

# A Study on a Methodology of Integrating Lean DFSS and Advanced Product Quality Planning (APQP) in ISO/TS16949

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## Abstract

Many 6-sigma innovation companies are obtaining ISO9000 series or ISO/TS16949 certifications. However, not many of them have considered the integrated management of ISO/TS16949 at the time of 6-sigma introduction. ISO/TS16949 focuses on the process of an overall company. In particular, APQP (Advanced Product Quality Planning) requires that from the beginning all the planning should have a clear quality planning business process. Each company can decide the best course of action to suit its individual needs. Lean DFSS in 6-sigma offers the concrete development steps of the product development process. And if analyses of Input, Output, Target, Process, KSF, KPI, and FMEA is done in each process and clearly defined in APQP, mutual organic and effective systems can be initially achieved.

## 1. Introduction

### 1.1 Background of the Study

Many companies are introducing various innovative methodologies such as ISO/TS16949, 6-sigma and DFSS to achieve continuous progress through innovation with great success. But introducing and using more than one methodology can cause a variety of side effects resulting in negative results instead of positive ones. ISO/TS16949 requires that business action process should be properly set with regards to customers. Also, the purpose of Lean DFSS is to have a properly set process that enables the individuals related to new product development to have the same methods by defining their working methods and processes. This also reduces quality variations among developers that can happen during developmental stages. By comparing the positive and negative aspects of these two methodologies, we need to research a better overall methodology.

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## **1.2 Purpose of the Study**

In addition to ISO/TS16949, many companies are introducing DFSS (Design for Six Sigma) to develop new processes in new product development. Through standardization and systematization of a new product development process, wrong decisions and errors of one person do not affect the whole development process. Varying the developers actually causes defects in the quality of the initial prototype. In addition, development delays due to continual development defects from design results for the second reliability to design results of the third mass-production can cause the delay of the advancement of new products into the market and therefore result in a loss for the company.

This study will show the method to improve the possibility of success of the new product development project by studying the DFSS, which standardizes the new product development process, and ISO/TS16949, which has a 5's core tool that prevents and minimizes the defects in the new product development.

## **1.3 Scope and Method of the Study**

In this study, APQP (Advanced product Quality Planning), which is used for the new product development in manufacturing among overall mega processes of the corporate action in the ISO/TS16949 and Lean DFSS, will be reviewed in terms of original theory documents. And hypothesis as an integrated model of two processes will be established and tested through survey and analysis of the data. Using these methods, result of this study will be concluded, and the purpose of the study will be met by presenting the method to integrate two processes.

# **2. Theoretical Background**

## **2.1 Background of the Introduction of ISO/TS16949**

### **2.1.1 History of ISO/TS16949**

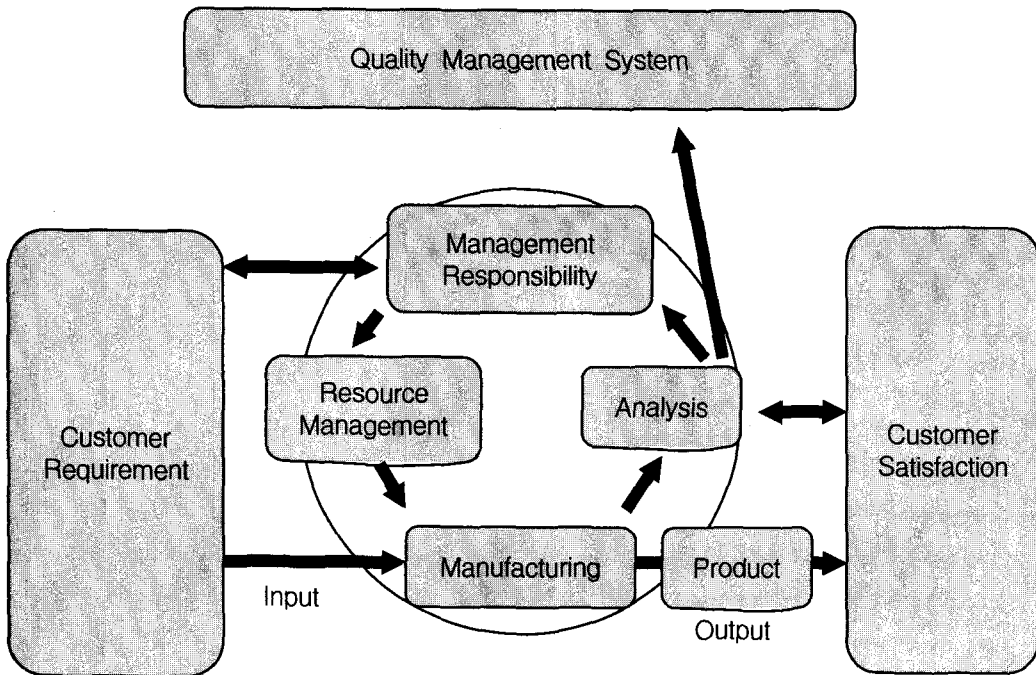
ISO which was founded in 1947 encourages international trade through standardization. ISO9000 series standard for quality management and quality warranty was established in 1987 by the ISO. Korea joined the ISO in 1992, and warranty action of quality systems began in full scale. American car-maker GM, Ford and Chrysler integrated existing standards and requirements that were used to select each company's part suppliers and drafted a quality warranty system ISO9001 in 1994. It was intended to apply these requirements to world wide companies, and in August 1994 QS9000 system was founded. After that, companies from all over the world started to be certified. According to the KCR, a total of 2489 Korean companies (53 large companies and 2436 medium and small companies) established certifi-

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cations from 1997 to 2004. But many companies with QS9000 certification went bankrupt in many countries, including Korea, so problems of the certification system arose. Prior to this, IATF (International Automatic Task Force) was organized by American and European car makers and based on ISO 9001:1994, ISO/TS16949 quality system was prepared to be established.

**2.1.2 Requirements of the Study ISO/TS16949**

Quality management system is based on process access method. Process is “to be managed as a one- process in order to achieve the organization’s goal by regulating input, management and output”. A clear understanding of all the process done inside is necessary to improve quality result by constructing quality management system. This applies not only to the quality management system but also the product development system. Figure 1-1 shows a model of quality management that supplies products or services to customers with flow of various information and many processes that inter-connect inside the organization. Customer demand is the input.



**Figure 1-1.** Quality management model

This access method clearly shows the purpose and goal of the organization. ISO 9001:1994 requires a documented system such as many documented procedures and work orders according to 20 detailed requirement articles. Many companies have different purposes before and after certification acquisition, so the problem was that only qualified and certified teams

managed the certification to maintain the acquisition status. To complement these problems further, in ISO/TS16949, PDCA of the process became more important than requiring formal input/output, documented procedures and work orders.

The process can be divided into: mega process, major process and sub-processes. "Mega process" stipulates overall company action so it can be stipulated as a process in charge of the creation of output directly related to the company's existence. Examples include: product planning process, research development process, manufacturing process, distribution sales process, and customer claim management process. "Major process," a subordinate concept of mega process, can be stipulated and managed as a process and measures and evaluates the effect. "Sub process," a subordinate concept of process, is an actual business action or a stipulated method to perform process. It is also called "Procedure."

This quality management system was also emphasized in ISO9000 and QS9000 but in ISO/TS16949, process and system, not output with fixed form, is important. After repeated checking of the possibility of continuous development, certification of the quality management condition can be established. ISO/TS16949 presents 5's core tool and requires the provision of the system.

### **2.1.3 5 Core tool of ISO/TS16949**

#### **(1) APQP (Advanced product Quality Planning & Control Planning)**

A concrete method that defines and establishes the necessary steps to make products that could satisfy the customers. Thus, it is the provision of the access method of actions to achieve the goal from product planning to mass-production.

#### **(2) FMEA (Failure Mode Effect Analysis)**

A tool supporting the method that assumes and prevents the possible defects in product and manufacturing line design development.

#### **(3) MSA (Measurement System Analysis)**

A tool of checking the change in the measurement system to maintain precision and accuracy

#### **(4) PPAP (Production Part Approval Analysis)**

A set of procedures in which the mother company approve the part manufacturing of suppliers

#### **(5) SPC (Statistical Process Control)**

A management method by which statistical analysis of product is done and the characteristics of the manufacturing line process are studied. Process in ISO/TS16949 and 5's core tool explained above can be summarized below in Figure 1-2.

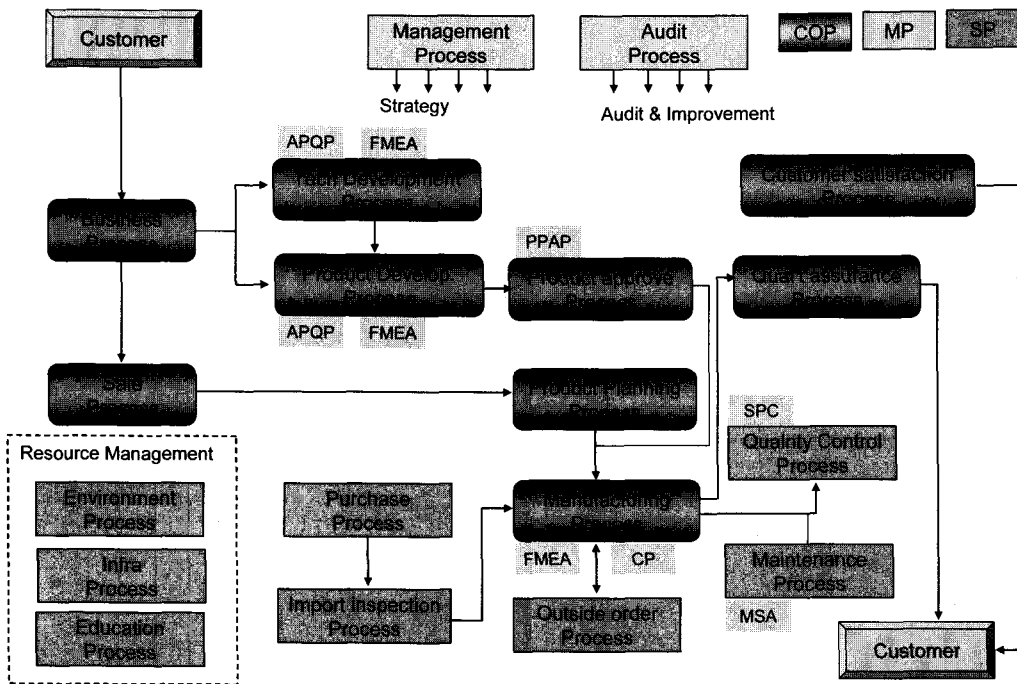


Figure 1-2. APQP

## 2.2 Background of the Introduction of Lean DFSS

### 2.2.1 Theoretical Background of 6-sigma

#### (1) Background of the introduction of 6-sigma

Motorola first introduced 6-sigma in the 1980's. Motorola, a company which was competing against Japanese companies in the pager market, was surprised by the high quality of the Japanese products. Motorola recognized that product quality was their most significant problem, and began extensive quality improvement for their line of pagers, which at the time was their main product. At that time, Michael J. Harry of Motorola led the development of 6-sigma system and in 1987 6-sigma management was spread throughout the company. Later, GE introduced 6-sigma, and thus the effects of 6-sigma became known world wide. GE, which experienced the power of 6-sigma, applied 6-sigma not only to products but also to all business processes such as service quality, product design process, manufacturing and sales and accounting.

#### (2) Problem solving process of 6-sigma

Initially, 6-sigma was approached as a problem solving method. One of many characteristics of 6-sigma is that it is "priority oriented." Applying 6-sigma as a problem solving

method will tackle the most severe problems first. Motorola invented DMAIC (Define, Measure, Analyze, Improve, and Control) as a method of problem solving. DMAIC solves problems that have already occurred by implementing statistical methods.

### (3) Why we need DFSS?

The introduction of DFSS problem solving process was already predicted at the success of DMAIC problem solving process. If defective products are sold to customers, even after they have met manufacturing inspection, this will be a significant loss to the company. So to reduce customer claims and defects, many quality improvement actions through DMAIC problem solving process were performed and found to be effective. But to improve the quality up to real 6-sigma level, design with defective-free manufacturing conditions should be done from the beginning of product design and development. In this regard, GE invented DMADV (Define, Measure, Analyze, Design, and Verify) and tried to solve the problems that could happen at the beginning of new product development.

## 2.2.2 Pre-Study of New Product Development

### (1) Concept of new product

The definition of new product was studied in various points of view. Typical classification include: “new products in the customer’s point of view” and “new products in the company’s point of view”. In the customer’s point of view, the definition of products conceived as new products are made by individuals customers. (Scheuing, 1997) That is, whether new products can give the customers better benefits and convenience is the important factor in deciding what is considered as a new product. The customers’ point of view can vary drastically, so it is quite possible that new products in the company’s point of view may not be considered to be new products in the customer’s point of view (Lee Kang Kun, 2006).

In the company’s point of view, new products can be classified as “non-continuous product” and “continuous product”. Non-continuous new products do not have any connection with existing products so usually new investment or formation of new market follows. Continuous new products are technologically improved products differing from the original technology. And many new company products in fact are considered continuous new product. Usually continuous new products have a firm basis with market demand so it can be said they have low level of risk. But if marketability of the continuous products declines, development of non-continuous new product should go forward to maintain the company’s operation. The classification of non-continuous new product and continuous new product is shown in Figure 2-1 based on “S-Curve” of Tushman and O’Reilly (1997).

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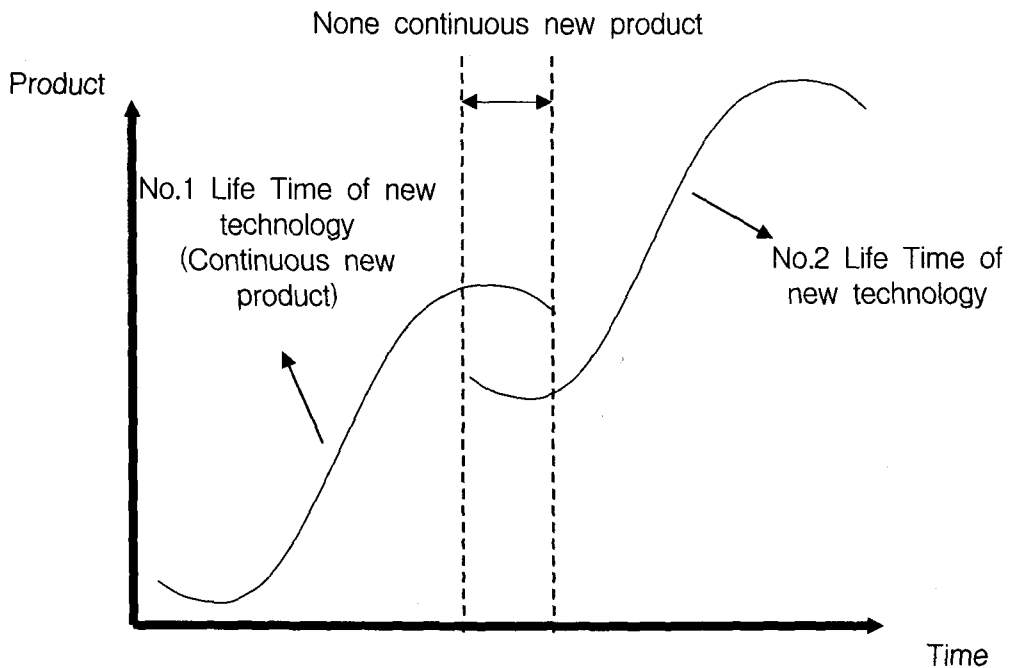


Figure 2-1. Based on "S-Curve" of Tushman and O'Reilly (1997)

## (2) New product development process

New product development process can be different according to a company's condition. Each step is vital for positive results as is stressed in the quality management system in which process is important. Because the development of new products requires high development costs and marketing resources, failure can cause significant damages. According to the study of problems of past product development, classification can be as follows: technical innovation point of view, communication point of view, problem solving point of view, and development process point of view.

In the technical innovation point of view, development of high end technology can make the products more complicated, so uncertainty in development increases. For example with regards to mobile phones, customers request not only the basic phone function but also many other functions including an MP3 players, cameras, and games, so creating these functions can cause the technical difficulties.

The communication point of view classifies the process into internal and external communications. In internal communication, sharing information among teams and establishing the system that can deal with the changes promptly in the process of business is important. This can affect the decision making process, and erroneous information can lead to making wrong decisions. External communication recognizes customer change, as well as

market and technical development of competitors. In the problem solving point of view, frequent modification of the development goal to obtain technology to solve problems can reverse the process and result in wrong decisions. Therefore, the systems need to not only solve existing problems systematically, but also prevent any unexpected problems are needed.

In conclusion, problems in the development process create excessive development cycle time. In the development process, there are processes needed to give customers valuable products, with the process not related in any way and even the one that can harm the product's value. These processes should be established in an effective system and be continuously maintained and improved.

### **2.2.3 Lean DFSS methodology**

Lean DFSS methodology improves the development quality by standardizing working method and procedures so that everybody involved in the product development can work in the same methods and thus variations among developers can be reduced.

- Establishment of value innovation strategy by 4<sup>th</sup> generation R&D strategy
- Establishment of Lean DFSS process that reduce waste in the development process
- Development of product structure system in each step in the new product development
- Establishment of development goals in each step that should be met in the new product development
- Using Design Checklist to see if development goals are met.
- Application of Design Scorecard for the decision in each step
- Design Review for the decision in each step
- Making and using Template & Manuals for Lean DFSS

## **3. Methodology of integrating APQP and Lean DFSS Process**

### **3.1 ISO/TS16949 APQP Processes**

#### **3.1.1 Customer-Oriented Process (COP)**

Customer-Oriented Process is a process of delivering values directly to customers, in which values are delivered to customers in the sequence of sales, research, development, production, and customer feedback.

#### **3.1.2 Management Process (MP)**

Management Process is a business management process that includes the planning of business strategies, internal audits and business innovations.

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### **3.1.3 Support Process (SP)**

Support Process is a process to support COP operations efficiently, which includes training, safety, administration and other supporting operations.

APQP defines and plans essential processes of developing products that satisfy customers at the research and development stages of COP. At the production level, Control Planning (CP) is used instead.

## **3.2 Lean DFSS Processes**

### **3.2.1 Marketing for Six Sigma (MFSS)**

This is a stage to make decisions in the development of a new product or products through planning and strategy. A new product that can bring financial outcome is selected based on the analysis of customer requirements, market environment, competitors, and costs.

### **3.2.2 Technology for Six Sigma (TFSS)**

TFSS is a stage where the concept design, selected at MFSS, is to be verified.

### **3.2.3 Redesign for Six Sigma (RFSS)**

At this stage, the concept design is investigated for acceptance into production. A prototype or prototypes are made at this stage, and technical feasibility and short term process capability can be identified.

### **3.2.4 Production for Six Sigma (PFSS)**

Marketing, design and production sectors are all involved at this stage. After the verification of production, all necessary data is delivered to the production line.

## **3.3 Integration of APQP and Lean DFSS Processes**

### **3.3.1 Analysis of APQP Process**

APQP requires thorough planning of quality assurance plans at the design and development stages. The development process is decided by the standards of each individual company. However, each process is required to set clearly the inputs, outputs, and targets of their mission. If a company already has its own development process at the creation of APQP, then the process can be easily modified according to APQP requirements. However, for companies which do not have a definite process established, it is not an easy task to create the mega processes, the sub processes and the activities required by APQP.

APQP requires each process to have targets, inputs, outputs, KSF (Key Success Factors) and CFT (Cross Functional Team), and be maintained and expanded with FMEA (Failure Mode and Effects Analysis).

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### **3.3.2 Analysis of Lean DFSS Processes**

Lean DFSS processes contain the following processes:

- Defining DKPI (Design Key Performance Index) for each process.
- Creating DIP (Design Innovation Process), which consists of 4 step mega processes, a 16 step major process, and 64 step sub processes and activities for new product development.
- Building DBS (Design Breakdown Structure), which unfolds the structures of the new products.
- Preparing and managing DM (Design Manual)
- Operating DR (Design Review) for correct decision making
- Utilizing DCL (Design Check List) to monitor the achievement of targets of each process
- Deploying DSC (Design Scorecard)

Lean DFSS offers the mega processes, the major process, and the sub processes required by APQP at the initial stages of product development. This implies that the companies that want to implement Lean DFSS must consider APQP, which is a part of ISO/TS16949 all together. For companies that have separate teams for Six Sigma implementation and ISO certification, the integration of the two must be considered in the early stages of implementation in order to avoid confusion at the work-site.

However, Lean DFSS does not reflect the elements of Inputs, Outputs, KSF, CFT, and FMEA, which are required by APQP. Especially, FMEA, which is a system to search and prevent unpredictable future problems, is a necessary element to be added to Lean DFSS. Also, Lean DFSS does not offer the system to find and manage problems that could generate in the new product development processes.

### **3.3.3 Integration of APQP and Lean DFSS Processes**

Both ISO/TS 16949 and Lean DFSS divide business operations into Mega Processes, Major Processes and Sub Processes. We can use Mega Processes and Major Processes from Lean DFSS and use the elements from ISO/TS16949, such as Inputs, Outputs, KSF, CFT and FMEA, in each process. In this integrated system, the individual works can be managed by WBS at each process. The integrated APQP and Lean DFSS system is depicted in Figure 3-1.

### **3.3.4 Method of the APQP and Lean DFSS Integrated System**

It is very important to divide business problems into different levels and manage them at each separate level. In this integrated system, problem solving is done at the 'Top-Down' method and can be difficult to achieve. Additionally, the 'Bottom-Up' method is not efficient enough for the system. Therefore, the 'Middle-Up-Down' method is recommended, in

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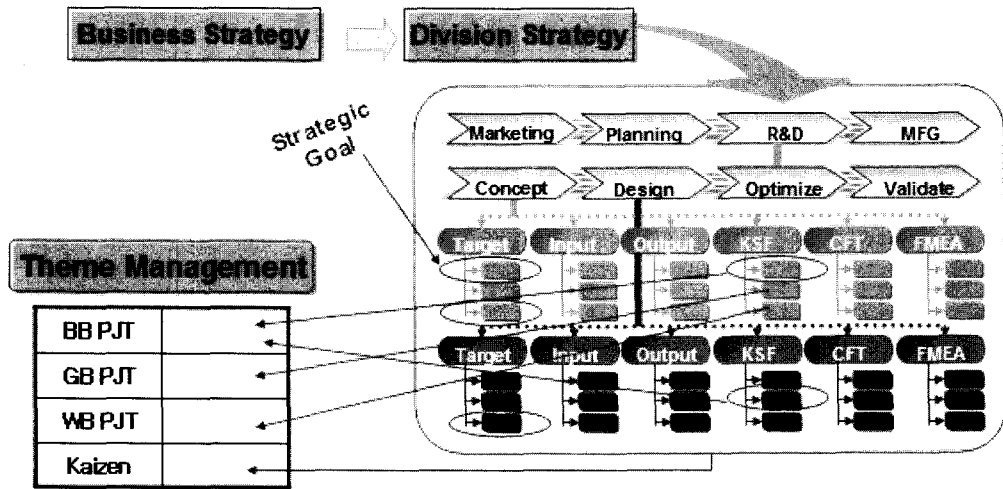


Figure 3-1. Integrated APQP and lean DFSS system

which the problems are approached strategically from the top, and the problems that should be executed at the bottom are collected and divided in order of priority. In the APQP and Lean DFSS integrated model, problems are deduced and prioritized systematically to deal with ever changing business environments.

### 3.3.5 Success Factors of the APQP and Lean DFSS Integrated System

#### (1) FMEA activities as a problem preventing tool

In Lean DFSS, FMEA is not defined as an essential tool in new product development processes. However, it is required as an essential tool in ISO/TS 16949. FMEA is a methodology to prevent possible future problems using the past data and experiences, and manage them throughout the projects.

#### (2) Deduction of KSF in the APQP and Lean DFSS integrated system

In APQP, KSF are defined at each process and managed. KSF has the same concept as CTQ concept in Six Sigma. There are five methods of selecting KSF as follows:

- Customers requirements
- Legal requirements
- Customer claims
- Top 5% characteristics of FMEA
- Critical paths of development processes

#### (3) Project Management in the APQP and Lean DFSS integrated system

Projects in this system, not much different from any other business operations, must be

divided into different levels and managed accordingly. Defining project levels can vary from business to business. However the levels can be defined as follows:

- A level (Black Belt)

A very significant KSF project needs to be managed by the headquarter directors. They have to decide the direction of a new product development in this level's projects.

- B Level (Green Belt)

This level project involves department managers. They should achieve targets to improve processes and solve technical problems.

- C Level (Green Belt)

Team managers are in charge of this level's projects.

- Improvement Suggestion

Part leaders are in charge at this level. All team members should participate in suggesting ideas to improve products. These activities will prevent any possible serious problems of the future.

(4) Managing CFT in the APQP and Lean DFSS integrated system

In this system, CFT is assigned the role and responsibility of selecting a project and CTQ, since solving problems is defined by Lean DFSS. The responsibilities of the CFT members are listed below:

- Review the background of KSF selection
- Check any missing and additional elements of KSF
- Review target feasibility
- Analysis of the quality of the project
- Set APQP and detailed project schedule
- Revise FMEA
- Produce and maintain the related data

The purposes of the organizing CFT are as follows:

- Reduction of the development lead time
- Assurance of the product quality and production margin
- Elimination of the bottle neck

## **4. Establishment of Study Model and Hypothesis**

### **4.1 Study Model**

This study is based on the model proposed by (K. Lee, 2006) entitled "A Practical Study

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on Methodology of Lean DFSS through the 4<sup>th</sup> generation R&D Strategy.” The model of Lean DFSS is as in Figure 4-1.

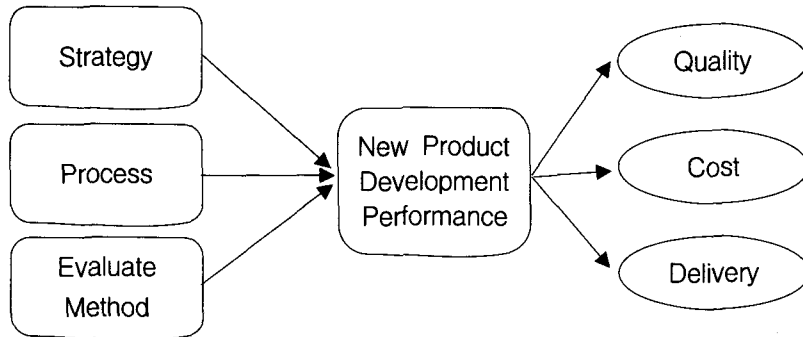


Figure 4-1. Lean DFSS research model

The model of the APQP and Lean DFSS integrated system is depicted in Figure 4-2.

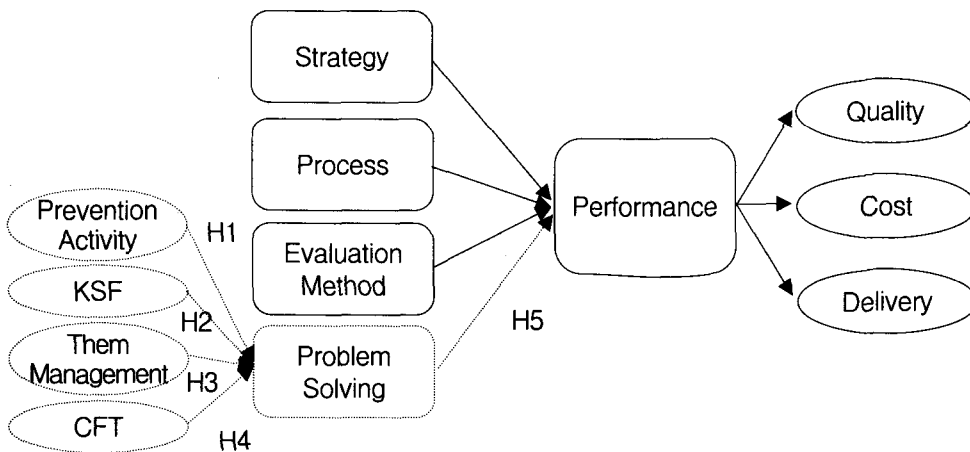


Figure 4-2. Model of the APQP and lean DFSS integrated system

#### 4.2 Establishment of Hypothesis

According to the study conducted by K. Lee, the development strategy, processes, and evaluation methods have positive effects to the new product developments. From this study, the author evaluates the preventive actions, the deduction of KSF, the management of CFT, and the project management as to be key and successful elements for problem-solving in the APQP and Lean DFSS integrated system. The hypotheses for the study are summarized as follows:

- FMEA as a preventive activity will have positive effects to problem-solving.

- Deduction of KSF will have positive effects to problem-solving
- Project management will have positive effects to problem-solving
- Management of CFT will have positive effects to problem-solving
- Problem-solving will have positive effects to new product developments

## 5. Conclusion

New product development is very important for a business for its competitiveness in the future. If a company doesn't produce new products timely for the demands of the fast changing market, its future business is hard to be guaranteed.

The standardization and systematic approach to new product development are to prevent from wrong decisions by one person and to assist making right decisions. In this study, the authors have analyzed factors affecting the performance of new product development in Lean DFSS and ISO/TS16949. The results have shown that the two processes together can be very effective to successful development of new products if used complementarily. Also, the authors propose an integrated model, using APQP in ISO/TS16949 as a method to deduce past problems and manage future ones.

The authors have hypothesized that, for the integrated methodology to have positive effects to new product development, first, FMEA should be used to predict and manage possible problems; second, KSF should be deduced; third, defining levels of problems and managing each level should be used for motivation; and fourth, CFT should be established to eliminate the barriers among departments.

This research paper focuses on how to integrate APQP of ISO/TS16949 and Lean DFSS. Lean DFSS processes can be considered as an optimize version of APQP processes. However, it is true that Lean DFSS has its weaknesses in defining Inputs, Outputs, KSF, and FMEA more so than APQP. Lean DFSS, on the other hand, is better at defining 4 step mega processes, 16 step major processes and 64 step sub processes. Since many processes in both APQP and Lean DFSS are identical in the integrated system, companies can eliminate losses in implementing both tools. In future studies, the authors will collect data to prove the hypotheses, perform reliability tests, and evaluate the integration model.

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