CHALLENGES OF IMPLEMENTING INTELLIGENT QUALITY MANAGEMENT IN ENTERPRISES

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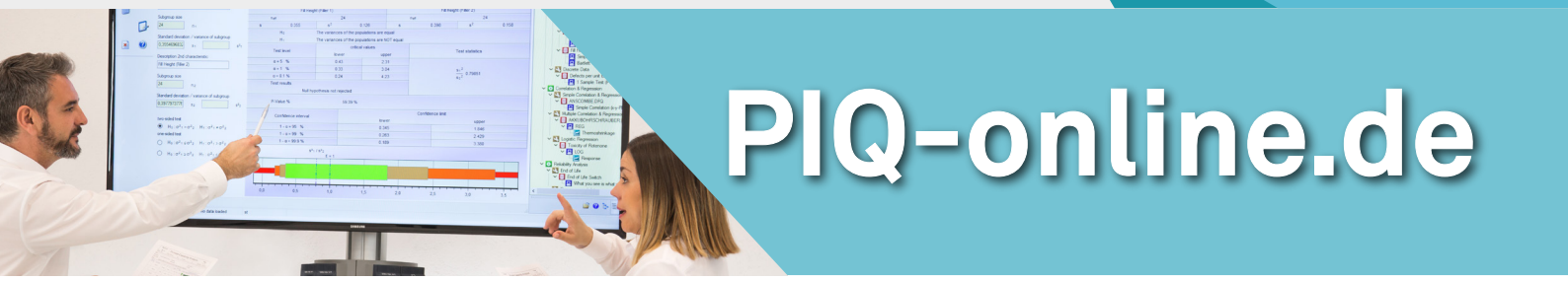

This article describes how quality management changed in industrial production and manufacturing during the last decades and gives an overview of the procedures and measures applied in companies.

HISTORY OF QUALITY MANAGEMENT SYSTEMS

From quality control to operator self-inspection

With the introduction of mass production, as implemented into the automotive industry by Henry Ford, the precision of components and sub-assemblies assumed a greater significance in the assembly process. When parts could not be assembled or proved to be defective, the entire assembly line had to be stopped or operators had to access this very part to rework it. To avoid this kind of situation, quality control became part of the production process. This development formed the foundation of a new department called “quality control” or “quality assurance”. This department did not depend on manufacturing, production or assembly at all and was responsible for the final release of a product after the final inspection. This responsibility, however, was frequently bound to provoke conflicts between product manufacturers and quality managers. Even though 100% inspections reduced the margin of error, they increased the required effort considerably.

As mass production started to prevail and quality demands on products continued to rise, sampling inspections helped reduce quality costs. This type of inspection is based on various procedures worldwide. In the 1930s, it was Walter Shewhart [1], [2] who introduced Shewhart quality control charts – named after him – successfully at the Bell Telephone Laboratories, his employer. Even though his procedures brought about a revolution in statistics at that time and attracted increasing interest, only few companies applied them in an increasingly industrial production and manufacturing environment.

As manufacturers broadened their vertical range of manufacture, outsourced the production of single components and received these products "just in time" from their suppliers, quality demands rose even further. This trend particularly affected the automotive industry.

It was again the Ford Motor Company changing the issue of quality control considerably at the beginning of the 1980s. This was due to the introduction of the quality management system Q-101 [3] (see Fig. 1) applying to both, Ford internally and to their suppliers. This system established quality control charts as developed by Shewhart and capability indices helping to assess the quality of machines, processes and products.

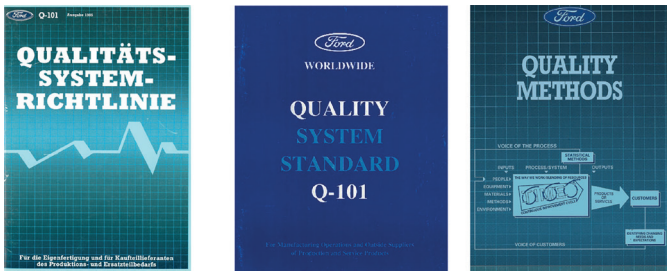

Fig. 1: Cover and sheet of Ford's Q-101 QM as published in 1985 [3]

In addition, companies started to replace the independent function of quality control by the operator self-inspection. From then on, the respective staff of the production and manufacturing division bore the responsibility for the quality of machines, processes and products. Companies thus no longer needed "quality control" departments and the associated name disappeared, too. "Quality assurance" and "quality management" were the new terms used in this context and the selection of methods and procedures they involved became known as a "quality management system".

Big Three established uniform rules in the automotive industry

In 1994, Chrysler, General Motors and Ford (also referred to as the Big Three) issued a joint quality management system in the US - QS-9000 Quality System Requirements [5]. To a wide extent, it was a kind of sequel to Ford's Q-101 quality management system but included some improvements. The main components of the QS-9000 quality management system were SPC (statistical process control), MSA (measurement system analysis), FMEA (failure mode and effects analysis), DoE (design of experiments), APQP (advanced product quality planning), PPAP (production part approval process) und ISI (initial sample inspection).

Quality management systems worldwide restructured

It was the German Association of the Automotive Industry (VDA) that published the VDA 6.x regulations [6] covering various quality aspects in Germany. In addition, there were separate reference manuals available on the topics of SPC, FMEA, reliability and measurement process capability.

- VDA Volume 3: Reliability Assurance of Car Manufacturers and Suppliers - Reliability methods and tools
- VDA Volume 4: Quality Assurance in the Process Landscape
- VDA Volume 5: Capability of Measurement Processes - Capability of measuring systems, capability of measurement processes, expanded measurement uncertainty, conformity assessment

Guidelines with a similar focus have been published worldwide since then. All these different guidelines were subject to continuous change since they were adapted to new requirements and the knowledge the industry gained over time. The problem, however, suppliers frequently faced was that they had to meet different requirements depending on their customers and the standards the respective customer applied. This is the reason why the IATF (International Automotive Task Force) of the automotive industry worldwide, except for Japan, decided to issue ISO/TS 16949 [11], a cross-company standard applying to all automotive suppliers. Its current name is IATF 16949:2015 (based on ISO 9001:2015) today.

ISO 9000ff provides a comprehensive basis

The first edition of the ISO 9000 ff series of standards was published in 1994. It consisted of multiple guidelines such as ISO 9000 Quality management systems - Fundamentals and vocabulary, ISO 9001 Quality management systems - Requirements and ISO 9004 Quality management - Quality of an organization - Guidance to achieve sustained success and caused a drastic change in companies. From then on, almost every producing company had to design their quality management based on the quality requirements given in these standards. Independent certification bodies checked whether these systems were designed and implemented correctly. Still today, companies successfully passing the audit receive a quality certificate.

As ISO 9000 defines the basics and terminology of quality management systems, ISO 9001 determines the minimum requirements of a quality management system. An organisation must satisfy these minimum requirements to provide products and services meeting customer expectations including their general official requirements. At the same time, the management system is supposed to be subject to continuous improvement. The organisation thus must fulfil customer requirements in a way that achieves high customer satisfaction. The PDCA cycle (Deming circle) provides a solution to this problem. Its four steps (plan, do, check/control, act) lead to the desired result.

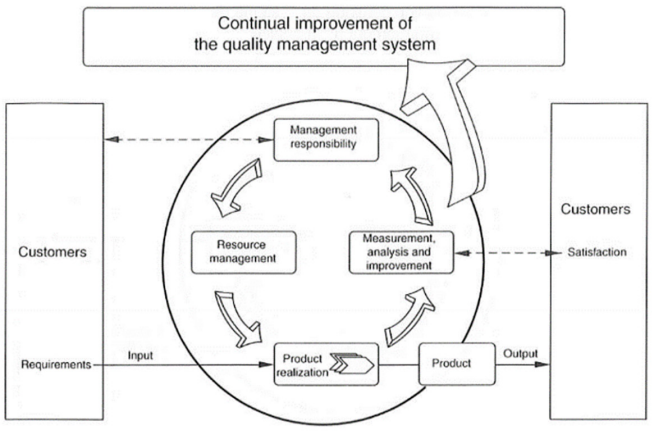

Fig. 2: Modul of a quality management system focused on the process

Developments and enhancements continue, and many companies use the PDCA cycle today to find solutions to specific problems.

After the introduction of the ISO 9000 series of standards, companies primarily dealt with organisational measures regarding quality assessment and quality improvement. A data-based process evaluation according to Walter A. Shewhart, as described in many SPC guidelines, thus became less important.

Six Sigma - a new approach

At the turn of the millennium, the automotive industry started to realise that strictly organisational measures were not enough to improve quality. Originated by Motorola in 1987 and introduced by GE General Electric in 1996, a new system called Six Sigma was developed. It uses various procedures to put the focus back on process knowledge.

The core of Six Sigma is to describe, measure, analyse, improve and control business processes based on statistical methods by frequently applying the DMAIC approach (define – measure – analyse - improve – control). The value targets focus on important fiscal statistics of a company as well as on customer requirements.

Six Sigma was also referred to as DFSS (Design for Six Sigma) in the field of product development. The purpose of this approach: "Do the right thing right from the start!" DFSS projects often apply an IDOV methodology (identify – develop – optimise – verify).

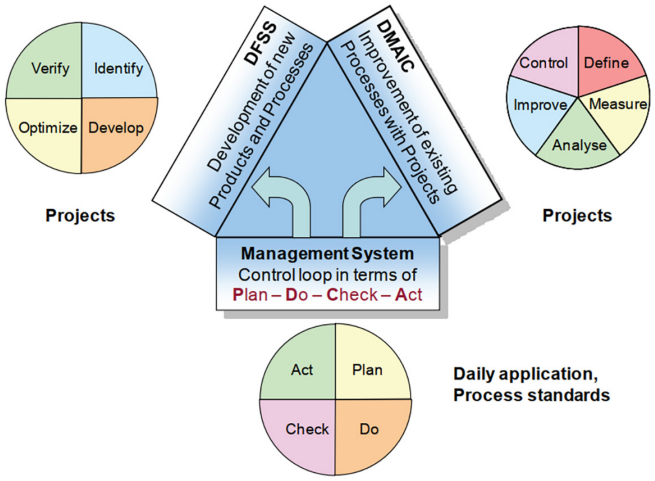

Fig. 3: Interaction between the DMAIC and IDOV project cycles and the PDCA management cycle

It was once again the automotive industry, similar to the introduction of SPC, that promoted these methods. Compared to the introduction of SPC, the implementation of Six Sigma meant implementing a whole set of techniques and tools. Still today, this "package" consists of training courses, software support, awards and specific DMAIC-based projects companies must run. Especially the statistical software packages available on the market facilitated the introduction of Six Sigma considerably.

INTERNATIONAL STANDARDS AND ASSOCIATION GUIDELINES AS A BASIS OF TODAY'S REQUIREMENTS

Worldwide approved ISO 9001 standards mainly define quality management system standards. In addition, IATF 16949 applies to the automotive industry and associated suppliers. Other industries such as the pharmaceutical industry, healthcare industry and food industry also apply supplementary specifications. Here is an overview of key subjects.

FMEA - Failure Mode and Effects Analysis

The earlier a company detects possible malfunctions or failures in the production process of a product and is able to prevent them, the lower the costs to avoid or correct defects. This is the purpose of failure mode and effects analyses (FMEA) or "failure modes" developed based on analytical methods of reliability analyses. An FMEA rates product failures based on their severity in terms of what a customer might experience, their likelihood of occurrence and the likelihood of detection.

The FMEA is a preventive measure in quality management or risk assessment to prevent defects and to improve technical reliability. It particularly applies to the design or development stage of new products or processes. In order that all suppliers have to use the same procedures, the AIAG and VDA published the harmonised guideline "Failure Mode and Effects Analysis" [8].

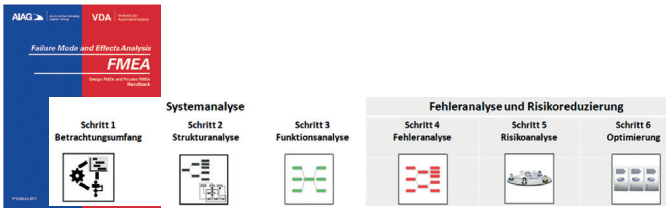

Fig. 4: Cover of the harmonised FMEA guideline and overview of the six FMEA steps

In general, the FMEA consists of the six steps (see Fig. 5). Cross-functional teams assess the ratings by awarding points on a scale from 10 to 1 based on their experience and the knowledge they have. The rating is descending from 10 to 1.

- **S**everity determines how serious an effect of a failure is, particularly from a customer's point of view (from catastrophic = 10 to insignificant = 1).
- **O**ccurrence rating estimated the probability of failure occurring for a specific reason (from inevitable = 10 to extremely unlikely = 1).
- **D**etection rating estimates how well the controls can detect either the cause or its failure mode after they have happened but before the customer is affected (from certainly not = 10 to absolutely certain = 1).

These three statistics lead to the risk priority number (RPN = S*O*D) to identify recommended actions.

APQP - Advanced Product Quality Planning

Quality planning describes the notional anticipation of the future quality a product or service requires to satisfy the customer. It is thus a major part of quality management. Both ISO 9001:2015 and IATF 16949 requirements define quality planning as "part of quality management focused on setting quality objectives and specifying necessary operational processes and related resources to fulfil the quality objectives". It is thus closely related to inspection planning.

The purpose is to prevent defects with the help of a uniform, product-related documentation structure/ hierarchy providing users (manufacturers) with the required transparency in the manufacturing process. Production control becomes easier and any information or document relevant to the project or product is planned, controlled and managed centrally.

PPAP - Production Part Approval Process

The production part approval process is a procedure given in IATF 16949. It samples parts from series production. The automotive industry applies this approach and has been implementing this method successfully for years. It is mainly about the quality of supplied parts and means that parts manufactured by series tools or in series processes must comply with the respective drawings. The inspection of supplied parts and the sampling are both core elements of the sampling process. Any important information about requirements and tests are summarized and documented.

All sampling processes have the same five levels in common.

- Level 1 - part submission warrant (PSW) only submitted to the customer
- Level 2 - PSW with part samples and limited supporting data submitted to the customer
- Level 3 - PSW with product samples and complete supporting data submitted to the customer
- Level 4 - PSW and other requirements as defined by the customer
- Level 5 - PSW with product samples and complete supporting data available for review at the supplier's manufacturing location

Inspection planning

Inspection planning refers to the planning of quality inspections in the entire production process, from goods receipt to delivery. It monitors that products meet quality requirements in the respective production environment. CAD drawings usually specify these requirements and serve as a basis of customer and supplier agreements. Typical requirements are product characteristics in terms of the GPS series (Geometrical Product Specification) [9] such as lengths, diameters, coating thicknesses, surface textures, form and location, sizes and positions dimensioned based on a specified tolerance. Other product properties such as hardness, viscosity, etc. are also toleranced.

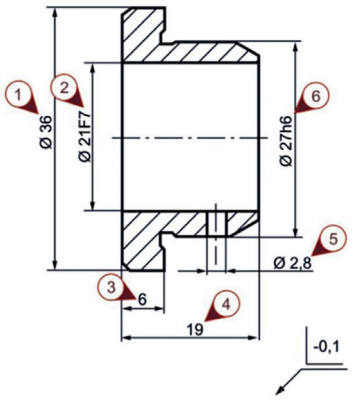

Fig. 5: Drawing indications according to the GPS series of standards

Test criteria (e.g. part to be inspected, inspection process, characteristics or properties to be tested, required inspection equipment and tools, test station/location, specifications etc.) are defined in inspection planning and documented in an inspection or test plan. The operator uses this plan as a work instruction describing how to operate the respective measurement process.

Some characteristics require a 100% inspection, others are subject to random testing. In case of sampling inspections, it is also important to define sampling frequency, sample size and the quality control chart required to monitor these samples.

Initial sample inspection

IATF 16949 defines sampling requirements according to the production part approval process (PPAP). The purpose is to provide evidence that the supplier comprehended all requirements, took all necessary quality planning measures and is able to meet customer expectations in series production.

Inspection and test equipment management

Sensors and measuring systems record quantitative and qualitative data to evaluate specific situations. After evaluating these test results, they will help assess the quality of a product. Since these test results form the basis of relevant decisions, the test results need to be validated. Test results that are not validated can be incorrect and might thus lead to assumptions and decisions that will turn out to be wrong.

ISO 10012 "Measurement management systems — Requirements for measurement processes and measuring equipment" specifies the measurement management system requirements. This standard focuses on the organization and management of measuring equipment and offers guidance on how to ensure that only qualified measuring equipment is applied. ISO/IEC 17025:2017 "General requirements for the competence of testing and calibration laboratories" specifies that accredited laboratories are responsible for qualifying measuring equipment. After completing the inspection successfully, the laboratory issues a certificate confirming the application area of measuring equipment and the time until the next certification is due. This evaluation takes place under ideal conditions and hardly allows any conclusions on the behaviour of measuring equipment under real conditions. It is thus crucial to determine the measurement uncertainty of the respective measurement process in practice.

GUM (Guide to the expression of uncertainty in measurement) [10] provides the basis for calculating measurement uncertainty. Since this manual shows a high complexity and involves many different influences, the measurement uncertainty needs to be calculated for the respective measurement process in terms of ISO 14253-1 "Geometrical product specifications (GPS) — Inspection by measurement of work pieces and measuring equipment — Part 1: Decision rules for verifying conformity or nonconformity with specifications". This is the reason why experts developed simplified procedures and approaches to express the measurement uncertainty of measurement processes under real conditions. The resulting standards and reference manuals describing these methods are as follows.

- ISO 22514-7 Statistical methods in process management — Capability and performance — Part 7: Capability of measurement processes
- ISO/TR 12888 Selected illustrations of gauge repeatability and reproducibility
- ISO/TR 14468 Selected illustrations of attribute agreement analysis
- MSA Measurement Systems Analysis (AIAG)
- VDA Volume 5 Capability of Measurement Processes (VDA)

These are general documents and some of these procedures have to be adapted. If the respective measurement uncertainty is known, the measurement result y consists of the measured value x and the calculated expanded measurement uncertainty: $y = x \pm U$. The same applies to inspections by attribute.

SPC - Statistical Process Control

To manufacture components, parts or products as efficiently as possible, it is important to establish machine performance and the capability of production equipment and assembling devices. The corresponding analyses ensure that they are suitable to produce parts meeting the respective requirements. This applies, in particular, to the initial purchase of such equipment and to any significant change during ongoing production. The ISO 22514 series supports users in performing these tasks.

Machines, production equipment and assembling devices whose performance has already been established still need to be monitored in the ongoing manufacturing process to identify significant changes affecting the product quality in a negative way immediately. Quality control charts as described in the ISO 7870 series facilitate this task. The automotive industry uses AIAG's SPC reference manual and VDA Volume 4 [9].

DoE - Design of Experiments

If an FMEA, performance study or capability analysis leads to the conclusion that the machine, production equipment or process needs to be improved, it is recommended to apply the design of experiments methods. They include

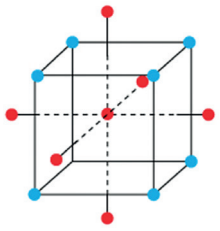

Fig. 6: Typical graphical representation of an experimental design

- various graphics illustrating recorded data
- statistical test procedures
- experimental designs (see Fig. 8)
- analysis of regression and correlation

These methods ensure that any relevant factor is considered while reducing efforts to a minimum; the results obtained from the experiments optimize parameters in a way that the quality of the process improves.

Reliability

Before launching a product, it is reasonable to assess the expected product life. Many defects during the warranty period will lead to higher quality costs. The automotive industry recalls several millions of cars each year, irrespective of the fact that these recalls cause considerable damage to a brand's image since the manufacturer is not able to provide the promised product quality.

To estimate the expected lifetime of a product, companies already conduct reliability analyses while developing this product. Depending on the type of product, companies develop an individual test stand to analyse several products under different conditions and to determine downtime. According to experience, a Weibull distribution describes downtimes quite well. Applying this probability distribution to the collected data, it is easy to calculate the expected lifetime. Risk assessments provide the basis for decision-making; they decide whether a certain lifetime is acceptable or whether the products need to be improved.

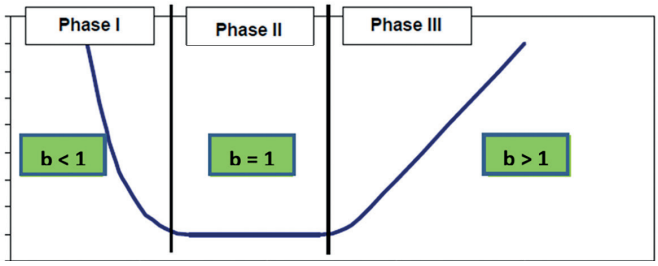

Fig. 7: Progression of failure rates based on the Weibull distribution

The results of this assessment may be divided into three phases:

- Phase 1: Early failures (b < 1)
- Phase 2: Failures after the customer (purchaser) used the product (b = 1)
- Phase 3: Failures caused by wear or aging (b > 1)

Figure 9 illustrates the typical failure rates in these three phases. Due to the progression of the curve, it is also referred to as the "bathtub curve".

IT SUPPORT

There are many different software packages available to perform the wide variety of tasks required to assess and evaluate machines, equipment, processes and procedures as well as produced components, parts and products. The same applies to quality management planning. The purpose of these software packages is to support users in their tasks in the best possible way. This support even includes automated operations controlled by individual workflows today, i.e. the software guides users reliably through the single tasks and supports them in their decision. Programs automatically prompt responsible staff members to approve certain decisions, workflows, etc. and inform specified persons about the status of the production process.

In the field of quality assurance, there are two different categories of software packages offering IT support - individual software programs available for performing specific tasks and software packages in the form of integrated solutions dealing with all principal tasks of quality management. The latter are referred to as CAQ (computer aided quality) solutions.

Even other systems such as PLM systems (product lifecycle management), ERP systems (enterprise resource planning), CRM systems (customer relationship management) or MES systems (manufacturing execution system) generally keep quality information. Further information can also be provided by the Internet (World Wide Web) or may be available in text files or tables. Unstructured data, however, makes the acquisition of information very difficult and automated evaluations can hardly be realised.

Today's challenge is to collect the quality information relevant to a specific task from the variety of different systems and, if possible, in real time and to make this data available for further processing.

Operators mainly need this information to monitor "their" processes whereas process owners require in-depth analyses and evaluations. The management level mainly deals with highly compressed statistics leading to statements about quality statuses of the company or various shop-floor areas. In general, there is a difference between

- ad hoc analyses with respect to different tasks that currently need to be fulfilled
- signalling of results (alarms) occurring when predefined criteria are violated
- time-triggered evaluations such as daily/weekly/monthly reports or reports by shift.

The intelligent sensor technology available today, high computing power and high storage capacities combined with high-performance communication options support companies in these tasks. Nowadays, it is all about Industry 4.0, IoT (Internet of Things) or IoP (Internet of Production). With respect to quality, current publications discuss and attempt to define the topic of quality 4.0.

What quality 4.0-based processes require the most are an automated recording of measured values of quality characteristics, including the recording and linkage of process parameters. This is how automated analysis systems can create a correlation between inspection and production. Optimization, predictive and prescriptive analytics are then a possibility. Companies are thus able to produce their products at lower costs (by reducing downtime, wear and expensive rework), respond to shifts in demand more quickly, reduce lead time and to advance their overall competitive edge.

SUMMARY

While the quality assurance effort invested in industrial production increased considerably in the last three decades, nowadays we rather focus on gaining and applying the knowledge the available data provide. This is how we evaluate and influence product quality today. In future, we are likely to use artificial intelligence to describe relationships and situations in order to plan and control quality in industrial production even better. Artificial intelligence will reduce the required measurement effort drastically and usher in a new era in quality management.

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