Product and Process Design
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, which 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 for their criticality where 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

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

CATEGORY	DESCRIPTION
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**.

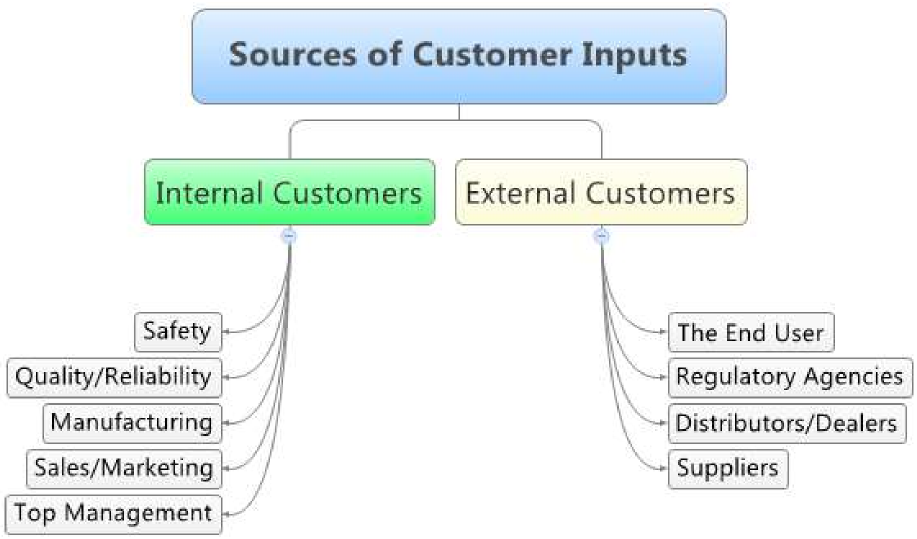
Design Inputs & Design Review

Sources of Design Inputs

To ensure that your final product meets your customer needs, 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.

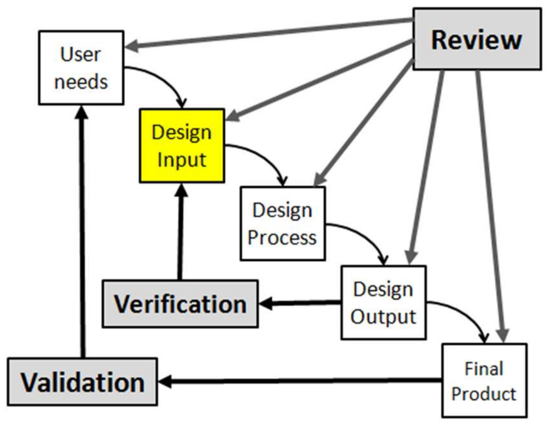
For example, the manufacturability of your design or the serviceability of your design are very important to your internal customers (the manufacturing team)

Design Inputs

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.**



Your Design Inputs 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.

Translating Design Inputs into Design Concepts

Once you've captured all of your design inputs, you'll then need to go through the process of translating those needs into potential design concepts and then applying the right design methodologies to ensure that your final product is optimized to meet your customer needs.

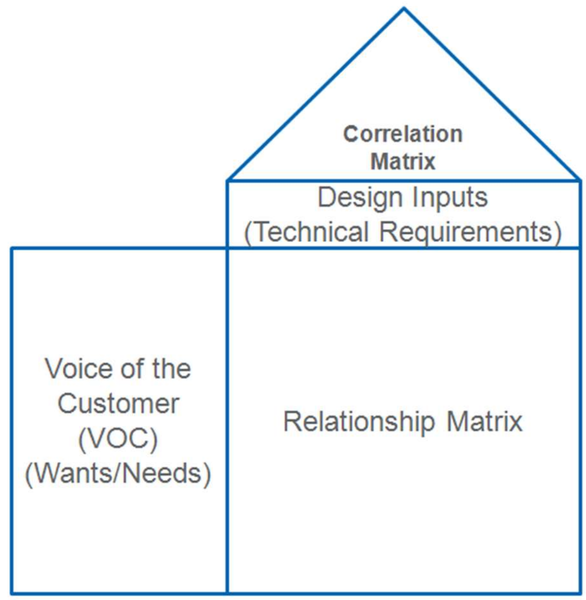
Many of the design concepts below start by capturing the voice of the customer and then translating those wants/needs into the technical inputs that drive the final design concept.

Within this section you'll learn about the 5 most common design methodologies that are used to deliver high quality products, these are:

1. **QFD (Quality Function Deployment)**
2. **Robust Design**
3. **Design for X**
4. **Design for Six Sigma**
5. **Quality by Design**

QFD (Quality Function Deployment)

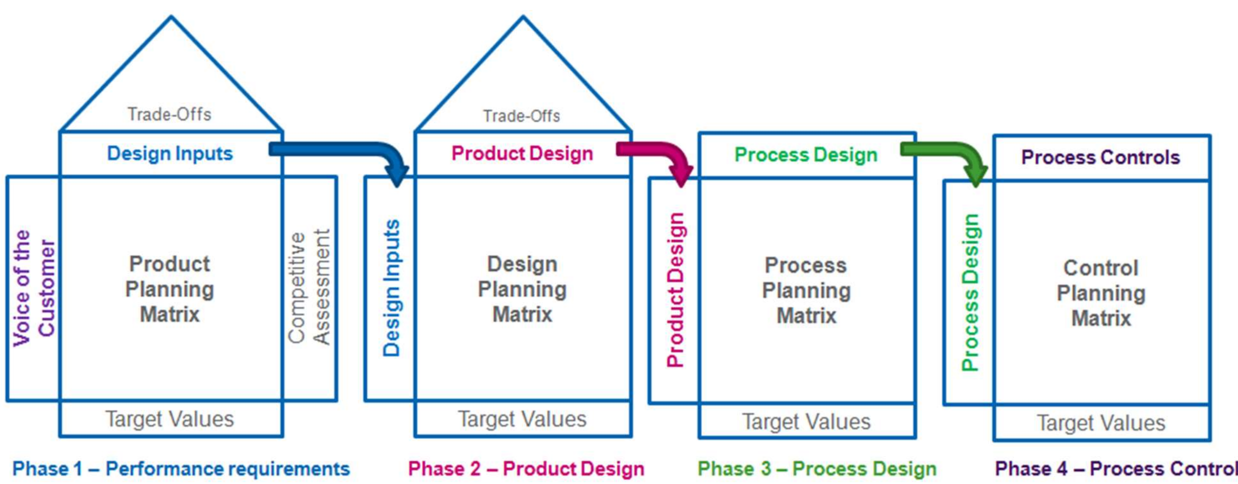
QFD is probably the most common tool used to translate customer needs into design inputs and design characteristics. This exercise is accomplished using the most popular QFD tool, the **House of Quality**.



With this methodology, the **Voice of the Customer** (Wants/Needs, etc.) are captured on the left side of the house, and along the top of the House are the design inputs (the technical requirements).

In the middle of the house is the **Relationship Matrix** which compares the Customer Needs to the Design Inputs to measure the relationship of each Design Input to each Customer Need. A *correlation matrix* is the roof of the house which compares the relationship of different (potentially conflicting) product features. This will reveal any competing design inputs.

While most people are familiar with the House of Quality, the full QFD process takes a multi-phased approach that translates your customer needs all the way down to process control requirements, all of which are meant to consistently deliver your design inputs. This phased approach is shown below.



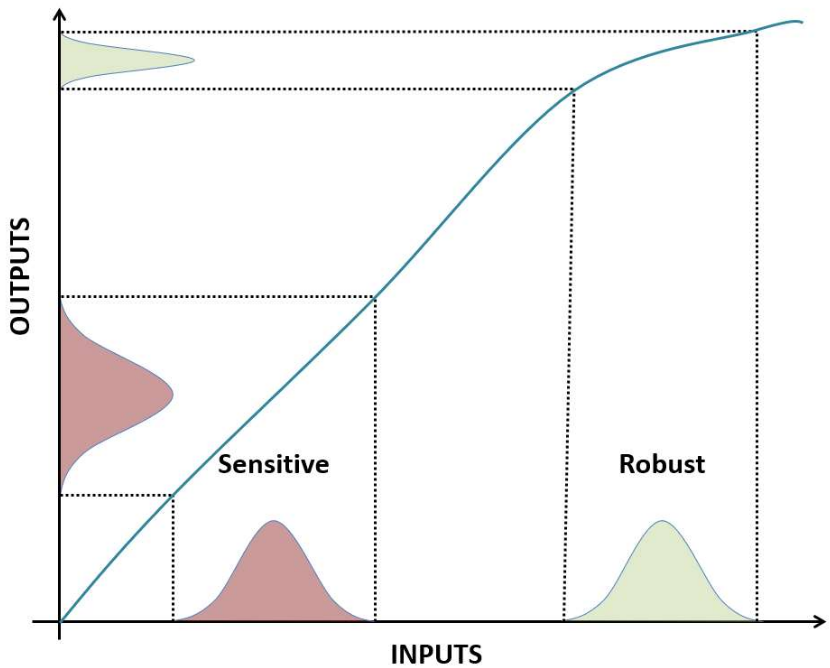
Robust Design

Robust Design was developed by the **Genichi Taguchi** as one of his Taguchi Methods for Quality Engineering to improve the Quality of manufactured goods.

Robust Design is all about *variation* and the impact that variation has on your product or process.

Both your product and your production process will experience variation, and this variation will take **two forms**; ***Controllable variation*** and ***uncontrollable variation***. Uncontrollable variation is also called **noise** or random variation.

Robust Design is the process of studying and measuring both forms of variation and then optimizing your design to reduce the impact that uncontrollable variation has on the final product, and selecting the right parameters for your controllable variation (optimal set point and allowable range).



Using Robust Design to Determine your Optimal Process Parameters

Robust design includes the study of **controllable variation** to determine the optimal nominal value for each control variable (process parameter, starting material dimensions, etc.) and the allowable ranges of variation for the process and the raw material.

Designed Experiments & Robust Design

Taguchi's Robust Design process is very dependent on the usage of Designed Experiments to study variation, and quantify its impact on product quality.

This is done through the intentional variation of controllable variables, uncontrollable variables & your process inputs (materials, etc.) to study their effects on the quality of the final product. These DOE's will allow you to determine the optimal setup point and ranges for your controllable variation and materials.

Design for X

Another common tool used during the conceptual stage of product development is **Design for X,** where the X can stand for the different design perspectives, which include:

- Design for Manufacturing & Assembly
- Design for Reliability
- Design for Maintainability & Serviceability
- Design for Life Cycle Cost
- Design for Environment
- Design for Testing

One of the hallmarks of Design for X is **Concurrent Engineering**, where a product and its process are developed in parallel with the goal to integrate the unique methodologies above for improved reliability, manufacturability, life cycle cost, etc.

This concurrent engineering requires cross-functional teams and can significantly reduce the time required to develop a product or service. For each of the approaches below, the design team would include subject matter experts from those areas.

Design for Manufacturing & Assembly

Design for Manufacturing and Assembly is an approach meant to design your product such that it is easily manufactured & assembled. Doing this means including a cross-functional design team of subject matter experts from manufacturing, operation, engineering & supply chain.

Below are *the 6 best practices* that are generally utilized when designing for manufacturability & assembly:

1. Reduction in the total number of parts
2. Use of a modular design
3. Use of standard, off the shelf components
4. Designing components that are easily handled or manipulated
5. Reducing tight tolerance or unnecessary part finishes
6. Use error-proofing techniques to reduce waste

Design for Reliability

This design approach includes collaboration with your organizations Reliability Engineers to ensure that the design concept is optimized for **reliability** (Quality over time).

Reliability includes an in-depth review of the different failure points of the proposed design concept using hazard analysis tools like FMEA, FTA, FRACAS along with prototype testing.

Improving design reliability will reduce warranty costs, increase product safety, increase product performance & ultimately increase customer satisfaction.

Design for Maintainability & Serviceability

When designing large scale equipment that will require servicing & maintenance throughout the products lifecycle, it is very beneficial to optimize your design for **maintainability and serviceability**.

This can reduce downtime associated with repairs, reduce the life cycle cost associated with maintenance, eliminate hazards to technicians during repair & improve customer satisfaction.

Essentially, this approach enhances your service teams' ability to diagnose, remove, replace or repair your product back to its original condition with ease.

Design for Six Sigma (DFSS)

Design for Six Sigma, or DFSS is the application of the Six Sigma Methodology & tools to the development of products or processes with the goal of increased customer satisfaction and increased product robustness.

Where traditional six sigma is used for *process improvement*, DFSS is used during the *design* phase of a products lifecycle. Other than this though, the two methodologies are similar in many regards.

Similar to Six Sigma, the DFSS process utilizes statistical analysis to translate The Voice of the Customer into a robust product design that satisfies those needs while at the same time being optimized for the variation that the product may be exposed too.

The two most common DFSS roadmaps are **DMADV & IDOV**, both are shown below.

DMADV Road map	
Define	the scope & goals of the product, process or project
Measure	and determine customer needs & specifications (CTQs - Critical to Quality); benchmark competitors
Analyze	the different design concepts for their capability of fulfilling the CTQs while maintaining robustness
Design	the final product & manufacturing process in detail, then test & optimize design ideas
Verify	that the final design concept actually meets your customer's needs, product requirements & intended use

IDOV Road map	
Identify	Your customer needs (CTQ's), project scope, goals & business strategy
Design	the product by creating, studying & analyzing multiple design concepts
Optimize	the final design chosen for your critical attributes (quality, reliability) & for your critical processes (manufacturing)
Verify	that the final design concept actually meets your customer's needs, product requirements & intended use

The DFSS approach, whether it's **Define** in **D**MADV or **Identify** in **I**DOV starts like every other design process - by capturing the needs/wants & expectations of your customers. *DFSS calls these customer needs your **CTQ's** or Critical to Quality.*

These CTQ's are utilized throughout the design process to steer the design and drive key decisions to ensure that the final product is aligned with the customers' needs. These CTQ's are also cascaded down through the product into the process to align it with the customer needs as well.

Once the CTQ's are established, DFSS uses common statistical tools & techniques to translate those needs into different, potential design concepts to be studies & measured to determine the optimal design concept.

Once a final design concept has been chosen, many DFSS road maps (DMADV & IDOV) will move into an optimization phase to further refine that design concept into a world class product.

Quality by Design

Quality by Design originated from Juran's concept of Quality Planning and has evolved into a set of tools & techniques which I'll summarize as a 3-step process:

Step 1 - Identify your products **Critical Quality Attributes** (CQAs) - other methodologies call these CTQ's, but essentially these are the Product Attributes or Characteristics that, when they are present, they ensure the functionality, performance, safety & reliability of the final product.

Your CQA's must be controlled within a given range to ensure product quality. CQA's can also be used as your acceptance criteria when you execute your process validation or supplier qualification. You can also calculate your process capability (Cp or Cpk) for these Critical Quality Attributes.

Step 2 - Identify the **Process Parameters** & **Material Inputs** whose variability can impact any of your CQA's. These can be determined through the usage of DOE's to measure this relationship.

This second step is all about variation. Specifically, the activity of studying & measuring variation; then controlling that variation or reducing the impact that any residual variation has on the final product.

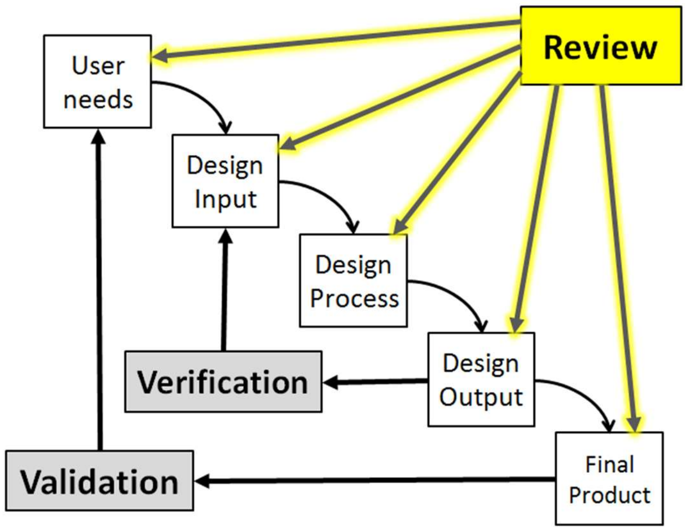
Step 3 - Develop a **control strategy** to ensure that your material inputs & process parameters are sufficiently monitored and that your final product contains all of the critical quality attributes that your customer requires.

This control strategy, or control plan should include your starting materials, process parameters & your measurement/inspection points that confirm the presence of your CQA's.

The Design Review Process

As your design project progresses through the different stages of your design process, you should be intentional about scheduling & holding periodic Design Reviews.

Below is that waterfall model where I want to point out the design review that is conducted at the conclusion of each major stage. This is a very important element of the product design process.



The design review is an important opportunity for your cross-functional team members and independent reviewers to provide insight, wisdom and experience from other projects to the new design.

This design review, which is often held as a special meet, is an opportunity to review your design progress to ensure that you're still on target to meet your customers' needs.

Design Reviews, as a best practice, should be performed at planned & periodic milestones throughout the development period, typically at the completion of each design phase.

From a cost of quality perspective, the Design Review process is a preventative activity because it can help you identify failure before they occur and take the necessary action to prevent those problems.

Introduction to Technical Drawings & Specifications

In the Design Inputs & Reviews chapter, we covered the three phases of product design, which often result in the creation of detailed engineering drawings associated with your new product.

These Engineering or Technical Drawings serve a number of different purposes.

One of the most important is to capture the intention of the designer and all of the requirements associated with the newly designed product. The next benefit or purpose of the engineering drawing is to *act as a communication tool* to all folks included in the value stream of your product.

Geometric Dimensioning & Tolerancing

To ensure that your engineering drawings are communicated effectively (error-free), drawing creators (designers) use a technical "communication language" called **GD&T or Geometric Dimensioning & Tolerancing.**

The GD&T methodology provides a robust method to communicate all of necessary information associated with a component which include; dimensions, tolerances, geometry, materials, finish and all other pieces of information about a drawing (revision, part number, etc.).

To do all of this, GD&T utilizes a set of standard symbols to describe the different features or requirements of a component.

Interpreting Technical Drawings

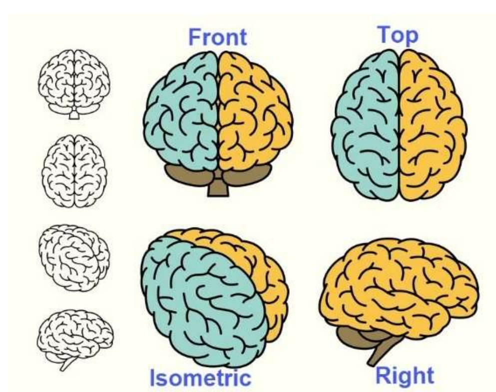
There are 7 aspects of the GD&T methodology that we will discuss, these include: **Views, Dimensions, Tolerances, Symbols, Datum's, Feature Control Frames & Title Blocks.**

Drawing View

The first tool in your engineering drawing toolbox is the **drawing view** which capture the representation of your component from multiple perspectives (front, back, top, bottom, left, right, isometric).

A general rule of thumb is that you should use *as few views as possible to fully convey the geometry of the part*, and give the reader some perspective of the different features of the component.

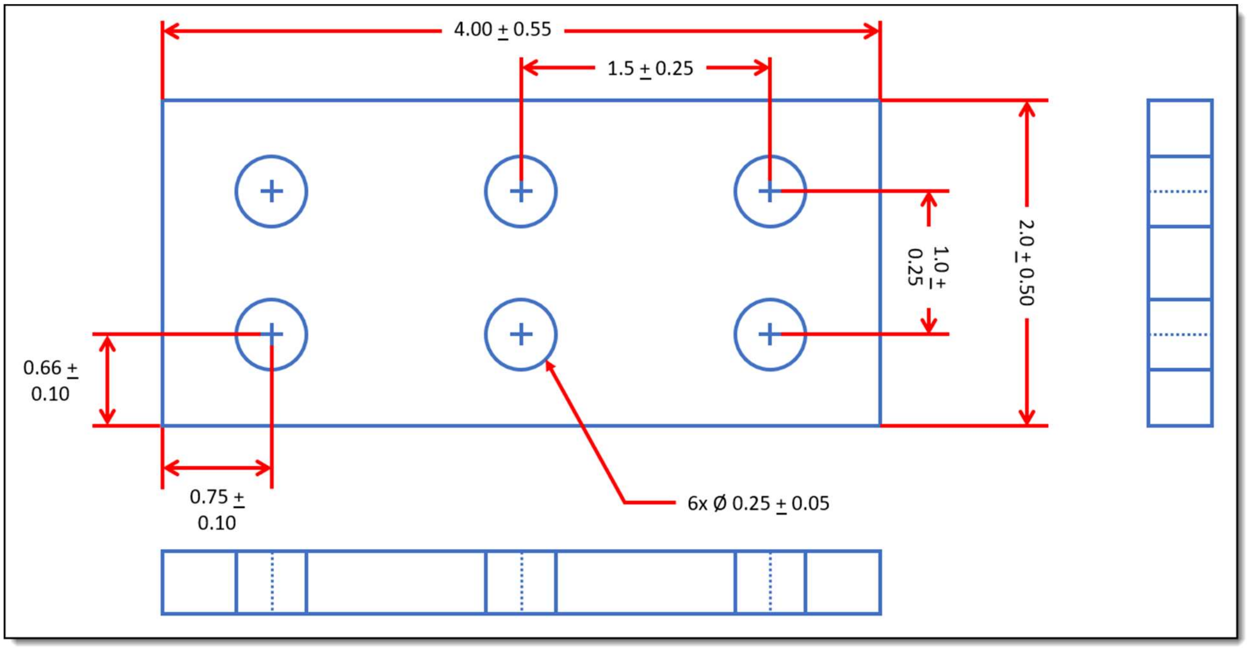
Views can also be taken at **a cross-section** of a component to show internal features or dimensions.



GD&T Dimensions

According to ASME Y14.5, **dimensions** are a numerical value(s) or mathematical expression in appropriate units of measure used to define the form, size, orientation or location, of a part or feature.

As you can see on the drawing below, dimensions are shown through the usage of "extension lines" (shown in red) that are spaced between the two features being dimensioned.



To properly dimension your newly designed product, there are a handful of important rules within ASME Y14.5-2009 that you should know:

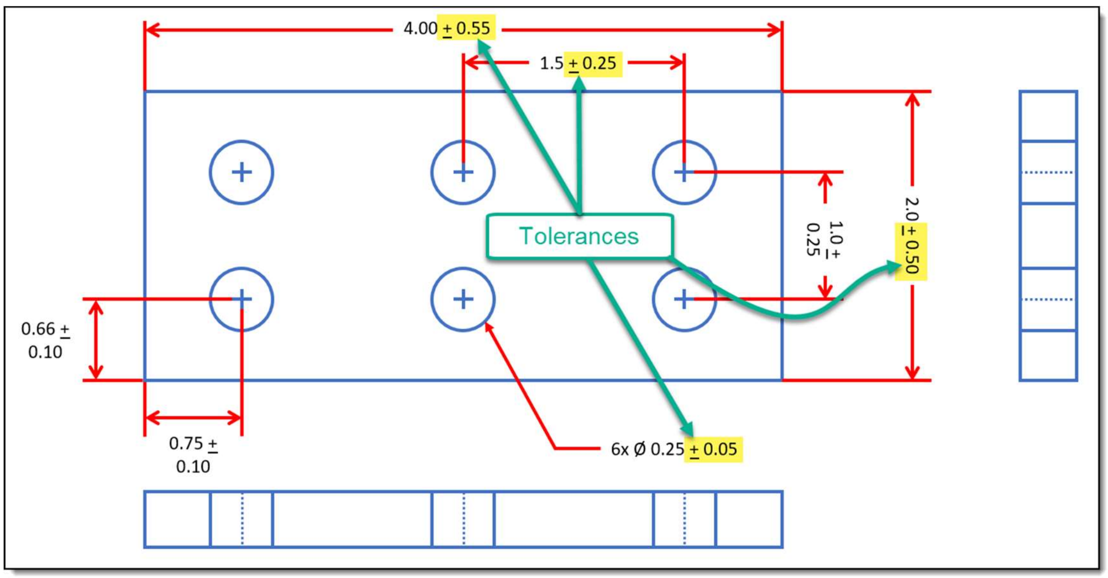
1. Dimensions [and tolerances] shall be complete so there is a full understanding of the characteristics of each feature
2. Dimensions should not be subject to more than one interpretation
3. Each necessary dimension shall be shown
4. Dimensions shall be selected and arranged to suit the function and mating relationship of a part
5. Non-mandatory (Reference Only) dimensions shall be identified by an appropriate note
6. Dimensions should be arranged for optimum readability
7. An angular dimension of 90° is implied for any 2D view where no angle is specified & lines are shown at right angles
8. Dimensions [and tolerance] apply only at the drawing level where they are specified
9. Dimensions are assumed to apply to the full length, width and depth of a feature unless stated otherwise

Tolerances

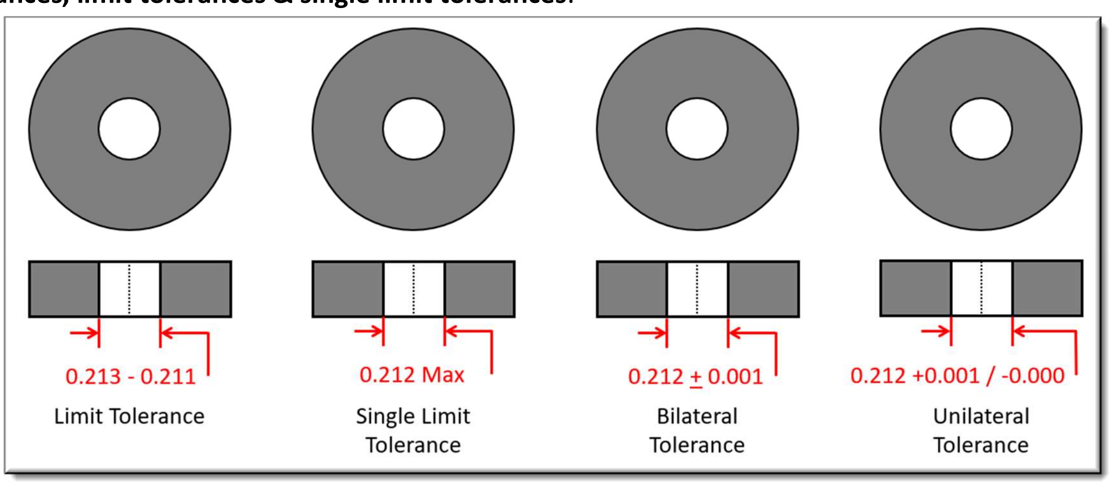
According the ASME Y14.5, **A tolerance is defined as the total amount that a specific dimension is permitted to vary.** This total amount is considered the difference between the maximum and minimum limits.

Tolerances are intended to create boundaries for the design, which create the design space associated with your product. Your product should be capable of functioning as intended throughout the entire tolerance range of your product.

Your tolerances should be created to account for the variation in your value stream (manufacturing process) which can never be fully eliminated, and which can originate from many different sources.



There are 4 different types of tolerances that we need to discuss, these are **bilateral tolerances, unilateral tolerances, limit tolerances & single limit tolerances**.



As shown, **Limit Tolerances** show both a maximum and minimum dimension allowable for the feature. A **Single Limit Tolerance** only defines one limit dimension, normally either the **maximum or minimum value** for a feature or dimension.

The **Bilateral Tolerance** shows the nominal dimension (0.212) and the allowable tolerance in either direction ± .001. The **Unilateral Tolerance** shows the nominal dimension (0.212) and a tolerance in only one direction +0.001.

Another method for tolerancing your dimensions is the usage of **standard tolerances**. For example, many drawings are created with a note that reads like this:

Unless otherwise specified, dimensions are in inches:

- **Angles: +/- 0.5 degrees**
- **.XX: +/- 0.01"**
- **.XXX: +/- 0.005"**

This allows the designer to put the nominal dimension on the drawing and then let the drawing control the tolerance. For example, the designer can show a dimension of 1.45" and the implied tolerance is 0.01" because the nominal dimension was specified to two decimal places X.XX.

Had the dimension been specified to the third decimal place (1.450"), then the implied dimension would be 0.005".

Tolerancing Rules

Similar to dimensions, there are a handful of important rules associated with Tolerance found within ASME Y14.5-2009 that you should know:

1. All dimensions must have a tolerance - unless they are specified as minimum, maximum or reference only.
2. Tolerances [and Dimensions] shall completely define the nominal geometry allowable variation
3. Tolerances [and Dimensions] apply only at the drawing level where they are specified
4. Tolerances [and Dimensions] should be arranged for optimum readability
5. Tolerances [and Dimensions] are assumed to apply to the full length, width and depth of a feature unless stated otherwise

GD&T Symbols

Tolerances don't just apply to dimensions, they also apply to other features and characteristics of your product including **straightness, flatness, position, orientation, etc.** This is where we use **GD&T Symbols** to further tolerance a design.

Below is a table showing the 14 standard geometric tolerance symbols used in geometric tolerancing as defined by ASME Y14.5. These geometric tolerances fall into one of five categories - **Form, Location, Orientation, Profile & Runout**.

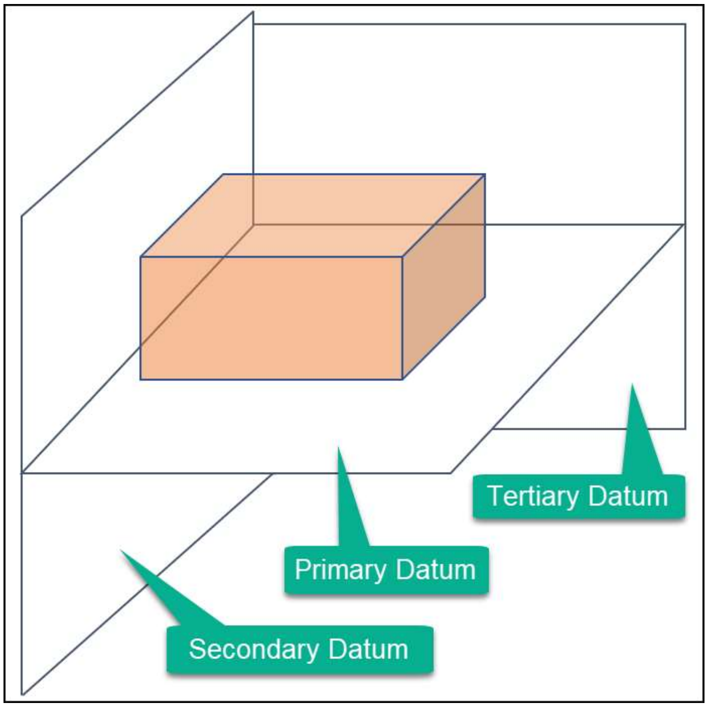
Tolerance Type	Characteristic	Symbol
FORM	Flatness	⏥
	Straightness	⏤
	Cylindricity	⌭
	Circularity	○
LOCATION	Position	⌖
	Symmetry	⌯
	Concentricity	◎
ORIENTATION	Angularity	∠
	Parallelism	//
	Perpendicularity	⊥
PROFILE	Profile of a Surface	⌓
	Profile of a Line	⌒
RUNOUT	Runout	↗
	Total Runout	⌰

In addition to these geometric tolerance symbols, there a handful of other modifier symbols that you should be familiar with, these are shown below:

Other Modifiers	Symbol
MAXIMUM MATERIAL CONDITION (MMC)	Ⓜ
LEAST MATERIAL CONDITION (LMC)	Ⓛ
REFERENCE DIMENSION	(REF)
DATUM FEATURE	A

Datum & Datum Feature

A **Datum** is an imaginary plane, axis, point, line or cylinder that are the origins from which the location of geometric characteristics of features are established.



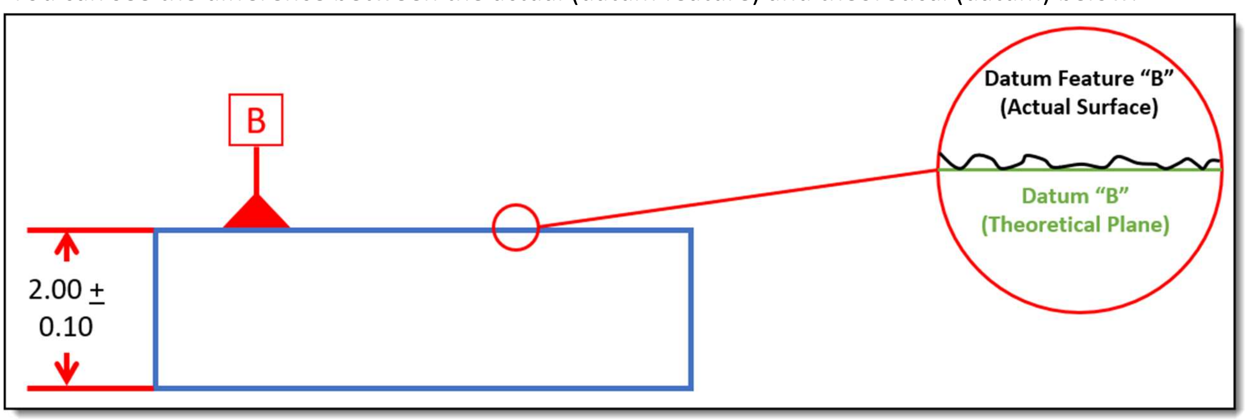
Datums are theoretical and only simulated by **Measurement Equipment** (Gauge pins, Granite slabs, angle plates, etc.).

A **Datum Feature** on the other hand is *a physical feature* of a part that are used to establish the imaginary datums'.

Datum Features are real, tangible features on a part where the measurement equipment would physically touch or measure.

Datum's and Datum features are both important because they become the frame of reference against which measurements are taken.

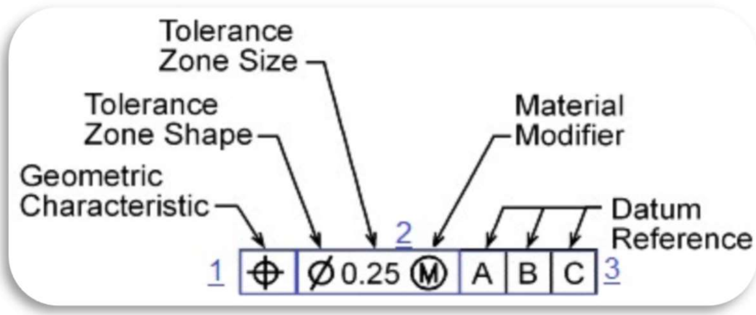
You can see the difference between the actual (datum feature) and theoretical (datum) below.



Feature Control Frame

A **Feature Control Frame** is a GD&T Tool that combines a Geometric Characteristic, the tolerance allowed (Tolerance Zone shape & Tolerance Zone Size), any material modifiers, and the datum feature references *to create a geometric tolerance*.

Feature Control Frames are an effective & compact method for providing clear & concise requirements for the many different features of your design. The Feature Control Frame can be broken down into three sections, shown here in blue.



The first box or section can contain any of the 14 different standard geometric tolerance symbols found above. In this example, the feature control frame includes a True Position Tolerance.

The next section contains the actual tolerance for the specific feature being toleranced. In this example, the true position tolerance is 0.25 with an additional diameter symbol to indicate a circular tolerance zone at maximum material condition (M)

The third and final section indicate the datum references associated with the tolerance. In this example Datum A is the primary datum, Datum B is the secondary datum, and Datum C is the tertiary datum.

This datum order is important because it standardizes the way the part is fixtured during inspection.

Title Block

The title block of any drawing can usually be found in the bottom right hand corner of most drawings and contains a ton of important information. This is where you'll often find:

- the Component Part Number
- the Drawing Description
- the Bill of Material or Parts List
- the Revision Level of the Drawing
- the Standard Tolerances
- the Units of Measure & Scale
- the Required Material &/or Finish
- the number of sheets on the drawing