ENGINEERING PHARMACEUTICAL INNOVATION

Process Map, VSM

Transfer Functions

Statistical Process Control

(SPC)

Capability

DVP

Gap Analysis

QFD House 4

Control Plans

Summary Scorecard

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



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

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



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.