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Welcome to Session 12 of the Six Sigma Awareness Training program. The topic for this session is Design for Six Sigma.

In this session, we will explore the application of Six Sigma methods to build processes and products with minimal defects.

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In this session, you will learn:

- Why Design for Six Sigma (DFSS) is used
- Design for Six Sigma Methods and Tools, including:
  - Simultaneous Engineering
  - Design Standardization (also known as Template Engineering)
  - Quality Function Deployment (QFD)

  and
  - Failure Mode and Effects Analysis (FMEA)

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There are many aspects of quality to consider when developing a product or process in today’s competitive marketplace. Designing quality requires **balancing the many factors** that the customer requires. For example, some customers are interested in the best quality but for a reasonable price, while others may be willing to pay a higher price for superior craftsmanship.

Product requirements can usually be explained in terms of four factors. These are customer expectations, functionality, value processing, and life cycle costs. The final process should meet the requirements for all four areas.

The first design quality factor is determining to what degree **customer desires are satisfied**. The customer has a certain expectation about the product. Does the product meet the customer’s expectations?

Another design quality factor is confirming whether or not the **product meets functional requirements.** Does the product meet the upper and lower specification limits?

Design quality may also reflect the degree to which the product permits **value processing**, which is the balance between quality and production cost.

Finally, quality design could mean the degree to which the **product lasts a reasonable life with relatively low maintenance costs.** The trade-off between achieving the best quality possible is a much higher cost. Is the customer willing to pay more for reliability and a lasting product?

The theory behind Design for Six Sigma is that correctly balancing these factors results in quality products that customers are willing to pay for.

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Design for Six Sigma (DFSS) uses metrics to address each design quality area.

Perceived quality is addressed through customer satisfaction scores and customer retention rates. Functional requirements are confirmed through DPM, quality yield, cost, as well as customer satisfaction. Rational (value) processing is measured by cost, cycle time, lead-time, and process capability. There also tests to demonstrate the reliability and maintainability of products.

There are four major Design for Six Sigma metrics: process development performance, operational performance, perceived quality performance among customers and objective quality performance among customers.

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Building quality directly into the product design is a worthwhile investment because of the high cost of poor quality at early stages of design. Product design may represent 5-10% of the actual product cost, but it influences 60-70% of material, labor and overhead costs in later phases of product development.

This design level chart or paradigm demonstrates the greater leverage or impact that product/service design and process engineering/procedures have, versus operations, on achieving quality goals. Internal changes made to existing operations will not make as significant a difference on quality than a change in the fundamental design or a new process approach for the product or service.

For example, consider a toy that users can put together by following either detailed written instructions or a visual diagram labeled with arrows corresponding to the toy parts. For most users, the diagram is better because less interpretation is required. The visual approach limits waste and opportunity for error.

The best product designers are also the best manufacturers; they are very good at developing products that balance all four design factors.

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Achieving design stability involves tracking changes to the design over time. The goal is to minimize these changes, thus lowering overall cost.

A design freeze defines when the design phase is done. Changes after the design freeze stage are inefficient, especially if the product has already reached the market. However, these changes are not uncommon. Design for Six Sigma prevents the waste associated with late stage changes.

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There are several different Design for Six Sigma methodologies. Any one of them can be selected for a given application.

One approach is called DMADV (pronounced duh-mad-vee), an acronym that stands for Define, Measure, Analyze, Design and Verify. This is a very common DFSS technique. Another methodology is known as I2DOV, pronounced eye-dov, which follows the Invent and Innovate, Develop, Optimize and Validate phases. A third technique is known as CDOV for Concept, Design, Optimize and Verify.

The emphasis for all these methods is on meeting customer needs. Different design alternatives are considered leading to a point of optimization. The best design reflects whatever is being maximized for the customer. It could mean optimizing on the lowest amount of variation or maximizing a performance measure.

The appropriate DFSS metrics for a given project are used to optimize the product design.

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There are many quantitative and qualitative design analysis methods used in Design for Six Sigma. Most DFSS tools and methods incorporate a voice of the customer analysis, innovation, creativity, statistical design and robustness.

An important part of design analysis is to identify the inherent capability of the existing process. If the existing process has a reasonable inherent variation, it can be re-used. But if the process that is re-used has high inherent variation, redesigning the process is recommended.

In this session, we will focus on qualitative methods such as failure mode and effects analysis, simultaneous engineering, template engineering and quality function deployment. Many companies bring different organizational functions together to make better quality design. Simultaneous engineering builds quality by having product and process teams to work together to determine good design and alternative solutions.

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When designing a new product, you can choose to use template engineering, an experienced-based or existing design option, or clean sheet engineering, a creative or completely new approach. Template engineering has less risk of failure because it has been done before.

While less risk may be desirable, that may limit innovation. Clean sheet engineering is more useful where innovation is desired.

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Design for Six Sigma uses systematic qualitative methods. Two tools commonly used to in DFSS are Quality Function Development and Failure Mode and Effects Analysis.

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Quality function deployment is a system for translating consumer requirements into company requirements at each stage from research & product development to engineering and manufacturing to marketing, sales and distribution. A matrix is used to compare customer needs relative to technical specifications.

During Phase 1, also called House of Quality, key customer requirements are identified and linked to key performance outputs across the company. Phases 2 through 4 translate these performance outputs into input variables and settings.

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Key activities during the House of Quality phase may include customer surveys to help identify their needs or satisfaction levels. It may also include product performance analyses and competitive benchmark assessments.

The goal of this phase is to determine product target values known as product technical requirements.

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This is an example of a Compression Process QFD. Customer requirements, which included wanting API to be evenly distributed in the tablet and wanting tablets to dissolve fast, have been translated into performance outputs such as dissolution, thickness, hardness and content uniformity. These become the Y variables of processes, which also have specification and optimization levels.

Quality function deployment incorporates the customer voice into product metrics.

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Failure Mode and Effects Analysis (FMEA) is a systematic tool for identifying potential future failures of a product or process. Solutions reducing the likelihood or severity of a failure result from this type of analysis.

FMEA is commonly used in the aerospace industry as crash prevention is of the utmost importance.

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FMEA can be implemented in two ways.

Design FMEA focuses on the product. It examines the functions of a component, subsystem or main system.

A process FMEA focuses on the process used to make the product.

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The **Failure Mode** is the physical description of a failure. A failure mode could be low yield.

A **Failure Effect** is the impact of the failure on people or the equipment. Perhaps the low yield also impacted the level of another impurity or the efficacy of the final drug product.

A **Failure Cause** refers to the cause of the failure. For example, an under charge of a raw material.

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This is an FMEA Process Roadmap. FMEA is used to address all the questions or potential issues that can impact the product.

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Each potential issue is ranked in three categories during an FMEA analysis. The FMEA variables are Severity, Occurrence, and Detection. Severity refers to the relative severity of the outcome. Occurrence is the likelihood that the issue will occur and detection is how likely it is that the process will detect the issue before it reaches the customer. A rating system is used to rank each issue in each category. The rating scale can be decided by the team. A scale from one to ten with one as the most desirable is common. In this case a one might be little or no impact on the customer while a 10 might be life-threatening to the customer and others. The rankings for each Severity, Occurrence and Detection are combined into a ranking for each issue. The combined ranking is called the RPN or Risk Priority Number. The ranking is used to prioritize which issues to resource first.

The rating system can also be implemented on a one to three scale or a one to five scale. The rankings are relative so the extremes at either end are also arbitrary. The team can determine what is appropriate. Note that it is easier to distinguish the issues by RPN with a wider scale where the whole scale is used.

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This is an example of an FMEA Severity Rating Guide. Rankings and the potential harm or impact of failure varies by industry.

Based on the situation, the product development team develops a scale from one to ten listing specific terms to describe the level of harm or impact at each level. A ten, for example, could mean that there is potential bodily harm to a customer.

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This is an example of an FMEA Occurrence Rating Guide.

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This is an example of an FMEA Detection Rating Guide.

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The Risk Priority Number (RPN) is used to identify the greatest areas of concern in a process. It represents a cumulative assessment of severity, occurrence and detection ratings.

To calculate the RPN, the ranking assigned to each of the three risk categories are multiplied together. Once calculated, the RPNs are compared. Then, the highest priority is given to addressing the issues with the highest RPN number first. How many of the risks to addressed is determined by the team based on their time, resource and quality constraints.

Rankings can be adjusted as solutions are put in place to maintain appropriate priority for other risks.

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A Cause-and-Effect Diagram can also be used in FMEA. It can help a team identify potential causes to be further analyzed in FMEA.

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Ultimately, a cause-and-effect diagram is transferred to an FMEA Cause-and-Effect Diagram. When creating FMEA diagrams, there may be multiple effects due to the same failure mode, multiple causes for the same effect of a failure mode and multiple Control Methods for the same cause and effect relationship.

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The last section of an FMEA worksheet is typically used to identify a continuous improvement plan. RPN numbers are relative, so those on the high end signify opportunities for improvement in the design.

In summary, the goal of DFSS is to lower the occurrence of potential failures and to increase the ability to detect these issues, in order to ensure quality from the beginning of the design process.

FMEA can also be used in the Measure and Improve phases of a DMAIC Six Sigma project for cause and effect analysis and solution generation and prioritization.

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We encourage you to apply the concepts and tools from this Six Sigma Awareness Training program for data-driven analysis of opportunities for improvement.

Please contact members of the WWPS Continuous Improvement team for help with specific applications or additional information.

We hope you found the sessions informative.