Quality Function Deployment for a Medical Device

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Abstract

Quality Function Deployment (QFD) is a system and procedures to identify, communicate, and prioritize customer requirements so that an organization can optimize its products and services to exceed customer expectations. Identification is achieved through voice of customer analysis, communication is achieved through a series of linked matrices, and prioritization is derived from the customer, competitors, and the vision of the company. Optimization activities are then focused on those areas that mean the most to the customer, beat the competition, and are in line with the vision of the organization. Users of QFD have reported that design costs can be reduced by one third and design time by one half. This paper will show the need for QFD in today's fast paced world of new product design and development, and will demonstrate its application with a case study of a medical device.

1: Introduction

Quality Function Deployment (QFD) was developed in Japan in the 1970s by Professors Yoji Akao and Shigeru Mizuno [1] as a system to assure quality in manufactured products. It applies the principles of function analysis to systematically break down quality assurance activities into greater and greater detail so that design intent can be realized in actual production processes. QFD differs from other design approaches in that it focuses not on inspecting problems out of the product, but on understanding customer requirements and building them in. In this way, potential features and functions critical to customer satisfaction can be designed in, potential failures can be anticipated and designed out, and savings in time and money can be realized by minimizing last minute design changes, product introduction delays, and market failures.

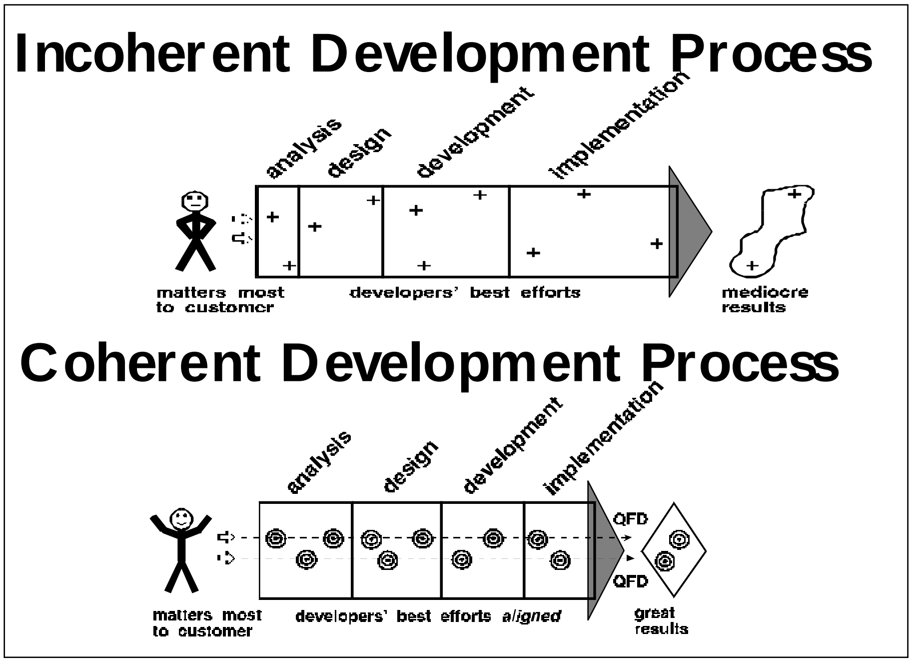
In 1983, QFD was introduced to the United States and was picked up immediately by the struggling auto industry. In the ensuing ten years, companies in the computer software and hardware, chemical, pharmaceutical, personal care products, consumer products, food and beverage, aerospace, defense, health care, education, utility, telecommunications, building and numerous other industries in Japan, North America, Europe, and Australia have found QFD a flexible solution to meeting the increasing demands of a fast changing world.

2: A coherent development process

Traditional design processes are often disconnected externally from the customer and internally from one organizational function to another. The metaphor of design tossing a ball over a wall and hoping manufacturing drops it has brought more than its share of knowing chuckles to students of QFD. In such a case, communication from upstream activities can be unreliable and sporadic and people in the organization, given no clear direction, default to what they do best. Product or service weakness is ignored while areas of superior performance continue to receive attention and resources.

Such as system can be called "incoherent" because like an incandescent bulb, it is unfocused and meek in its inefficient attempt to illuminate everything. Products designed this way will be mediocre; they will include some features that matter most to customers and lack others. As production deadlines near, inadequacies that become evident require expensive and hurried design changes; those that are not evident become field complaints. Delays are not uncommon, giving competitors an advantage. (Figure 1.)

Figure 1. [2]



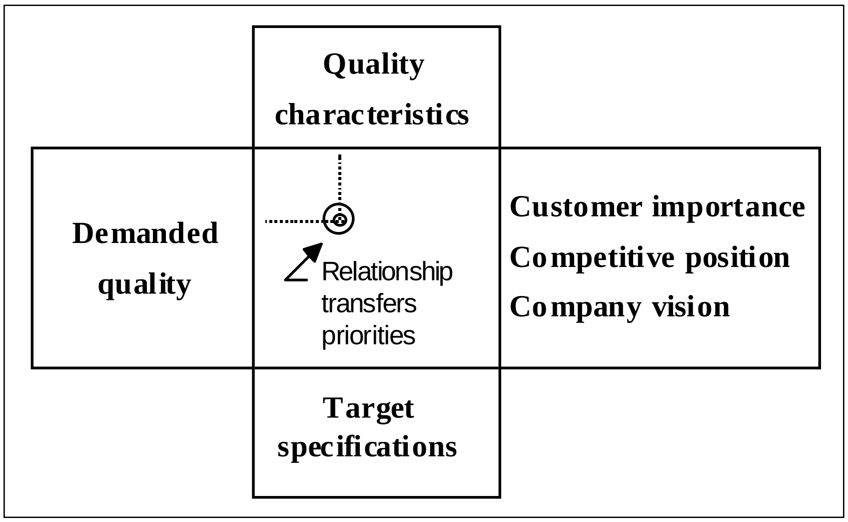
With QFD, the design and development process becomes coherent; that is, focused like a laser on what matters most to customers. Customer requirements are analyzed in great detail at the marketing, product planning, and design phases to assure that they are met by the specifications, functions, and features, and that reliability, cost, safety, and manufacturability concerns have been taken into account. The result is that the best efforts of the organization are aligned with customer needs and the resulting product successfully exhibits features and performance with fewer mistakes and delays. This coherent process has been found to save product development teams up to 33% in cost and 50% in time.[3]

3: QFD's comprehensive system - from customer to construction

Quality Function Deployment begins with an analysis of customer requirements. Since customers are not necessarily adept at communicating their needs to us in ways that directly lead to design, it is advantageous to see them "at work" using the product or service. This helps the designers understand the customer's problems, opportunities, and even image requirements.

Customer requirements are then sorted into categories that will then be deployed in the design. Categories include quality (level of satisfaction), performance, functionality, reliability, cost, methodology, etc. Quality requirements (called demanded quality) are based on customers' language which can be qualitative and fuzzy. They must be translated into quantitative and explicit performance characteristics (called quality characteristics) for which design targets will be set. Since there will be many demanded quality items and many quality characteristics, their interrelationships are best managed in a two dimensional matrix. (Figure 2.) The ◎ indicates a strong relationship between the demanded quality and the quality characteristic.

Figure 2. [4]



The matrix is next used to prioritize the demanded quality items based on customer importance, competitive position, and company policy or vision. Through the matrix, these priorities are transferred into quality characteristics priorities. Performance levels of the quality characteristics are benchmarked with competitors so that design targets for the most critical quality characteristics can be set to superior levels. This helps design engineers focus constrained resources on areas that are meaningful to customers and will enhance competitiveness.

Design concepts are then proposed to achieve these targets, the best is selected based on cost, reliability, safety, etc., and critical parts determined. These parts are examined for critical manufacturing and process control parameters and operator training, inspection criteria, and other production standards are developed. The QFD system thus drives product development from planning to production, all based on what matters most to the customer, where there is an opportunity for competitive positioning, and what is consistent with the goals and vision of the organization.

4: QFD for development of an endotracheal tube for laser surgery

Any endotracheal tube, regardless of construction, risks combustion or perforation from the intensive heat from lasers. Methods to resist combustion, such as metallic wrapping, can reduce flexibility, traumatize tissue, and reflect the laser. Further, the tube is still subject to indirect ignition due to its inherent combustibility, and the cuff is unprotected. The development of a new endotracheal tube will be used to demonstrate quality function deployment.

Hospital visits combined with studies [5] published in professional journals gave ample data on the needs of surgeons, anesthesiologists, and other personnel regarding the performance of several types of endotracheal tubes. This data has been organized into the QFD matrix in Figure 3.

Figure 3.

Endotracheal Tube
Demanded Quality
vs
Quality Characteristics
House of Quality

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WHATs vs. HOWs

Strong Relationship:	◎	9
Medium Relationship:	○	3
Weak Relationship:	△	1

DEMANDED QUALITY	QUALITY CHARACTERISTICS	Flexibility	Lumen diameter	Resistance to combustion	Permeability	Customer importance rating (1)	Competitive position	Our current product: foil wrapped rubber (2)	Competitor X (Silicone elastomer)	Competitor Y (Al w/silicone)	Competitor Z (Stainless Steel)	Plan (3)	Improvement ratio (4) (4)=(3)/(2)	Sales point (5)	Absolute weight (6) (6)=(1)x(4)x(5)	Demanded quality weight (7) (7)=(6)/sum(6)
Easy to place		◎	○			4		4	4	2	2	4	1.00	1.0	4	13.1
Secretions easy to suction			◎			3		3	3	2	2	3	1.00	1.0	3	9.8
Minimizes tissue damage		◎		◎	◎	5		2	3	2	3	5	2.50	1.5	19	61.4
Large surgical exposure		△	◎	○		3		3	3	3	2	4	1.33	1.2	5	15.7

	QUALITY CHARACTERISTICS	Flexibility	Lumen diameter	Resistance to combustion	Permeability
Absolute weight		686	269	600	552
Quality characteristic weight		32.6	12.8	28.5	26.2
Competitive benchmark					
Our current product		30	.25	15	
Competitor X		9	.20	25	
Competitor Y		190	.35	50	
Competitor Z		137	.67	any	500
Target specifications		6	.20	40	
Unit		N/mm2	ID/OD	Watts	u max

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The best way to explain the QFD matrix is to follow a single thread. A common concern among anesthesiologists is the damage to surrounding tissues during otolaryngologic surgery. The demanded quality for this can be expressed as “minimize tissue damage,” the third row on the left side of the matrix. At the top of the matrix, the quality characteristics “flexibility,” “resistance to combustion,” and “permeability” are the quantitative design characteristics that must be considered in order to design a tube that will minimize tissue damage. The ◎ indicates a strong relationship between each of these.

On the right side of the matrix, “minimize tissue damage” receives a customer importance rating of 5 on a scale from one to five, indicating strong importance to the anesthesiologist. In the customer’s view (the anesthesiologist), the company’s current product, red rubber wrapped in foil, is rates only a 2 on a scale of one to five - not very good. This is due to combustibility and the loss of flexibility due to the foil wrap. Competitors are not rated much better. Since this is the most important customer requirement and none of the manufacturers are adequate, a competitive opportunity arises for the company to create a new product that will score a five with the anesthesiologists. Hence, a five is planned.

Next, the necessary degree of improvement, or improvement ratio, is calculated by dividing the plan by the current product’s performance. ($5 \div 2 = 2.5$) The vision of the company is reflected in the sales point, to emphasize that patient health is their main concern. Sales points are given values of 1.2 (moderate) and 1.5 (strong). An absolute is weight is calculated by multiplying the customer importance rating x improvement ratio x sales point. (5 x 2.5 x 1.5 = 19. Finally, the demanded quality weight is calculated by normalizing the absolute weights to a percentage. $\frac{19}{4+3+19+5} = 61.4\%$ This weight indicates the criticality of “minimizes tissue damage” based on importance to the customer, competitive position, and company vision.

The demanded quality weights can now be converted into quality characteristic weights in order to focus design activity on the most critical characteristic. The matrix makes this easy. Each relationship is assigned a value based on its strength: ◎=9, ○=3, △=1 is a commonly used. Each demanded quality weight is multiplied by the relationship value in the cells in its row. (This multiplication product is not shown in Figure 3. due to software limitations.) The products in each column are summed to give an absolute weight in the lower part of the matrix. For “flexibility,” multiply the demanded weight of 13.1 x ◎ or 9 = 117.9, 61.4 x 9 = 552.6, and 15.7 x 1 = 15.7. Sum 117.9 + 552.6 + 15.7 = 686.2. These are normalized to a percentage, yielding a quality characteristic weight of 32.6%. This means that based on customer importance, competitive position, and company vision, 32.6% of the design focus should be in the area of flexibility. The flexibility of the current red rubber wrapped in metallic foil as measured in N/mm^2 is benchmarked against the competition. Since flexibility is critical to minimizing tissue damage which is a competitive opportunity, a target specification of “6 N/mm^2” is selected to assure that the new product is superior to the best competitor. Achieving this becomes the challenge of the project team. After much experimentation, a biocompatiable silicone rubber including the tube and cuff with a highly flexible shaft was developed. To assure quality in the product, the QFD should be carried forward into designing the rubber compound, its additives, mixing recipe and processes, as well as the molding and final assembly. The new product has earned a leading position in the market.

5: Conclusion

Quality Function Deployment has achieved remarkable popularity around the world in a wide variety of software, hardware, and service products. This is due to its systematic linking of customer requirements to and throughout the entire design, development, and implementation process. As customer requirements and technological advancements rapidly change, it is necessary to assure that customer satisfaction is achieved in the quickest, least costliest, and most efficient way possible. QFD is a very effective means towards this end.

References

1 Akao, Yoji & Mizuno, Shigeru, ed., *Quality Function Deployment,* Revised edition [Translated by Glenn Mazur], Quality Resources, 1993.

2 Zultner, Richard, "QFD for Software: Satisfying Customers," *American Programmer,* February, 1992. Available from Zultner & Co. at (609) 452-0216. Figure adapted and used with permission.

3 Akao, Yoji ed., *Quality Function Deployment: Integrating Customer Requirements into Product Design,* [Translated by Glenn Mazur], Productivity Press, 1990.

4 Mazur, Glenn, *Quality Function Deployment - An Executive Briefing,* v 1.2, April, 1993. Available from Japan Business Consultants, Ltd. at (313) 995-0847.

5 Sosis, Mitchel, "Anesthesia for Laser Surgery," *Adu Anesthesia,* 6:175-194, 1989, Year Book Medical Publishers, Inc. was referenced for this report.

About the author

Glenn Mazur has been active in QFD since its inception in North America, and has worked extensively with the founders of QFD on their teaching and consulting visits from Japan. He has worked as a QFD facilitator, instructor and training materials developer since 1989 for GOAL/QPC, Kaizen Institute of America, OEM Omnex, and private clients in industries such as aerospace, automotive, chemical, computer, controllers, consumer and food products, defense, finance, health care, medical device, pharmaceutical, rubber, service, telecommunications, and warehousing applications. He is one of America's leaders in the application of QFD to service industries, sits on several advanced QFD research committees, and is GOAL/QPC's special liaison to the steering committee of the Symposium on Quality Function Deployment held annually in Detroit. Those interested in more detail about QFD are encouraged to review references 1-4 or to contact the author directly at (313) 995-0847 or by facsimile at (313) 995-3810.