Quality Management System Performance – The Missing Links

a report by
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International Organization for Standardization Technical Specification (ISO/TS) 16949 is becoming the fundamental requirements document for quality management systems in the international automotive industry. It is based on the latest edition of the ISO 9001 quality management standard. Various terms used in ISO 9001 are defined in a separate document in the same family – ISO 9000.

ISO/TS 16949 is the culmination of more than a decade of harmonisation activities in the automotive sector. In the US, these activities began in June 1988 with the sanctioning of the Supplier Quality Requirements Task Force (SQRTF) by the Purchasing Vice Presidents of the 'Big Three' – Chrysler, Ford and General Motors (GM). At that time, no supplier quality manual had more than one company logo on its cover and all were customer-specific or even division-specific. Large automotive suppliers were forced to dedicate key personnel to specific customers to perform the simple tasks of tracking and interpreting customer requirements.

The SQRTF began its work modestly, producing a common part submission warrant form after the first year. However, based on supplier cost/benefit analysis, SQRTF chartered a number of simultaneous projects that, over the next several years, produced a the following series of quality reference manuals common to Chrysler, Ford and GM:

- Statistical Process Control (SPC);
- Measurement Systems Analysis (MSA);
- Advanced Product Quality and Control Plan (APQP);
- Potential Failure Mode and Effects Analysis (FMEA); and
- Production Part Approval Process (PPAP).

Based on these and their existing company-specific quality standards, SQRTF then produced *Quality System Requirements QS-9000*. The same basic approach was taken in the European automotive industry, with automotive manufacturers and their trade associations in France, Germany, Italy and the UK developing similar consensus documents for their supply base.

As QS-9000 was launched in Europe, discussions began that resulted in the release of an international automotive consensus document – ISO/TS 16949: 1999. The second edition, released in 2001, included the Japanese auto manufacturers for the first time. This significant level of international harmonisation of automotive quality requirements has greatly reduced the amount of redundant paperwork now required of suppliers. This translates to fewer resources required as a result of less sector variation. Why does it seem like the remaining documentation is often ineffective?

The Missing Links

In retrospect, it seems that something may have been missed by publishing separate deliverables for SPC, FMEA, quality planning and the like. In treating these as separate deliverables, their use may have been confounded in practice as a 'system'. Furthermore, training developed to support the implementation of these manuals over the years may have emphasised the 'what' and the 'where' almost to the exclusion of the 'how' and 'why'. This may have led to the completion of FMEAs, quality and/or control plans and control charts as separate independent, e.g. 'paperwork', exercises instead of their being carried out with a cross-functional approach and used as inputs or outputs to the others.

Another omission is error proofing of designs and processes. This is not a new technology, but it has been slow in deployment in the automotive supply chain. Where an FMEA generates a high Risk Priority Number (RPN) for a characteristic, the product design should be reviewed and revised to reduce the risk. The RPN should then be recalculated to reprioritise the risk. Error-proofing devices should be periodically verified and tested by sending a known good or bad part through the process.

Complicating problems further over the past couple years, organisations have been downsizing and aggressively reducing cost, especially discretionary spending, e.g. training. New practitioners are being assigned to the quality function without a proper understanding of fundamental quality management science.

The Role of the Characteristic

The 'right' thing to do when it comes to quality is often counterintuitive. Even the definition of quality varies greatly by industry or by organisation. The ISO definition of quality is *"the degree to which a set of inherent characteristics fulfils requirements."* This definition did not reach consensus until the third revision of the ISO 9000 series in 2000. Note the use of the term 'characteristics' in the definition.

Quality Characteristics

In the *Quality Control Handbook*, 'quality' is defined as 'fitness for use' and it is stated that *"the basic building block on which fitness for use is built is the quality characteristic"*. ISO 9000 defines 'characteristic' simply as a 'distinguishing feature' and a 'quality characteristic' as an *"inherent characteristic of a product, process or system related to a requirement"*. This is contrasted with 'assigned' characteristics such as product price. The *Quality Control Handbook* adds that quality characteristics can be classified into the following categories:

- quality of design (where higher quality typically costs more);
- quality of conformance (where higher quality costs less, e.g. fewer defects);
- the 'abilities' (time-related, e.g. dependability, reliability); and
- field service (e.g. promptness, competence, integrity).

This helps to explain why there are often disagreements over whether quality adds cost or reduces cost. The outcome is dependent on what type of characteristic is being discussed.

ISO 9000 states that *"customers require products with characteristics that satisfy their needs"*, therefore customer requirements must be addressed in the supplier's planning and design activities. They must be translated into product and process characteristics and managed according to their relative cost/risk benefit. One tool for deploying customer requirements throughout an organisation is Quality Function Deployment (QFD), which should be used with the other specified tools, e.g. APQP or FMEA.

Design and Development

Design and development are linked in ISO 9000 and are defined as *"a set of processes that transforms requirements into specified characteristics or into the specification of a product, process or system."* Design costs typically represent less than 10% of the total cost, while the design itself has more than a 70% influence in reducing those costs compared with material, labour and burden.

It is during the design process that product and process characteristics are identified. They can be identified from a number of sources including QFD, FMEAs, warranty or recall data, simulation or modelling studies, designed experiments, SPC data on similar parts or processes and group consensus. Where these activities are not well implemented and deployed in an organisation's design function, the characteristic identification function is compromised.

Design Cycle

The Taguchi Methods classify the design cycle into three phases: system design, parameter design and tolerance design. In design and development, the system must be designed to meet cost, quality and any other strategic objectives. Parameter design should be used to determine characteristic target or nominal values and material properties. Tolerance design should be applied to set the characteristic tolerances using statistical tools. This is critical because tighter tolerances drive additional cost. This may be a significant cost-savings opportunity if tolerances were arbitrarily set in product design. Statistical process capability or performance is a function of the tolerance spread and process capability is integral to production part approval.

Key or Special Characteristics

All characteristics are not created equal. Auto manufacturers define at least two types of product characteristics: standard and key, critical or significant.

ISO 9001:1994 used the term 'crucial' for the latter, while QS-9000 and ISO/TS 16949 use the term 'special' to harmonise the various company-specific terms in use. ISO/TS 16949 defines a 'special characteristic' as a *"product characteristic or manufacturing process parameter which can affect safety or compliance with regulations, fit, function, performance or subsequent processing of product."* These characteristics require extra care to mitigate the effects of a potential problem. The types of controls necessary are customer-specific.

It may be that, for some organisations, the quality management system is breaking down at the point of this critical activity – the designation of special characteristics.

ISO/TS 16949 states that the organisation shall use a multidisciplinary approach to prepare for product realisation, including the following:

- development/finalisation and monitoring of special characteristics;
- development and review of FMEAs, including actions to reduce potential risks; and
- development and review of control plans.

Suppliers are also required to identify and undertake the following processes:

- include all special characteristics in the control plan;
- comply with customer-specified definitions and symbols; and
- identify process control documents including drawings, FMEAs, control plans and operator instructions with the customer's special characteristic symbol or the organisation's equivalent symbol or notation to include those process steps that affect special characteristics.

These requirements emphasise the fact that it is a joint responsibility of the customer and the supplier to identify and designate special characteristics, even for customer-responsible designed parts. The supplier is, in some cases, the only party in a position to identify some special characteristics because of their unique knowledge of their production processes. The customer should begin the identification and designation of special characteristics for their designed parts, but the supplier should finish the task.

This is one area in which the quality management system could fail. If the supplier takes a minimalist approach to the identification and designation of special characteristics, the customer stands to lose much of the power of the ISO/TS 16949-specified quality planning and control tools, e.g. FMEAs, control plans, operator instructions and standard operating procedures.

PPAP only requires that initial process studies be performed for special characteristics. This assumes that special characteristics have been properly identified and designated by both the customer and supplier. Over time, this may be seen as a bad assumption. Incomplete or inadequate FMEAs can compromise the proper identification of special characteristics, thus impacting on the effectiveness of this part-qualification activity. This results in the risk of an end-user finding the problem in the field, which would be likely to generate customer dissatisfaction and possibly warranty or recall exposure.

Process Capability Versus Process Control

Prior to launch, a process needs to demonstrate capability to meet specified customer and internal requirements. Often there is more emphasis on process control than on process capability, especially in the organisation's administrative or support functions. Some are satisfied if a process performs acceptably 80% of the time and consider it their responsibility to manage the exceptions. This tolerates often unnecessary variation and waste, as portrayed by the Six Sigma™ initiative.

Processes should be designed to provide the needed outcome or result at all times. Six Sigma is a discipline using statistical methodology by certified practitioners to drive quality improvement and cost reduction project-by-project. The role of statistics is also discussed in ISO 9000. *"The use of statistical techniques can help in understanding variability, and thereby can help organizations to solve problems and improve effectiveness and efficiency… variability can be observed in measurable characteristics of products and processes…"* Again, the critical importance of effective characteristic management, e.g. identification, designation and control in reducing variation, is evident.

Attribute or Variable Characteristics

Much emphasis over the past decade has been focused on variable characteristics to improve quality. This focus has produced some impressive results. However, GM's recent data indicates that 80% of supplier quality problems are caused by the following five significant failure modes, the majority of which are attribute data:

1. set-up error (33%);
2. worn or broken tooling (26%);
3. incorrect assembly (17%);
4. incorrect labelling (13%); and
5. process changes that drove incapable processes (11%).

For example, thread size is a variable character-istic, but presence of the thread altogether is an attribute. Most of GM's supplier-fault disruptions, also known as 'spills' at GM plants, are due to attribute data.

This points to another missing link to the quality management system: more focus is needed on attribute characteristics. Error proofing should be directed at these failure modes and additional verification activities need to be implemented with attribute statistical process control charts. Experience demonstrates that most spills could have been avoided if defined processes had been followed and if the customer had been properly notified of supplier changes made after production part approval.

The Pursuit of Perfection

The automotive industry continues to be a highly competitive market. Quality is expected and perfection should be pursued. In the meantime, excellence will be tolerated. ■

A version of this article containing graphics and full references can be found in the Reference Section of the CD-ROM accompanying this business briefing.