Product Design, Product Manufacturing and Product Quality Control Issues

Quality control starts at the point of product conception and is carriesd all the way through to the final design and manufacture of a product. Product defects and failures can be attributed to poorly designed product, a poorly designed manufacturing process and/or a poorly designed quality system. Separate engineering groups within a company are assigned to (1) design and develop products referred to as product design engineers, (2) design and develop the manufacturing processes referred to as industrial-manufacturing-process engineers and (3) design and develop the quality system referred to as quality control or quality assurance engineers. Some companies require their manufacturing and process engineers to function as quality control engineers as well which is usually the practice of smaller companies.

Product Design

When a company designs a product for sale in the open marketplace, the engineers should use the engineering design sciences to design each component of the product. During the initial design phase, a prototype is made. The prototype should then be tested in the lab and in the field. These tests should determine functionality, safety, product durability and life span. If design problems become apparent during testing, a product redesign should be performed to eliminate the issue. Then product testing should resume. If the product is improperly designed and not thoroughly tested, design flaws could be the result, and the product could be unsafe and could fail. Failure may be catastrophic or may fail from use over time. The failure may or may not injure a customer depending on the type of product. The bottom line is that if a product has one or more design flaws and has not been properly tested before it is released for mass production, it will fail in some way at some point. The failure could be either from lack of performance, safety or durability.

In the world of engineering, good engineers use the engineering sciences to design products. In this endeavor, design problems must be worked out and solved if the engineering science is available. A product must be designed to operate safely and must be designed and manufactured with a reliability that will ensure a long and trouble free life. But whether the science is available or not, performance, durability and safety issues must be solved, and whatever form the design solution takes under these conditions is called “Engineering”.

Product Manufacturing

Most products are made up of one or more components. Depending on a component and its material, the product is manufactured using a specific process. This process could be made up of tooling and dies, material handling and holding fixtures, high precision high volume multi-axis machining and turning centers, high pressure injection molding machines, punch or forming presses, roll formers, finely detailed electronic manufacturing etc. These components must then be transported from one operation to the other either by conveying, by robots or by forklift utilizing palletizes containers. Once each component part of the product has been manufactured, the components must then be assembled into a complete and functional unit. This can be performed manually by hand or using automated processes via robots and other automatic assembly machines. The

final assembly must then be inspected for proper function. And finally it must be packaged and shipped to the end user. In any one of these operations, the product or its components can be made incorrectly or damaged in some way. If a defect is mistakenly manufactured into the product and is not discovered through inspection, then performance or safety issues could surface at some point. For example, if a jagged edge is machined onto a component by mistake, it could cut the end user. If a shaft that is designed to experience torsional stresses is mistakenly manufactured in a machining operation leaving an undesirable tool mark on the circumference of the shaft, this tool mark could become a stress riser and cause the shaft to fail catastrophically in service due to fatigue. It is important for a company to inspect components and assemblies for manufacturing defects before the product reaches the end user to avoid a catastrophic failure that could lead to a personal injury.

Quality Control

Some companies design a product, manufacture and inspect it all in-house. These companies have direct control of their product's quality. Other companies design a product and then have it manufactured by a contract manufacturer (contractor). Contractors may be located in the United States or in other countries. Today, more and more contractors are being chosen in Mexico, Asia, Central and South America and the Middle East. Companies that have their products made by contractors' loose direct control of quality assurance.

A company that wished to contract out the manufacturing of it products must establish a professional relationship with a contractor and audit the contractor to assure themselves that the contractor has the employees, talent, capability and capacity to produce their products. These contractors must have experience manufacturing similar products. The contractor will be instructed by the customer company on how they wish the product to be manufactured. They will also instruct the contractor on inspection procedures to make sure that a quality system is in place so that the product quality will meet their requirements. If a customer company has no prior relationship with a contractor in a foreign country, a customer company may retain a broker firm that has expertise in establishing relationships with companies in other countries. The broker communicates with and establishes the relationships and bring the customer company and contractor together. The brokers also assist the customer company in establishing the manufacturing and quality control processes.

When products first arrived from the contractor, the customer company will usually inspect 100% of the products to make sure that the product is manufactured correctly, meets appearance criteria and inspect for proper function. As this relationship grows, 100% inspection is reduced to a random sample inspection of products. If the contractor fails to always control the quality of the product, defects can start showing up in products. Defects may be difficult to find with random sampling inspections. If these defects are not discovered, these products will make their way to the consumers. It is not until a consumer files a warranty claim that the customer company learns of the defect. If the number of warranty claims increase, the customer company then goes into crisis mode in an attempt to discover what the contractor has done wrong. If this defect affects the safety of the product, customers may contact the Consumer Product Safety

Commission and post this information. The manufacturer may then be required to submit a recall notice to repair or replace the defective product.

Manufactures' Quality Systems

The International Organization of Standardization (ISO) is the world largest standards developing organization. ISO has published more than 16,500 International Standards, ranging from standards for activities such as agriculture and construction, through mechanical engineering, to medical devices, to the newest information technology developments. ISO was created from the union of two organizations: the International Federation of the National Standardizing Associations established in New York in 1926, and the United Nations Standards Coordinating Committee established in 1944. In October 1946, delegates from 25 countries met at the Institute of Civil Engineers in London and decided to create a new international organization of which the object was to facilitate the international coordination and unification of industrial standards. The new ISO organization officially began operating on February 23rd 1947.

The name ISO is not an acronym but was derived from the Greek word "isos" meaning "equal". The name eliminates any confusion that could result from the translation of International Organization For Standardization into different languages which could lead to different acronyms. For a detailed history of ISO, go to www.iso.org to read about this organization.

American manufacturers that plan to export their products to other nations must be ISO registered to do so. If the manufacturer does not have this ISO registration, the overseas companies may not accept their products. The purpose of this registration is to assure that the customer is getting the best and safest product possible. The current registration for the design and manufacture of products of technology to be exported around the world is ISO 9001:2008. When a company wishes to become an ISO registered firm, their quality system must incorporate the requirements of the ISO 9001:2008 standard. When the standard is revised by ISO, an American ISO registered manufacturer has approximately one year to update their existing ISO quality system to meet the revised standard.

ISO 9001:2008

For manufactures that design and manufacture mechanical/electrical products of technology that will be exported to other nations, the current standard is ISO 9001:2008. This standard is an assembly of eight elements and sub-elements as follows:

1.0 Scope
    1.1 General
    1.2 Application
2.0 Normative Reference
3.0 Terms and Definitions
4.0 Quality Manager System
    4.1 General Requirements
    4.2 Documentation Requirements

- 4.2.1 General
- 4.2.2 Quality Manual
- 4.2.3 Control of Documents
- 4.2.4 Control of Records

5.0 Management Responsibility
- 5.1 Management Commitment
- 5.2 Customer Focus
- 5.3 Quality Policy
- 5.4 Planning
  - 5.4.1 Quality Objectives
  - 5.4.2 Quality Management System Planning
- 5.5 Responsibility, Authority and Communication
  - 5.5.1 Responsibility and Authority
  - 5.5.2 Management Representative
  - 5.5.3 Internal Communication
- 5.6 Management Review
  - 5.6.1 General
  - 5.6.2 Review Input
  - 5.6.3 Review Output

6.0 Resource Management
- 6.1 Provision of Resources
- 6.2 Human Resources
- 6.2.1 General
- 6.2.2 Competence, Awareness and Training
- 6.3 Infrastructure
- 6.4 Work Environment

7.0 Product Realization
- 7.1 Planning of Product Realization
- 7.2 Customer Related Processes
  - 7.2.1 Determination of Requirements Related to the Product
  - 7.2.2 Review of Requirements Related to the Product
  - 7.2.3 Customer Communication

7.3 Design and Development
- 7.3.1 Design and Development Planning
- 7.3.2 Design and Development Inputs
- 7.3.3 Design and Development Outputs
- 7.3.4 Design and Development Review
- 7.3.5 Design and Development Verification
- 7.3.6 Design and Development Validation
- 7.3.7 Control of Design and Development Changes

7.4 Purchasing
- 7.4.1 Purchasing Process
- 7.4.2 Purchasing Information
- 7.4.3 Verification of Purchased Product

7.5 Production and Service Provision
- 7.5.1 Control of Production and Service Provision
- 7.5.2 Validation of Processes for Production and Service Provision
- 7.5.3 Identification and Traceability

7.5.4 Customer Property
7.5.5 Preservation of Product
7.6 Control of Monitoring and Measuring Devices
8.0 Measurement, Analysis and Improvement
8.1 General
8.2 Monitoring and Measurement
8.2.1 Customer Satisfaction
8.2.2 Internal Audit
8.2.3 Monitoring and Measurement of Processes
8.2.4 Monitoring and Measurement of Product
8.3 Control of Non-Conforming Product
8.4 Analysis of Data
8.5 Improvement
8.5.1 Continual Improvement
8.5.2 Corrective Action
8.5.3 Preventive Action

The ISO registered manufacturer must be registered by a certified registrar. The registered ISO American manufacturer must have a functioning quality system in place that meets the above eight element requirements. The registered manufacturer must undergo external periodic audits by an external lead auditor sent from the registrar to perform the audit and assure that the manufacturer is following to the letter its own quality system. If the external lead auditor discovers quality control system issues during the audit, then the manufacturer must correct these system issues through their own quality and corrective action system. If these issues are severe enough where the external lead auditor determines that there is a major breakdown in the ISO registered manufacturer's quality system, the lead auditor can then recommend to the registrar that the manufacturer's ISO registration be suspended until such time as the manufacturer has permanently corrected these quality system issues. At that time, the manufacturer can then approach the registrar and ask for a re-audit for recertification and registration.

In addition to the ISO 9001:2008 quality system, companies and their suppliers may utilize some or all of the following quality system methods to enhance their ISO 9001:2008 quality system:

Six Sigma
Advanced Product Quality Planning (APQP)
Production Part Approval Process (PPAP)
Failure Mode and Effects Analysis (FMEA)
Design and Analysis of Experiments (DOE)

These additional systems go above and beyond the standard ISO 9001:2008 quality system in making sure that both the manufacturer and its suppliers are making the best product possible.

Six Sigma
A company that promotes and drives Six Sigma from the top down in their corporate cultures are Customer Centered organizations where Six Sigma is applied to all levels

and functions of the company. Six Sigma gets its name from statistics and the normal bell curve population distribution. The bell curve is distributed into twelve standard deviations, six standard deviations on both sides of the mean (μ). A standard deviation is denoted by the Greek letter Sigma or σ. Hence the name Six Sigma. It involves an effort to reduce process variation to a minimum so that processes consistently meet or exceed customer expectations and requirements. This is done by performing statistical calculations, statistical based tracking and monitoring of all plant operations and processes. When an improvement project is launched, the engineering department must have or accumulate numerical data on a current operation to know where the operation or process is performing at that time and before any changes are made. Once improvement strategies are determined, these strategies are then put into place. Then operation or process monitoring begins and numerical data is collected and statistically analyzed. The numerical results of the analysis will determine if the changes to the operation or process was successful. If successful, continued numerical monitoring can take place for some time to make sure that the changes made work long term as intended. Six Sigma trained and certified professionals achieve levels of knowledge and expertise. These achievement levels are known as belts such as the Green Belt and Black Belt. For example, a professional with a Six Sigma Black Belt has successfully completed several hours of training (more than a Green Belt) and has obtained experience working in a Six Sigma corporate environment. The Black Belt is the highest belt of Six Sigma training to achieve. The next level is Master Black Belt where the professional is qualified to train and certify students to the level of Black Belt.

Advanced Product Quality Planning (APQP)

Product quality planning is a structured method of defining and establishing the steps necessary to assure that product satisfies the customer. The goal of product quality planning is to facilitate communication with everyone involved to make sure that all steps are completed on time. Effective product quality planning depends on a company's top level management commitment to the efforts required in achieving customer satisfaction. The following steps encompass a product quality planning timing chart as follows:

1) Plan and define program
2) Product design and development verification
3) Process design and development verification
4) Product and process validation
5) Feedback assessment and corrective action

Production Part Approval Process (PPAP)

The Production Part Approval Process or PPAP defines generic requirements for production part approval. The purpose of PPAP is to determine if all customer engineering design record and specification requirements are properly understood by the supplier and that their manufacturing process has the potential to produce product consistently meeting the requirements during an actual production run at the quoted production rate. The PPAP encompasses a completed set of documents and is asked for by the customer by Levels of Evidence which are levels 1 through 5; 5 being the most demanding requirements. The PPAP was developed by the American automotive industry and is used exclusively by General Motors, Ford and Chrysler.

A full level 5 PPAP contains the following requirements:

1) Design Records
2) Authorized Engineering Change Documents
3) Customer Engineering Approval
4) Design FMEA
5) Process Flow Diagrams
6) Process FMEA
7) Control Plan
8) Measurement System Analysis Studies
9) Dimensional Results
10) Records of Materials/Performance Test Results
11) Initial Process Studies
12) Qualified Laboratory Documentation
13) Appearance Approval Report (AAR)
14) Sample Production Parts
15) Master Samples
16) Checking Aids
17) Customer Specific Requirements
18) Parts Submissions Warrant (PSW)

This entire list of 18 items are required by the customer from the supplier before product is shipped by the supplier to the customer. The customer will no accept any product from the supplier until it receives the completed PPAP from the supplier.

Failure Mode and Effects Analysis (DFMEA) and (PFMEA)

(DFMEA): Design Failure Mode and Effects Analysis and a (PFMEA): Process Failure Mode and Effects Analysis.

A Failure Mode and Effects Analysis (FMEA) is a group of activities intended to:

a) recognize and evaluate the potential for failure of a product or process and the effects of that failure.

b) identify actions that could eliminate or reduce the chances of the potential failure occurring.

c) document the entire process.

It is complementary to the process of defining what a design or process must do to satisfy the customer. Because of the general industry trend to continually improve products and processes whenever possible, it is important to use the FMEA as a disciplined technique to identify and help minimize potential concern. One of the most important factors for the successful implantation of an FMEA program is timeliness. It is meant to be a “before the event” action not an “after the fact” exercise. To achieve the greatest value, the FMEA must be done before a product or process failure mode has been incorporated into the product or process. Up front time spent properly completing an FMEA, when product or process changes can be most easily and inexpensively implemented, will minimize late change crises. A Risk Priority Number (RPN) is calculated that determines the severity of a particular issue. This number ranges from 1 to 1000, 1 meaning no risk and 1000 being very risky.

Root Cause Analysis

Root Cause Analysis is a structured investigation that attempts to identify the true cause of a problem or issue and the actions necessary to eliminate it. The following is a list of tools used in root cause analysis:

1) Cause and Effect Analysis
2) Flow Charts
3) Fishbone Diagrams
4) Spider Charts
5) Critical Incident
6) Brainstorming
7) Nominal Group Technique
8) Paired Comparisons
9) Data Sampling
10) Surveys
11) Check Sheets
12) Histograms
13) Pareto Charts
14) Scatter Charts
15) Relations Diagrams
16) Affinity Diagrams

Design and Analysis of Experiments (DOE)

Design of Experiments is a statistical technique introduced by Sir R. A. Fisher in England during the 1920s. After World War II, Dr. Genechi Taguchi, a Japanese scientist, spent much of his professional life researching ways to improve the quality of manufactured components. Dr. Taguchi's work was adopted by many Japanese companies. During the 1980's, some US companies began adopting DOE to improve their product quality. Several years ago, the Global Harmonization Task Force (GHTF) assembled a technical committee to create formal requirements for the design and manufacture of medical devices in the United States. During June of 1997, these requirements were completed and are referred to as Current Good Manufacturing Practices (CGMPs). The Code of Federal Regulations (CFR) which documents these requirements is known as 21 CFR 820 and is enforced by the United States Food and Drug Administration (FDA). DOE is a part of the design and manufacturing process verification and validation qualification protocols. The following is a basic guideline for designing experiments:

1) Recognition and statement of the problem.
2) Choice of factors, levels and range.
3) Selection of the response variable.
4) Choice of experimental design.
5) Performing the experiment.
6) Statistical analysis of the data.
7) Conclusions and recommendations.

A good functional quality system will assure that a manufacturers' product meet all customer requirements. It will also promote future business with current customers and get the attention of inquiring potential customers as well. If a manufacturer does not have a strong management backed quality system in place to make sure that their product

meets their customers' expectation, then quality related problems can and will usually manifest themselves into the form of internal quality problems, external customer complaints, safety issues and failures with their products.