5S

- The main goal of 5S is to reduce waste and improve efficiency in the workplace. This involves sorting, setting in order, shining (cleaning and organizing), standardizing, and sustaining the process. It is a systematic approach used to create and maintain a safe, organized, and productive work environment.
    - Sort
    - Set in Order
    - Shine
    - Standardize
    - Sustain

10-to-1 Rule

- A measuring tool should be at least 10x more sensitive than the total variation in measurement (e.g. if the tolerances are expressed in thousandths, the tool should be able to measure to the ten-thousandths)

Acceptance Sampling

- The primary purpose of Acceptance Sampling is to verify that an entire lot of products meet specifications. It involves taking a sample from a given lot and testing it for conformity. If the sample passes all tests, then the entire lot is considered to meet specifications. This method is used to reduce risk and ensure quality when dealing with large quantities of products.

Accuracy vs. Precision in automated inspection

- Precision: minimizing false positives
    - High precision = if a defect is identified, it probably is actually a defect
- Sensitivity (recall): minimizing false negatives
    - High sensitivity = unlikely that defects will pass undetected
    - Not catching defects during an inspection is the same as having false negatives.
    - Excessive sensitivity can be mitigated by using larger sample sizes, which are less prone to major variations
- Accuracy: overall correctness, considering true negatives and true positives
    - An overall performance measure

Affinity Diagram

- Organizes large amounts of data into related groups
- A tool used to organize the results of a brainstorming session. It helps to group related ideas together and identify patterns in the data. The process involves sorting the ideas into categories and then connecting them with lines or arrows to show relationships between them. This can help teams quickly identify key themes and prioritize tasks for further development.

ANOVA

- Analysis of Variance

    - Compares *means*, not *variances*
    - Can be good for initial evaluations
- Follows Bartlett's Test, assumes equal variances
- Works for independent groups
- For three or more groups
- Compares means of multiple groups - good when everything is ok on average but there is individual variation
    - Determines differences in measurable characteristics (e.g. paint adhesion strength) under different circumstances
    - Can be used in conjunction with a factorial analysis, i.e., determining the means of different combinations of factors as they relate to a particular output.
    - ANOVA allows for the comparison of means across multiple groups and determines if the observed differences are statistically significant, rather than due to random chance.
- One-way ANOVA is a subset of ANOVA:
    - One-way ANOVA: You test recovery times across 3 dosage levels (low, medium, high). There's one factor: dosage.
    - Two-way ANOVA: You test recovery times based on dosage and also gender. Now there are two factors.
    - One-way ANOVA is suitable for comparing the means of two or more groups when the independent variable is categorical and the dependent variable is continuous.
- The degrees of freedom "within the groups" in ANOVA is calculated using the formula df = n - k, where n is the total number of observations and k is the number of groups.
- The ANOVA table breaks down the total variation in the data into two parts:
    - SS Between (also called "Sum of Squares Between Groups"): Measures differences between the group averages (in this case, between the machines). If this number is big, the machine averages are different from each other.
        - The amount of variation caused by differences between machines.
    - SS Within (also called "Sum of Squares Within Groups" or "Error"): Measures how much variation there is within each group (each machine). Even if all machines are the same, random variation in the products causes some defects.
        - Variation that happens within each machine's products.
    - Total SS: The overall variation in the data — combining both within and between group variation.
    - $$\text{Total SS} = \text{SS Between} + \text{SS Within}$$
    - ANOVA DF = (K-1)+(n-k), where K is the number of groups and n is the number of observations
    - ANOVA DF Between (# of inputs -1)
        - Total DF = DF Between + DF within

ANSI Sampling Tables

- See appendix

- ANSI/ASQ Z1.4 and Z1.9 are two different types of acceptance sampling plans.
    - The ANSI/ASQ Z1.4 plan is used for attribute data, which is data that is discrete or categorical in nature. Attribute data can be either pass/fail or a rating system like good, fair, and poor. Used the determine the acceptability of a test.
    - The ANSI/ASQ Z1.9 plan is used for variable data, which is data that is continuous or numerical in nature. Variable data can be measurements such as length, width, and height.

ANSI/ESD S20.20

- A comprehensive electrostatic discharge (ESD) control program involves identifying ESD hazards, implementing preventative measures (grounding, shielding, etc.), and training personnel.

AQL

- Acceptable Quality Limit
- Increasing = making acceptance more lenient (increasing limit)
- AQL sampling plans accept a certain level of defects
- According to ANSI/ASQ Z1.4 standard, when two out of five consecutive lots are rejected, the subsequent lot should be sampled using tightened inspection. This means that a larger sample size is used than with normal inspection in order to ensure that defective items are not passed through the acceptance process.

Attribute Agreement Analysis

- An attribute agreement analysis directly compares the vision system's classifications to a validated standard (manual inspection), determining its effectiveness in correctly identifying defects (and avoiding false positives/negatives).
- Output is a *kappa statistic*

Audits

- Direct observation and correction
- Verifies protocol adherence
    - Knowledge tests cover understanding only, not application
    - Incident reports are reactive
    - Redistribution of protocol (aka reminders) don’t actually assure anything
- Verifying compliance, not identifying root causes or quantify variability
- A surveillance audit is used to ensure ongoing compliance with certification standards. This type of audit is conducted periodically or on an ongoing basis to verify that the organization has maintained its quality management system and continues to meet applicable requirements.

Automation

- Esp. in data collection, provides objective data and eliminates human estimation

Availability

- MTBF: Mean time Between Failures
    - MTBF = (1 / Failure Rate)
    - MTBF formula: where T is the total observed time, N is the number of repairs, and R is the average time per repair
        - $$\mathrm{MTTF} = \frac{T - (N \times R)}{N}$$
        - $$\mathrm{MTBF} = \mathrm{MTTF} + \mathrm{MTTR} = \frac{T - (N \times R)}{N} + R = \frac{T}{N}$$
- MTTR: Mean time to Repair
- Availability MTBF / (MTBF + MTTR)
    - This formula provides a measure of the percentage of time that a system is available for use. In this, MTBF is uptime, and MTTR is downtime.
- Probability of failure, given MTBF (modeled with an exponential distribution):
    - $$\exp(x) = e^x$$
    - $$P(\text{failure by time } t) = 1 - \exp\left(-\frac{t}{\mathrm{MTBF}}\right)$$
        - Where t is the time of failure and MTBF is the mean time between failures.
        - This formula only applies if the system is in the constant failure rate section of the bathtub curve.

Balridge Award

- Criteria for award provide a framework for QMS improvement

Bartlett's Test

- Test for variance equivalence
- Checks that variances are homogeneous
- Done *before* ANOVA, which assumes equal variances

Benchmarking

- Strategic benchmarking is a technique which can be used by organizations to measure and compare their performance against organizations of similar type, size, and offerings. It helps determine whether an organization's strategies are effective and efficient compared to its peers.

Benefit-Cost Ratio

- (Expected Revenue) / Cost

Bias Chart

- Specifically designed to quantify and visualize the systematic difference (bias) between a measurement system and a reference standard or another measurement system.

Bias Study

- assesses the accuracy of a measurement system by comparing its measurements to a known standard

Bland-Altman Plot

- Assesses agreement between two measurement methods quantitatively
- Need to compare automated anything to known good or bad units confirmed under known processes
- Compares difference of two measurements to their average
    - Visualizes bias
- It plots the difference between the two measurements against their average, allowing for visualization and quantification of bias and limits of agreement.

Binomial Probability

- To figure out the chance of achieving a certain number of successes or more in a set of repeated attempts, you add up the probabilities of all the outcomes that meet or exceed that number of successes.
    - This involves considering how likely each specific outcome is, based on the chance of success and failure in a single attempt.
    - When the chance of success isn't very high, getting many successes in a small number of tries is usually unlikely. The final result tells you how rare or common it is to reach or surpass that level of success under those conditions.
- $$P(X \geq k) = \sum_{x=k}^{n} \binom{n}{x} \cdot p^x \cdot (1-p)^{n-x}$$
- - $P(X \geq k)$: The probability of getting **at least** k successes.
  - $\sum$: This means you're adding up multiple terms.
  - $x = k$ **to** n: You add the probabilities from k up to the total number of trials n.
  - $\binom{n}{x}$: This is "n choose x" — the number of ways to get x successes in n tries.
  - p: The probability of success on a single trial.
  - $(1-p)$: The probability of failure.
  - $p^x \cdot (1-p)^{n-x}$: The probability of getting x successes and $n-x$ failures.
- To find the chance of getting at least a certain number of successes, you calculate the probability for each possible number of successes at or above that threshold, and then add them all together.
- When broken out, the formula is as follows:
    - Where X is the number of trials
    - Where y is the number of successes in a trial
    - Where p is the probability of successes
    - Where (1-p) is the probability of failures (because successes + failures adds up to 1)

    - (x choose y) * p^y * (1-p)^(x-y) and adding each of these up until y = the limit number (typically, the number of trials)
- “x choose y” is a way of counting how many different ways you can choose y items from a group of x items, without caring about the order. Ncr on calculator.
    - $$\binom{x}{y} = \frac{x!}{y!(x-y)!}$$
- Other ways of referring to the number of successes could be the number of acceptances or accepted defects.
    - A zero-defect sampling plan has an acceptance rate of 0. The X would then be the sample size (sample choose defects). The defect level would then be p, since that is the probability of a defect.
    - Formula is P(X=k) = (n choose k) * p^k * (1-p)^(n-k) , or Binomialpdf in a calculator. In the calculator, trials/sample size is N, test value is P, and acceptance number is X.
        - Remember that ‘choose’ needs to be expressed with *all* possible options. For example, if the acceptance level is 1, it means that you have to check for the possibilities of accepting 1 AND 0, since they are both possible. Similarly, if there is a maximum of 10, but the acceptance level is *at least 8*, you have to check for the possibilities of it being 8, 9, or 10, and add them all together.
- Defects per hundred or per thousand are expressed as a decimal.
- Binomial CDF does probabilities given an upper bound (i.e., *at most value X*) automatically.
Exactly x	`binompdf(n, p, x)`
At most x (≤ x)	`binomcdf(n, p, x)`
At least x (≥ x)	`1 - binomcdf(n, p, x - 1)`
Between x and y (inclusive)	Add `binompdf(n, p, x)` through `binompdf(n, p, y)`
- To find the mean of the binomial distribution, multiply N (number of trials) by P (probability of success on each trial).
    - $$\mu = N \times P$$

Brainstorming

- Multi-voting is a tool used in brainstorming and problem-solving sessions. The idea behind it is to allow each team member to vote for multiple ideas so that the most important ones can be identified quickly and easily. This helps teams prioritize their work and focus on the most impactful topics.

- Brainstorming is an effective method for identifying stakeholders, as it encourages a broad range of ideas and allows participants to contribute their knowledge and experiences to the brainstorming process.

CAPA

- Corrective action eliminates root cause of a nonconformity
- Preventive action prevents a *potential* nonconformity from occurring

Certificate of Analysis (COA)

- Not typically worth the trouble to check it since it's just a manufacturer snapshot of initial quality
- Verifies conformance at the time of production but not over time
    - On-site audits are more effective to understand supplier QMS and process controls
        - OSAs help identify potential weaknesses

Check Sheets

- Used for data *collection*, not analysis
- Systemic collection at the point of data generation

Chi-Square Test

- For *categorical* data
    - Looks for statistically significant association between categorical variables
    - Similar to a regression analysis, but for categorical rather than continuous
    - E.g. : relationship between types of failure modes (if the failure modes tend to occur together)
    - Typical analysis for a contingency table
- Chi-square test of independence asks "does x deviate from y more significantly than if the variables were independent?"
- *Two* categorical variables (e.g. before and after)
    - Similar to T-Test, but for categorical instead of continuous data
    - Checks if there is an association between the two categorical variables
- P-value = significance level
    - If the P value > significance level, accept the null hypothesis
- Chi-squared variance = 2*d (where d is degrees of freedom)
    - DF doubled, not squared.
    - Chi Square checks for variance
        - The chi-square test is used to compare the variance of a sample to a given value. This test can be used to determine if the variance of a sample is significantly different from a certain given value.
- Chi-square mean = total degrees of freedom
- Chi-square statistic:
    - calculate the expected values for all cells.

- Where E is the expected value of a cell and O is the value actually in the cell, apply this formula: $$\frac{(O-E)^2}{E}$$
- Add up the results of all the formulas. Written with sigma notation:
$$\chi^2 = \sum \frac{(O-E)^2}{E}$$
-

Choosing Combinations

- Choose notation is used to determine how many possible combinations exist.
- For X total possibilities with Y possible outcomes, it's (X choose Y)
- On a calculator, it's X nCr Y

CI-CD

- Continuous improvement/Continuous deployment
  - Focuses on real-world scenarios and critical functionalities
  - Emphasis on end-user perspectives
- CI CD pipeline is automated testing
- CI: frequent code integration
- CD: automates software release into different environments

CMM Reference Sphere

- Ensures CMM machine function and calibration

Confidence Interval

- A confidence interval is a range of values that's likely to contain the true value of something you're trying to measure, like an average. It's based on sample data and includes a confidence level (like 95%) that tells you how sure you can be about the range. For example, a 95% confidence interval means that if you repeated the same experiment many times, 95% of the intervals would contain the true value.

$$CI = \bar{x} \pm z\frac{s}{\sqrt{n}}$$

CI = confidence interval

$\bar{x}$ = sample mean

z = confidence level value

s = sample standard deviation

n = sample size

-

    - The Z in the confidence interval formula is called a z-score (or critical value), and it's not calculated from your data. It's based on the confidence level you choose and comes from the standard normal distribution (a bell-shaped curve with mean 0 and standard deviation 1).
        - Confidence level 90%, Z-score 1.645
        - Confidence level 95%, Z-score 1.96
        - Confidence level 99%, Z-score 2.576
    - If you're building a 95% confidence interval, you look up the z-score for 95% (which is 1.96). It's a known value from statistical tables or built-in functions in software like Excel, Python, or calculators.
        - You don't calculate it from your sample, you choose your confidence level, and the corresponding z-score is fixed based on that.
- Another confidence interval formula uses a T-distribution:
    - $$\text{Confidence Interval} = \left(x - t \times \frac{s}{\sqrt{n}},\ x + t \times \frac{s}{\sqrt{n}}\right)$$
        - Where X is the sample mean
        - Where S is the sample standard deviation
        - Where N is the sample size
        - And where T is the number from the t-distribution table.
            - The T number simplifies a step.

Cohen's Kappa

- Cohen's kappa is a statistical measure used to assess the agreement between two raters when categorizing items, particularly in situations where chance agreement is a factor. It's a more robust measure than simple percent agreement because it accounts for the possibility of agreement occurring by chance. The kappa coefficient ranges from -1 to +1, with +1 indicating perfect agreement, 0 indicating agreement equivalent to chance, and negative values indicating agreement worse than chance.

Comprehensive Quality Manual

- Proactive and allows for supplier audits to address quality issues

Comprehensive Study

- Equipment Qualification
- Material Categorization
- Operational Procedures
- Proactive method to ensure consistent process performance

Constant Stress Testing

- Contrast with step-stress testing
- Requires more test units, takes longer to do

Conflict Resolution

- The *Compete* conflict resolution strategy involves trying to gain the upper hand in a dispute and taking an aggressive stance to ensure that one's own needs are met. This approach can be effective in some situations, as it can help settle disputes quickly and decisively. However, it can also lead to a lack of cooperation and teamwork between the two parties involved, which can ultimately damage relationships

Contingency Table Analysis

- A contingency table analysis (e.g., using Cohen's Kappa) is the most appropriate method to assess the agreement between two categorical variables, such as the machine vision system's 'Defect/No Defect' classification and the human inspectors' 'Defect/No Defect' classification. This directly assesses the frequency of true positives, true negatives, false positives, and false negatives.

Contour Plot

- A spatial representation of defects that may help identify root causes
- A contour plot is a 2D graphical representation of a 3D surface, where lines connect points of equal value. It's like looking at a topographical map where lines represent elevation levels. A contour plot differs from other plots by focusing on visualizing a function's behavior in its input space, rather than plotting the function's output directly.

Control Charts

- Not for comparing different groups, only observing a process and if it's in control
  - A control chart is used to monitor a process over time, not to determine the optimal settings for process parameters.
- They look at all components together in the process to determine overall process stability
  - In doing so, they detect special causes of variation
  - They are for monitoring, not predicting
- Control chart limits are established as NP charts when the sample size is constant.
  - UCL = (n*p) + (3*√(n*p)(1-p))
  - LCL = (n*p) - (3*√(n*p)(1-p))
  - - np = average number of defectives per subgroup
    - $\sqrt{np(1-p)}$ = standard deviation of the number of defectives
    - Multiply standard deviation by 3 (for control limits)
    - Subtract that from the average to get the UCL in this version of the formula.
    - Np = n*p
    - If LCL turns out to be negative, you round it up to 0, because you can't have fewer than 0 defectives.
  - For constant sample sizes, a C chart is used. The lower control limit formula is LCL = c - 3xSQRT(c) where C is the count of defects per cycle.
- Nelson's rule: 9 points in a row on a control chart can happen .1953% due to chance. Most likely there is an assignable cause. If there is a 50-50 chance of this happening, the formula would be .5^9, since it's 9 incidents.

- The control limits for a p-chart are determined by the subgroup size. As the subgroup size increases, the control limits become narrower. Since n is in the denominator of the formula, as it increases, the control limits become narrower.

Control Plan

- Outlines how a process will be controlled, but doesn't validate the reliability of a measuring system.

Coordinate Measuring Machine (CMM)

- Bridge CMMs are the most suitable type of CMM for measuring large parts with high precision. They feature a fixed bridge or frame that supports the moving X-Y table, providing stability and enabling accurate measurements over large distances. They are commonly used in automotive, aerospace, and other industrial applications where precise measurements of large parts are required.

Corrective Actions

- The process of identifying the root cause of a problem and taking steps to prevent its recurrence.
    - This may involve developing an action plan and ensuring that appropriate resources are allocated to carry out this plan effectively.

Cost of Quality

- Prevention costs are those associated with activities designed to prevent defects from occurring in the first place. This includes activities such as training employees on proper quality control procedures.
- Appraisal costs are those associated with activities designed to detect defects before the product or service is delivered to the customer. This includes activities such as inspecting and testing products for defects before they are shipped to customers.

CP/CPK

- CP = is the process in the bell curve
    - High CP = wide margin for error
    - Cp = (USL - LSL) / (6 * σ)
- CPK = considers if the process mean is centered on the mean of the bell curve
    - High CPK = process is close to the *center* of spec limits
    - Cpk = min[(USL - $\bar{X}$) / (3 * σ), ($\bar{X}$ - LSL) / (3 * σ)]
- CP & CPK numbers (CPK considers process centering and uses the same thresholds)
    - < 1.00 process is not capable
    - = 1.00 barely capable, hits the minimum level of capability (99.73% of output is ok)... should focus on improving centering
    - >= 1.33 process is acceptably capable (99.99% of output ok)
    - >= 1.67 or 2.00 high capability (6 sigma)
        - Important for critical functions like medical or aerospace mfg
- CPK lower than CP = process is not centered

- CPK cannot be greater than CP, only equal to or lower
- A capable process would be centered (the mean is equal to the target), and also have an acceptable spread (variation) around that mean such that parts will rarely deviate outside of the USL and LSL.
- To calculate the process capability index (Cpk), you need to know the upper and lower specification limits (USL, LSL) for the manufactured item. With just the mean and standard deviation, it is not possible to calculate Cpk.
- CpL = (Process Mean - LSL) / (3 * sigma within)
    - $$CPL = \frac{\bar{x} - LSL}{3\sigma}$$
    - It shows how capable the process is of staying above the lower limit. The higher the CPL, the better (more capable). A low CPL means you're too close to the lower limit or even going below it.
- Cp and Cpk are used to measure the capability of a process that is in statistical control. If the process is not in statistical control, then these metrics cannot be used to accurately measure the process capability.
- Ppk uses sigma overall
    - Sigma within: short term variation
    - Sigma overall: long term/total variation

CPM/PERT

- A PERT chart is a project management tool used to plan, schedule and control activities in a project. It includes probabilistic time estimates, which account for potential delays or changes in the duration of tasks. A CPM (Critical Path Method) chart is also used to plan, schedule and control activities in a project.
    - Unlike PERT charts, CPM charts use deterministic time estimates, which do not account for potential delays or changes in the duration of tasks.
    - The expected duration (Te) of activity in a PERT chart is calculated using the formula Te = (a + 4m + b) / 6, where a is the optimistic time estimate, m is the most likely time estimate, and b is the pessimistic time estimate. This formula takes into account both potential delays and changes in the duration of tasks.

Critical Control Points

- Where hazards can be identified and controlled

Cronbach's Alpha

- Internal consistency of a multi-item test
- Cronbach's alpha is a measure of internal consistency, or reliability, of a set of scale or test items. It essentially indicates how closely related a set of items are as a group. A higher Cronbach's alpha, closer to 1, suggests a high degree of internal consistency,

meaning the items are measuring a single underlying construct. It's commonly used in surveys and questionnaires, particularly with Likert-type scales.

CUSUM Chart

- Detects small sustained shifts in process mean quickly

Datum Reference Frame

- Primary datum controls 3 degrees of freedom
- Secondary datum controls 2 degrees of freedom
- Tertiary Datum controls 1 degree of freedom.

Defect Map

- Overlay defect data into a spatial representation

Degrees of Freedom

- Number of independent pieces of info required to calculate a statistic
    - Degrees of freedom in statistics refer to the number of values that are free to vary in a calculation, given certain constraints. Using a coin flip example, if you flip a coin three times and know there were exactly two heads and one tail, only two of the flips can vary freely—the third is determined by the need to meet the total. So, in this case, the degrees of freedom are 3 (flips) minus 1 (constraint), which equals 2. This concept is important in statistical tests because it affects how we interpret data and calculate things like p-values.
- Degrees of freedom affect the usefulness of a p-value because they help determine the shape of the statistical distribution used to calculate it. With fewer degrees of freedom (like when you have a small sample size or many constraints), the results can be less reliable, and the p-value may be less accurate or more sensitive to extreme values. As degrees of freedom increase, the p-value becomes more stable and trustworthy, making it easier to draw meaningful conclusions from your data.
    - The degrees of freedom for a two-sample t-test with unequal sample sizes is calculated by taking the sum of the degrees of freedom for each sample, which is (n1 - 1) + (n2 - 1). This formula assumes that the samples are independent and that the population variances are equal.
- The degrees of freedom for a contingency table is calculated by taking the number of rows minus one times the number of columns minus one.

Deming's 14 Points

- Deming's 14 Points are a set of recommendations for managers to improve the quality of their products. One of these points is that management should eliminate numerical goals, posters, and slogans, as these can lead to short-term motivation but generally don't improve long-term quality improvement.
    - Driving out fear = encourage trust and respect

Descriptive vs. Inferential Statistics

- Descriptive presents data to facilitate understanding
- Inferential statistics involves using sample data to make inferences and draw conclusions about a larger population

Design of Experiments (DOE)

- Choose parameters that are safe, realistic, and within operating limits
- Done by varying input factors to observe impact on components
    - Used to optimize performance and identify impacts
- For when most impactful parameters are as yet unknown
- Resource intensive

Destructive Testing

- The Charpy test measures impact resistance.
    - It is used to measure the amount of energy required to break a material sample. This test involves striking the sample with an instrumented hammer and measuring the energy absorbed by the sample before it breaks. The results of this test can be used to check the material's toughness and ductility.
- Brinell test assesses hardness through indentation.
- A tensile test is a destructive test. It involves applying a force to a material sample until it breaks, providing information about its strength and ductility.
- A creep test is generally considered a destructive testing method. Creep tests involve subjecting a material to a constant load at elevated temperatures, causing it to deform over time.

Dimensioning

- Chain: multiple data references - measurements are taken relative to previous estimated points
- Parallel: all measurements are taken from a single reference point

DMAIC

- Define (the problem)
    - The Define phase establishes the problem statement, project scope, and goals, which is important but doesn't directly address the data collection challenge.
- Measure - includes determining methods and processes for measurement
    - The Measure phase focuses on collecting accurate and reliable data to understand the current state of the process, including identifying the types and frequency of defects. This data is critical for subsequent analysis.
- Analyze - determine root causes based on *measurement data*
    - The Analyze phase utilizes the data collected in the Measure phase to identify the root causes of the problem, which can only be done effectively with good data.
    - Analyze establishes relationships that exist within the data collected during *measure*.
- Improve - address root causes

        - The Improve phase focuses on implementing solutions to address the root causes identified in the Analyze phase, and cannot proceed without understanding the process.
- *Six Sigma Component*
    - Data is used to identify root causes, implement solutions, sustain improvements
- Structured problem-solving methodology for improving existing processes through root cause analysis
    - May be too rigid to use during the implementation phase of a process
    - Appropriate when major process overhauls are necessary

Double Sampling

- Necessary when the first sample is inconclusive

EHR

- Electronic health record

Elcometers

- Check paint thickness

End of Line Inspection

- Reactive QC

Error Type

- I = False Positive
    - Error is when the null hypothesis is rejected when it is actually true. This type of error is also known as a false positive.
        - It happens when the researcher incorrectly rejects the null hypothesis and concludes that there is a statistically significant difference between two data sets or treatments, even though there is no real difference.
        - When you reject the null hypothesis, you're saying: “The evidence from the data is strong enough to say that something is going on — it's not just random chance.”
        - Null hypothesis (H_0): Nothing interesting is happening. Rejecting H_0: "Whoa, this result is too unusual to be just luck — something is happening here."
        - Rejecting the null doesn't mean you're 100% certain — it just means the data is unlikely if the null hypothesis were true.
- II = False Negative
    - You fail to reject the null hypothesis, even though it’s actually false. “There’s nothing going on,” when in reality, There actually is something going on.”
- Roman numeral mnemonic
- These error types have an inverse relationship (as I increases, II decreases, etc.)
    - The relationship between the Producer's Risk (α) and the Consumer's Risk (β) is inverse; as one increases, the other decreases. The Producer's Risk refers to the

probability of rejecting a true null hypothesis, while the Consumer's Risk refers to the probability of failing to reject a false null hypothesis. Therefore, if α decreases (the chance of rejecting a true null hypothesis decreases), then β increases (the chance of failing to reject a false null hypothesis increases).

EtO Sterilization

- Ethylene Oxide
- Chamber temperature is the most critical parameter as it directly impacts the efficacy of EtO sterilization. Small deviations can significantly affect the process's ability to kill microorganisms, requiring constant monitoring for optimal results.
    - The most critical parameter to monitor and control continuously during a sterilization cycle is the temperature inside the sterilization chamber. Temperature is directly related to the efficacy of the sterilization process. If the target temperature is not reached and maintained, the microorganisms may not be effectively killed, leading to potential safety risks.

EVOP (Evolutionary Operation)

- Makes small continuous improvements to a process *while it is running*

Expected Value of a Table

- E = (row total * column total) / grand total
    - This will end up isolating a row against a column and simplifies the process for having the expected value of any individual cell.
    - Multiply the row total by column total

Exponential Distribution

- The exponential distribution is a special case of the Weibull distribution and the gamma distribution.
    - The Weibull distribution is a continuous probability distribution used to model events that occur over time.
    - The gamma distribution is a generalization of the exponential distribution.

Facilitators

- Ensure all opinions are considered and respected
- Neutral third party in a meeting

Factors

- Factors are response variables

FDA PAI (Pre-Approval Inspection)

- A complete, accurate, and traceable Design History File (DHF) is essential for a successful FDA pre-approval inspection (PAI). The DHF provides evidence that the medical device's design process was controlled, documented, and compliant with all

applicable regulations. This is a primary focus for the FDA during a PAI to ensure the device is safe and effective.

Fishbone/Ishikawa

- Used to prioritize potential factors for further statistical investigation
    - Good for initial exploratory phase of a problem solving process
- Also known as Causal Diagrams
- 8 Ms of Quality Control:
    - Manpower - The training, skill, and attitude of the employees or workers
    - Machines - Maintenance of machines, whether upgrades to better technology is needed
    - Materials - Are raw materials and inputs properly labeled, stored, and of high quality. Have they been ordered in the right size and quantity?
    - Measurement - Are methods of measurement and control correct and accurate. Do they need to be adjusted?
    - Mother Nature - Often uncontrollable environmental factors like fire or bad weather, but certain safety measures can be undertaken, as well as insurance purchased for damage or disaster
    - Method - Does the production process have the most efficient number of steps, are there bottlenecks, is it overly complex and error-prone?
- Or: 3Ms of Quality Control
    - Man
    - Machine
    - Materials
- Or: 8 Ps of an Organization
    - Procedures - What are the set of instructions in place to complete a task or activity?
    - Policies - What internal rules dictate how things are done, and are they being followed accordingly?
    - Place - Where are events occurring, are there better locations the events could occur, and what are the implications of events happening at these places?
    - Product - What is being produced, why is it being produced, and what else could be produced?
    - People - Who is involved in the process, and who is incorrectly being omitted from processes?
    - Processes - What are the steps of a process, and are they being followed accordingly?
    - Price - What are the financial inputs of the process, and what are the financial outputs of the process?
    - Promotion - How are goods introduced to the market, and what strategies are used to convey the benefits of the product?
- Or: 4 Ss of Service
    - Suppliers - Who do we rely on for goods, and what do we need from these third-parties?

- Systems - What overarching processes are in place, and how can they be improved or changed to better serve a customer?
- Surroundings - What physical experience does a customer have when they engage with our business, and what circumstances in close proximity to our business impact the way we operate?
- Skills - What talents do we have, what talents do we need, and what do customers demand from us that we must be good at?

Flowcharts

- Not used for real time data collection, only for mapping out processes.
    - Checksheets are used for data collection

FMEA (Failure Mode Effects Analysis)

- Process:
    - 1. Determine potential causes of each failure mode
    - 2. Identify effects
    - 3. Assign risk priority number (RPN)
        - RPN = severity x occurrence x detection cost
            - RPN (Risk Priority Number) is calculated by multiplying the ratings for the likelihood of a failure occurring, the severity of the failure's consequences, and the effectiveness of the existing controls in place to detect the failure.
        - Standard metric in FMEA
- Proactive method to identify failures and effects.
    - Different from RCA, which is reactive and focuses on individual failures
    - Identifies failure modes, analyzes causes & effects, prioritizes actions to prevent or mitigate failures
- Types of FMEA
    - Design FMEA focuses on design improvements
    - Process FMEA
    - FMECA - failure mode effect and criticality analysis
- Takes a bottom-up approach by focusing on a component and the potential problems in that component and how they may interact
    - Contrast with Fault Tree Analysis (FTA) where the starting point is the failure itself, taking a top-down approach
- In a design FMEA (Failure Modes and Effects Analysis), the severity of a potential failure mode is rated on a scale of 1 to 10, with 10 being the most severe.

Force-Field Analysis

- A tool used in decision-making that helps identify and analyze the existing forces for and against any particular situation, decision, person, or process. It can be used to identify the forces and factors driving change in an organization. An organization wanting to introduce a new product into the market can use force field analysis to understand the various factors affecting successful product entry into the market.

    - driving forces are factors that work for the movement in a certain direction and restraining forces are factors that work against it

Fractional Factorial Testing

- Best for screening experiments to identify the most influential factors
- Cheaper, quicker, and focused
- Resolution III: Main effects are confounded with two-factor interactions (e.g., the effect of factor A is indistinguishable from the interaction between factors B and C). These designs are useful for initial screening but require careful interpretation.
- Resolution IV: Main effects are not confounded with two-factor interactions, but two-factor interactions may be confounded with each other. This is a common choice when you want to estimate main effects with reasonable confidence.
- Resolution V: No main effects or two-factor interactions are confounded with each other. Two-factor interactions may be confounded with three-factor interactions. These designs offer the most reliable separation of effects but require more experimental runs than lower-resolution designs.

Full Factorial Testing

- OK when there are a small number of potential factors
    - E.g., two options (left-right) compared with three options (up-center-down) creates 2^3, or 8 possible total factor tests.
- OK when the test does not require a limit to the number of runs

Gage R&R

- Can a piece of equipment reproduce and repeat the same measurements every time?
    - Important to to validate against older known good methods before implementing new ones
    - Repeatability: variability in measurements due to the instrument itself
    - Reproducibility: variability due to different operators using the same instrument
- Paired with ANOVA to determine the overall reliability of a measuring tool
    - Gage R&R results from two different devices can be compared to get verification that they're producing the same results
- Test is time-consuming and typically not a first-step when needing to quickly identify the source of a variation
- A GR&R study assesses the measurement precision of the automated system *in isolation*, but doesn't determine if the new system provides statistically similar measurements to an old *validated* manual system.
- Not to be confused with a *repeatability study*, which focuses on one operator's ability to get the same results multiple times (or assesses the variation of one operator using one piece of equipment).
- Typically for continuous data
    - Can work for categorical responses, such as a satisfaction survey
    - Cohen's Kappa or Kappa statistic rages agreement between observers for categories

- % Study VAR (% of variability in a process due to the measuring system itself)
    - Also called %R&R, Also called P/T ratio
    - < 10% measurement is acceptable
    - 10-30% may be acceptable based on factors like device cost
    - > 30% unacceptable
        - Lower values are better
- % contribution
    - < 1% acceptable
    - 1-9% may be acceptable
    - > 9% system must be improved
- Reproducibility is the degree to which a measurement is reproducible by other operators or measurement systems. It measures a measurement's consistency when taken by different operators or using different measurement systems. Precision measures how consistent a measurement is and how free it is from random error. Repeatability measures how consistent a measurement is and how free it is from random error when repeated measurements are taken by the same operator using the same measurement system. Bias measures how far a measurement is from its actual or true value.
- The Number of Distinct Categories (NDC) measures the number of distinct categories that can be used to classify the data in a GRR analysis. A minimum acceptable value for NDC is 5, which means that there must be at least 5 distinct categories for the GRR analysis to be valid.
- Range method: two operators check 5 parts each for a quick estimate
- Designs:
    - Nested = destructive
    - Crossed = non-destructive, multiple measurements
- Gage block wringing = aligning blocks to form a stack with a high degree of accuracy

Gantt Chart

- Also good for operational scheduling and tracking

Hatch Lines

- Hatch lines, also known as section lines, are used to indicate sections or cross-sections of a particular part in an engineering drawing.

Hazard vs. Risk

- A hazard is a potential source of harm, such as a machine or a chemical. A risk is the likelihood that harm will occur from the hazard. It is the probability that an event will cause harm or loss.

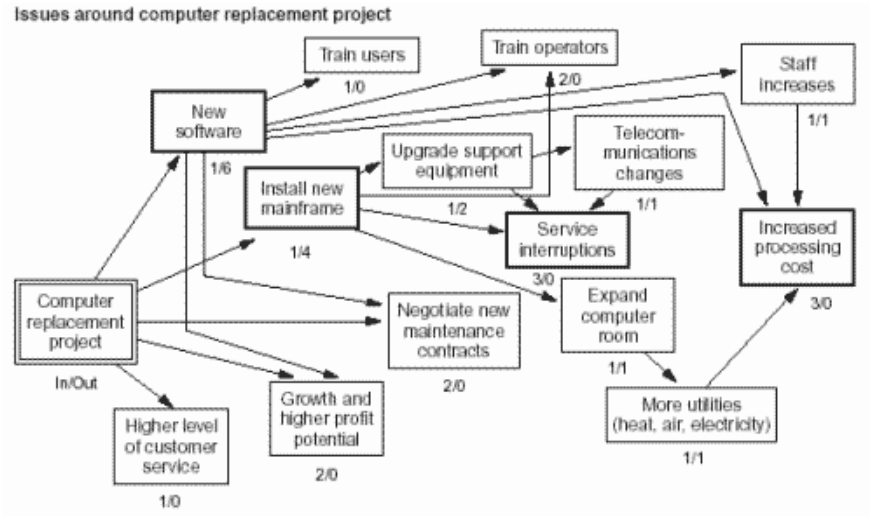
Histogram

- Considers a single variable
    - Displays data normality, confirms the presence of a bell curve
- Pareto chart considers multiple categories

Hypothesis Testing

- To check if there is a statistically significant *difference* between X and Y.

Interrelationship Diagram

- Maps out cause and effect relationships between elements of a problem
- Identifies primary drivers and feedback loops
    - Identifies most influential factors for targeting improvement
- 

IPO Input

- Process-output computing model

ISO 13485

- Quality management system standard specifically for the medical device industry. It outlines requirements for organizations involved in the design, production, installation, servicing, and related activities for medical devices.
- Emphasizes risk-based supplier management
- Implementing a documented process for periodic performance evaluations of *critical* suppliers, based on defined metrics derived from risk assessment allows for a focused and proactive approach to managing supplier quality, addressing the identified gaps and aligning with the standard's intent.
- Implementing a corrective action plan, that follows ISO 13485 requirements and includes a comprehensive review, is the first step to address the non-conformance and ensure patient safety.
- Tracing test results to requirements is essential for demonstrating that the design meets specified needs, as required by ISO 13485.
    - Medical device standards for verification and validation are processes used to ensure that medical devices meet the stated requirements for safety, performance, and usability.:
        - installation qualification (IQ), operational qualification (OQ), and process qualification (PQ)

ISO 14971

- The 'Information out of Production' clause emphasizes actively collecting and analyzing post-market data to identify previously unknown risks or validate existing risk assessments, and taking corrective actions.
    - Information out of Production = gathering and analyzing data in the field (post-market)
    - Establishing a robust system for handling customer complaints and adverse event reports, including investigating and analyzing root causes demonstrates compliance with this requirement. This feedback loop ensures that real-world experience informs and improves the risk management process.
- ISO 14971 is an internationally recognized standard that specifies a process for risk management specifically for medical devices. It provides a framework for manufacturers to identify, analyze, evaluate, and control risks associated with their devices throughout their lifecycle. The goal is to ensure the safety of patients and users by minimizing potential hazards and maximizing the benefits of the device.

ISO 9001

- QMS standard that identifies requirements for QMS
- Context = internal & external issues that may impact the objective (of a QMS)

Juran Trilogy

- The Juran Trilogy is a term used to describe the three universal steps for quality improvement. The three steps in the trilogy are Quality Planning, Quality Control and Quality Improvement. Quality Planning involves setting goals which are measurable and achievable. Quality Control is the process of ensuring that these goals are met, while Quality Improvement focuses on finding ways to improve the quality of products and services and implementing those improvements.

Kaizen

- Focus on incremental improvements across all aspects of an organization, to improve efficiency and eliminate waste
- A key principle of this approach is involving all employees in the improvement process in order to identify and address problems quickly and efficiently.
- Uses value stream mapping to identify waste and inefficiency

Kanban

- Kanban is a visual method for managing work that helps teams stay organized and efficient. Its core principles include starting with what you do now, making work visible (often using cards on a board), limiting how much work is in progress at one time, and focusing on continuous improvement. By seeing each task move through stages like “To Do,” “In Progress,” and “Done,” teams can spot bottlenecks, avoid overload, and deliver work faster and more smoothly.
    - Basically, a scheduling system
- Work is “pulled”

        - A team member "pulls" the next task when they're ready.
        - Nothing moves forward until the next step is ready to handle it.
        - This helps prevent overload and keeps work flowing smoothly.
        - The "pull" approach to work scheduling in the Kanban system is based on customer demand or requirements. This approach ensures that the right amount of resources and materials are available when needed and that tasks are completed in a timely manner. This helps keep production running smoothly, resulting in shorter lead times and improved customer satisfaction.
    - Work is not "pushed"
        - Tasks are assigned or sent forward even if the next person is still busy.
        - This can lead to bottlenecks, stress, and delays if people get overwhelmed.

Kaplan-Meier Survival Analysis and Log-Rank Test

- Estimates the survival function (probability of survival over time) for each group (supplier).
- The log-rank test then statistically compares these survival functions to determine if there are significant differences in failure rates between the groups.
- Used with accelerated life testing (ALT)

Kappa Statistic

- Agreement between raters for categorical data
- Similar to Gage R&R but deals exclusively with categorical data
- E.g.: in a pass-fail output do these two inspectors pass and fail the same items?

Key Words

- Efficiently (Fractional Factorial)
- Minimizing runs (fractional factorial)
    - Suitable for initial screening
- Optimal (RSM)
- Proactively (FMEA)
- Visually representing steps (flowchart)
- Identifying *and ranking* (Pareto)

Kirkpatrick Model

- Evaluates training efficacy

Latent Defects

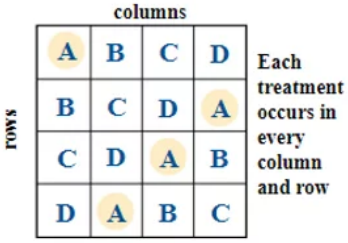
- To find latent defects that impact reliability:
    - ALT: Accelerated life testing
        - Estimate of life of product due to subjection to higher than normal stress levels
        - Must apply acceleration factors that realistically simulate operational stresses

        - If the failure mode changes under accelerated conditions, the results cannot be extrapolated to normal use conditions.
    - HALT: highly accelerated life testing
        - Uncovers design weaknesses through extreme stresses *beyond operating limits*. Finds intermittent failures and weaknesses.
    - Burn-In Testing: test that stresses electronic components to identify weaknesses, typically at elevated temperatures

Latin Square

- A Latin square design is a type of experimental design used to control for two sources of variability (nuisance factors) in an experiment while testing the effect of a treatment. It's essentially a square grid where each treatment appears exactly once in each row and each column. This arrangement helps isolate the treatment effect by balancing it across the nuisance factors.

A	B	C
C	A	B
B	C	A



-

Letter Charts

- C chart (Count of defects per unit in a sample; fixed sample size)
- I-MR (individual and moving range)
    - Best for individual measurements instead of subgroups
    - Specifically designed for situations where data is collected individually or in small subgroups (n=1 or 2), making them suitable for infrequently sampled data.
- P chart (Proportion of defective items in a sample)
- R chart (Range)
    - Good for monitoring variability, since the range is a direct measure of variability
- S Chart (St. Dev.)
    - Monitors *process* variability
- U chart (counts defects per unit)
    - This is for when the sample size varies
    - C chart is for when the sample size is fixed throughout
- X-bar chart (Mean)
- X-bar and R chart (Mean and Range)
    - X-bar (average of subgroups)
    - R (range/variability within subgroups)
    - Better for small subgroups
- X-bar and S chart (Mean and StDev)
    - Better for large subgroups, for tracking variation

- XmR chart (for when subgroups are not available)
    - An XmR chart (aka Shewhart's Control Chart) calculates the control limits from the moving average range. XmR chart, also called an I-MR chart, is a combination of two charts (Individual and Moving Range) to track the process variability based on the samples taken from a process over a period of time. In the XmR chart, each data point consists of one observation of continuous data.

Letter Tests

- F test
    - Compares *variances* of two populations
        - Not medians or means
    - Different from ANOVA, which primarily compares means of sample groups
    - AKA Variance Ratio Test
- T test
    - Hypothesis test
    - One sample T-Test: compares a sample to a population
        - Asks if this sample is representative of the population as a whole/is the population different from the sample?
        - E.g. validating political polling
    - Independent T-Test (T test = Two Test) (AKA Two-Sample T Test)
        - Two groups sampled
            - Normal distribution
            - Variances are equal
        - What is the difference between the two groups?
        - Is there a statistically significant difference between these two groups?
        - E.g. a control group and a test group for a new medication
            - When the data are not normally distributed, it's a Mann-Whitney U Test/Wilcoxon Signed-Rank test
    - Dependent T-Tests
        - One group sampled two times
        - 2 measurement points are often before & after
        - Compares if there is a statistically significant difference between the samples taken
        - E.g. Test scores before and after a change is made in the curriculum
- U test - same as a Wilcoxon test
    - Can check medians of non-normally distributed data
- Z test requires several assumptions that may impact test reliability

Levene's Test

- Designed to assess the equality of variances between two or more groups. It is specifically used to determine if the variances are significantly different.

Likert Scale

- Survey responses like 'satisfied', 'neutral', 'dissatisfied'

- Use Chi-square test before/after to check for changes

Linear Regression

- Continuous independent variable(s) vs. 1 continuous dependent variable (correlation)
- Pearson correlation coefficient measures the linear relationship between two continuous variables, but here, the data is categorical (defect detected or not).

Linearity Study

- used to assess the accuracy of a measurement system across its entire range of measurement values

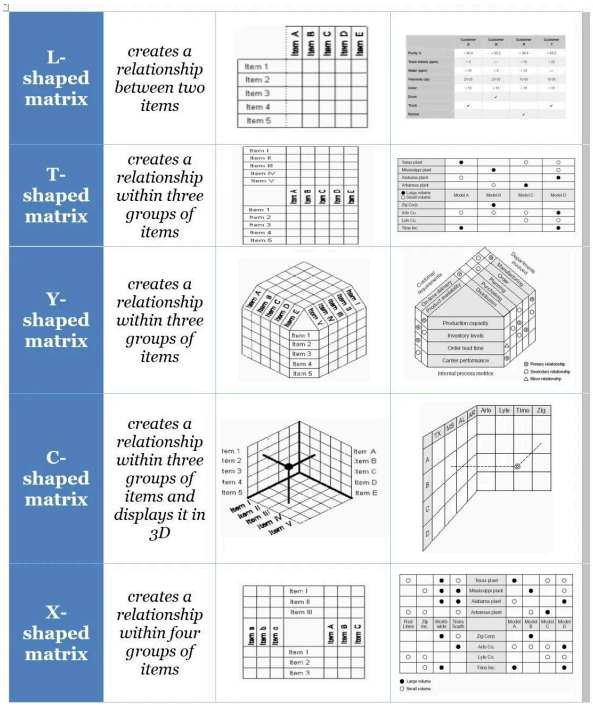
LSS

- Reduces waste and variation
- Streamlines processes and improves usability
- SS reduces variation and defects

Mann-Whitney U-Test

- This is a non-parametric test used to compare two independent groups when the data is not normally distributed.

Matrix Diagrams

- 

McNemar's Test

- Specifically designed for paired categorical data, allowing us to determine if there is a significant change in the proportion of positive responses (defect detected) between two related samples. It focuses on discordant pairs (where the two systems disagree).

Measurement System Analysis (MSA)

- The main purpose of the rule of 10 in MSA (Measurement System Analysis) is to ensure that the measurement system has sufficient resolution/discrimination to measure the characteristic being measured accurately. The rule states that the resolution of a measurement system should be at least 10 times greater than the expected variation in the characteristic being measured) This ensures that any changes in the characteristic can be accurately detected and measured.

Mechanical Properties

- Mechanical properties of a material include strength, hardness, and elasticity.

Meetings

- Facilitators help guide the conversation and facilitate open dialogue. This includes asking questions, stimulating creative thinking, facilitating problem-solving, and encouraging participation. A facilitator should not be making decisions for the group or providing technical expertise, which is best left up to other members of the group.

MSA Bias Study

- Determines accuracy of medical devices
- IQ, OQ, PQ answer regulatory requirements

MTTF

- $$\text{MTTF} = \frac{\text{Total operating time}}{\text{Number of failures}}$$
    - When using actual data
- $$\text{MTTF} = \frac{1}{\lambda}$$
    - For constant failure rate systems

Multi-Vari Chart

- Analyzes variation within a process, broken down to different levels
- A multi-vari chart is a graphical tool used to visualize and analyze variation in data, particularly in manufacturing or process improvement contexts. It helps identify the sources and magnitude of variation within and between different factors or units. The chart displays the means at each factor level, allowing for the examination of interactions between factors.

Non-Parametric Tests

- Do not assume any specific data distribution.
    - E.g.: Wilcoxon signed-rank

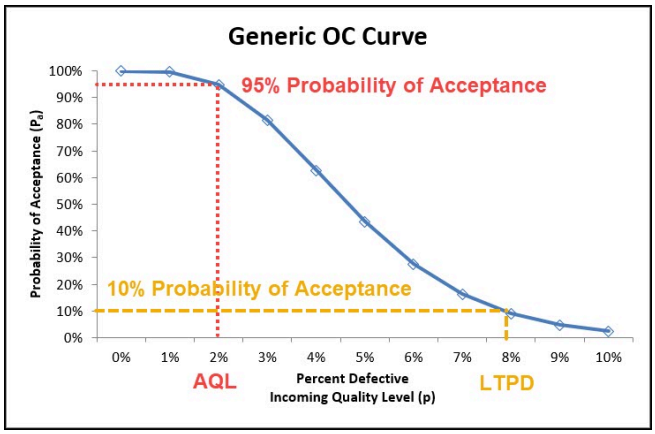
OCR

- Optical character recognition

On-Site Audits

- Comprehensive overview of:
    - Operations
    - QC Processes
    - Adherence to Standards

Operating Characteristics Curve (OCC)

- An OC curve (Operating Characteristic curve) is a graph that shows the relationship between the producer's risk and consumer risk for a given sample size. The x-axis of an OC curve represents the proportion of nonconforming items or the fraction of defective items in the sample size. The y-axis represents the probability of accepting the lot.
- 

Overall Equipment Effectiveness (OEE)

- Standardized procedures and training are proven methods for reducing changeover time and improving OEE by ensuring consistent and efficient execution.
- Measures a machine's availability, performance, and quality.
    - OEE = Availability x Performance x Quality
- Process efficiency percentage

Overprocessing

- Using higher grade material than necessary
- Any action that adds unnecessary cost without benefit

Pareto Chart

- Categorizes and prioritizes known defects based on the 80-20 principle
- Only addresses patterns *after* they occur (not proactive)
- Not for identifying causes, only to prioritize known problems
    - Can also prioritize costs associated with those problems
- Pareto analysis is just ranking *known* failure modes by frequency

- Stratified Pareto Chart groups defects by component then breaks down components by supplier
- Good for *defects*, not *variation*

PDCA

- Plan
    - Defining the problem or opportunity for improvement
- Do
- Check
- Act
- Best when process changes are easily reversible
- Problem solving method for continuous improvement

Physics of Failure Model

- A robust ALT relies on understanding the relationship between applied stress and failure rate, which allows for accurate predictions of reliability under normal operating conditions. This approach ensures that the accelerated test results are relevant and can be used to make informed decisions about the gear's design and manufacturing process. Additionally, considering all potential failure modes and going beyond only MTTF are important for comprehensive reliability assessment.
- This model will help understand the relationship between the applied stress (e.g., increased load, elevated temperature) and the resulting failure rate, allowing for accurate extrapolation to normal operating conditions.

Plackett-Burman Design

- A Plackett-Burman design is specifically designed for screening many factors with a minimal number of runs, allowing for estimation of main effects, but not interaction effects. An 8-run Plackett-Burman design can efficiently screen up to 7 factors.

Poisson Process

- Imagine you have something that happens randomly but at a steady average rate, like cars passing by a spot or emails arriving in your inbox. This kind of situation can be described using a Poisson process.
    - Now, say on average, x events happen in a certain time period. You want to know the chance of seeing exactly y events in that same time period. To find that chance:
        - Start with the average rate: Here, that's x events per period.
        - The chance of exactly y events is found by combining:
            - A number related to how often events happen on average (this part is e^(-y)
            - The average rate raised to the number of events you want (that's x^y).
            - And dividing by the number of ways to arrange those events (called "y factorial" or y!)

- Stated traditionally: P(x; λ) = (e^(-λ) * λ^x) / x! where
    - P(x; λ): is the probability of exactly x events occurring.
    - λ (lambda): is the average number of events in the given interval.
    - e: is the mathematical constant approximately equal to 2.71828 (Euler's number).
    - x: is the number of events you're interested in.
    - x!: is the factorial of x.
- On the calculator, a PoissonPdf takes lambda (average rate) and x (number of events).
- Only info necessary is the average rate during a specified period, the likelihood of other rates can be extrapolated through a poisson process.
- Poisson mean variance = λ

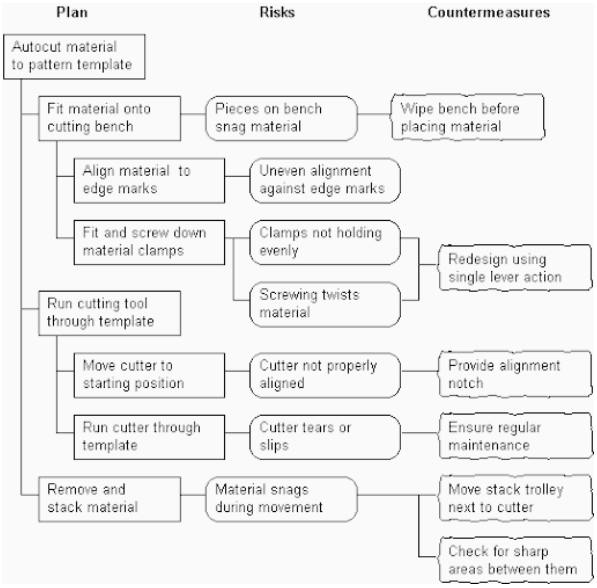
Positive Material Identification (PMI)

- Positive Material Identification (PMI) is a test used to verify the composition of materials in order to ensure their accuracy and integrity. This is done by using various analytical techniques such as X-ray fluorescence (XRF) or optical emission spectroscopy (OES). PMI is a valuable tool for manufacturers, as it helps to ensure the quality and safety of the materials used in their products.

Preventive vs. Predictive

- Preventive maintenance.: includes inspection and cleaning at regular intervals
- Predictive maintenance: includes sensors to catch impending failures

Process Decision Program Chart (PDPC)

- Used to indicate the cause-and-effect relationships between different steps or inputs.
- 

Process Improvement

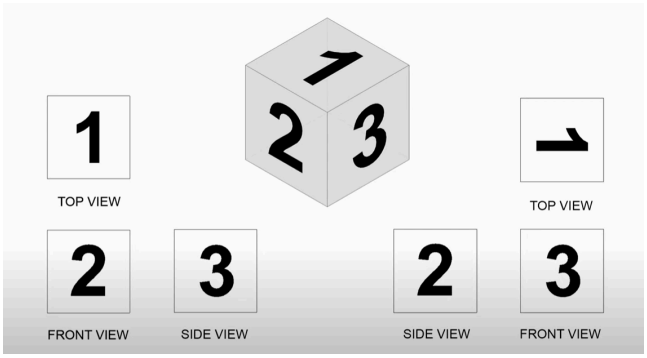
- Lean: Waste Reduction
- Six Sigma: Variation Reduction

Process Inputs

- The inputs of a process are customer requirements and components needed to execute those requirements (e.g. a food order, and the ingredients for a meal)

Projection

- Third angle:



    - In a 3rd angle projection, the plane of projection is transparent. This means that the object is located behind the projection plane, and the viewer has to look through the projection plane in order to view the object.
- 1st angle: top is the front view

Proportional Hazards Model

- The Cox proportional hazards model is a statistical tool used in survival analysis to examine how different factors (like age, treatment, or lifestyle) affect the timing of an event, such as death or failure. Rather than predicting exact times, it estimates how each factor increases or decreases the *risk* of the event happening at any given moment, assuming that these effects stay constant over time (the "proportional hazards" part). It expresses these effects through *hazard ratios*, which compare the risk between groups (e.g., smokers vs. non-smokers). One key advantage is that it can analyze incomplete data — for example, when some people haven't yet experienced the event by the end of the study.

Qualitative Risk Assessments

- FMEA
- Risk Ranking & Prioritization
- Delphi Technique
    - Delphi technique is to gather and summarize the opinions of a group of experts.

Quality Characteristics

- Discrete quality characteristics are those that can be counted and recorded accurately, such as numbers or frequencies. The number of defects in a batch of products is an example of a discrete quality characteristic. On the other hand, the amount of paint

applied to a product, the overall length of a product, and the level of brightness on display are examples of Continuous quality characteristics that are measured using numerical values.

Quality Function Deployment (QFD)

- A Quality Function Deployment (QFD) matrix is a tool used to identify and prioritize the most important quality characteristics of a product or process.

Quality Information System (QIS)

- Provides increased accuracy, efficient access, control and auditability for data that is important for delivering quality processes or products. The features of QIS real-time data capture, comprehensive storage options, unlimited searchable records, report retrieval, customizable reporting and analysis tools, and alerts for corrective/preventive action.
- Easy access to data
- Data is organized and ready for use

Quality Manual

- A document that provides an overview of the quality management system and its requirements. It outlines the quality policies, procedures, and processes that are used to ensure that products and services comply with established standards and customer requirements. The Quality Manual also serves as a reference document for all employees involved in the system.

Quality Plan

- Demonstrates and understanding of requirements and details how to meet them
- May include KPIs (measurable targets for quality performance)

Quantitative Risk Assessments

- Monte Carlo Simulation

RACI Charts

- Responsible
- Accountable
    - An accountable person is ultimately responsible for ensuring that tasks within a process or project are completed correctly and on time. This means they are not only responsible for delegating tasks or preparing reports - they are primarily responsible for providing guidance and oversight during each step of the project or process.
- Consulted
- Informed

Randomized Block Design

- An experimental design where subjects (experimental units) are grouped into blocks based on similar characteristics, and then treatments are randomly assigned within each

block. This helps to reduce variability and improve the accuracy of treatment comparisons by accounting for potential differences between blocks.
- Primarily used to reduce the effect of nuisance variables.
- Doesn't efficiently explore multiple factors and their interactions.

Rate Ratio

- A rate ratio is the most appropriate metric for assessing the effectiveness various control measures, because it compares the *incident rate* across control measures.

Regression Analysis

- All continuous data (no categorical data, see Chi-Square)
- One dependent variable, multiple independent variables
    - E.g. is there a correlation between inputs X Y Z and output A?
- Simple linear regression: one independent, one dependent variable (is there a correlation?)
- Multiple regression: one dependent variable, multiple independent variables
- Models the relationship between the variables
    - DOE (Design of Experiments) does this for the purpose of optimizing one of them
- Requires a lot of data to execute, not typically an efficient *starting* point for analysis
    - Ideally, lots of historical data will be available
- *Logistic Regression:* used when the dependent variable is binary or dichotomous (e.g., yes/no, success/failure). It allows for the simultaneous analysis of multiple independent variables to predict the probability of the outcome.

Reliability

- Reliability of a component in series is calculated as an exponent of the number of that component in a series.
    - Where n = the number of a component in series and where X is the reliability of one component, series reliability is X^n
    - Typically, reliability of a series will be lower than any individual component part.
- Reliability of components in parallel that have the same reliability is going to be higher than individual component reliability, since the probability of them all failing or being inoperative at the same time is lower.
    - Where n = the number of a component in parallel and where X is the reliability of one component, parallel reliability is 1−(1−R)^n

Reliability Demonstration Testing

- Defined confidence level
- Product meets a specific reliability requirement over a given time frame

Resiliency

- Business resiliency describes the ability of a business to not only recover from disruptions but also continue to function and thrive despite them. To be prepared for any kind of disruption, businesses need to have a sound disaster recovery plan in place,

which includes risk management and proactive measures like data encryption and quality assurance.

Response Surface Methodology (RSM)

- Creates a model of the factor-response relationship
- Used to optimize a particular output when other factors are known
    - Optimizes one factor to meet specific requirements by altering input factors
- Best for late-stage experiments where optimal settings are already close
    - Too complex for initial factor screening
    - Use factorial design analysis instead for early stage investigation
        - While useful for optimization, it typically follows initial screening experiments and is less efficient for understanding interactions between factors with limited data.
- Explores the relationship between factors (inputs) and response variable (yield)
    - Key factors are already identified
    - Fine-tunes the process
- More labor-intensive than factorial experiments (more experimental runs)
    - Does not necessarily model interactions between factors
    - Ideal if the response is curved
- Subset: Central Composite Design (CCD)
    - Good at modeling *curvature* in the response surface, allowing for precise optimization around a target. While it requires more runs than some fractional factorial designs, the extra effort is warranted when understanding the shape of the response is critical to finding the optimal settings.
        - In the context of the CQE exam and response surface methodology, "curvature" does not refer to the physical shape of an object, but rather to the mathematical shape of the response surface — that is, how the output (response) changes in relation to the input variables.
        - When you run experiments (e.g., in manufacturing or quality improvement), you're often trying to understand how different input factors (like temperature, pressure, speed) affect a response (like product strength, yield, or defect rate).
            - If the response increases or decreases linearly with the input, the response surface is a flat plane — there's no curvature.
            - But if the response behaves nonlinearly — say it increases up to a point and then decreases — the surface is curved (like a hill or valley). That’s the curvature being referred to.
        - CCD: Curvature Checking Design

Risk-Based Thinking

- Encourages proactive problem-solving and encourages organizations to consider all potential risks when making decisions. This helps to identify potential problems before they occur, which can help to reduce the cost of errors and enhance customer satisfaction.

- A proactive process of assessing and mitigating risks before they occur. It involves identifying potential risks, analyzing their likelihood and severity, and implementing measures to prevent them from occurring.

Risk Management Strategies

- Acceptance
    - Do nothing
    - Ignore small, unlikely risks
- Mitigation/Reduction
    - Reduce risk (does not eliminate)
    - Install fire alarms
- Transfer
    - Shift it to someone else
    - Buy insurance
- Avoidance
    - Eliminate a risk entirely
    - Cancelling a risky project
- Exploitation
    - Use good risks to gain
    - Bet on a high-potential opportunity

Risk Management Systems

- Seek to reduce the probability of accidents
- Identify, analyze, and mitigate potential sources of harm
- Organizations increase their understanding of possible events that could cause damage and develop strategies for preventing or reducing the likelihood of these events occurring
- The first step in implementing a Comprehensive Risk Management Process is to identify and analyze the potential risks that exist in the supply chain.

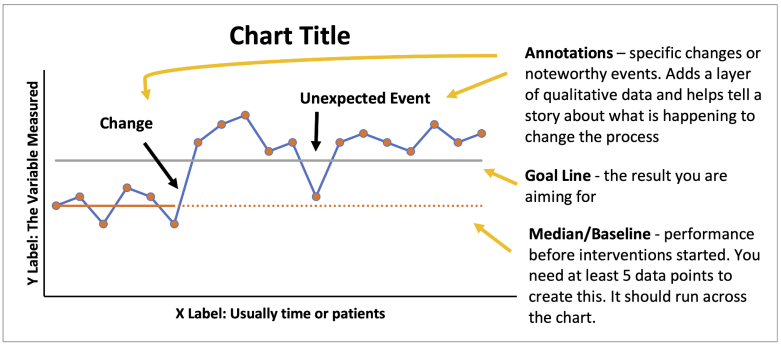
Risk Monitoring

- Includes tracking risks after product delivery

Run Chart

- Run charts are a type of qualitative process improvement method that can be used to measure changes in supplier performance over time. A run chart plots data points into a sequence, usually on a line graph, and allows data trends over time to be easily identified.

-



Sample Size Calculation for Proportions

- Formulas based on:
    - Desired confidence level
    - Margin of error
    - Estimated population proportion (sample population/what you're looking for in this population)

Scatter Plot

- Establishes an *initial* relationship between multiple variables
- Not used for a single variable (two or more only), establishes correlation
- Independent and Dependent analogous to Input and Output variables

Screening vs. Optimization

- Designs like fractional factorial designs are great for screening — finding out which factors matter, but they assume that the relationship between inputs and outputs is linear.
- Screening experiments are used to identify which parameters or factors will affect the output of a process. They involve testing many variables and measuring their impact on the output. This allows researchers to quickly determine which process elements can be manipulated in order to improve performance.
- When you're ready to optimize — to find the best combination of settings — you often need to model the curved nature of the response surface. That's where designs like Central Composite Designs (CCD) and Box-Behnken Designs come in. These are response surface designs that are good at modeling curvature, because they include center points and quadratic terms.

Sequential Sampling Plan Options

- Accept, Reject, Continue
    - Best for expensive/destructive testing of critical components or difficult-to-obtain samples
- Minimizes the need for destructive testing because it allows for a decision to be made after each test
    - Requires strict adherence to stopping rules to work
- No predetermined sample size

- Continued sampling based on predefined rules

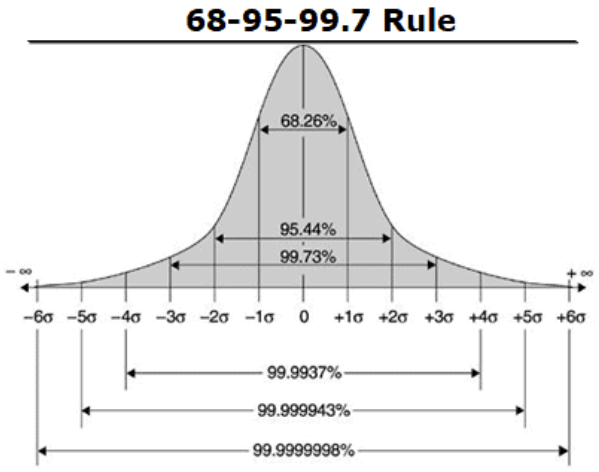
Set Theory Probability (Probability of Combined Events)

- For the probability of Condition A and the Probability of Condition B to be independently true, the probability of having either condition be true is P(A)+P(B)
    - To know the probability of one *or both* of these conditions to be true, the prevalence of both conditions is subtracted from the sum of the two independent ones, to avoid double-counting: $P(A \cup B)=P(A)+P(B)-P(A \cap B)$

SI Base Units

- kilogram (kg)
- meter (m)
- second (s)
- ampere (A)
- kelvin (K)
- mole (mol)
- candela (cd)

Sigma Levels



- Left or right of a sigma level includes the total of everything beyond the next sigma level
- Left skew = the majority of the data points are on the right (long left tail)
- Right skew = the majority of data points are on the left (long right tail)

Signal-to-Noise Ratio

- Higher = system is more robust (higher ratio of signal to noise)

SMED

- Single Minute Exchange of Die (SMED) is a lean manufacturing technique used to reduce the time it takes to set up a production line for a new product. One of the key concepts of SMED is separating setup activities into two categories.

    - It's a method used in manufacturing (and other industries) to drastically reduce the time it takes to switch from making one product to another — ideally in less than 10 minutes (that's the "single-minute" part).
- Internal processes take place while the equipment is stopped
- External processes take place before stopping the equipment

Solder Reflow

- Before any process adjustments or training can be effective, the quality engineer must first verify the PCB laminate's material composition is able to withstand the higher reflow temperatures of lead-free solder, without causing delamination or other temperature related failures. By ensuring that the selected materials (e.g. laminate) can withstand the required temperature, it is possible to proactively minimize heat related failures in later phases of design, process creation, and manufacturing.
- The key takeaway is interoperability between components is essential before enacting any kind of process changes, etc.

Sprint Retrospectives

- Good time to check failures w/5 whys method of identifying root causes

Statistical Comparison Test

- A statistical comparison test establishes whether the automated system produces results that are equivalent to or better than the existing manual process within acceptable tolerances.
    - Compares data that has already been collected.

Statistical Process Control (SPC)

- Monitoring and controlling (DMAIC) a process through statistical analysis
- Can be used to adjust and assess process parameters in addition to outputs
- A tool for continuous monitoring
    - Pair with frequent inspections to minimize defects
    - Allows for real-time control and adjustment
- Monitors process stability over time

Step-Stress Testing

- Can quickly induce failures
- Rapid reliability estimation with fewer units
- Good for when failure mechanism is known
- Contrast with Constant Stress Testing

Stratified Sample

- Proportional to sample sources
- Similar to how BORA rides are chosen, based on division size

Strict Acceptance Criteria

- Low acceptance number

Supplier Capability Assessment
- Stress test
- Evaluates supplier systems for:
    - Risk management
    - Business continuity
    - Proactively addressing potential problems
- Goes beyond looking at current performance

Taguchi Method
- Focuses on robustness of a process or design in the face of uncontrollable factors
    - Minimize sensitivity to uncontrollable factors
- Maximizing signal, minimizing noise
- Uses orthogonal arrays, which are systematic matrices that guide experimental design
- Can be used as a follow-up to a fractional factorial study, once it reveals the various interactions between factors

Takt Time
- Takt time, in lean manufacturing, is the rate at which a product or service must be produced to meet customer demand. It's essentially the "heartbeat" of a production line, ensuring that output aligns with customer needs and prevents overproduction or underproduction. Takt time is calculated by dividing the total available production time by the average customer demand.
    - Takt time is determined by customer demand, while cycle time is the actual time it takes to complete a task. By comparing the two, inefficiencies and bottlenecks can be identified.
    - Lead time encompasses the entire duration from customer order to delivery, while takt time focuses on the production pace.

Team Formation
- Forming - Democratic leadership to foster open communication
- Storming - Directive leadership to manage conflict and maintain focus
- Norming - Coaching/Mentoring
- Performing - Delegative or Transformational leadership to let team members set their own goals and display trust in their abilities, encouraging creativity
- Adjourning - Supportive
- Tuckman’s analysis
- Single function teams are not generally used for project management

Tests seek to answer:
- ANOVA: "Are there statistically significant differences between the means of three or more groups?"
    - Means, not variances

- Attribute Agreement Analysis: How consistent and accurate are appraisers when assessing categorical attributes of items, both among themselves and with a standard?
- Bland-Altman Plot: How much agreement is there between two different measurement methods for the same variable?
- Chi-Squared: Is there a significant association between two categorical variables?
- Contingency Table Analysis: Is there a relationship between two or more categorical variables, based on their frequency distribution in a table? (Same core question as Chi-Squared Test when applied to tables)
- Design of Experiments: How do different factors and their interactions affect the outcome of a process or system, and what combination optimizes the result?
- F-Test: Do two populations have significantly different variances?
- Fractional Factorial: Which factors significantly influence the output of a process, using a subset of possible combinations to reduce experimental effort?
- Gage R&R: Is the variation in measurement primarily due to the measurement system (i.e., instrument or operator), or the actual parts being measured?
- Paired T-Test: Is there a statistically significant difference between two related or matched groups (e.g., before and after measurements)?
- Regression Analysis: Is there a relationship between one or more independent variables and a dependent variable, and can we use this relationship to make predictions?
- Two-Sample T-Test: Is there a statistically significant difference between the means of two independent groups?
- *Potential overlapping questions:*
    - Chi-Squared Test and Contingency Table Analysis both examine relationships between categorical variables.
    - Paired T-Test and Two Sample T-Test both assess differences between group means, but for related vs. independent samples.
    - Fractional Factorial and DOE both address how factors affect outcomes, but fractional designs do so more efficiently.

Theory of Constraints (TOC)

- Identifies systemic Bottlenecks:
    - Identify
    - Exploit
    - Subordinate
    - Elevate
    - Repeat

Tips

- Think about whether the question is asking for something proactive or reactive.
    - QC = reactive, QA corrective actions, FMEA = proactive

Total Productive Maintenance

- Reliability concept
- Includes both predictive and preventive maintenance

- Involves all employees in the process
- Holistic continuous improvement
- Helps to already have a large amount of failure data
    - Equipment operators take ownership of proactive/autonomous maintenance.
    - “Empowers” employees to take ownership of maintenance

TQM

- Does not include inspection and testing
- Customer focus

Tree Diagram

- Organizes components of a complex process
- Does not establish relationships

UCL-LCL

- Exceeding upper and lower control limits indicate that a process is out of control
    - If control limits are exceeded (as viewed on an R-Chart), an assignable cause is typically present
- 6S principle of seven consecutive data points on the same side of the mean gives the same indication
- Toyota principle is that production should be stopped immediately when a process is observed to be out of control

Usability Testing

- Direct observation and feedback with users
- Data collection from users

Variables Sampling

- Measurement data is already available
- Population StDev is already known
    - Known sigma can be incorporated into sampling plan to reduce sample size
- Replaces destructive testing for critical parts
    - A variables sampling plan utilizes continuous data and provides more information per tested gear compared to attribute sampling.
- Most efficient for continuous data with costly measurements
- Fixed sample size using variable:
    - Needs fewer samples than when using attribute data (e.g. pass/fail)

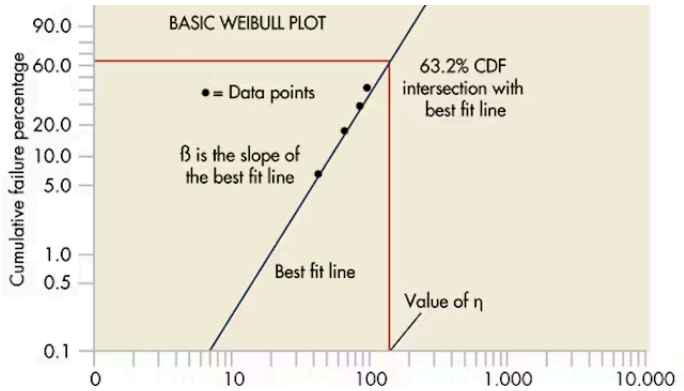
Version Control

- Used to track changes (hence, ‘control’)

Vision

- The purpose and primary objectives of an organization

Weibull Analysis

- Weibull analysis is a statistical method used to analyze failure data and predict the reliability of products or systems over time. It uses the Weibull distribution, a flexible probability distribution, to model various failure patterns and estimate parameters like characteristic life (eta) and shape parameter (beta). This helps engineers understand failure mechanisms, predict future failures, and optimize product design and maintenance.
- 

    - A Weibull distribution with a shape parameter (k) less than 1 indicates a decreasing hazard function, meaning that the failure rate decreases as time progresses.
- Can be used in conjunction with accelerated life testing to get an estimate of overall component reliability.
- Exponential distribution has no shape factor but is a derivative of Weibull K=1

Wilcoxon Signed-Rank Test

- The Wilcoxon signed-rank test is a non-parametric statistical test used to compare two related samples, often when the data is not normally distributed or when dealing with paired observations. It assesses whether the distribution of differences between paired observations is symmetric around zero. This test is particularly useful when the assumptions of a paired t-test are not met.
    - No assumption of data normality
- Related samples (e.g. before & after), similar to a T-test

Zero-Defect Sampling

- Any defect found in any sample results in rejection of entire population