Manufacturing Fundamentals.

Understanding the Key Operating Principles that World Class Manufacturers Adopt.

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Nov.2020

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Introduction

No matter what size a company is, or how long a company has been established, in the field of manufacturing there are always challenges, whether it be the quality of the product manufactured, the fluctuating demand for the product, the business cash flow, operating expenses, shareholder dividends, the price the company can get from its products or its EBITDA, manufacturers manage it. With all these issues prevalent on a daily basis, how does an organization stay focused in the midst of what often seems like chaos?

In this busy environment, decisions have to be made quickly and effectively, so how does an organization position itself to make fast decisions? On what foundation are decisions made? Is the company approaching the business from a customer first basis? if so is it based on risk, service, or cost?

The fact is, that most organizations have the groundwork pre-established and have a deep understanding of who defines quality, value and the design of the product, and the specifications needed to achieve the quality required, but what happens if there is a quality issue in manufacturing. We can try to predict obvious failures of our processes and do so through exercises like FMEA studies, but we cannot foresee what we do not know. When managing manufacturing processes the unknown will be uncovered, things will go wrong; it is how the organization manages the events that ensures its success.

This book is written to provide manufacturers a logical foundation on which to base their operations and processes in every aspect of the product lifecycle, from concept through design, then process development, qualification & validation to volume production. The book has compiled best practices from numerous companies, from mid-sized product manufacturers, contract manufacturers to some of the World's largest corporate entities. Here we have developed a list of 11 key principles that we suggest you incorporate in your operating system. This foundation can be adopted by the smallest or largest organization, and yield potential savings in the millions, through avoiding the pitfalls organizations typically fall into as they grow, make mistakes, recover, and start over again.

Personally, I have worked in manufacturing for most of my life, starting as an apprentice in a company making cranes and excavators, developing into an engineer in heavy steel manufacturing of buildings then into management in the medical device industry. Having worked in most aspects of manufacturing, from operations, quality, product design engineering and manufacturing engineering, I have myself made many mistakes, some of them costly in terms of missed deadlines, or projects that did not fulfill their full-anticipated benefits. Consequently, the lessons from these experiences have been priceless, as too, the realization that the main cause of the mistakes was that foundational principles were absent or not fully understood.

Having discussed these types of issues with many of my colleagues in manufacturing, the mistakes we all made are commonplace, and usually due to focus of the timeline and we were trying to run before we walked. In the fast-paced environment of needing projects executed faster, time to market shorter to maintain the competitive edge, it is essential that the stepping-stones and foundation for success are established first.

Looking back, is of course is hindsight, and we have perfect 20/20 vision on all the things we have done right and wrong over the years, this is where we can see the things we did and did not understand or anticipate and how that affected the outcome of our efforts. This true understanding of what we missed and how this affected the projects and business allows us to improve the foundational processes creating the foundation stones of a successful business.

Through this book we look at the 10 key "Principles" of manufacturing, to explain what is important about each piece of the puzzle, suggest tools to help organizations manage that aspect and then move to the next step of the process. By establishing and creating the foundations, the organization will have at hand the basis for decisions to be made, and will avoid second-guessing, what ifs, and paralysis by analysis. The importance of the understanding, of these foundation building blocks cannot be understated. Manufacturing businesses are complex, tailored to the product they manufacture and often considered unique, but all the businesses need to understand where the potential pot holes are, what they look like and what to do when they see one.

We explain what is meant by "risk based decision making" how risk based decisions are made, how the operating system needs to be structured to incorporate these principles and how these principles can simplify the everyday management of manufacturing. It is our hope that you will see how these principles, if properly adopted form the grass roots of a manufacturing organization, reduce the complexity of your business and allow you to focus on what can benefit your organization.

This fast-paced environment and drive to project schedule completion time acceleration can and has been the cause of many mistakes, that said, we cannot take our own time leisurely working through a project either, to be competitive we have to be the best and most efficient at what we do. As we learn, we must build on that knowledge, continually update processes so that projects can move swiftly through the process and achieve the aggressive timelines. So when we have a failure caused by haste, impose a safeguard to ensure steps are not missed and the process is thorough. Most importantly, people need to truly own the processes and procedures they work by, refer to them often, simplify and automate the processes where possible, analyze the process flow to determine how multiple tasks can be conducted concurrently and create the most efficient and robust process possible.

This is how we get from "Good to Great," "Top Class to World Class" and how as a country we compete on the World stage. We may not have the lowest cost workforce, but there is nothing stopping our ability to do things better than anyone else. I often wonder why the

Japanese are so revered in manufacturing for their Operating Systems and Lean methodology, but what they preach makes sense. We in the western world struggle to implement their philosophies because we simply do not have their discipline, we do our best, but we can do better.

I hope you enjoy this read, I hope it makes you think and you adopt some of the principles where you can and I hope you take this and expand on it to create your ideal operating system based on your values. Good luck.

Principle 1: Understanding Quality

We all talk about the quality of a product or service either in a good or bad way, when we admire something we talk about all the things that are good about it and how well it was created, or maybe the functionality of something: what it can do that we like. On the other hand, we can complain about how bad the quality of something is, how poorly it looked or functioned and how badly it was put together. Either way, this is the "*perception of a customer"* in which lies the true source of what determines Quality.

To start the quality discussion we need to review the definition of Quality, and what it means for a given product or service.

Quality*: "The standard of something as measured against other things of a similar kind; the degree of excellence of something".*

Quality is specific to each unique thing and is the measure of how good that thing is, for example: If you ask different people to describe quality, you will get a myriad of answers because Quality is perceived. The first thing that comes to my mind when I am asked about quality is a fine piece of Jewelry, it has intrinsic beauty, it shines and sparkles, and, for a piece of jewelry, that is probably how many others see Quality.

If we now dig just a little deeper and look at what other aspects of the piece of jewelry determine quality, for example how well it is constructed, if it holds a precious stone, just how good is the hold on the expensive precious stone? Will it hold the stone for a long time? Is the mount strong? You would not think a piece of jewelry as a high quality, if the stone fell out after only a few weeks and was lost, leaving you with a frame worth a fraction of what you paid for it. No matter how pretty that piece of jewelry looked, it was not what we would define as good quality because it did not stay in one piece as we expected it to.

Another example of quality for a mechanical inclined person like myself would be a Snap-on wrench, because of the way the wrench is shaped and molded, if you pull hard on the wrench when you tighten a fastener or try to break loose a rusty nut, there are no sharp edges that will dig into your hand. The way the jaws of the wrench are designed it seldom lets go of the hexagon bolt, the designed "flank drive" of the sockets mean a rusty bolt can still be undone and the wrench will rather shear a bolt shaft, than round the edges of a hexagon nut or bolt head. Why is this so important to a mechanic? Because every time a wrench slips off a nut the mechanic's hand often hits a hard or sharp surface on the machine he is working on resulting in a cut, or at least a bruise. What this means is that a quality wrench that avoids slips is well worth the money the mechanic pays for it.

Tech industries they are often focused on enhancing quality by adding functionality to a product, and a perfect example of this is the smart phone. All kinds of new Apps, new functions that the Customer may never have perceived they wanted from a phone have been designed into, or to work with the product and we now accept that a smart phone will

have numerous functions like a mini computer as well as being a communication device. This advanced design has not come without a cost impact, which the customer has accepted because the phone does so much more than make calls; we must understand though that not every product can be developed in this way and if costs are added to a product, there must be customer benefits that will be acceptable.

Quality is specific to the product or service that is being looked at, what the product is designed to do, or how well a service was performed, in the eyes of the Customer. This means that Quality starts, and is defined by the Customer, so to understand the quality of product or service, one must first understand what the Customer requires from that product or service.

To understand what constitutes the Quality of a product and what ultimately determines if the product is high quality or low quality we must listen to the User or Customer. This is usually done in the design stage of a product, based on the Voice of the Customer, this information is used to understand what the Customer wants the product to do, how the customer will use the product and what the customer expects the results of using the product to be. Once a product concept has been defined, the designer needs to determine what about the product is "Critical to Quality". Gathering the voice of the customer is far more than just asking what the customer requires in a product, these are the spoken inputs, now what about the unspoken inputs? A customer will answer questions and give great inputs but to understand all the design requirements we must observe how similar products are used so that we can capture what will be some of the most important design requirements. Another aspect of this process is to have more than one person doing it so that you can really capture as many aspects of the use of the product as possible. Understanding the product you manufacture is essential to development of the design of the product, and the understanding of what factors are the most important and which are nice to have's is key.

Critical to Quality requirements are the requirements that the product MUST meet, so the design of the product and the way the product is manufactured must at least result in the product meeting or exceeding these defined requirements. If only Critical to Quality requirements were met and as a result the product always functioned, then the manufacturer would have achieved the minimum Cost of Quality. This is good, however the product (although fully functional) may not look or feel good in the hands of the Customer and as a result may not sell, so there are many aspects of a product, that although not Critical are still important. The question becomes: how much cost do we need to add to achieve good quality in these aspects? Obviously, there is a balance to be defined between cost, functionality and cosmetic appearance and the person who should define this is again, the Customer.

Once the Quality of the product has been defined through the Voice of the Customer then the manufacturer can get to work designing the product with as many aspects as possible of the quality designed in. The more quality aspects and Customer requirements that can designed in to the product (usually) the cheaper the product will be to manufacture.

After the initial design has been completed, Critical to Quality aspects defined and quality expectations for all other aspects, cosmetic requirements, functional requirements etc. defined. The Quality aspects of the product can be designed into the product, and the manufacturing process Proactively.

Cost of Quality

In manufacturing, the most obvious cost of Quality is manufacturing scrap, materials or partially manufactured product that do not meet requirements and so must be either reprocessed or discarded. This cost is directly linked to the manufacturing process and in many organizations, is one of the highest losses the organization has from its operations.

Directly linked to scrap are Non-Conformances found in the process, product that is not exactly what the process should deliver, but not necessarily product that should be discarded. Now there is the added cost of determining what to do with the nonconforming product, scrap, reprocess/rework, or use as is. This is often determined at each occurrence on a day-to-day basis with repeating discrepancies escalated into CAPAs for resolution. The hours and effort needed to manage the non-conformances and CAPAs also adds to the cost of Quality.

NCs and CAPAs are requirements for manufacturing organizations operating under ISO certifications and are ISO's way to ensure continuous improvement. These requirements are an example of good manufacturing practices but often culminate in less than effective results because of timelines imposed to the correction, and the expertise of those organization individuals assigned.

Cost of Quality also extends to suppliers, and their ability to deliver the required quality of materials and products to the business. Defective supplier products and materials can cause operational delays stopping the manufacturing operations of your business resulting in non-scheduled downtime as well as cause extra work investigating the deficiencies, increased inspection and disposition then potential shipping costs to return the product to the suppliers. Repeat discrepancies from a supplier may result in the needs for a supplier visit, an audit of their processes and numerous hours spent developing the supplier to an acceptable level.

In summary, Quality of a product comes at a cost. This cost can be minimized and controlled through a sound Quality Planning Process, which is the most effective way to achieve Proactive Quality.

One thing that must be clearly understood in manufacturing is that a quality product needs to be the normal output of a manufacturing process. Since any inspection that is done in the manufacturing process only determines what parts are non-conforming or bad, it is essential that the parts coming from the process are always good, you cannot inspect quality into a product, you can only determine the bad which then have to be scrapped or reworked. This is why understanding the process through process validation is such an important part of manufacturing.

Principle 2: Understanding Risk - the Key Decision Point

In manufacturing, there are thousands of decisions that need to be made, on any given day, literally hundreds of decisions will be made by your organization, so a basis for decision-making must be established. In order for your teams to make the right decision for the organization and that as a leader you can have confidence in their decision making, a key decision point needs to be established and every leader needs to ask themselves the following questions:

- What is the alternative?
- Am I ready to make every decision?
- Do I want to have to micro-manage every decision in my organization?
- Do I even have the time?
- How can my organization grow, without confidence that my team can make the right decision?

The main reason for micro-management is that the leader has little or no confidence in his or her team's ability to make important decisions. This is usually caused by either not having all the information they need to make the correct decision, or they do not have a basis on which to rationalize a decision especially when the team does not have consensus.

This is where "Risk" comes in. Often referred to as "Risk Based Decision Making" this approach has proven to be probably one of the best methods to use as a basis for making rational decisions. Obviously, this approach has to be based on well-defined principles of how "Risk" is assessed and measured, which needs to be consistent through the organization. Risk to who or what also has to be defined, and there are many risks we could consider, such as the effect to end user, patient or customer as well as business risks like recalls of product or risk of non-compliance.

The next few pages discuss how to define risk

Measuring Risk

There are many risk assessment methods including Failure Mode and Effect Analysis, Hazard analysis, and numerous others, so a solution needs to defined that is consistent across the different types of risk assessments. FMEAs can include application, design and process FMEAs all of which should all have the same methodology to determine the risk level.

The understanding of how to measure risk needs to be fully understood if it is to be a successful tool.

Risk levels are normally measured from a combination of two main inputs:

- The severity of the issue or failure to the end user, patient, customer or business
- The potential frequency that the issue or failure will happen

The next part of the equation is to rank the severity based on the outcome (normally looking at the worst case scenario that could happen). Here a numerical scale is needed to quantify severity levels, the scale needs to have sufficient levels defined, but not too many levels where the difference between the levels would not be obvious. When FMEAs were first introduced the scales were often 1-10, 10 being the highest severity, however the issue with a 1-10 level scale was that folks would often spend long periods of time trying to agree if the severity should be ranked at a 6 or a 7. Because there was little difference between the descriptions of the severity levels on a 1-10 scale most risk assessment users have reduced their scales to a 1-5 so that each level is more defined and the difference is more substantial and less open for interpretation. Here is a typical 1-5 scale for severity:

Severity Table:

S1	Cosmetic defect that may be noticed by the Customer but will not affect the functionality or purpose of the product and will not cause harm.
S2	Minor defect that may affect the proper functionality of the product, but does not render the product unusable, inconvenience to the user and possible complaints.
S3	Defect will affect the functionality of the product and possible minor harm to the user that may result in minor surgery to correct. Will result in complaints.
S4	Major Defect that has the potential to cause serious harm, however the harm can be addressed and is not fatal. Or, a compliance issue that may result in a product recall.
S5	Acutely Life Threatening, possibly Fatal

As you can see this scale has good definitions for both customer and business issues, the different severity levels are substantially different, and can now be well understood. There should be little disagreement as to which outcome needs to be chosen based on the worst case outcome of the issue or failure.

The second part of the equation is the frequency that the issue or failure will occur; this is a little more subjective. There are many ways to measure frequency; it is good to have scales set up for different circumstances so that your risk assessments can be applied to any issue. The table below shows five different measures but the measure for the company is the same not matter which measurement type is selected. The table is again a 1-5 level so and the measures apply to different applications of the risk assessment. The process capability measured in Ppk or Cpk is not always known, but if this measure is available it is the most accurate. If capability is not known, then DPM or Yield is a similar measure that can be

calculated easily. DPM is defective parts per million, so how many parts in 1,000,000 are not to specification. DPM is not appropriate for low volume circumstances so that is when we can turn to yield. Yield is the percentage of good parts (or events) per 100. All three of these measures are great for manufacturing but if we are looking at design or even a business issue we need a more generic measure such as qualitative or even time based.

Which measure type you decide is most appropriate the table shown has an "equivalent" measure type for each of the five frequency levels. If we look at Frequency level F1, for process capability the Ppk is greater than 1.67, which would have less than 0.6 defective parts in every million parts produced, the yield would be in excess of 99.999%, the chance of a defect is improbable, and we should not see a defect like this any more than once a year. In summary each of these measure types has the same frequency rate. The Qualitative and time based measure types may need to be calibrated based on the business and volumes of products made, so they may need to be tweaked a little, however the principle is the same.

Frequency Table:

	Process Capability (Cpk)	DPM	% Yield (min)	Qualitative (Used in Hazard Analysis)	Time Based
F5	> 0.67	19,300	95	Frequent	Daily
F4	> 1.00	2,700	98	Probable	Weekly
F3	> 1.10	1,000	99.9	Occasional	Monthly
F2	> 1.33	63	99.993	Remote	Quarterly
F1	> 1.67	0.6	99.999	Improbable	Yearly

Here you can see different ways of measuring frequency:

- Process Capability – often used in Process FMEAs based on qualification data
- Defective Parts per Million – used when looking at either production data or complaints data from the field.
- Yield – used when looking at manufacturing scrap rates from processes
- Qualitative – Used when you have some data but when you are estimating
- Time based – again when you have some knowledge but not definitive.

What does each different measure have in common? – They are all equivalent, so no matter which column you choose they are (roughly) the same.

Now we have the two inputs, we need to determine the risk level. The way we prescribe is a simple matrix that takes the severity number and the frequency number and looks up the risk level based on the following risk matrix:

Risk Matrix:

	F1	F2	F3	F4	F5
S1	BA	BA	BA	BA	ALAP
S2	BA	BA	BA	ALAP	ALAP
S3	BA	BA	ALAP	HLMR	HLMR
S4	BA	ALAP	HLMR	HLMR	HLMR
S5	BA	HLMR	HLMR	HLMR	HLMR

The Risk Matrix has been created to accommodate a 1-5 level severity to 1-5 level frequency inputs.

- BA means “Broadly Acceptable”,
- ALAP means “As Low As Possible” using state of the art technology currently available,
- HLMR means Hazard Level Management Review.

So based on this Matrix we would like the following:

- No HLMR risks
- As few ALAP risk levels as possible, however this risk level may be accepted if no other option exists at that time that will reduce the risk.
- BA is acceptable and ideal

HLMR risks need to be understood by everyone in the business and that is why they are titled Hazard Level Management Review, because senior management need to understand where this level of risk is, and what the organization is doing to reduce the risk.

Since the severity of something happening will never change, the way to reduce risk, is the control that will determine the frequency the event or failure happens. This basic measurement of risk approach drives the business to deal with what is important, to safeguard their customers and their business against failures of manufacturing processes, business processes or product that would cause harm to the customer or the business. This is why Risk should be the “Key Deciding factor”.

So how is the frequency of a failure reduced?

This is done in many ways: If the failure is caused in manufacturing then we should be measuring the manufacturing processes so that we can understand their capability to produce conforming product that meets the specifications of the design. This is where process qualification comes in to the equation. If we measure a process and define its capability by statistical analysis we can calculate the Cpk or Ppk of the process to make a part to the designed tolerances. When we measure the capability, we can see where the process capability is not where we want it and we can focus on developing the process so that the capability is improved. If we improve the capability from a Cpk or Ppk of 0.67 to 1.67 then we can effectively reduce a HLMR risk to a BA risk level.

If the process cannot be improved by the desired amount, we must look at what controls we can put on the process to ensure defective parts manufactured in the process are detected and removed from the process so reducing the frequency that way. The best approach here is to remove the defective product as soon as the defect is detected, this helps in two ways, first, we add no further value to a defective part and second, we do not have to track the defect though other process steps where it could be missed.

If the design of the product is such that potential high severity defects can occur then the designer needs to look at different design concepts that could eliminate that failure mode and so reduce the frequency by designing out the issue. This is obviously the best solution and the reason Design FMEAs are so helpful.

Now we have established how we can measure and define risk consistently, the next question is “what level of risk is this organization going to accept?”

We all need to realize that there is risk in everything we do; there is even risk in everything we do not do. There will always be failures or issues to resolve, if we do not change anything, then we will not improve. In this regard, the company needs to understand what risks it is taking, and look at the controls needed to mitigate the risk. The other aspect is the conversation on Risk/Benefit Analysis. In some cases there may be high risk that is acceptable, a perfect example I was given was in the case of a blood coagulant powder that was being developed, there were substantial risks in what the powder would do in an open wound if the damage went beyond just tissue damage. In this instant, the injured person would bleed out and die without the use of the product and even though the product use was high risk, it could save the life. The project was completed understanding the risks, making the risks clear to everyone, the regulatory bodies, the FDA and most importantly the end users, the product has save thousands of lives that would otherwise have been lost.

This is the reason that Principle 2 is “Understanding Risk” how to measure it, how to reduce it, how to assess risk versus benefit and how it forms the basis of key or difficult decisions related to the product the organization manufactures. This principle should be used in every stage of the manufacturing and product design processes and should be the

foundation that drives design concepts, process capabilities and controls needed for the product manufacture.

Principle 3: Understanding Quality Management Systems

The Quality Management System of an Organization is the core of any manufacturing operation no matter what industry the business serves, and is the documented processes that the organization follows to conduct business. The importance of the system is essential to the business success. Smaller businesses have to be nimble and cannot withstand a heavy QMS that requires a lot of maintenance and resources to support. In this case the procedures should be written in a manner that the business can follow easily and developed to suit the business's processes (in compliance to a standard, such as an ISO standard).In this case procedures should be based on meeting at least the minimum requirements of the standard they are certified to.

So why are procedures so important?

Simple really, they are the baseline of how an organization operates, they document the process followed in order to complete a task. This is how we ensure that all employees complete the task in the same manner, and if properly defined and documented should result in a successful output. Without such documents each employee would possibly approach the task differently and the probability of success in every case is little to none, wasting time and money.

The second advantage of documented processes (procedures) is that when something goes awry, we can look to see where in the process it broke down, and what could have been done differently that would have prevented the failure. Knowing this information, we can then modify the procedure and improve the robustness of the process to ensure such failures do not happen again.

No matter how big or small the organization is, if the people operating under the system do not take ownership of the procedures that they are required to follow, the system is rendered useless.

ISO based systems are requiring a process approach for their systems, meaning the inputs to a processes step result in outputs that feed into the next process step as inputs. This process-based approach is essential to the QMS as it ensures that process steps are not missed or skipped. If we simply take the ISO requirements, stated "shall" do's and write those in the QMS procedures we will not be setting up a process flow and people will do the least, often creating less than desirable results. When less desirable results occur there is often haste to understand who messed up and why, but when we have a process based procedure we should be focused on where the process broke down and allowed the less desirable result to happen, then as the owner of the process, make corrections or improvements to ensure the issue does not re-occur.

Understanding the base principles first is essential, and these principles build on themselves creating logical methods for doing things "Right". Principle 1 and understanding

Quality has to be first because your organization manufactures a product and we must understand what about the product makes it a quality product. Principle 2 understanding Risk and how to measure it sets up the foundation for all the rest. As you build your processes and procedures, create the process flow then run a risk assessment on it. Sounds strange? Let me give you an example:

If we look at one of the first steps in Design it will be to gather design input:

Process Step	Failure Mode	Failure Cause	Failure Effect	Severity	Current Controls	Frequency	Risk
Solicit Design Input	Key Design inputs not collected	Insufficient customers canvassed	Product does not meet customer needs	3	Design Control Procedure	3	ALAP
		Customers canvassed did not convey all the needs	Product does not meet customer needs	3	Design Control Procedure	3	ALAP
		Only one person gathered customer input	Product does not meet customer needs	3	Design Control Procedure	3	ALAP

By simply going through the process of mapping the process step and considering the main failure mode what do you see?

Immediate away:

- Procedure needs to state minimum number of customers to be canvassed
- Need to create questions to drive input conversations
- Need to have more than one person gather input so more detail is gathered

Would you have put any of that in the procedure the first time? See the value?

Another aspect of Voice of the customer is all the things they do not say but assume you know, these are the *unspoked requirements*. Since we cannot assume anything what do we need to do? The answer here is to observe. Part of the process for design inputs should be that the input gathering team observe the use of the product or similar product that they are about to design and document needs that no-one talked about.

Look at what you have now created, it is a robust process to gather design inputs for the first step of the design process, which will prove to be the most important step when the final design is completed and the first prototypes are placed in the hand of the customers for feedback. Now let's look at where this puts the risk assessment:

Process Step	Failure Mode	Failure Cause	Failure Effect	Severity	Current Controls	Frequency	Risk
Solicit Design Input	Key Design inputs not collected	Insufficient customers canvassed	Product does not meet customer needs	3	Minimum number of customers defined so that a staisticall valid amount are canvassed	1	BA
		Customers canvassed did not convey all the needs	Product does not meet customer needs	3	Questionairs will be created to drive customer discussions. Observations of customers using the product will be documented	1	BA
		Only one person gathered customer input	Product does not meet customer needs	3	A team consisting of marketing and design engineering will together gather design input	1	BA

If we look at the controls that have now been put in place the process is robust and the risk level is acceptable.

This is not to say this process cannot be improved upon further, all processes can, but by using Risk and the risk based approach to what we do, look how much better we can make things.

Taking the “Shall’s” from the requirements creates the skeleton for compliance, taking that and developing the process puts in the tools to ensure the inputs of a step are gathered and the outputs are defined for the next process step. Running the developed process flow through risk assessments can develop the content for procedures and work instructions to ensure the process step was completed properly and show where the process is not robust.

The best people to do this work are the process owners, those who own the procedures and work instructions so continuous development and improvement can happen. If the QMS is developed in this manner, the organization will be off to a flying start.

The Quality Management System covers every functional aspect of the business other than financial, it is far more than any one group can manage, so ownership of the respective sections of the system has to be absolute. Managers should understand their responsibilities in this regard as the success of their employees should reflect the processes they are following. In reality this is seldom the case, which often results in the employees bypassing procedural steps and just trying to put something together that can meet the “Shall” requirement. Due to the lack of a robust process we find that the Risk assessments are completed after the process so that the box can be checked and the employee can move on. When this happens all the value of this approach is lost, processes are not robust, results are poor and work-around’s abound so that timelines that are already missed can be mitigated. This is the chaos in manufacturing that can be avoided.

In summary, use Risk to measure and assess all processes. Drive for a robust process by considering potential shortfalls or failure modes, work towards a risk level of BA (Broadly Acceptable), and as documented above, the same format can be used to measure and assess any process, manufacturing or business. Make sure the process owners truly own their processes and procedures. Audit all the processes often, and develop the process as soon as an issue is identified, do not wait for an audit to find it!

Principle 4: Understanding the Design Process

This is an area that very much depends on the industry your organization serves and there are many manufacturers that do not have product design as part of their business, either way an understanding of the process is important for any manufacturer to appreciate. If you do not design in your organization this insight should allow you to understand your customer's process and where you fit in.

First and foremost, the customer or end user defines Quality, and so should be the driver of design. Research and development has to have both aspects working all the time and the feeder to this group is usually the Marketing division of a company. Marketing are usually the face of the business to the customer and this group is key to defining what the customer needs are, either designs for unmet needs or better designs for things they already have. A constant pipeline of opportunities needs to feed into the R&D group so that ideas can be assessed, concepts developed and prototypes made that can be tested and reviewed by Marketing and the customer to see if the preliminary solution is what the customer is looking for.

Design Inputs (Customer Needs)

Customer needs that will eventually develop into design requirements should be gathered through the marketing division of the company in cooperation and with assistance of the Design Engineers. Gathering customer needs is far more than asking someone what they want in a product, that is a small part of the process.

When an idea is floated, marketing and design engineers need to get together and discuss so they can define as many questions for the customer as possible that will help shape the idea so a concept can be developed. Several customers or potential end users need to be identified as Key Opinion Leaders for the business to ensure multiple sources agree that the idea is a good one and can give design input.

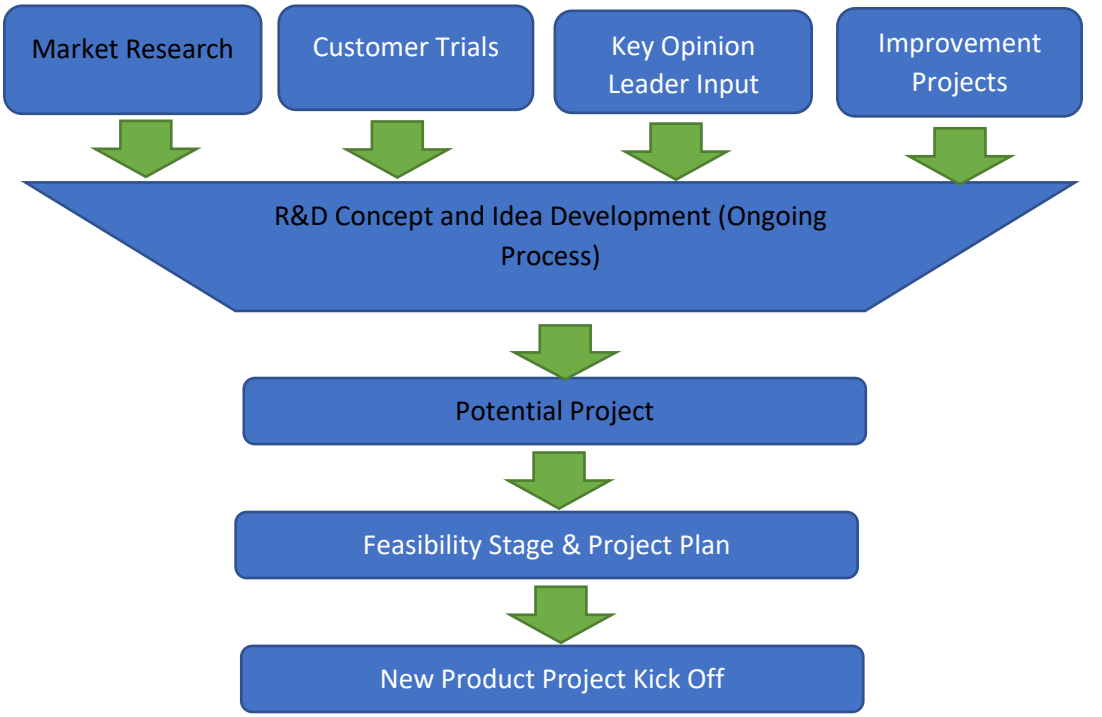
Another part of customer inputs are the unspoken requirements. As with most things, assumptions are always made that the person gathering information understands all the obvious needs and this is an area where that is very often not the case. So unspoken requirements need to be considered by observing a similar product in use and documenting how the product is used. For this reason, Customer requirements need to be a team event, the more people observing and asking questions, the better the input and because this is the very start of any new product, it is probably one of the most overlooked.

From this pipeline, and as concepts are developed projects should be formed, at which point the feasibility work should start in earnest. Defining the scope of the project, the preliminary design concepts for the project, an assessment of potential risks the product

may have, the market size for the product once it is released, and the expected timeline to transfer the design to full scale manufacturing and commercial release.

Once the feasibility stage of the project has been pulled together it should be reviewed by Senior Management and approved to move forward or halted if the business case criteria for a project is not met.

Project Pipeline Process



From Concept to Project

Once a project is launched, a cross functional team is assigned to the project and further develops the design and defines the design requirements that need to be met in order to meet the customer expectations. Parts will be manufactured for testing purposes and manufacturing processes for the parts will be defined and validated.

Defining Design Requirements

Defining the Design Requirements is a process by which the design team reviews the Design inputs gathered and works with Marketing and Customers to rank the importance of each input. Once the most important inputs are defined, the team transposes the input into a design requirement and adds more specific details based on the scope of the project. The team will try to create a design for the product that meets all essential needs and

accommodate as many of the less important features as practical so that the customer is satisfied with the product.

With the design requirements now defined, the team will identify which of the requirements are essential to the product and must be met so that the product meets expectations. This is an important step as these requirements will be essential to the quality of the product, and any related design feature of the product should be defined as a CTQ (Critical to Quality). By defining key features and CTQs we can ensure the design of the product and the manufacturing processes are robust and will always produce product with CTQ features correct per the design should be the Design Process. These CTQ's will then be traced down through the design process from the Design requirement to the feature of the product designed to meet the requirement, then to the dimensions of the feature and finally to the manufacturing process that creates that feature. This is known as "Quality Flow Down" QFD and uses simple matrices called "Houses of Quality" to track and trace the CTQ from requirement to process.

Use Risk to Drive Design of the Product

The key Risk assessment that drives and prioritizes the design of the product is the Design FMEA which should be started as soon as the design requirements and CTQs are defined. Adopting this risk approach, design concepts and features can be assessed and risks of feature failures defined by rating the severity of the potential failure, then based on the design, the frequency the product feature might fail. If the combination of severity and frequency result in a high risk, either the design needs to be refined or testing of the product for that specific failure needs to be conducted so that the actual frequency of a failure can be defined. If the actual frequency (based on the testing) is lower than the estimated frequency in the dFMEA, then the risk assessment can be updated accordingly which should result in a lower risk level (Mitigated Risk Level). If however the estimated frequency and the actual frequency are the same, the team must make the decision to redesign or accept the risk. NOTE: HLMR risks should always be reviewed by senior management so that the organization is aware of any high level risks and a Risk/Benefit analysis should be the basis for acceptance of that risk.

The dFMEA needs to be the tool that measures the robustness of the design and where the risks of a product feature failure are high, this drives the designer to look for more robust design concepts. Another output of the dFMEA is what needs to be done to verify and validate the design. Based on the risk level of a potential failure mode, the verification that needs to be done to test for the failure, the sample size for the testing, and the acceptance level can be defined based on the risk and level of capability or control needed to mitigate the risk to an acceptable level.

For example: A potential failure mode could result in a failure that has a severity rating of S4, meaning a serious injury to the user or patient but not fatal. Based on the Risk Matrix, the ideal frequency for this failure to occur would be F1 mitigating the risk level down to Broadly Acceptable. In order to accept the design we would need to test the product for

that failure sufficiently to meet that level of capability measured either by Ppk, Defective parts per million or yield. Using soft-wares like Minitab, the sample size for the testing can be established. If the product passes the testing, then the dFMEA can be updated and the risk mitigated accordingly. This is the principle when applying risk to drive design and using the dFMEA to define the verification and qualifications needed to design validate. If the testing shows that the product does not meet the required capability then the designer should either change the design or accept a higher than desirable risk level.

Designers also need to take into consideration the manufacturability of the design they are making to ensure the product can be repeat-ably produced, meeting all the defined specifications and tolerances. This is known as “Design for Manufacturing” which will be the key focus of the manufacturing engineer assigned to the design team.

The product should be designed so that it can be readily manufactured using known processes, so as the design concept is being developed so too should the manufacturing process that will be adopted to make the product.

Use Risk to Drive Design of the Process

As the Manufacturing Engineering team engage, they will review the product design and start to define the manufacturing process for the product. The core Risk assessment used in this phase of the project is a Process FMEA, which should be used to measure and define the risks at each process step. By using the output of the design FMEA, the manufacturing team can understand the severity of any design feature failure not being to the specified dimensions and tolerances. This is key to the definition of what process should be adopted in order to meet the specification. Tight tolerance dimensions are always a challenge for manufacturing and an appropriate manufacturing process needs to be selected based on the tolerances of dimensions in the product drawing. The tighter the tolerance, the more precise the manufacturing process will need to be, and so cost is added to the product based on this premise. Since not all manufacturing processes can be performed by a single manufacturer, outsourcing some process steps may be needed, again adding cost to the product but also logistical challenges.

Normally after the manufacturing engineers have defined the process, there will be qualification of the processes. The qualifications will allow the team to understand the process capability and robustness to deliver quality product. Normally a two stage process, Operational Qualification followed by a Performance Qualification.

Designing the Frequency levels with the option to select the qualified process capability levels is a great way to accurately define the frequency. This is a direct measure of the process you are working on, and if the process capability is high, then you are assured that the product coming from the process will be conforming. This however can only be confirmed if the qualified process is properly controlled, the programs developed for the process are not changed and there is some sort of process monitoring in place demonstrating process control and stability. As stated in Principle 1, Quality comes from

the process and can never be inspected into a product, so process capability and process controls are where the quality of the product is assured.

Design Verification

Design verification should be conducted on product that has been manufactured using the qualified process, as this is the product that the customer will see. Testing prototype product can be misleading and may be useful to see provisional results, but product from the defined and developed manufacturing process is a true verification of the design.

Design Verification is the physical testing of the product to ensure it performs as designed. The testing will be either determined by standard tests for similar products or tested needed to define the frequency of a failure as determined by the risk level in the Design FMEA. Attention should be given to representative sample sizes that are statistically justifiable. Once the testing has been completed, the Design FMEA can be updated and high-level risks potentially reduced based on the verification testing results.

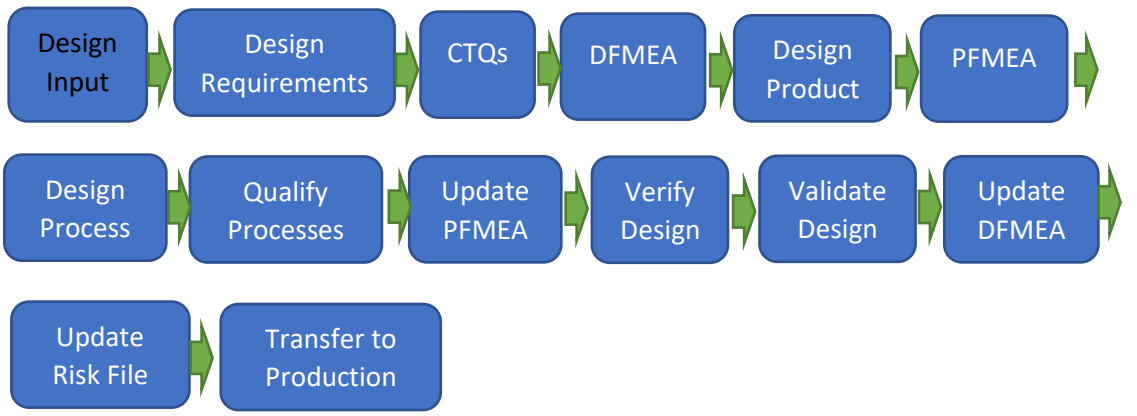
Design verifications can also include simple verifications to confirm that all design requirements have been met, these verifications may include physical size, color or other simple requirements and may be verified by a single sample. Other verifications may be complex testing of multiple samples needed to demonstrate capability. Design Verification is the physical testing of the product to ensure design requirements are met.

Any remaining “Higher than desired” risks in the DFMEA need to be considered in the Process FMEA and should be reported out in the Risk Summary Report prior to commercialization of the product.

Design Validation

Design Validation is conducted when the new product is given to the customer or Key Opinion Leader to establish that the design meets the customer’s expectations and real life testing. This is the process of validating the R&D team has delivered what was intended. This process usually starts with a list of the design requirements and questions for the user, use of the product by the user and assessments to determine with objective evidence that the design was successful.

The Design and Transfer Process



Principle 5: Understanding Process Qualification

Many people if asked will tell you they understand process qualification and cite you the usual IQ/OQ/PQ, they know what each of them are, but how many understand all the foundational principles that a solid qualification and validation system needs to stand on?

Again, this is a process and you need to have a bit deeper understanding of, to be able to connect the dots from the foundation documents and principles to the development of a robust qualification and validation plan that covers all aspects of the manufacturing process, the equipment, the key process input variables and the capability of the process.

First, consider the intent of process qualifications:

"To measure, develop and qualify a ROBUST manufacturing process that can repeatedly produce product to specifications".

Now we understand that quality comes from the process and not through inspection or other controls, we must understand the dynamics and variables of the process we need to qualify and through the qualification process, confirm the process parameters and capability.

The first step we need to take is to investigate the process to gain understanding. We do this through what are known as Design of Experiments or DoEs. These are test runs of different process set ups of what we call Key Process Input Variables or KPIV's. Process Input Variables are whatever settings of the manufacturing equipment that can be adjusted. For many machines these are temperatures, pressures and timings of machine cycles but can also be mechanical settings, speeds, or feeds, whatever is adjustable. Key Process variables are the one's that have a direct control over the output of the process or the effect to the product.

Principle 7 gets into a lot more detail on DoEs so at this point we will leave that subject for now, and we will say that the process we are discussing has been developed.

Once the process has been developed we need to qualify any variable parameters to ensure the extent of the variables still produce conforming product, then we need to validate the long-term capability of the process to ensure it is robust. Sound simple enough?

Let me throw out a few things that often arise as we get into qualification:

- What will we measure?
- What will be the capability I need to achieve?
- Should I us Cpk or Ppk?
- What if the variable data I get is not normal?
- Do I need to do a gage R&R or a TMV?

- What if the data I have is just pass/fail (attribute)?
- What will be my statistical rationale for sample sizes to inspect?
- How does the dFMEA and pFMEA play in to qualification?
- What do I need to measure after the qualifications have been completed?

If you have all these questions already answered, then you probably have a good system in place for qualifications and you understand the process well, if you do not have all these questions answered and you stumble over them every time you try to do a qualification, then this Principle may give you some options for the future.

What to Measure?

Products can have literally hundreds of dimensions and it is not practical to measure all of them so we need to determine which dimensions are important to the functionality of the part. If the Design team has done the "Quality Flow Down" Matrices, the CTQs of the product (Critical to Quality) are defined and the associated dimensions of the product's important features are what we need to measure. If this is not the case, we need to direct our attention to the Design FMEA to understand which features have potential failure modes with high severities. Based on this information we can identify the dimensions associated with the features of the product that must not fail and focus on those dimensions. So, if CTQs are not available and if you need to use the dFMEA you will need a matrix that associates the dFMEA severity to a defect classification that is in line with the severities defined in the FMEA. See below:

Defect Classification/Severity Table

S#	Defect Class	Defect Description
S1	Class 3	Cosmetic defect that may be noticed by the Customer but will not affect the functionality or purpose of the product and will not cause harm.
S2	Class 2	Minor defect that may affect the functionality of the product, inconvenience to the user and possible complaints.
S3	Class 1	Defect will affect the functionality of the product and possible minor harm to the user that may result in minor surgery to correct and complaints.
S4	Major	Major Defect that has the potential to cause serious harm, however the harm can be addressed and is not fatal or a compliance issue that may result in a product recall.
S5	Critical	Acutely Life Threatening, possibly Fatal

Whatever method you use to define what you measure in a qualification, it needs to be based on Risk, so a correlation of the CTQ to the risk needs to be made in the dFMEA. This does require a defined amount of granularity of the dFMEA and this factor needs to be captured in the procedure or work instruction related to design risk assessment.

What Process Capability do I need, Cpk or Ppk?

Now we have identified what we will measure, the next foundation we need is to answer is what capability do I need to achieve and will I be looking at Cpk or Ppk?

Having linked our dFMEA severities to a defect classification we have in effect established the Severity level which we can now correlate to the level of process capability needed.

Severity/Defect Classification/Capability Table:

S#	Defect Class	Required Capability	Defect Description
S1	Class 3	0.67	Cosmetic defect that may be noticed by the Customer but will not affect the functionality or purpose of the product and will not cause harm.
S2	Class 2	1	Minor defect that may affect the functionality of the product, inconvenience to the user and possible complaints.
S3	Class 1	1.1	Defect will affect the functionality of the product and possible minor harm to the user that may result in minor surgery to correct and complaints.
S4	Major	1.33	Major Defect that has the potential to cause serious harm, however the harm can be addressed and is not fatal or a compliance issue that may result in a product recall.
S5	Critical	1.67	Accutely Life Threatening, possibly Fatal

Since the highest severity is Death (in the table above S5) the capability needs to be such that we would have less than one defect in a million. A capability of 1.67 gets us to 0.3 defects in a million and is a practical capability to meet.

Major defects that could cause harm but not fatal we have set to exceed a capability of 1.33. This capability is commonplace in industry and is often the required capability for all dimensions measured in a qualification, but that is not Risk based, so if the industry you are in is focused on Risk, a severity risk table like the one shown will get you there. Other factors that need to be understood is the volume of product that your organization will manufacture. If you are manufacturing millions of products in a week, the process capabilities you need to achieve may need to be higher than those prescribed here.

Next part of the question is Cpk versus Ppk? We would prescribe Cpk to be used for OQ runs and Ppk to be used for PQ runs, this is because we apply Cpk to a single lot and for a snap-shot it is the method to use. For PQs we require a minimum of three lots with the process being cleared and re-set-up before each lot run to simulate long term and in this

case we use Ppk. One thing to bear in mind is that PQs will usually result in lower capabilities when measured over three lots, as this will be a "worst case" scenario. When you run multiple lots you need to expect your data to reflect it and you may see that data is not normal but Binomial or other Non-Normal distributions potentially caused by process set ups not being the same or other variables in the process. This leads nicely into the next question that is often asked when statisticians start reviewing data.

What to do if the variable data is non-normal

I have seen this question drive hours and hours of deliberation between quality, manufacturing and design engineers to really no god end. The fact is non-normal data can be attributed to all types of things and defining the true source of what is driving the non-normal data is not an exact science.

Of course, if the data from a give process is always non-normal then we can use one of the non-normal distribution options and calculate the Ppk, which will result in a better Ppk capability score than by using normal data option. When however, some of the data is normal and some is not-normal what do you do? My suggestion here is to treat all the data as normal, since this will give you the worst case result, and as long as you meet or exceed your required capability level, you have done your job.

By using this approach all the hours of debate over the normality of the data is avoided which gives time for the engineer to focus on just what is the issue that is behind any low capabilities he or she is dealing with.

This is the true beauty of this Risk based approach, the severity is defined by the dFMEA along with the product failure mode, the capability to achieve is predefined by the Severity table, so again, as long as the Ppk level is achieved the data normality is not a factor.

Do I need a Gage R&R or a TMV?

When do we need to conduct a Gage R&R or Test Method Validation?

First we need to understand the capability of different measurement devices we use and this capability *is not* the accuracy. Some people think that if a measurement device has a digital display that has 4 or 5 decimal places it is that accurate when in fact it is not. Measurement technique is a huge factor in hand held measuring devices especially with micrometers and calipers, how tightly it fits on the part can affect the measurement substantially up to 0.002 – 0.003" for some calipers. For this reason it is a best practice to conduct baseline Gage R&Rs on all measurement devices and establish their true measurement capability.

Optical measurement equipment has extremely high accuracy and is highly used these days. Accuracies of some of these pieces of equipment is claimed to be up to half a micron (0.00002") which is extremely impressive. That said, these pieces of equipment are programmed to detect edges of a part and determine the distance between the edges.

Since edges are not always sharp such as radius edges, the equipment can have difficulty finding the true outer edge, if the part has a very small burr it may measure the edge of a burr and not the side of a part. Another issue is the fixturing of a part, for an accurate measurement the part must be presented perpendicular to the measurement lens, if the part is at any angle other than 90 degrees to the lens, the part will measure small. So if asked if gage R&Rs should be conducted on vision equipment, the answer is yes, and especially if trying to measure a tight tolerance less than a couple of thousandths.

Next level up is the CMM Coordinate Measurement Machine, which use a probe to touch the part at a predefined pressure. Again these have super high accuracy but their capability is still based on how the dimension is measured and the fixturing of the part.

The practicality of doing gage R&Rs for numerous dimensions on a given product is not realistic, we can sometimes look at the really tight tolerances that are called out on a part and do a gage R&R on those but the most practical approach are process capability studies completed during a qualification. The fact is, if we run samples to measure during either a DoE or even an OQ we can see which process capabilities do not meet our desired level. There can only be two reasons:

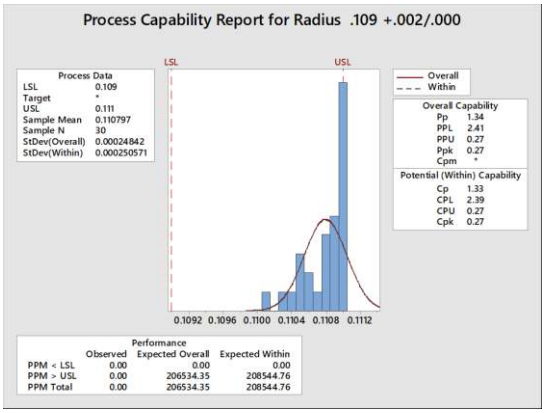
- The process is not robust and has a large variance, or
- The measurement technique is low and not accurate enough.

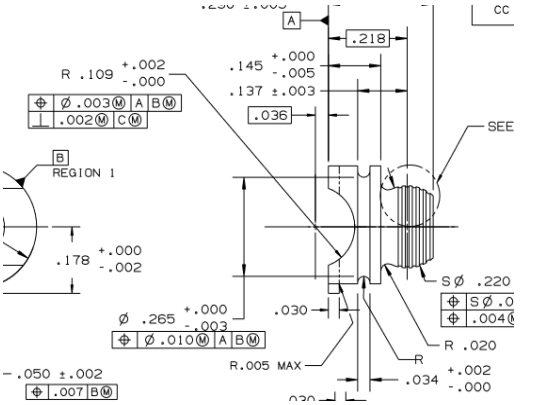
The truth is, that it is often easier to conduct a gage R&R to determine the accuracy of the measurement method than optimize a process further to achieve the desired capability. If the variability is in the measurement, it can often be fixed by modifying the measurement method, or improve the fixture or by simply using a different measurement tool or piece of equipment. Due to this, I prescribe doing a 30 piece capability study, calculate the Ppk for all the dimensions to be measured and only do Gage R&Rs when the process capability level needed is not achieved. This saves wasting time and resources on test method qualification that are really not needed.

So whenever process capabilities are low and below the desired level an engineer needs to first determine the source of the variability. When first looking at the process capability in either the Process Development phase or the OQ, if the engineer sees a wide range of measurement results, we need to rule out the measurement variability and this is done through either a Gage R&R or TMV. I try not to determine which measurement methods need to have a TMV until I see the initial data because if the data has a very small range, then the measurement method must be fine, this avoids wasting time on unnecessary tasks.

Data tells us a huge amount about a process and engineers need to develop their skills at reviewing data and attributing the data to the process. Here is a great example of reviewing capability data:

The graph below shows the measurement data from the radius of the part on the right.



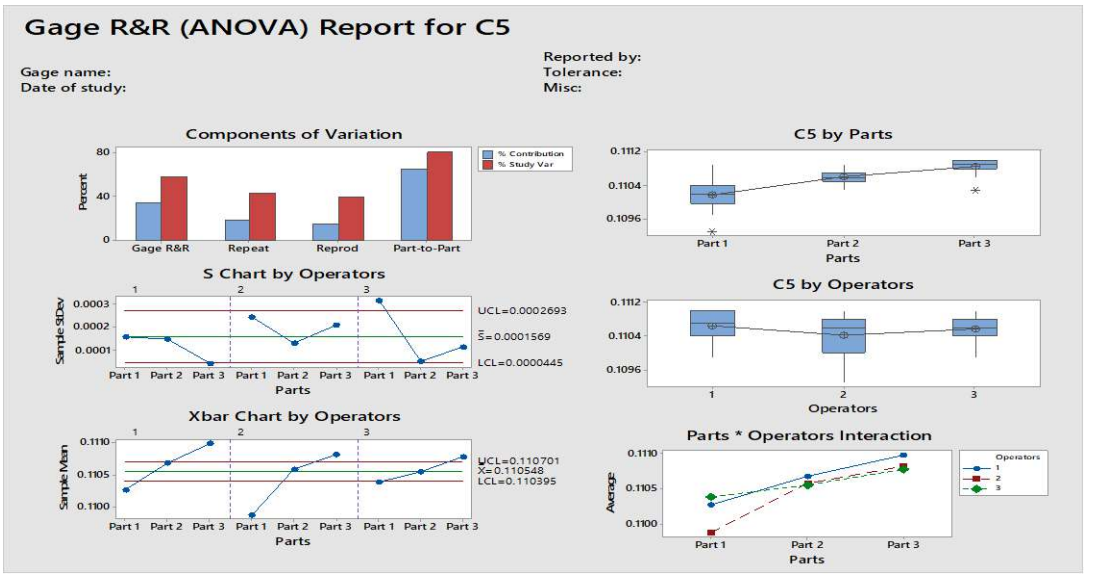


What is unusual about the data?

- We have a range of data below the USL but nothing above the USL – Why?
- Data usually results in a bell curve and we get data above and below the most popular dimension but this is different.
- The measurement device used had extremely high accuracy and is a vision-based system.
- We are measuring a radius in a round part
- The process capability calculated from the capability run is 0.27

Is this a measurement Issue or a process Issue?

Let's rule out or rule in the measurement, here are the results:



As you can see, way too much variation in the measurement. This was caused by the fixturing of the part on the inspection system. If the part is not at 90 degrees to the

inspection lens then the vision system will measure smaller than the actual dimension. This is the reason there are no data points larger than the USL. When we asked what the tool size was that cut the radius it was 0.111". What is the Conclusion?

- Variability in the measurement due to the fixturing of the round part being measured.
- Dimension of the feature should measure 0.111" (size of the tool that created the feature).
- Is this the reason for the low capability – No the size of the tool is the max tolerance of the radius.

In this case we could change the tool size to 0.110" to center the dimension within the tolerance, or as we did in this case, accept the 0.111" dimension knowing that any tool wear would result in the dimension moving into the tolerance, not moving out of tolerance. Because we elected to do the latter: we now need to treat this dimension as attribute not variable.

Keep in mind, the goal for process qualification is to measure, optimize and qualify a robust process. So because we measured this dimension, found that the measurement of the dimension was not robust, but the ability of the process to meet the specification was robust (low range of the data), we have met our objective. We measured the process, we understand the process, and we have made a sound decision, the process will be robust.

How do I qualify with attribute data and how do I calculate sample sizes?

Often there will be features of a part that can only be either visually inspected or best inspected with a gage and this data will be simply Pass or Fail, this is known as attribute data. Sometimes during the process qualification there may be the need to change the inspection of a feature from variable to attribute, so the process qualification procedures need to have an equivalent method to process Ppk for attribute data that is as equivalent as possible.

Statistically the amount of data points needed for attribute are higher than for variable data but equivalences can be made to give options. The following table gives you the key data inputs needed for Minitab to get there.

Defect Class Qualification table:

	Business Requirement Quality Level AQL				
Defect Class	**Ppk (Variable Data)**	**Overall Ppm**	**Input AQL (Attribute Plan, *critical must be a c=0 plan)***	**Input AQL[1] (Variable Plan)**	**RQL (Spec-AQL from Table 1)**
Critical	1.67	0.6	0.00006%	0.00003%	0.65%
Major	1.33	63	0.0063%	0.0032%	1.0%
Class I	1.10	1000	0.10%	0.05%	2.5%
Class II	1.0	2,700	0.27%	0.14%	6.5%
Class III	0.67	44,400	4.44%	0.98%	10.0%

When using this approach for attribute data enter AQL, RQL, α, and β. Ensure β≤0.05 for the RQL input. For critical defects, adjust the plan (such as by reducing the AQL =RQL/45) until it is a c=0 plan.

When using this approach for variable data enter the AQL, RQL, α, β, and specification(s). Adjust the plan (such as by increasing n) until β≤0.05 for the RQL input.

There are certain assumptions using this approach that need to be understood. The sampling plan for evaluating the results against the acceptance probability will be calculated using the hypergeometric distribution. The hypergeometric distribution identifies the total number of successes from a sample size drawn without replacement from a finite population. Hypergeometric distribution is assumed, since the lot size is not greater than ten times of the sample size and since the products are not selected from an ongoing process. Type-A OC curve is used to calculate the probability of acceptance on a lot-by-lot basis when the lot is not a product of a continuous process.

The above rationale allows us to define all the measurements and features to be qualified, define for each item, the measurement method will be variable or attribute data and determine the sample sizes for each of the different data types.

When calculating Ppk for variable data using the methodology we have discussed the sample size that Minitab will define is often less than 30 pieces. This is because it assumes that more than one lot will be manufactured as part of the qualification and for PQs we prescribe running a minimum of three lots. So if a capability Ppk of 1.33 is needed Minitab will require a minimum sample size of 24 pieces. In this case it is 24 pieces for each lot total 72 pieces. If we run a single lot verification protocol we should also require 72 pieces.

For Operational qualifications which only require one lot to be run at each minimum/maximum conditions or when capability studies are run, I would recommend a minimum of 30 samples be run and all 30 samples measured. Ppk and Cpk calculations are more representative if the quantities are higher than 29 samples and no greater than 75 samples.

How do the dFMEA and pFMEA play into the qualifications?

The dFMEA and the pFMEA for a product need to be used to define the baseline acceptance criteria for qualifications based on potential failure mode defect severity, and mitigation needed to achieve a frequency level that is acceptable to the business (based on the Risk Matrix – Page 10). This is how the risk based qualification process works:

The dFMEA provides the severities of certain potential failure mode effects in regard to features of the product, which have associated dimensions linked to the product features. High severity failure effects should drive the dimensions related to the product feature that could potentially fail. These features and dimensions should be included in process qualifications.

- **This defines the “Where” to measure the product from the Design Standpoint.**

The severity defined in the dFMEA also defines the defect Classification based on the Classification/Severity table shown on Page 22, (an expansion of the severity table). This defect classification then determines the process capability needed, (based on the Defect Classification, Qualification Table on page 27). This process capability is directly linked to the Frequency (see Frequency Table on Page 10).

- **This Defines the Process Capability Level that needs to be achieved for a given feature or dimension the "Level" of capability from a Design Standpoint.**

Therefore, by using the Risk Tables (Risk Matrix, Severity Table & Frequency table) we are using the risk methodology Principle 2 to be the basis for all our qualifications.

The process FMEA looks at the risks related to every process step of the manufacturing process, what effect the process failure mode could result in to the user or patient if the product is defective and how severe that effect would be. This risk assessment looks at more than just the part design but adds in the potential failure effects of the manufacturing process to the part such as cleanliness, structural integrity etc. The pFMEA therefore adds criteria to the process qualifications. Again high severity failure effects define the process steps to measured and either qualified or controlled.

- **This Defines the "Where" in the manufacturing process to measure from the Process Standpoint.**

Again, we have the process capabilities needed for the qualification predefined by the severity of the failure effects.

NOTE: when drafting FMEAs there will be times when the frequency of the current controls are not known, this will be often when designing new products and new processes. In these instances the "Pre-Control Frequency" should be set at F3. This is the midpoint of the frequency range but results in a good level to assess and define what needs to be done in qualifications, both design verification/validation and process qualification.

Once the qualifications have been ran, the data crunched and actual capabilities calculated we can update the FMEAs with the actual frequency levels and review the risk levels. If all the risk levels are at "BA" or Broadly Acceptable you have a robust Design or process, if there are any ALAP or As Low as Possible risk levels remaining, these need to be reviewed and the question asked: is this as low as we can get with "current state of the art technology". In some cases it may be cost prohibitive to get to a lower risk level or the magnitude of the changes needed are too great for the company to complete in a timely manner. When this happens it is a good practice to put the project on a continuous improvement list, and the next time a project comes up try to design in the solution with the next project.

So by selecting the Frequency Column Highlighted below we can determine the Post control (Post Qualification – Validated) Frequency.

Frequency Table:

	Process Capability (Ppk)	DPM	% Yield (min)	Qualitative (Used in Hazard Analysis)	Time Based
F5	> 0.67	19,300	95	Frequent	Daily
F4	> 1.00	2,700	98	Probable	Weekly
F3	> 1.10	1,000	99.9	Occasional	Monthly
F2	> 1.33	63	99.993	Remote	Quarterly
F1	> 1.67	0.6	99.999	Improbable	Yearly

What do I need to Measure After the Qualifications are Completed?

After all qualifications are completed there are a couple of areas we need to be aware of, the residual risk and monitoring of the validated processes.

An assessment needs to be conducted to define what the residual risks remain for the project and look to see if they have all been mitigated down to their lowest possible levels. Based on the three risk levels we have BA is acceptable, ALAP is only acceptable if we have done all practical things to reduce the Risk and HLMR risk levels need to have a Risk/Benefit analysis completed and reviewed with upper management to be acceptable.

As stated earlier, higher than desired levels of risk need to be the source for continuous improvement efforts moving forward for the Organization.

For validated processes we need to have in place some sort of process monitoring, either directly from the process or data from receiving inspection for lots that are outsourced. Either method should be used to ensure the results of the process remain stable over time.

With these foundations in place your organization will be set to execute qualifications, you will gain a deep understanding of the capabilities and weaknesses of the processes you employ to manufacture your product and drive Quality at the point the product is created. This is by far the most cost effective and LEAN process you can create.

Principle 6: Understanding Operations Problem Solving

Manufacturing Operations is obviously, where the rubber hits the road and has to be the core focus of the business, ensuring production plans are achieved, customers get their products on time and the product delivered meets the quality level defined. Summed up and in order of priority the most common approach is Quality, Cost, Delivery and then People, our people, their wellbeing, job satisfaction, career advancement, development and rewards.

As far as operating models, every business has its own unique approach depending on the type of customers they serve, and in Manufacturing Operations "Lean" usually plays a part. Some organizations have tried to fully adopt the Lean systems and culture; other companies adopt principles and methods from Lean but not the entire culture. We must understand that Lean (as defined by Toyota) is more than just the Philosophy; its full implementation is a disciplined culture that has to be enforced and maintained at every level of the organization. Here in the Western world most manufacturers have adopted some level of Lean however, it is usually more on the operations shop floor than other levels of the business, so the true full culture is often not embraced.

With Lean there needs to be a level of understanding of the principles and methodology, which goes beyond training to ensure effective solutions are rolled out. This means the experience of engineers and operations teams still plays an essential part of the equation; Lean gives us the tool set, but the understanding and use of the tools need to be practiced and coached on an ongoing basis for success.

Manufacturing operations is a dynamic environment that tends to be very fluid with changing priorities and targets based on customer demand, daily challenges within the supply chain from materials suppliers, supplier quality, internal quality issues and management of people. Decisions must be made quickly to ensure available resources are focused on the correct priorities and issues that are preventing the desired performance are resolved in an efficient and effective manner.

Operations performance is usually monitored through "Key Process Indicators" or KPIs, which are measurements of performance strategically identified to determine the status of a process. We will talk more about KPIs in Principle 8. Whenever we are not meeting a KPI we need to be able to execute a process that defines the problem so that corrective measures can be taken to improve the performance gap. This problem solving, performed by the operations support groups usually, deals with the day-to-day challenges of the business.

Lean Problem Solving

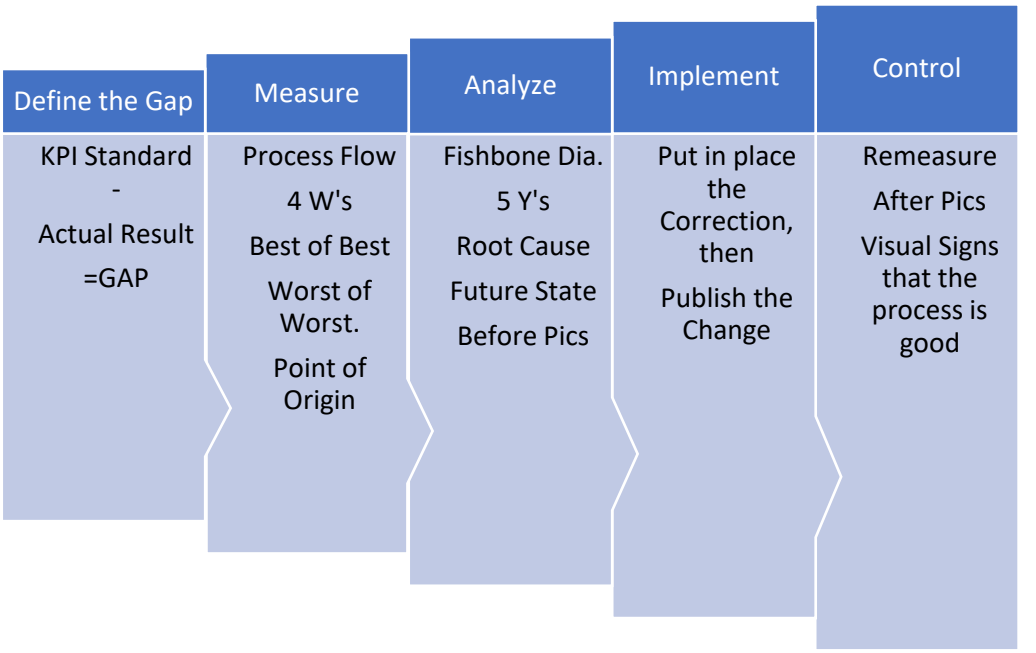
There are numerous methodologies to problem solve and the one we will discuss here is an adaption of a Lean system put into a Six Sigma DMAIC approach and this was developed by Chuck Carlton. This is a very effective method and gives good structure for the process. Based on A3 reporting and conducting Kaizen events with the team members from the affected area to gather the measure data and analyze so that the team develops the solutions to implement, this process is a tried and tested method.

As with most problem solving we need to start by defining the problem of in this case the "Gap". To define this we need to understand what the Standard is, this is usually defined by the KPI. When the KPI standard is not met then we need to problem solve and define the root cause for not meeting the standard. This can also be used as an improvement method. If we always meet the KPI, then we can "raise the bar" if a KPI is for order fulfillment level of 95% and an organization meets this consistently, we could raise the KPI to say 97% then use this process to determine what needs to be done to achieve that level of performance. This is called creating a Gap. The Gap is the difference between the desired standard and the actual result.

For example the KPI for First Pass Yield is 95% and for the past 2 weeks we have been achieving only 85% the Gap is therefore 10%. This is what we are going to use throughout the problem solving process as the baseline for what we need to change.

Here is the flow:

Lean Problem Solving Process



Once we have defined the problem and the "Gap" we now need to measure.

We start by mapping the process and creating a process flow chart to understand the steps in the process and determine at which point in the process it broke down and caused the problem.

Next tool to use is wat is known as the 4 W's

- Who
- What
- Where
- When

4W's is a great way to narrow down the point in the process where the issue lies, and it does not matter which of the W's you start with, it will take you to the same place. The key is to gather as much information about the process as possible, things like:

- Shift data
- Product data
- People data
- Type of failures

When working through the 4W's we use the data to determine which of the data types has the worst results. So if we have 4 shifts and most of the defects happened on shift 3, then we narrow down the data to just shift 3, if all 4 shifts had similar results, then shift is not a factor so move to the next data set and apply the same logic. This process is to find the main contributor to the issue and not to totally eliminate the issues, we work on what can have the most effect first then keep working on the process in this manner until it is back to the desired standard of performance. Using this method we can determine two key factors:

- Point of Origin – the step in the process where the most failures happen
- Extremes – The Best of the Best or "BOB" and the Worst of the Worst or "WOW"

The BOB and WOW are the combinations of the data that result in the best and worst results, this information can be key to understanding what, in each scenario, is the key difference that makes good or bad results.

After the Measure step we get to Analyze the data, using tools like Fishbone diagrams and 5Y's to determine the possible causes, and if possible drill down to a single root cause. Once the causes are identified we can then look at what corrections we need to make to prevent the causes, brainstorming solutions then challenging the solutions to ensure they will indeed fix the problem. This will determine what the future state needs to look like. Now we can move on to the implement step.

A plan needs to be created to implement the fix, if this is a quick change you should do this during the Kaizen event so you close the day with a completed solution, this is the ideal. Often this is not something that can be immediately fixed and in that case the actions, responsible parties and completion dates need to be defined in a SMART format, then the implementation needs to be managed.

Finally after implementation is complete, the process needs to be monitored to ensure the changes made have the desired effect and the problem has been reduced. If the key measure is still not achieved this process is repeated dealing with the next issue that is preventing the target level being achieved.

The summary of each event is documented on what is known as an A3 report that summarizes each step of the process and captures the summary of each step and the actions implemented.

This problem solving method is great for teams in a Kaizen event, having operators, technicians and supervisors discussing the data and working through the process. The more this method is used, the better the teams get at problem solving and as a continuous improvement tool this method achieves great results over time.

NOTE: this methodology relies on process data, so is not an approach I would recommend for setting up a new process or for analyzing a complete process for improvements. For these types of projects I would use the MPQP process which I would recommend every Manufacturing Engineering group to adopt as the basis for all they do and this is what I would like to discuss next.

Principle 7: Understanding how Manufacturing Engineering functions

Manufacturing engineering is the group of engineers normally tasked to transfer new products from Design to Production, designing and developing the manufacturing processes and equipment, qualifying the processes and starting up new production lines. Along with the new product side of the business comes the existing manufacturing operations and here the Manufacturing Engineering department are responsible for sustaining and developing those processes in order to continually drive improved performance of the operations side of the business.

When new products and new processes are added to a business it is a great advantage to have a manufacturing engineering group who are well versed in Lean Methodologies. This way, new processes are properly designed to minimize as much waste as practically possible, have good flows, (as close to single piece flows as achievable) and have the highest efficiency in resource use.

Manufacturing Processes need to be designed in a similar way to how products are designed. Process steps identified, layouts on the manufacturing floor developed for new equipment, all Lean aspects of the future process defined. Then processes should be developed to ensure capability to produce conforming product is at an acceptable level.

The following Criteria should be at the forefront of everyone's mind when designing a new process:

I Inspection does not improve Quality of a product.

N Never Pass a mistake – stop a defect at the time it is created

C Controls are in place to ensure conforming product.

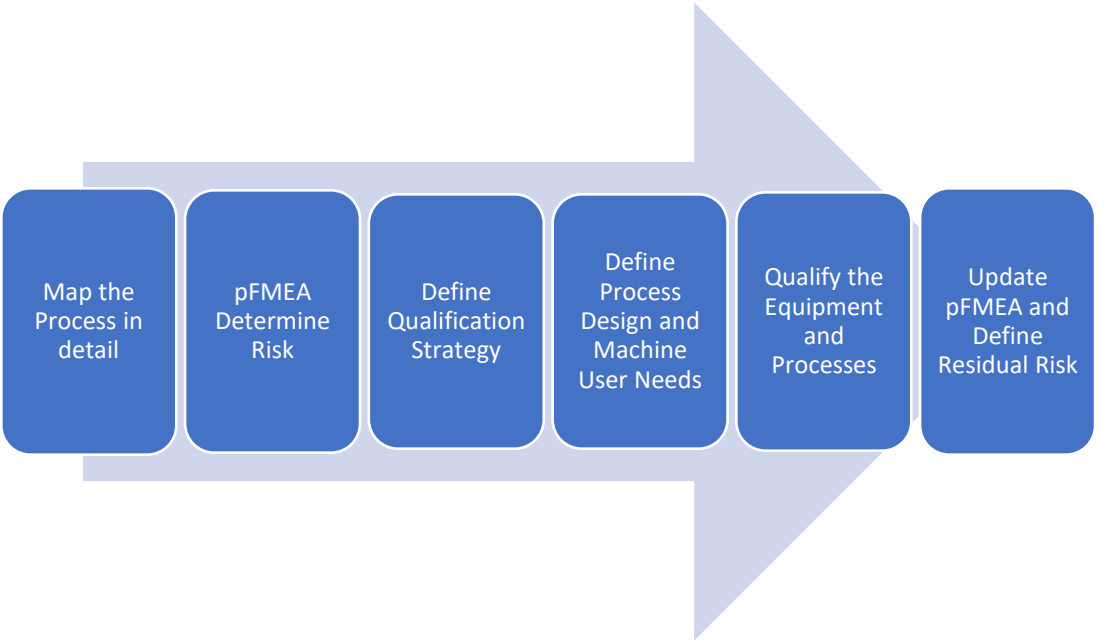
O Occurrence or Frequency of potential failures are defined and measured.

M Monitoring of validated processes to ensure maintenance of state.

E Efficiency is best in a single piece flow process.

There is a basic methodology for the role of Manufacturing Engineering that, if applied yields excellent results and this is based on Automotive's Advanced Product Quality Planning which is somewhat abbreviated down to MPQP Manufacturing Product Quality Planning also known as just Quality Planning. This process is built around the key risk assessment: the pFMEA.

Quality Planning and Process Design



Mapping the process is the first step and getting as much detail as possible is the key to defining a robust process. Once the process is mapped, the flow should be reviewed looking at every process step in a pFMEA to understand what could possibly go wrong, what the potential failure mode causes and effects are and what would be the severity of the potential failure. Then by estimating the frequency of the potential failure, define the Risk level.

If the process step has acceptable Risk and is Robust, move to the next step, if the risk is high, what can be done to control the process step? If we can qualify the process step and confirm that the failure will not happen by showing good capability we have created *Quality at the source*. If we cannot get an acceptable level of capability, is there a robust control we can put in place at the process step? If we use inspection as a control, it needs to be capable enough to reduce the frequency of passing a bad part to the next process to an acceptable level, thus reducing the risk. The goal has to be to design a process that has no risk levels higher than “BA” (Broadly Acceptable).

Once the pFMEA is complete, the qualification plan can be created, designs of machines can start to take place based on sound information. User requirements for machinery need to be driven by the process FMEA and if we know we need certain process capability levels, we can add these to the equipment user requirements so the equipment builder can design the machinery accordingly.

Once all the equipment is built, tested and installed, the qualification and validation processes can begin. Starting with the IQs (Installation Qualifications) to verify the equipment is properly installed per the manufacturers specifications and functions to the requirements set out in the User Requirements created for the equipment.

Once we have the equipment qualified we can start to develop the processes that will be run on the equipment, what equipment settings result in conforming quality product. When we have optimized the process we can move forward qualifying the variable parameters we have defined for the equipment by testing the worst case minimum and maximum conditions, this is known as the OQ (Optimization Qualification). In some cases there are not any variable setting ranges to qualify so the OQ may become a capability study (Operational Qualification). In this case the qualification will be run and product will be measured to understand the process capability of key product dimensions or features. This is valuable information and allows the engineer to further optimize the process for any less than desirable capabilities before starting the final qualification the PQ (Performance Qualification).

In many cases where lower than desirable capabilities are found, it is a result of not only the process but the measurement method, so review and qualification of the measurement method is needed to rule it out that as a factor of the lower than desired capability. If the measurement method shows low variance, then we can focus on the process again but it is essential to know this before going into the PQ.

Finally the PQ, multiple lots of product will be manufactured (usually a minimum of three), multiple operators used over multiple shifts. This is a worst case qualification that will be measured by the capability of the process to maintain conforming product over time. Once completed the pFMEA post control frequencies can be updated with the process capabilities achieved in the qualifications, giving us an accurate assessment of the final process risk and residual risks.

This engineering process can be applied to all processes both internal and external at suppliers, it can also be applied to business processes to determine the robustness. Map the process, analyze each process step to ensure that any potential failure modes are either designed out of the process or controls implemented in the process to ensure the process step is completed correctly every time. This is the basis for everything we do.

We create processes that we follow every day for every task we do, and if we would put that process through this analysis, we would put in place ROBUST processes. Documenting and drafting procedures to control processes will not control a process that is not robust. Controls need to be reviewed to ensure they are strong just like the process step we analyze in a pFMEA, we should also add the controls as steps to be analyzed to determine what potential failures they may have.

The other advantage of this structured approach is that it pulls engineers into the details so robust processes are designed. Engineers by their nature like to get into the details of things they have interest in and that are the products they design and machines they build

so a structured process that is applied in every project they work on is essential to ensure details are not missed and risk is used to drive their inventions and designs, not to assess their shortfalls after the design is completed.

Principle 8: Understanding Design of Experiments

Design of Experiments or "DoE's" as they are commonly referred to, is a method of testing and measuring a process to develop and define the most optimal set up of the process variables. DoE tools provide a structured approach to experimentation that allow us to learn the idiosyncrasies of a process, using analysis methods that ensure that valid conclusions are drawn in an efficient manner.

The key to process development is what the engineer learns about the process through conducting DoE's. Often there are several factors that can be varied and usually there is some understanding of the "Key Process Input Variables" or KPIVs that if adjusted result in a change of the process output. Since the Output is what we are looking to achieve I like to start there.

As an example of this, I would like to share data from what was a tricky but common process for sterile packaging. The packaging consisted of a Polycarbonate thermoform tray, a Tyvek Lid, zone coated with a higher than usual temperature adhesive. We knew that the peel strength of the current process was highly variable, and based on some extensive transit testing results, we needed to target the average peel strength to exceed 2.6lbs/inch.

Starting at the output and knowing that our results historically had shown a high level of variability, we needed to understand where the variability was coming from. We had the process (the reason for the DoE), the equipment, and the measurement method.

We started by looking at the KPIV's and the design and performance of the equipment to deliver repeatedly the same parameters. The three KPIVs were temperature of the platen of the sealer, the pressure exerted by the platen to the nest and the dwell time of the cycle. Testing showed that the variability of the temperature across the face of the platen when fully heated was +/- 3°F which was acceptable, the pressure of the platen to the nests was then measured along with the uniformity of the pressure to the nest which was tested with pressure paper. The pressure was measured to be +/- 4psi and acceptable. The machine was then cycled for a number of sealing runs and the time the platen was engaged with the nest measured, this again was deemed to be acceptable and within the expected range. It was determined that variation caused by the equipment was highly unlikely.

Next, we investigated the test method by conducting several Gage R&R's. The measurement was conducted on a vertical Instron with a load cell calibrated to +/- 0.02lbs. Three QC inspectors took part in the Gage R&Rs each peeling 10 trays, sealed under the same process settings and the same lots of materials. The results were as expected varied (as was the history) however one QC inspector had far more variable data than the other two. We investigated by observing two of the QC operators to determine if they did anything differently and sure enough there were differences in the set up that was not well documented. We asked each inspector to perform the testing in the manner that the other

had performed the test to see if the variability would follow the observed difference, and sure enough it did. This variability accounted for as much as 50% of the historical data variability. The procedures and fixtures for the testing were modified to eliminate as much of the variability as possible and Gage R&Rs were re-run and the Coefficient of Variability was acceptable.

A note here, packaging testing is destructive, so the exact test cannot be repeated which means the Gage R&R is far more complex that a traditional Gage R&R measuring key dimensions that can then be re-measured. Peel strength testing, we found was best performed by use of a Vinatoru Horizontal peel strength tester as the fixturing of the package is well designed, this, together with good speed controls and load cell proved to have the most consistent results. Completing Gage R&Rs with adhesive tapes with known and narrow variability was also found to be the best solution since the product we were manufacturing still had a lot of variability.

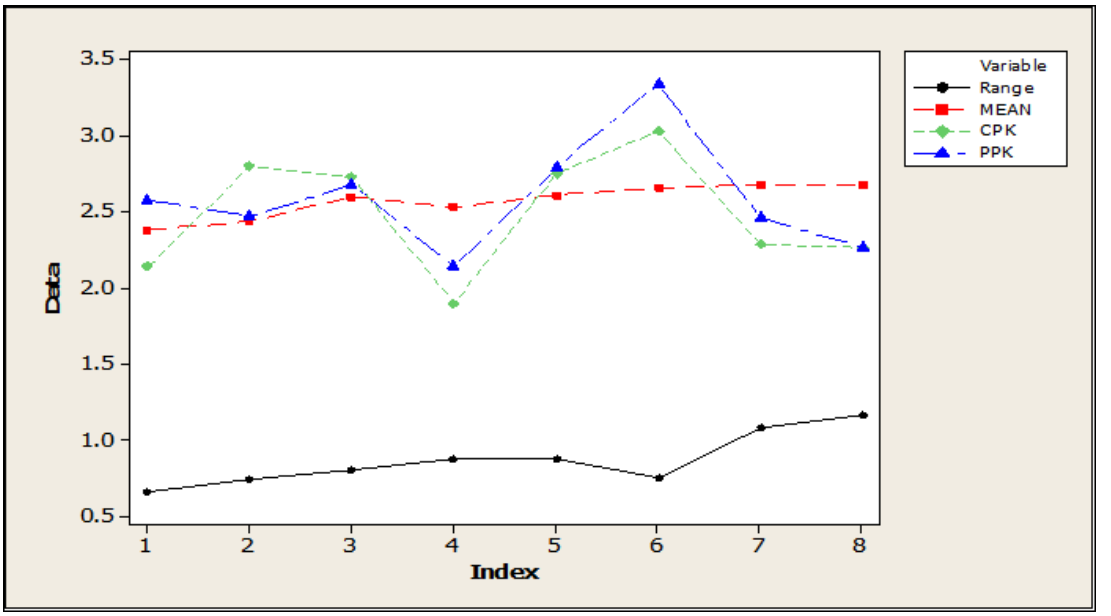
Having now established a reliable test method to measure our process and reduced as far as possible that source of variation, we tested the equipment and noted all were within the desired capability, we were now ready to start a DoE.

In order to get the best from a DoE we need to measure more than a single item such as the peel strength in order to get as much as we can from each test. So in this case we took the peel strength data and calculated the Mean, Ppk, Cpk and variability range for each sample group.

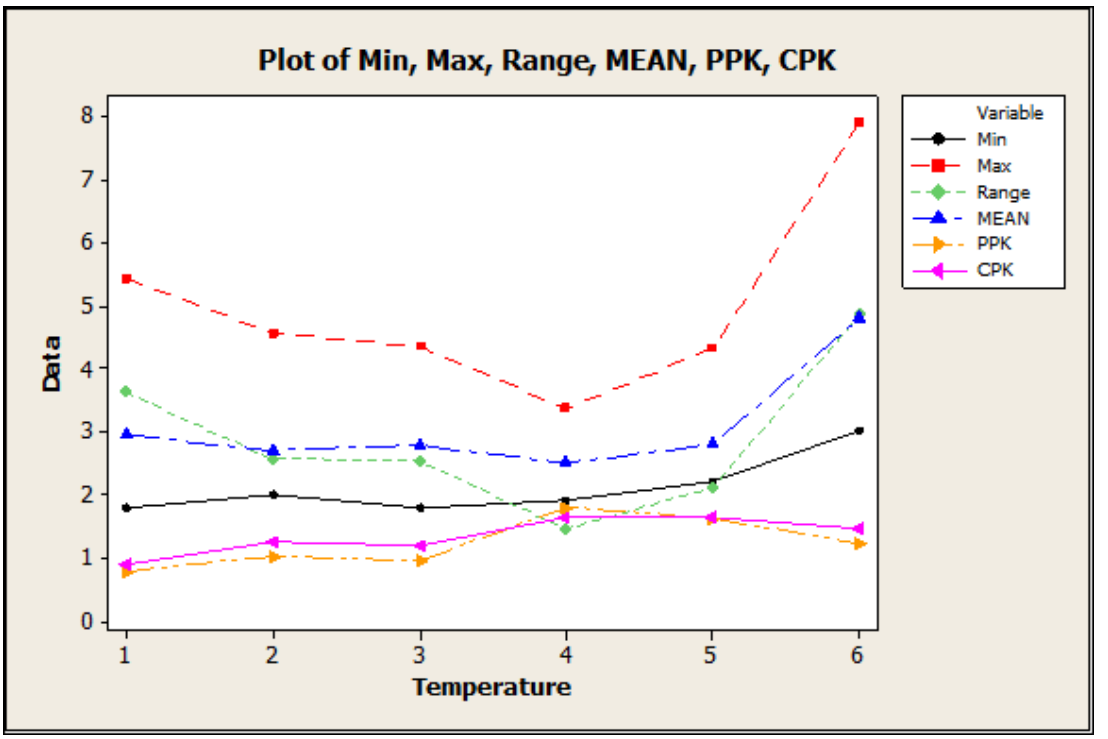
We are aiming for good process capability since the seal of the Tyvek to the tray is the sterile barrier we want to see a process capability of higher than 1.67 Ppk so any failure would be critical. This means ours sample size for each set up needs to be at least 30 data points. We wanted to see the minimum, maximum and range of the results for each setting, and we wanted to see good seal transfer of the glue from the Tyvek to the tray plastic. We also did not want to see any transparency of the Tyvek that may be caused by too much heat and pressure in the process. The above gave us plenty of important features to measure and record. For the attribute data (transparency and glue transfer) we created criteria ratings from 1-10, 1 being the worst and 10 being the best.

The point of DoEs is to test in a manner that detects interactions of parameters in an effective manner and not to test one variable at a time. This said, I have found that when there are only 3 or less variables, baseline testing of each variable can be very informative and gives a great insight to the first round of parameters to be tested in a DoE.

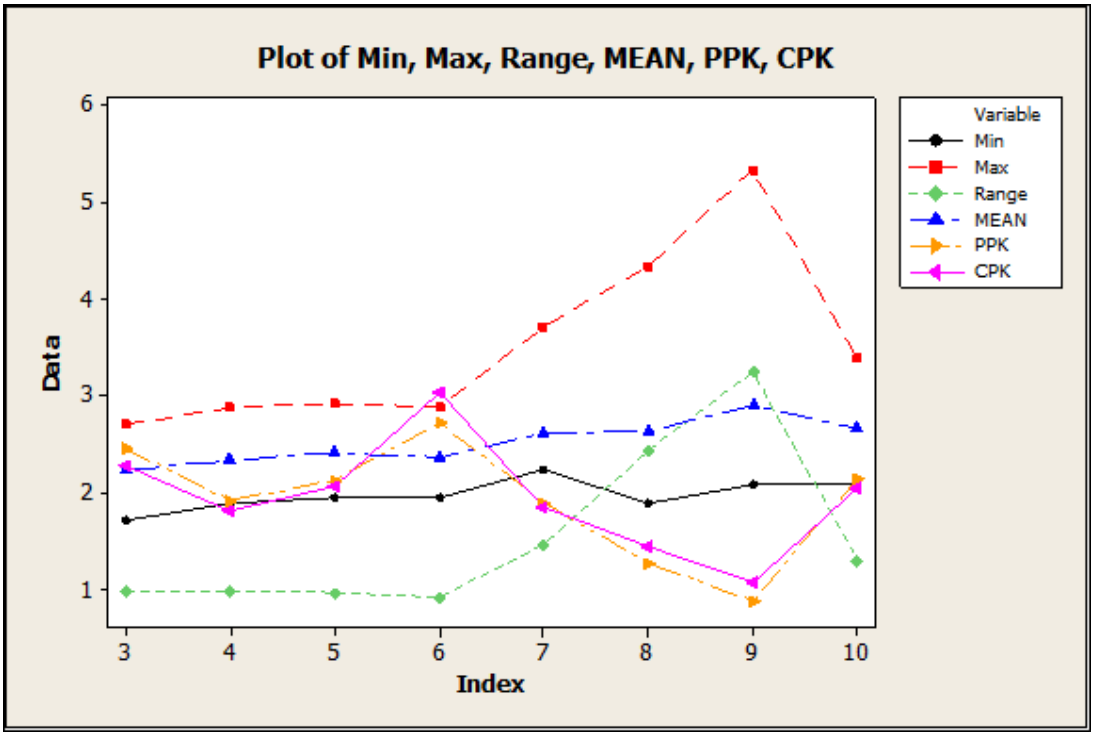
Here are the results of baseline testing we completed in this project:



The above baseline testing for the pressure revealed that increasing the pressure did not really effect the peel strength dramatically, however a specific pressure did dramatically effect process capability.



Above we can see the effects of temperature, what this revealed was that temperature did not have a big effect on process capability, however high temperature did result in higher peel strength values.



Here we can clearly see that the dwell time is also a key factor in capability and beyond a certain point increases the peel strength but also increases the Standard Deviation and range so losing capability.

Therefore, with this understanding, and the lid manufacturer's recommended sealing ranges for each of the parameters we can move forward with a DoE.

For the last 20 years plus I have used MODDE software for DoE's, this Software is created by Umetrics and I would strongly advise anyone who will do any amount of DoE's to purchase it. The software is easy to use after a little instruction and is very powerful as it adopts all the different types of DoE approaches, not just the traditional Anova.

We first completed a screening DoE Round 1 as follows:

> Upon Completion of the baseline testing and review of the resulting data the variable input parameter range was defined for the first round of Design of Experiment (DoE) testing. Use of MKS Umetrics MODDE, the software was programmed with the input variables and ranges to be tested, and 12 test groups with 4 repeats were defined and generated by the software.

Results of first Round testing

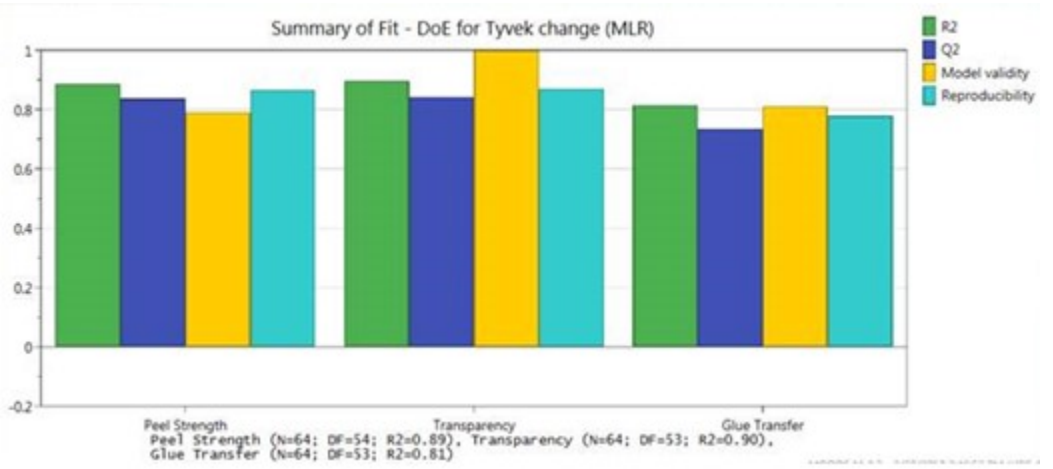
	Temp	Pressure	Dwell	Visual Insp. Pass/Fail	Reason
1	250	70	8	Pass	
2	250	70	5	Pass	
3	250	60	6.5	Fail	Poor Glue Transfer
4	250	50	8	Pass	
5	250	50	5	Fail	Poor Glue Transfer
6	265	60	6.5	Pass	
7	265	60	5	Pass	
8	265	50	6.5	Pass	
9	270	70	8	Pass	
10	280	70	7	Fail	Excessive Transparency
11	280	70	5	Fail	Excessive Transparency
12	280	63.3	8	Fail	Excessive Transparency
13	280	50	8	Fail	Excessive Transparency
14	280	50	5	Pass	

As you can see from the results we tested a range of parameters that we would fail at both extremes, the lowest, resulting in poor glue transfer, and the highest resulting in excessive transparency. Of the 14 test parameters, 4 repeats were made. The test groups that did not fail were then tested for peel strength and the data assessed.

Sample Group #		Ppk	SD	Mean	Max	Min	Range
1	280-50-5	1.34	0.381	2.534	3.16	2	1.16
2	270-70-8	1.35	0.318	2.29	2.87	1.8	1.07
3	265-50-6.5	1.28	0.318	2.218	2.86	1.52	1.34
4	265-60-5	1.33	0.296	2.18	2.59	1.69	0.9
5	265-60-6.5	1.33	0.275	2.1	2.73	1.66	1.07
6	250-50-8	1.78	0.222	2.1	2.59	1.77	0.82
7	250-70-5	1.36	0.21	1.86	2.27	1.45	0.82
8	250-70-8	1.71	0.209	2.07	2.51	1.76	0.75

DoE Round 2:

After analysis of the DoE round one results, and programming of the results into the MODDE software, the software was programmed to ensure the experiment model validity and reproducibility showed an acceptable range. The chart shown in Figure 2 shows the results of the Model Validity, Reproducibility and the R2 and Q2 factors for each of the responses (process outputs) as indicated on the graph:

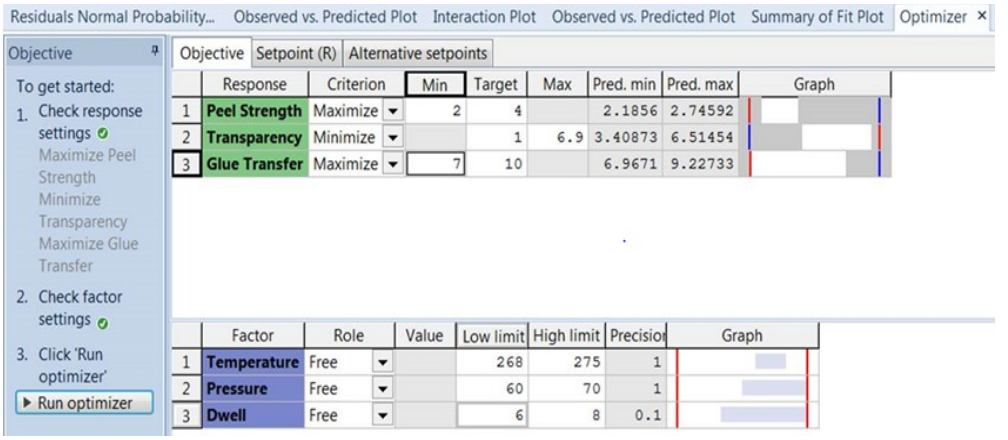


Once the validity of the model is established and confirmed, the Key output variables were defined as follows:

- Peel strength – set to maximize
- Transparency – set to minimize
- Glue transfer – set to maximize

The software then calculates the most optimum process input settings and predicts the Key process output results based on the experiment results.

The Output parameters are also generated for Minimum and Maximum Process input parameters based on the desired output result ranges programmed into the software.



Confirmation runs were conducted with each of three sizes of thermoform to ensure that the process output variables are within the desired ranges. The results of the confirmation runs were as follows:

	Pressure Setting	Temp Setting	Dwell Setting	Number samples	Ppk	Glue Transfer	Transparency	Ave Peel Strength
Small Inner	46	270	7.4	15	2.24	8	3	2.77
Small Outer	73.5	270	7.4	15	2.71	7	5	2.79
Large Inner	62	270	7.4	45	2.72	8	5	2.59
Large Outer	84	270	7.4	45	2.34	7	4	2.56
X Large Inner	51	270	7.4	15	2.95	9	4	2.73
X Large Outer	62	270	7.4	15	2.5	8	3	2.95

As you can now see the nominal temperature and dwell time do not change however the pressure does because it is based on the surface area of the seal, the larger the tray, the larger the surface area and so the greater the pressure. We had targeted 2.6 lbs/in average peel strength and needed process capabilities in excess of 1.67 Ppk.

The reason I show this example is because this effort was extensive, the company previously had capabilities less than 1.0 Ppk, and by taking a thorough approach we now understood the effects of each parameter and their interactions. The Original study DoE was based on the Large size and we understood that the pressure was the variable between sizes, so we measured and calculated the seal area for each tray. The pressure settings you see are the air pressure setting for the machine (psig), the machine had a 12" pneumatic cylinder on each platen, and the platen size was 18" X 32", so we calculated the pounds needed per square inch, then based on each different tray size calculated the psig for each tray as shown in the table below:

Size of Tray	Area of Seal (in^2)	# of Nests	X factor (195 psi)	Required Force (lbs)	Cylinder psi(g)
Small Inner	6.73	3	195	3939	46
Small Outer	9.938	3	195	5813	73.5
Large Inner	8.63	3	195	5048	62
Large Outer	11.15	3	195	6522	84
X Large Inner	11.25	2	195	4387	51
X Large Outer	12.56	2	195	4898	62

The confirmation run data confirmed our engineering calculations with uncanny accuracy, the MODDE software did a text book job, we exceeded our Ppk expectations and the average peel strengths that resulted were almost perfect.

This is an example of Process, (Manufacturing) Engineering at its best, development of a once incapable process to a process with in excess of 6 sigma capability. This is the power of doing the job right, using the correct tools, not shortcutting. The baseline data makes absolute sense and the result exceeded our target.

Principle 9: Understanding how to Maximizing Cash Flow

Cash flow is the lifeblood of an organization, the smaller the company, the more essential the flow is. Ensuring that you maximize all opportunities is very important, so understanding where the opportunities lie is the starting point.

Here are the areas we will discuss:

- Accounts Receivable
- Accounts Payable

Understanding that everyone is trying to play the same game is essential when negotiating payment terms, so develop your approach and justifications carefully. The larger the business often leads to the longer they want before paying their bills. Net 90 has been the latest push by larger companies, which can be crippling to a small or medium sized business but this is usually negotiable down to a Net 45 or even a Net 30, if you give a little on the price, and make the point that the hit to your cash flow is more than you can accept. Know the payment terms at the time of quoting, price accordingly, then negotiate the shortest terms you can without giving up too much margin. There are many great benefits to supplying larger companies, such as stability of future orders and quantities ordered, which may allow your organization to drive down the manufacturing costs because of quantities, so keep an eye on the big picture and know your variables so you get to the best terms possible to maximize your cash flow.

The same approach applies to you paying your suppliers and here, the bigger the supplier usually the better the terms that can be negotiated. In the past when I worked in the contract manufacturing space and supplied to some of the larger Medical Device businesses we were allowed to leverage the terms our customers had negotiated. Obviously this allowed us to control our price better for the customer, but it also got us price and payment terms that we could not have negotiated on our own.

Working the two ends of the cash flow equation can allow an organization to hold on to its cash the longest which can help compensate for emergency purchases that are needed for the business and minor fluctuations in business volumes.

Inventory

This is a key part of the cash flow equation that is often overlooked and underappreciated. Idle inventory has an ongoing cost to an organization in many ways and this includes raw materials, finished goods and work in process as follows:

- The initial investment into the inventory is sunk cost with no return
- The inventory has to be stored which takes:
    - Space

    - Labor to maintain it
- Sometimes the inventory has to be kept in environmental controlled conditions
    - Cost of maintaining the environment
    - Space needed in that environment.

When you consider these things you may find that some of the inventory you are holding costs more to maintain than it actually cost.

For the most case, raw materials are readily available and can be sourced with short lead times so avoid carrying and more raw materials than you will use in say, 30 days. Put in place processes to accurately maintain that inventory so you do not run out, but do not get in the habit of storing inventory just in case, as this is a false economy.

Now let us look at work in process. First recognize that manufacturers turn raw materials into sellable product. There is no value to anything that cannot be sold as a finished product. Yes, I understand that as we manufacture a product we invest in it all the way through the manufacturing process and so in essence, the value is increasing as it changes from a raw material to a finished product, but you cannot sell it to your customer until it is in the state the customer has defined it finished. What this means is there is no value in WIP and consider this: even when the product is finished, if there is no demand for it from the customer what is it's value. The lesson here is to design your manufacturing processes so that the product moves through it without stopping (ideally single piece flow, or as close as you can get it) AND only manufacture what you have open PO's for, do not build to a forecast without a PO.

Finished Goods should be packaged and shipped as soon as the paperwork is completed, as stated above, if you have a PO for it sell it and get it invoiced. The value of finished goods is to the customer who will sell it or consume it, the value to the manufacturing organization is the invoice and payment for the manufacturing.

So what about VMI.

Value managed inventory is a way in which a customer keeps a level of inventory at a supplier that it can pull from, often because they want a shorter lead time for that product. I have seen some manufacturers that store partially complete product that they finish up when a customer places a PO, thus taking a far shorter time to get the customer the product they are wanting. Understand this can be a very risky undertaking for a supplier. If demand for the product goes down and you are left with surplus inventory who will be responsible for the cost? If the product has issues and the design changes, who will be responsible for the cost? If the responsibility of any product at any stage of manufacturing is not defined then the manufacturing organization is exposed and I have seen hundreds and thousands of dollars lost by inventory write offs.

So why do VMI? If the lead-time for the product is longer than the customer is prepared to accept, work to reduce the lead-time. Holding any type of inventory is a work around for an

issue, apply Lean thinking to the issues and drive down the lead-time to an acceptable level that the customer can accept, there is always a way to get there unless the expectation is just not practical and if so, demonstrate that to the customer with data from your investigation.

We live in a manufacturing world now that Lean has influenced for years, we understand that machine change-over times have to be minimized and that manufacturing processes have to be efficient to compete in the world market and no-one can tell me that it is quicker to manufacture in China than here given the delivery time logistics. It may be that there are cheaper manufacturing costs in other countries, but there should not be any faster lead times that we cannot beat or match.

Principle 10: Understanding Profit (EBITDA)

Different manufacturing operations face different challenges but to be successful an organization has to be profitable to sustain its existence. The measure of a company's performance is often EBITA (Earnings before Interest, Tax, Depreciation and Amortization), this is a measure of a company's performance without factoring in financial decisions, accounting decisions or tax environments. The reason this has been the measure of a company is that it looks at the net profitability (performance) of the business stripping away factors that would distort the measure such as decisions made on financing, the effects of acquisitions and losses that effect taxes and the subjective judgements that come with depreciation and amortization.

The Issues with only looking at EBITA

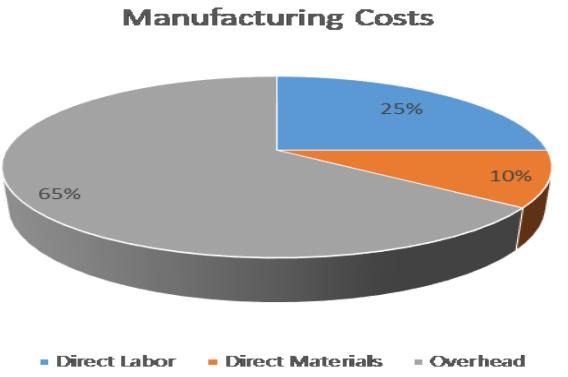
Using EBITDA as a single measure of earnings or cash flow can be very misleading. A company can make its financial picture more attractive by looking only at its EBITDA performance, shifting attention away from high debt levels and expenses against earnings. In the absence of other measures, EBITDA provides an incomplete and dangerous picture of the financial health of a company.

So there are pros and cons of the EBITDA measure and all aspects of financial burdens of an organization have to be considered and understood to ensure financial security of the business. As far as employees are concerned understanding the operating costs of the business they are working for, the EBITDA measure is really what they can effect and sharing the information has proven to be effective so the employees understand at least some of the financial decisions the business makes.

Therefore, for the rest of this Principle I want to look at a few key areas that effect the profitability of a manufacturing Organization. The top 3 manufacturing Costs are usually:

- Direct Material Costs
    - Raw materials that become part of the finished product
- Direct Labor Costs
    - Cost of the workforce that manufacture the product
- Manufacturing Overhead
    - All other costs to support the manufacturing processes and the business.

Here is typically what we see:



Overhead

Overhead is usually the biggest cost of a small to mid sized manufacturing operation, the cost of buildings, utilities, and indirect labor that has to be paid for in order for the manufacturing operations to be conducted and for the business to function and exist. If we look at the chart this is obviously the biggest area of opportunity affecting the profitability of the business and usually the area least focused on. In order to understand the potential opportunities here we will break this down:

Overhead consists of the following:

- Buildings: Rent, mortgage, taxes associated with the properties the business occupies.
- Facilities: Utilities such as water, gas, electric and possibly emissions and waste controls.
- Equipment: Costs of maintenance and upkeep, replacement and expansion.
- Indirect Labor: Costs of all labor to support manufacturing and/or the business.
- Operating Systems: MRP, QMS, Finance, Product Design, Engineering Research & IT
- Management: Internal & External to the facility
- Sales & Marketing: Maintaining and growing the business.

As far as the buildings costs go, there is not too much that can be done to affect these costs. If the business has purchased the property and/or secured the funding the costs are what they are, the best that can be hoped for here would be reductions in interest rates, or letting of building space that is not fully utilized, and not needed for immediate expansion. As far as taxes, make sure you have good representation with the local council and you keep them up to date with the state of the business. Partnering with the local council can open many doors of opportunities and if your business is expanding, you can leverage this to get tax concessions or even help in the expansion financing. Different cities have different incentives and if you do not keep close to them you can miss some very lucrative opportunities that could help your business.

Facilities & Utilities: Be energy aware and kit your buildings with as much energy saving apparatus as you can afford. Turn off power to machinery when not in use and maximize the use of energy when the business is operating. Look for waste and keep on top of buildings maintenance, minor air leaks in compressed air systems cost thousands of dollars per year in wasted energy so ensure your employees are well informed and they report issues as soon as they come up so that they can be resolved.

Equipment, Maintenance and replacement is an area you need to be on top of all the time. Utilization of each piece of equipment needs to be understood to ensure you are utilizing your investment efficiently. Monitor and record actual production time on the machine, by this I mean how many hours is the equipment actually manufacturing product, not how long the equipment was turned on. Often you will find that your equipment utilization is a lot less than you think, things like change over time, maintenance and calibration time, shifts that the machine is not utilized all add up. Making the decision to invest capital dollars in new equipment needs to also be based on the level of utilization of existing equipment that can do the same work. All this being said, you need also to understand at what level of utilization results in the best payback for your business. We will address this more when we talk about Amortization of Overhead.

Indirect labor is obviously an area that is effected by the manner in which we choose to operate the business. When managing ISO certified businesses (which is the majority of manufacturing operations these days) there is a requirement to resource the facility sufficiently enough to run effective Quality Management Systems. If your business is highly regulated such as aviation or medical device and compliance to federal standards are required the resources needed will be substantial more that an operation running a QMS compliant to only ISO 9001. All things considered you can make the Quality Management System as complex as you like but the more complex it is the more resources you will need to maintain it. My advice here is to simplify the QMS as far as you can and focus on the processes just as we discussed is Principle 3. If the process is effective and robust, the management needed to maintain it will be minimized. If you are a paper based business adopting a lot of forms and templates within the QMS, then simplify the forms and try to adopt a common base template so your employees get used to what they need to fill in and so minimize Good Documentation issues. Do not create forms with lots of data entry fields that will not be used as all these fields will need to N/A, initialed and dated, which makes for a really scruffy record in which numerous errors can be made. Only have data fields for the data that needs to be recorded, you will be surprised how much difference this makes in a manufacturing record.

For all indirect employees, have metrics they need to hit and ensure they work effectively to achieve their given metrics. This is especially the case with your marketing teams, often these guys are left on a very long leash and actually achieve very little, ensure you have short term metrics like customer visits, new leads, cold call metrics to drive them to achieve your company goals. Indirect labor costs can be substantial so having a good understanding

of how many employees you need and what drives the headcount number is important, as too is the control of that headcount number.

As far as the Operating systems go, I think we have discussed that enough, ensure the systems and process are simple, intuitive and effective so that the management level needed to maintain is minimized. Also, be aware that going paperless always sounds like a fantastic approach that will result in fewer documentation errors, less time wasted on document reviews and a potential Cost Improvement initiative for your company, however in reality I have yet to see a paperless system that needs fewer than 2-5 people to manage, validate and update on an on-going basis.

As far as Management go, an organization needs to be structured properly to ensure checks and balances are always maintained. There needs to be a division between Quality and Operations, they can both report up to the highest official of the business but a separation needs to be maintained at levels below the execs. Apart from that obvious exception, any other manager can wear as many hats as he can manage depending on the size of the company and what its financials can afford.

For the sales and marketing guys, have a good leader, simple metrics and goals that each sales representative needs to deliver and monitor the progress often to ensure forecasts and company growth or stability is maintained.

As you can see from what we have discussed there is quite a lot that needs to happen in the overhead cost area and substantial financial gains can be made. This needs to be a key consideration when the company makes a decision to grow or if a company needs to reduce costs because of lost sales.

Direct Materials

Direct materials are usually the smallest part of the cost factor but can be a crucial part of the equation if you are a volume product manufacturer, where your profit margin is small to begin with. In these circumstances, I have seen where the customer of the product can help in the price paid for materials because of their overall consumption of the materials. This is often the case in Medical consumable production of plastic products, and is the case for other plastic product manufacturers. Leveraging a customer's relationship with suppliers can also ensure supply of the material and even favorable stocking and delivery terms.

Storage of raw materials needs to be managed appropriately in that only the amount of raw materials that are required for manufacturing is maintained. If delivery of a key material can be weekly then store at max only 8-9 days worth, do not stock slow moving materials if they are not required for open orders or at the least minimize the safety stock to levels that support production but do not result in money sat idle on a shelf. The cost of storage is not a cheap one, especially if the storage needs to be environmentally controlled.

Exercise a FIFO process to ensure materials are consumed in order of age and inventory often so that your levels are accurate and reliable for production planning.

Do not build product that you do not have an open PO for. Storing finished goods that are not sold is high risk and expensive. Yes, it's nice to have some on the shelf for when the customer calls, but if they never call, then you lost the value of the raw materials and the time you invested in making the product. If a customer asks you to store product for them, charge them appropriately, the cost of the product and the ongoing cost of storage and inventory maintenance.

Direct Labor

Operate a Lean organization, review processes often and improve continuously. This is where you want your operations workforce fully engaged, they often have observations and suggestions the management does not see. Learn and understand Lean, teach Lean at all levels keep an ongoing effort to reduce all waste streams and use your workforce effectively and efficiently. This is the best way to manage direct labor, by allowing the personnel to be part of the solution, they feel like a bigger part of the business and valued. The more you teach them and challenge them the more pay back you will receive in the way of efficiencies.

No matter how automated a business gets, there will always be direct labor involved in manufacturing. In the case of low volume production, automation is often not an option and the reliance on the direct labor force is far higher. Look after your workforce, keep them engaged, invest in their education and knowledge and challenge them to be an active part of the business. The people you employ are the key to your success; it is not you that will make a quality product it is they.

Paying for the Costs & Maximizing EBITDA

Obviously, the more product you can make and sell the more money you should make and the manufacturing costs we have discussed are paid for. All true, but if a manufacturing operation is growing, starting up or is having a lull in orders the costs still have to be paid, and these costs are covered by a part of the price of every product sold. What I am leading you too here is an example of a situation I found myself in when managing a contract manufacturing operation and the lessons I learned which were not what I had imagined.

Over a period of months I had listened to the sales force who had been complaining about not being able to win new business and that our quoting calculations always resulted in us having a higher price than our competitors. We had been quoting based on a template created by the finance guys which had a built in 15-25% profit margin. The business was a turn-around so had reasonable customer volume but the overall profit by year was at 5%.

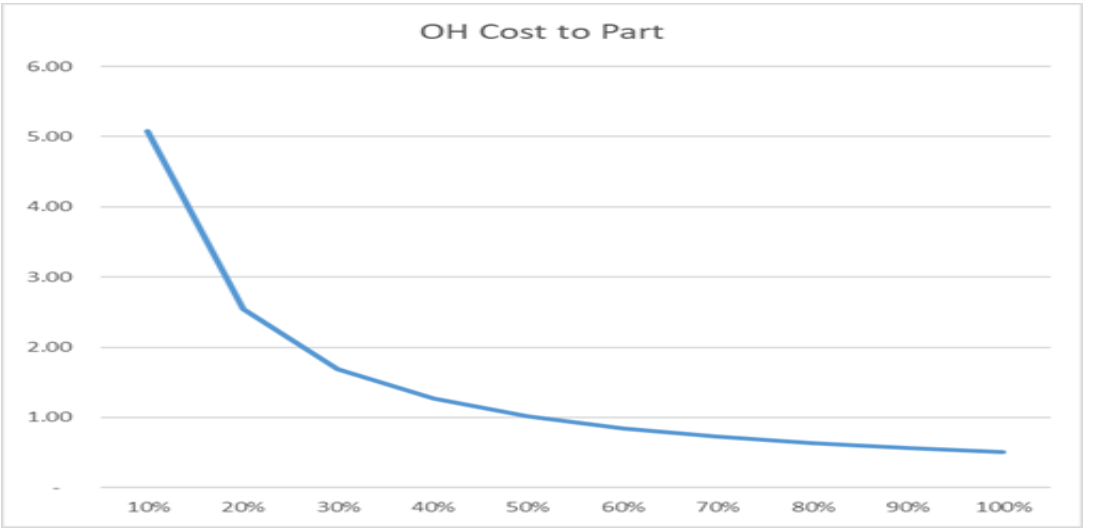
We knew if we could just get a couple more customers we would vastly increase the profit as utilization of the site's equipment was relatively low and we could use the current workforce far more efficiently if we just had a little more business. The Indirect labor levels

were reviewed and we did not think we had excessive headcount in any area but we were staffed to grow the business and were willing to hang on and wait for the business to materialize. We served the med device industry so I had worked extensively in the Quality Management System and the Project management side of the business, we had registered the business with the FDA and had undergone several good external audits and had exceptional systems to show the customers.

The problem was, we did all the right things but the customers we needed were just not being pulled in. We reviewed the older customer list with the sales team and asked why some of the customers had reduced their business with us, then sent the sales guys out to the businesses to find out more details. The answer we received was that we did service them well but we were more expensive than other suppliers so they moved their business to more cost effective sources.

It was at this point I looked at the effect of our overhead costs to the quoting model. As our business and volume had reduced we were amortizing our overhead costs into fewer products and the overhead costs were the basis of the quoting model we were using.

The graph below shows the effect of utilization on cost and was the key to the problem:



The site machine utilization had fallen to around 15-18% and as a result driven our production costs up substantially. Based on this I immediately focused on how we could sell off utilization and reduce our quoting prices.

To start with we removed the 15-25% profit margin in the quoting model and sent out the sales guys to the older customers in an effort to bring back some business. This worked, our prices were once again competitive and several new products were transferred back to our business. Over the next 3 months the utilization increased to around 26% and the profit increased by over 15% because of the increased volume and amortization of the overhead.

Because of the nature of the curve of this graph I understood where the gains were and could strategically plan to improve the business. I also learned that after around 55% utilization is achieved the gains are far less but you are in a healthy range for your business.

This is a fitting lead in to the next principle “KPI’s” because you need to know what you are measuring and what are the acceptance levels you need to achieve and why. In other businesses I later managed there was intense focus on utilization with goals set to achieve 85%+, the company however focused more on utilization than FPY and lost customers due to poor quality. Lessons learned the hard way always stick!

Principle 11: Understanding KPIs

What are KPI's? Key Process Indicators. A numerical measure of a process. Two great quotes here, the first by Peter Drucker: "If you can't measure it, you can't improve it." and the second by W. Edwards Deming: "In God we trust, all others must bring data."

Key process indicators can come from many different measures, from a manufacturing process we may look at quality of the product by "First Pass Yield" we may look at quantity by "Parts per Hour" or machine efficiency by "Percentage Uptime." If we are looking at customer order fulfillment we may monitor "Customer Backorders" and for customer satisfaction we could look at "Complaints Rate."

The main thing is that we have in place measures to ensure what is important is being measured so we can monitor and improve it. The challenge is that there are a great many things within a manufacturing operation that need to be measured and sometimes the number of KPI's an operation has can be too much to manage.

So, when you look at the KPI's you need to define at what level you want that KPI to be looked at and what would happen if that KPI was not meeting the target, what would be the next effect? A good solution is to have three levels of measures starting with the manufacturing floor and process operators, the next level being supervisors and the highest level being management.

As an example, we can look at productivity. The first KPI could be parts per hour from a manufacturing process, monitored by the folks operating the process. If they are consistently not meeting the target then the daily volume will also, not be met. The next level of KPI would be daily production targets monitored by the manufacturing supervisor and the final KPI monitored by management will be the weekly production target. By this means, as long as the operators are meeting their target, the manager and supervisor KPIs will stay green, (at the desired performance level) if the hourly rate is not met, the supervisor will know within a day, and can look into the reasons why the target is not being met and correct the situation before it effects the weekly goal and the manager level KPI.

So what KPIs should we be looking at in manufacturing operations? As we discussed earlier, People (or employees) should come first with Safety, then Quality of the product, followed by Delivery to the customer then finally Cost, Safety, Quality, Delivery, Cost.

Here is an example of a three level KPI monitoring set up. Note that the measures should be whatever is best for your operation and the measures below are simply suggestions.

	Employee & Safety	Quality	Delivery	Cost
Manager Level	Accidents. Assigned training completion	Late CAPAs	Customer Backorders	MUV
Supervisor Level	Action to prevent Near Miss. Training not completed (late)	NCRs Investigated, repeat NCRs open CAPA	Daily production rates not met	
Operator Level	Record Near Misses. Establish training & schedule	Quality Defects found and NCR created	Hourly Production rates	Scrap, downtime

Logic:

Safety – Record near misses – Prevent near miss – avoid Accidents

Employee – Have defined training requirements – ensure training completed – address missed training

Quality – Defects recorded in NCR – Cause of defects established, repeat defects – Create CAPA

Delivery – Hourly Output – Daily Output – Customer Backorders

Cost – Scrap and line downtime – Daily output effected – Material Usage Variance

Once the measures have been established, the next step is to make the measures as instantly visible as possible throughout the operations. Visual Indicators are a great way to show how things are running, process scrap placed in a visible bin that is emptied at the end of a shift shows everyone how much product is lost and if measured, recorded and dispositioned each shift the data is priceless for process improvements.

Finished goods rack locations that hold 1-2 hours production are a great indicator to see if the production process output is on track. Safety boards with lists of near misses and actions taken to prevent re-occurrence is a good communicator that the workforce is looking out for issues and addressing them promptly.

Weekly boards showing the results of all four high level KPI's with Green and Red magnetic labels showing which KPI's are being met and which are lacking is an immediate way of knowing how the operations are performing.

Maintaining the standards is then a continuous process of the operations team breaking down the data to understand the root cause of why a KPI was missed and conducting corrective actions to get the metric back on track.

This is a data driven process, levels of performance need to be established so that the goal is achievable but a stretch. As the performance improves the KPI targets need to be raised to drive the organization to perform at the next level. Well thought out KPI's drive behaviors which then become habits, good habits that benefit everyone. I have personally seen highly mechanized production processes with dangerous machinery go years without a lost time accident by measuring and driving near miss incidents and actions to avoid repeat incidents. It encourages all employees to look out for each other "your brother's (sister's) keeper" mentality which drive people to care about each other more, these rewards are priceless.

Summary

For each one of these principles we could write a book, however the goal of this document is to give a fairly high level view of Key manufacturing and operating processes and show some best practices for how each aspect can function successfully.

I have often seen comments made about what is “risk based decision making?” what are “risk based systems and processes?” and the answer is: Processes and procedures that use Risk to drive the business and be the key deciding factor for decisions.

The appreciation and understanding that if you have some simple Risk driven processes in your organization as a foundation, then it is set to flourish. My goal is that you understand at a reasonable level, the role Risk can and should play in almost all your processes. If you know that you are starting out with a robust process with a level of mitigated risk, you can better manage the process and improve on it over time.

There is no perfection and even the best products and processes fail, but if you have a good understanding where the weaknesses are in your operations and processes it can be factored in to difficult decisions.

“Ignorance is not Bliss” and for manufacturing organizations can be the difference in success and total failure. Spending time understanding and analyzing processes by looking at risk, using risk to define what you need to do, and ensuring actions are conducted to reduce risk, all need to be pushed to the front end of all projects, as this will vastly reduce failures in designs, processes and compliance. Having risk assessment methods that can be applied quickly to measure the robustness of a design or a process is essential for an organization to embrace using the tools. If risk assessment methods are not built into our processes or are cumbersome or complex to complete they will be used seldom or after the fact, and be rendered useless. Used proactively they can make for quick decisions, directing the focus on the things that matter that pose high risk, and be the deciding factor for difficult situations.

The nicest thing about a good risk assessment is that the inputs to the risk, the severity of the failure and the frequency can be debated and inputs adjusted based on the rationale of the team.

I hope you share my view, that there is method here that connects the dots of manufacturing operations and creates an overall process that if adopted results in success.

Thank you for your time, and please give candid feedback or ask questions, there is always improvement that can be made.