Document-base QM practices are not sufficient for modern level of the quality management

Companies that in the past have implemented a quality management system according to ISO 9001 and have not modernized their management have great difficulty in complying with modern development and production standards required by foreign companies. They encounter both outdated ways of managing the entire system of information used by the systems and a lack of understanding by auditors who do not understand the requirements of detailed quality management.

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What companies have learned with ISO 9001

Most companies and quality managers think of ISO 9001 as a quality manual and a number of other necessary documents that sit on the company server disk. Once a year the manager dusts them off when he or she is about to visit the external auditors. Besides, everybody knows that internal audits must take place to fill in the forms and find some non-conformity that will be resolved promptly. This will be an opportunity to demonstrate to the auditor that the processes are being taken seriously.

Even companies that are very concerned about the quality of their services and products often have standards formally implemented in the way just described. But in addition to this, they carefully monitor the quality of everything they do. But they monitor this using tools and processes that are

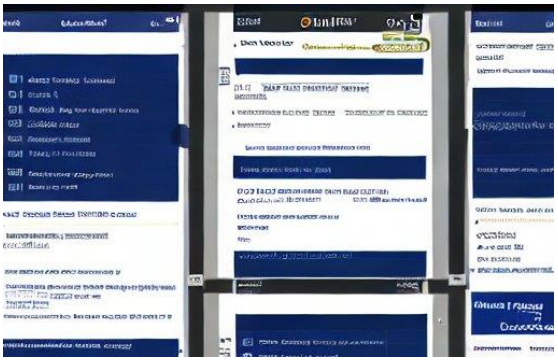
not governed by the standard. But the main reason why standards are not translated into everyday work is that their understanding as well as the way they are implemented is very much behind the times and is often subject to the computerization of documents as it emerged in the 1990s. It is therefore not surprising that it is completely inadequate to the dynamic needs of today's businesses.

Even internal audits themselves, often the only thing that people in companies perceive from a quality system, are often an inadequate tool in today's rapidly changing conditions. The once-a-year audit serves more as a reminder to watch out than it does to effectively help improve quality in operations. Internal audits should help to identify systemic problems, but these need to be addressed quickly today and will certainly not wait six months.

The document-based quality management is not sufficient

Quality management systems built on 1990s technology are based on documents and generally inflexible information handling. They completely ignore modern automation capabilities that ensure documentation of activities and compliance control.

Outdated perception of the information



A fundamental problem with the usual implementation of quality management is the focus on documents. Documents are omnipresent - the standards themselves, but also all reports, findings and measures are perceived as documents. Even if they are long out of print, they usually end up as PDFs or at least sheets in an Excel file.

The problem with a document is that it functions as a way of recording the status at the time of its creation, but it is not handled further. It doesn't serve as instant information that is worked with and in people's hands when they need the information. Without exaggeration, it can be likened to a program manual that came with a CD in a box in the 1990s. It's on the shelf above the monitor and no one would think of flipping through it today. On the contrary, you expect a description to be provided for every function of the system, which will be offered as soon as you need it.

Similar to the manual on the shelf, the company guidelin The new generation of tools takes advantage of the fact that we do basically all activities at the computer, or with a mobile phone or similar device in hand. Therefore, these systems can bring all the information instantly to everyone's desk, which is of course on display and therefore at hand, for example, even during site inspections. On a mobile phone, but ultimately also on a screen, we do not want to open PDFs or Excel files, but quickly open just the one piece of information we need - for example, a description of the problem we are solving. Of course, we may want to access online help when we need advice - i.e. a description of the correct procedure, for example. Especially on a mobile device, we don't want to fill in cells somewhere to write down what we've done when, but click away and move on.

es work the same way. The shelf is electronic, perhaps even displayed on the intranet, but no one looks at it. A modern standard, like a help manual, should be at hand whenever it is needed. But this requires a completely different approach to its handling.

As with guidelines, the approach to all the information that a company creates and uses to meet quality standards needs to change. If it is in people's hands when they need it, they will appreciate it. If they actively work with them, they will serve a purpose; otherwise they stall when they are created

but do not add value. For example, you don't take a problem recorded in Excel to your workbench in the workshop. You don't write a note about what you found and what you need to do next. Sometimes later in a meeting, the problem is checked off as solved, but recording it doesn't help the problem itself.

Work records

The ISO 9001 standard can be maintained in this way and many companies do so. Even systems that have been developed to support compliance support this "documentation" method. This is particularly the case for extensions in ERP systems, for which support for the standards is often a checkbox in the list of functionality they support, but the whole agenda is marginalised in the purchasing and selection of the system and understandably so for development teams.

For more sophisticated standards such as ISO 61508, ISO 26262 or Automotive SPICE, the method described is not applicable and development and manufacturing companies that must comply with these standards must look for more modern ways of managing them. However, they also run the risk of "bumping into" auditors looking for documents they are familiar with.

A fundamental compliance problem arises with records. Without exception, standards require that people's work can be audited. Records of all activities are therefore required. Whereas an internal audit according to ISO 9001 is satisfied with stating that workers know where the guidelines are and where to put tools (or store documents), for example, the standards for development and production processes require auditable records of every single prescribed operation. Crucially, the record never has a prescribed form, but a prescribed content. What matters is not where and how it is stored, but whether it allows to verify who did the activity, and to prove that they actually did it and when. In doing so, it is good to recall that a row-type record in an Excel spreadsheet may contain information, but it does not allow any way to verify that it is true. How, for example, to prove that it was not all created the day before the audit? To a diligent auditor, therefore, they should not be enough. And while a company may find such a "record" sufficient, when an audit comes in sent from a key customer, such as a car company, the lack of evidence will cause the company to lose key contracts.

It is not possible to create all records conclusively without system support. Even the standards directly assume that such system support exists. Just as manufacturing creates records of individual products and the preservation of digital twins becomes standard, standards like ISO 26262 expect the same in the processes of development, preparation and production control. They also expect records to be kept not only of non-conformances found, but of everything that happened in the controlled processes.

Missing information relations

The second major shortcoming of the documentation approach is the lack of links between information. The standards call them traceability in English, the Czech translation is traceability. In short, traceability means that you know what is related to what. It is also possible to make a link to another document in a document, but real traceability requires relationships that are bidirectional (so you know where the information is referenced from, for example), maintained (the link does not mislead us by pointing us to an old document, for example), and of course practically usable.

A typical case where traceability is problematic for companies without system support is requirements. If a customer requires compliance with, for example, product safety conditions, it is essential to be able to demonstrate how these requirements have been worked into the solution.

Technical drawings use special features for this, but information about the influence of a requirement or product feature must be maintained for everything that may affect safety. Similarly for other features - e.g. impact on cyber security etc.

However, special tags are not sufficient to ensure traceability. Not only do they not allow for auditing (how to retrospectively verify that something has not been forgotten), but they do not allow for effective change management. The moment a customer comes in with a suggestion to change a product, the team needs to be able to assess where the change will translate. At the same time, they need to be able to assess whether it will affect any of the special requirements.

But the need for change can also come from the other side, e.g. directly "from the product". A component used for production ceases to be available on the market and the company has to deal with a change in the product or in the production process. New typing by the customer may be necessary, but especially it is necessary to be able to effectively determine what all the change of the component will affect. To do all this, you need to know the context. At the level of technical design, tools such as CAD systems can usually take care of this, but standards and norms require that all information that is related to each other has the same level of coherence.

What company needs from the modern QA system

Modern management systems do not work with documents, but with records. "Directives" and related workflows are not documents, but many short concise workflows that become part of each task assignment. Thus, the worker has not only the assignment, but also the methodology, quality requirements and checklist immediately at hand and does not have to search for anything. As well as online help, everything is available. This greatly facilitates training, but also changes to procedures and standards. But linking methodologies to electronic task management is only the most obvious change. This change alone does not solve the key problems.

How to manage records

Electronic tasks have a major benefit on record creation. Like a digital twin in manufacturing, an electronic task is a digital image of what people do. This creates a digital trail that can be audited afterwards. Mandatory records of activities are thus created at the same time as people perform the activity. And just as a digital twin of a product makes it possible to verify what machine ever processed the product, an electronic task stores information about who performed the activity and when.

Moreover, an electronic task makes work easier. It simplifies process management and task assignment, so that in the overall result it is a source of labour savings, especially at the level of organisation and management. In addition to sleepy record creation, it saves time for project managers in particular and lower management in general.

But processing documents are not the only important records. Records of problems, disagreements, as well as the results of tests performed (logs) must be part of the task management ecosystem. If they stand outside, the link between e.g. the problem and its solution will be missing. At the same time, it is essential to be able to document who fixed the problem and how, and without a link to the problem, important information will be missed - not only during an audit, but especially when the same problem is repeatedly solved. The electronic processing of all quality-related information must therefore include all information that is related - requirements, risks, problems, tests and more. And all of them must be part of the electronic task management.

Efficiency is based on the information management

Anyone who has ever searched for something in an untidy room knows that clutter interferes with efficient work, The more things, the more clutter affects efficiency. This applies not only to the toolbox in the workshop, but also to information, which is an essential tool, especially in product development and production preparation. And the standards mentioned in the introduction, such as ISO 26262, ISO 61508 and others, also require order because without it, something important is bound to be forgotten. Or at least it will be impossible to verify that it has not been forgotten. Therefore, all the information that is used must be easily accessible and obvious how it relates to each other.

An information management system according to these standards must meet a number of requirements that the basic ISO 9001 standard contains only a hint of, or none at all. Closely tied to ISO 9001 is the concept of controlled documentation, but people tend to associate it only with the quality system documentation (QSD) pyramid. Maintaining controlled documentation is not difficult when it is changed once a year. But for example, CMMI, ISO 26262, and in principle the PMBOK methodology and others require the same quality of information management for most project documents, from the project plan to the last requirement. But these documents change, for example, every week. The standards have separate chapters for this (configuration management, and partly change management) and compliance with them is not possible without system support. The standard tools of managed documentation are completely inadequate for this, just compare the amount of requirements for working with the configuration package, and it is obvious that this is an activity significantly more complex than what is required by SMJ managed documentation.

Just as standard document-management tools are not sufficient for configuration management, they are also not sufficient for traceability. Effective information handling requires that information are mutually interconnected and connection could be used both by control systems and users. We have been used to this from websites for decades, but documents do not allow this. Even documents exported to the website (like documentation in the Atlassian Jira) do not creates interconnections necessary for the traceability management. The quality management need to replace documents by linked information that everyone who creates and uses information in any way works with. So we need to get it on the desk and into every task for every worker. This is what next-generation management systems are built for.

New-generation tools required for QA

The new generation of quality management tools is based on the same management principles that companies are familiar with from manufacturing. As already indicated, every activity has an electronic twin in the form of an electronic task. The task, as well as all other records, are interlinked and immediately accessible to everyone involved. The progress of processing is documented alongside the activity so that no one is creating records 'by hand'.

The new generation of tools takes advantage of the fact that we do basically all activities at the computer, or with a mobile phone or similar device in hand. Therefore, these systems can bring all the information instantly to everyone's desk, which is of course on display and therefore at hand, for example, even during site inspections. On a mobile phone, but ultimately also on a screen, we do not want to open PDFs or Excel files, but quickly open just the one piece of information we need - for example, a description of the problem we are solving. Of course, we may want to access online help when we need advice - i.e. a description of the correct procedure, for example. Especially on a mobile device, we don't want to fill in cells somewhere to write down what we've done when, but click away and move on.

Figure 1 Modern management systems enable efficient and fast work with all information (example from AyMINE)

The described way of managing corresponds to how people are used to work and communicate. They simplify all administration as much as possible, so ultimately people have less work to do because of them. On the other hand, they require that they are actually used because they prevent the common habit of completing documentation after the fact. They therefore also require a change in the approach to quality supervision in general. By bringing it to every worker's desk and to every task, they push everyone to do the job properly from the start. They reward them for this by not having to go back on anything they do and "click off", i.e. finish properly. And even internal audit doesn't have to examine whether the work was actually done as it should have been.

About author

The author has many years of experience with quality management systems both from the perspective of an auditor and especially from the perspective of a consultant who helps companies to comply with the standards. His first audits were carried out under ISO9001:1995 and since then he has followed not only the development of the standards but also the approach of companies to their compliance.

Currently, the author mainly helps companies in the Automotive sector to meet the requirements for the development and production of reliable components, where the development must meet not only the standards of automotive manufacturers (e.g. Formel Q), but also the general standards of ISO 26262, Automotive SPICE, ISO EN 1501-1 and others.

The author is involved in the implementation of the AyMINE system, where he creates support for quality standards.