

Classification of Quality Characteristics

The Product & Process Design pillar of the CQE Body of Knowledge is the critical first step in delivering a high quality product.

Delivering a high quality product starts with capturing your customers needs and then translating those needs into Products Features, which are also known as Quality Characteristics.

Quality Characteristics

Your **Quality Characteristics** are the features about your product that deliver the functional performance that your customers need, want and are *willing to pay for*.

These are the features about your product that your customers find *valuable*.

As we learned in the **Customer Relations** chapter, the best way to translate your customers needs into product features is the use of the **Quality Function Deployment tool** (House of Quality).

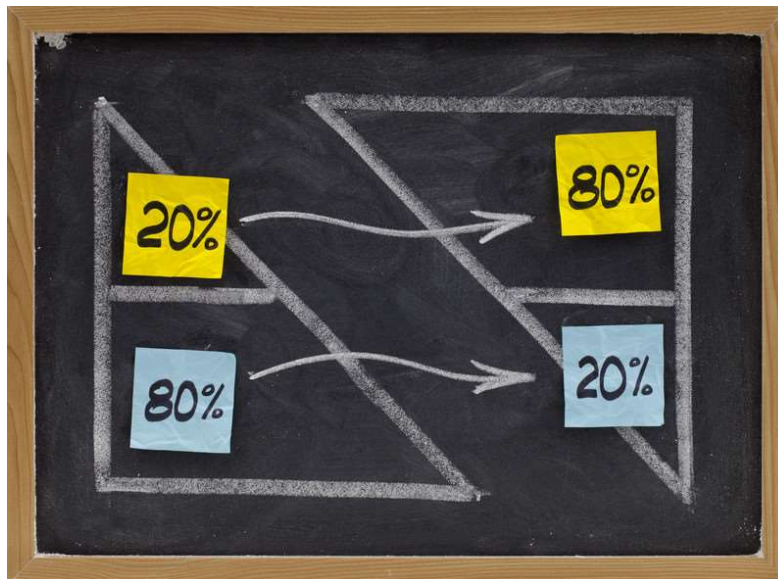
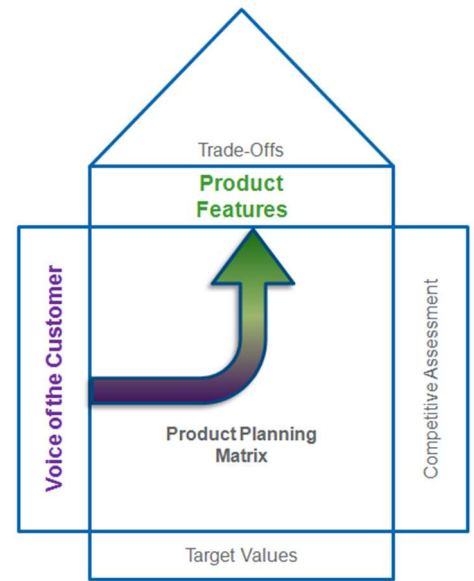
Classification of Quality Characteristics

Once you've got your list of Product Features, or Quality Characteristics, it's time to classify those features. Wait, aren't all product features equal in terms of their importance?

No - You'll have some product features that are way more important than others and by classifying them you'll be able to isolate & define those features that are critical to quality, safety & performance.

This process takes advantage of the **Pareto Principle**, which tells us that 80% of your customers satisfaction will be delivered through 20% of your products features.

By going through this process, you will *identify those product characteristics that ensure the Safety, Quality, Performance, Functionality & Reliability of your product*.



And as a result, you will have established a hierarchy of importance for the various characteristics of the products.

This hierarchy will allow you to strategically focus your resources on the most critical characteristics to ensure customer satisfaction.

Characteristic Categories

Ok - so we're ready to classify our quality characteristics (product features), how do we do that?

We must define the **classification categories** that we want to use.

The following categories are generic examples that you can use as a baseline for defining your products categories.

For example, the description below for Critical is based on the potential for injury or harm to the end user.

You can adapt this definition to fit your needs if your product is not likely to result in any sort of injury. Same goes for the other categories.

<u>CATEGORY</u>	<u>DESCRIPTION</u>
Critical	A feature whose failure would result in a hazardous or harmful situation for the end user.
Major	A feature whose failure would result in a major reduction in quality (performance, functionality or reliability), but would not likely result in a hazardous situation for your customer.
Minor	A feature whose failure would be noticed by the end user but would not significantly impact the users experience (safety, quality, etc).
Incidental	A feature whose failure might go unnoticed by the end user and would not impact safety, quality, performance, functionality, etc.

These Quality Characteristics, and their associated classifications are going **used during the design input phase** and will be **converted to Product Specifications, Process Specifications & Process Controls**.

Design Inputs & Design Review

As Quality Engineers we get the exciting opportunity to support the development of new products or services.

Product or Process Design, like everything else, is a process. Oftentimes, companies will call this their New Product Development Process.

This chapter will cover the 3 critical steps to designing a product that your customers will rave about!



1. The first step in creating raving fans is to *identify all the sources of design inputs* & then capture their needs/wants & expectations! These design inputs will become your design targets.
2. The next major step *is the process of transform your customers needs (design inputs) into an epic design concept* using tools like **Quality Function Deployment (QFD)**, **Robust Design**, **Design for X (DFX)**, **Design for Six Sigma (DFSS)** & **Quality by Design**.
3. Finally, you must utilize the **design review** process throughout the development process to periodically confirm that you're still on track to deliver an epic product.

By doing these three things really well, you will ensure that your customers needs & wants are fulfilled by your products design.

This process of capturing design inputs & reviewing that design at periodic intervals (design review) has been shown to be so valuable, that it has become an ISO 9001 requirement.

Sources of Design Inputs

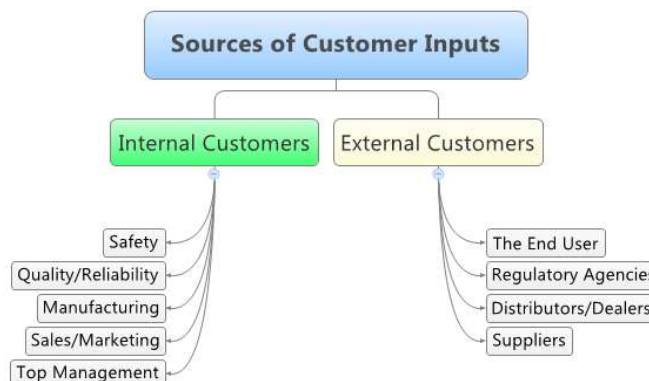
Like I said above, developing a new product is like everything else you work on - it is a process, and all processes, no matter what the goal is, are all basically the same. There are inputs, a process and an output.

Designing a new product is no different. To ensure that your output (final product) is appropriate (or epic), you must start by determining all of your inputs (design inputs) because they will guide & drive the design process.



In the design process, your inputs are your generally your customers needs/wants/etc. These are the things (features, performance, reliability, quality, etc) that your customers find valuable and thus are willing to pay for.

Before you can determine what your customers needs and expectations are you must first understand WHO your customers are, because every organization or product has way more than just one customer (the end user).



In fact, every organization actually has two different *types* of customers: **Internal Customers** and **External Customers**.



Most people are familiar with their external customers - these are your end users and even your intermediate users (dealers, distributors, brokers, etc).

If you're in a regulated industry (and which ones aren't these days), you'll have Regulatory Agencies as another type of external customer.

Your other customer, those internal ones, are extremely important when you're designing a new product, process or service.

For example, the manufacturability of your design or the serviceability of your design are very important to your internal customers (the manufacturing team or the service team)- much more in this below.

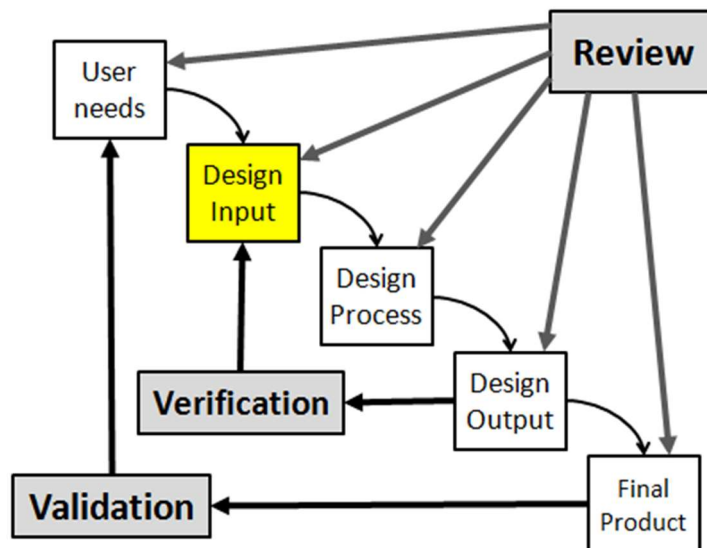
As you go through the process of capturing your customers needs, I would encourage you to go back to the Customer Relations chapter.

What are Design Inputs

Simply put, your design inputs are the technical reflections of your customers needs and they represent your customers requirements for the final product relating to safety, performance, functionality, quality, reliability and the intended use of your product.

Your design inputs can also capture any regulatory requirements or internal requirements driven by the organization.

The FDA popularized the waterfall design model that is common in the medical device industry where you'll notice that **the first step is the translation of User Needs into Design Inputs**.



You may also notice that your Design Inputs then become the requirements that must be met by the final design concept and represent the *acceptance criteria for Design Verification*.

In this way, your design inputs will guide you when making all of the difficult design trade-off decisions during the design process.

Design Terms and Definitions

If we follow this waterfall model, we can add some terms and definitions that will support the remainder of this chapter:

User Needs: The non-technical customer needs (VOC). Includes both internal and external customers.

Design inputs - the technical reflections of your customers' needs and they represent your customers' requirements for the final product relating to safety, performance, functionality, quality, reliability and the intended use of your product.

Design Process: The tools and techniques to translate your inputs into outputs using tools like QFD, DFX, DFSS, QbD.

Design outputs – The detailed engineering drawings, product specifications, requirements, bill of material, inspection criteria, and assembly procedures that describe your final product.

Design review – A documented, periodic activity within the design process where a cross-functional team meets to review, analyze and discuss the current design concepts to determine their ability to meet the customer needs.

