AUVESY.

White paper

Audits

in automated production.

versiondog

data management for automation

Introduction:
Audits in automated production

In the field of production management, audits have become an important tool for analysing quality deficiencies and highlighting operational risks. The information gained from audits can be used to implement corrective measures and ultimately improve production processes.

Quality, standards and efficiency play a particularly important role in automated production. They can give companies a competitive advantage, while also serving as a basis for measuring success.

But what is the best way to approach such an audit, what exactly is involved, and what are some of the potential pitfalls?

The following white paper „Audits in automated production“ provides an initial overview of this topic and explains how a data management system can be a useful tool throughout the auditing process.

How does a data management system help to answer the typical questions arising from process documentation (who, what, where, when and why), and how does this provide a reliable foundation for audit trails?

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Motivation

Essentially, audits serve to provide information that can be used to initiate improvements or ensure compliance with applicable standards. This information must be reliable and contain a sufficient amount of detail. It must also be collected systematically over a short period of time and allow the analysis of the current situation in a company. It all sounds rather straightforward, but the following questions still remain: What is the best way to approach an audit? And what tools are available to help?

When carrying out an audit, it is important to consider the most efficient working method and, equally importantly, to ensure that the audit is documented correctly. It would be foolish to put in so much effort without documenting where nonconformities occur and how to rectify them. This diligent approach also applies to deadlines for implementing corrective measures and assigning responsibilities. If these deadlines are not regularly reviewed and strictly adhered to, then any commitments to constant improvement are nothing but empty promises.

Quality improvement through audits

To achieve quality management targets, audits require the complete support of all employees. Particularly in the field of automated production, it is extremely important that everyone involved in the company works together. Quality managers know this, too, as they prepare for an upcoming quality audit. By acknowledging that quality is an ongoing, ever evolving process, the quality manager can view audits in a positive way. In fact, audits can even be a source of motivation, as they provide the opportunity to prove that everything has been done correctly and that the company's processes are efficient, environmentally-friendly and better than they were during the previous audit. For a quality-conscious worker, an audit is also a great opportunity to improve.

Companies have been striving to improve quality through audits for more than 100 years. To obtain valuable certificates, independent bodies are called upon to ensure that a company is meeting the required standards. This type of certification is always an indication that a company has made a sustainable commitment to quality. In many fields, such as the chemical and pharmaceutical industry, this type of certification is compulsory and highlights a company's sense of responsibility towards customers and authorities such as the FDA (Food and Drug Administration) and the EMA (European Medicines Agency, formerly the EMEA - European Agency for the Evaluation of Medicinal Products).

As part of this process, the participating companies or departments exchange various documents in advance. Producing these documents has now become almost a matter of course for those involved in the audit process. Sometimes these "paper audits" can partially replace regular audits involving on-site questioning. In most cases, however, one or more visits to the company are required for the audit itself.

The documentation of nonconformities or recommendations, as well as the measures implemented by a company following a quality audit, are key tools for improving business processes. As mentioned above, the purpose of an audit is generally twofold: to check quality standards and to initiate improvements.

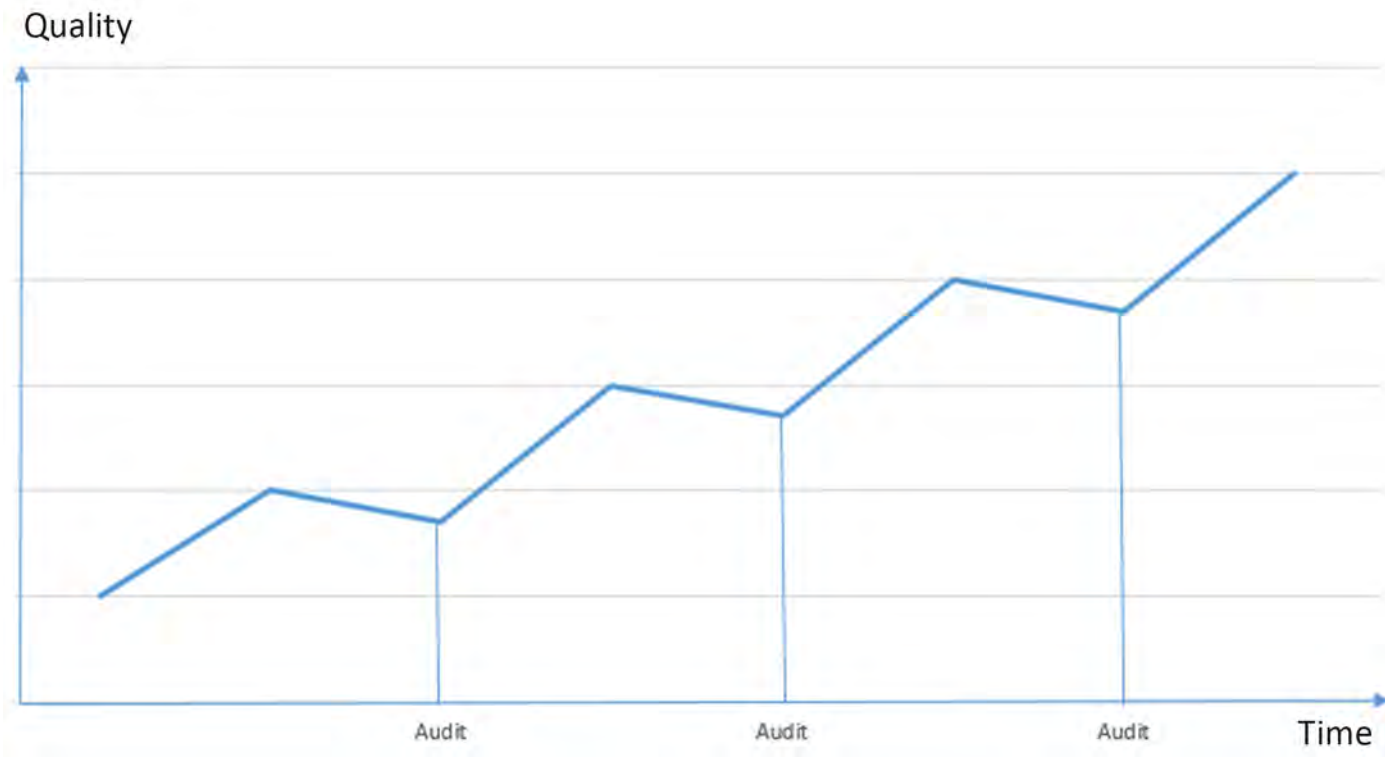


Fig. 1: Increase in quality through regular audits

The aim is constant improvement, and this is what customers and business partners, with their ever changing requirements of the company, tend to expect. As a rule, carrying out audits on a regular basis will improve the quality of a company's processes and products.

Without systematic checks of work processes, any deficiencies or potential areas for improvement in a company will usually not be discovered. When mandatory processes are revised and efficiency is improved, new opportunities can arise. Regularly reviewing business processes – or even just questioning them – can result in a process of continuous improvement. This then leads to an increase in quality and, ultimately, a more satisfied customer.

Audit preparation

There is a lot of effort involved in preparing an audit. The auditor, for example, has to take another look at the documents of the company or department he is auditing, while the department being audited also has to prepare. First of all, organisational preparation is required. This can involve the organisation of premises for the audit, or making sure that the necessary contact persons are present. The rights of the auditor must then be agreed upon and certain documents must be prepared. Some examples are listed below:

- Annual audit schedule to determine the aims and scope of the audit
- Reference documents such as certificates, QM manuals, procedural or working instructions, audit logs from past audits and documentation for corrective measures
- Business plan
- Customer or supplier assessment
- List of measuring or testing equipment
- Marketing strategy
- Organisational chart of the company and relevant department
- Qualification overview and training schedule of workers

In addition, the employees concerned must be informed of the date and time of the audit so they can provide the auditor with certain documents if necessary.

Professional quality managers will generally be prepared to such an extent that all key information related to the department being audited will be ready on the day of the audit. This mainly includes:

- All relevant legal principles, regulations and contractual requiremen
- Corporate documents such as the company profile or information questionnaires
- All relevant registration documents
- Changes made to rooms, facilities, procedures, key personnel (since the last audit)
- Nonconformities and corrective/improvement measures from previous audits
- Any known complaints or product recalls
- Results from quality inspections
- The current production schedule of the facility

The documents required by the auditor for a trouble-free inspection are already building up. And all of these documents must be updated and inspected according to the latest auditing standards. Good preparation for an audit requires year-round documentation by the quality manager and all of the employees in the company who are involved in quality processes. In the run-up to an audit, the same questions are always asked:

- Who changed which processes in the company and when were the changes made?
- Do the processes in the company still correspond to the process documentation?

Answering these questions will be easy if the actual situation is regularly compared with the ideal situation as part of a quality management process.

Fig. 2: Typical questions regarding changes to process documentation

The audit schedule, the audit team and the audit participants are determined several weeks in advance. Based on process descriptions such as work and planning instructions, process instructions or work and inspection schedules, an audit questionnaire is created and then authorised by the quality manager.

The quality manager will be aware of any corrective and preventive action (CAPA) from the previous audit, which means that the auditor can check if these measures have been effective and targets have been met. CAPA is a key part of a quality management system. It is therefore particularly important to document the measures that have been implemented and their effectiveness. If steps are taken all year round to ensure traceability, then simply retrieving the full documentation on the day of the audit will ensure a stress-free audit experience.

Audit performance & evaluation

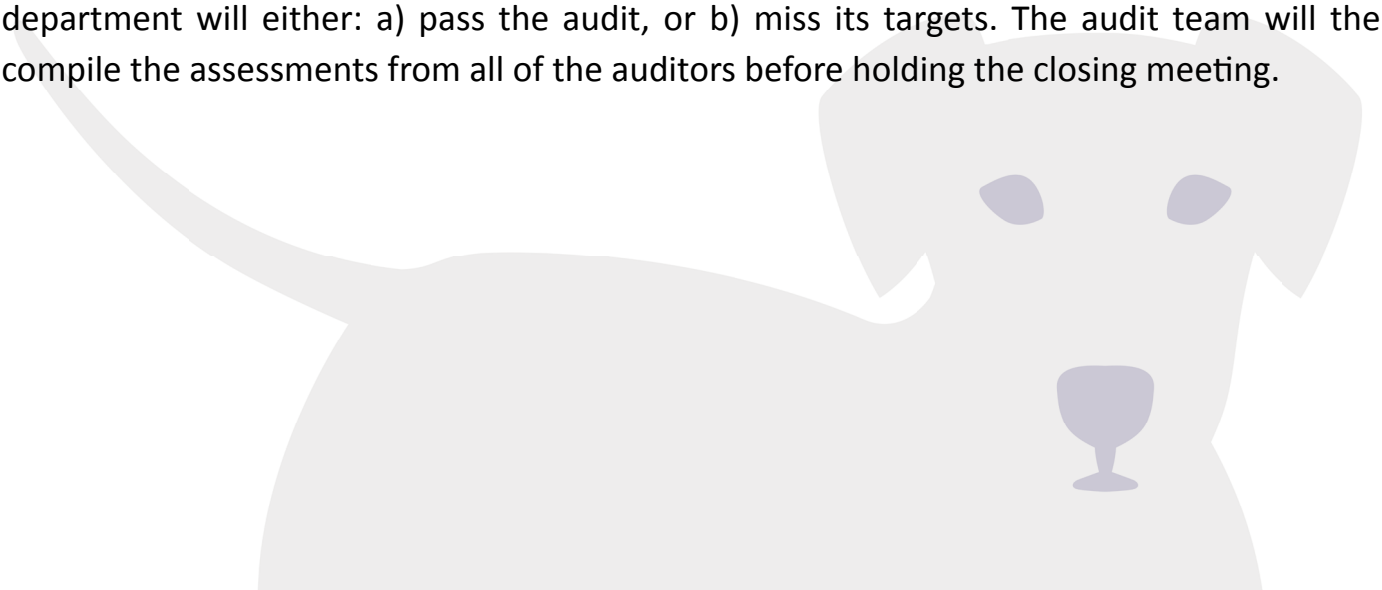
The day of the audit generally commences with an opening discussion. This is where the participating managers and the team can get to know the auditors. The discussion is usually moderated by the head of the auditing team and typically also includes the most senior unit manager (division/department manager) and their senior staff. In this meeting, the participants agree upon the premises, audit participants, schedule and main issues to be covered during the audit. It is then time for the audit itself.

The auditor is tasked with assessing whether the processes documented within the company are also reflected in reality. Based on the most recent audit and the procedural changes that have been made over the past year, the auditor begins his questioning. First of all, the auditor reviews the existing measures:

- Have the measures that were agreed upon in previous audits been implemented successfully?
- Are there any measures that were only partially implemented or not implemented at all, and is there a good reason for this nonconformity? Possible reasons are:
  - The measure will take three years to complete.
  - Requirements have changed to such an extent that the agreed upon measure is no longer sufficient.
  - The measure is no longer necessary, e.g. because the relevant product is no longer being produced.

At this point it is advantageous if the quality manager is well prepared, has access to the necessary documentation and answers the questions comprehensively. This is usually the start of the system audit. Workers who are directly involved in a particular process will then be interviewed by the auditors. Sometimes the auditors will look at customer surveys and use this feedback to submit an assessment of the situation. After the interviews, the team of auditors will usually withdraw to evaluate the answers before making their final assessment of the audited department. Based on the entire range of assessments for individual units, the audit results are then determined and classified.

The auditors can then compile the audit report. This contains the audit team's conclusions based on their findings from the preceding questionnaire. The sum of all evidence from the questionnaires and the resulting classification allows conclusions to be drawn regarding conformity or nonconformity with the relevant regulations. Based on this, the audited department will either: a) pass the audit, or b) miss its targets. The audit team will then compile the assessments from all of the auditors before holding the closing meeting.



In this closing meeting, the auditor will summarise the positive and negative points of the audit results to a group of pre-determined participants. Action plans will be created and specific measures determined for future changes. A points-based system for comparing similar processes is often considered a requirement for the audit result. The scoring system set out by the VDA (German Association of the Automotive Industry) in Volume 6.3, 2010 serves as a good example here.

Each question can receive either 0, 4, 6, 8 or 10 points. Points are awarded based on proven compliance with requirements (see table 1).

Points	Level of compliance with requirements
10	Meets requirements in full
8	Largely meets requirements; minor nonconformities *
6	Partially meets requirements; larger nonconformities
4	Does not sufficiently meet requirements; serious nonconformities
0	Does not meet requirements

* „Largely“ in this context means that more than 3/4 of all requirements have been met and there are no particular risks

Table 1: Scoring system according to VDA, Volume 6.3

The compliance level CX of a particular process element is calculated as follows:

X – Index for type and scope of the audit

$$C_X = \frac{\textit{Sum of all points awarded for evaluated questions}}{\textit{Sum of all available points for evaluated questions}} \; x\ 100\%$$

The audit result is based on the compliance level of the answers and is divided into three categories[1]:

A = 90% to 100%; B = 80% to 90%; C = < 80%

1 VDA Volume 6, Part 3 | Quality Management in the Automotive Industry – Process audit | 2010-06

Audit follow-up

However, all of this effort will mean very little if there is no record of where nonconformities occur, who caused them and why. This can include instructions for the implementation of corrective measures and deadlines for completing the tasks set out in the audit documentation

The audit documentation, which consists of the preparation documents and the audit report, will form the basis for the subsequent action plan. The audit report generally covers the following points:

- Process owner / audit participants
- Short process description
- Motive e.g. audit for DIN EN ISO / IEC 17025 certification
- Audit result
- Non-conformance with criteria (including justification)
- Deadline for completion of action plan or immediate measures to correct nonconformities
- Questionnaire with evaluation; references to valid documents in case of nonconformities

When the auditor identifies a nonconformity, the company will initiate measures to rectify it. The goal of CAPA is the sustainable improvement of all processes that were found to be lacking during an audit.

To conclude the audit, the auditor prints out the audit report. This must then be signed to show that all participants accept the results. In summary, an audit can essentially be divided into the following stages:

Fig. 3: The three stages of an audit

Conclusion & outlook

The general method by which an audit is carried out changes only in rare cases depending on the certification a company is trying to attain. Whether an audit is carried out according to VDA 6.3 (process audit in the automotive industry) or DIN EN ISO/IEC 17025 certification (standard for testing and calibration laboratories), the approaches are always similar on a fundamental level.

Most quality management audits involve testing in some way, shape or form, as their aim is to provide evidence for contractual agreements (e.g. certification audits according to ISO/TS 16949). Internal audits are another key part of a quality management system. In most cases, these audits are not merely used to verify compliance with particular guidelines, but rather to find suggestions for potential improvements. Employees who have to comply with various standards on a daily basis are perfectly positioned to provide suggestions for how they could be implemented more effectively. Each time these accompanying audits are carried out, their conclusions become more and more valuable.

As far as data is concerned, the key factors are documentation, changes made within the documentation and signatures which prove that processes, lists, deadlines and role distribution have all been checked. This data is modified every day by various employees so that everything remains up to date. By documenting all of these changes, a company proves that it does not merely pay lip service to quality as an idea, but that it actually lives up to this idea on a daily basis. The reward is a seal of quality such as the DIN EN ISO/IEC 17025 accreditation certificate. For a modern commercial enterprise, an investment in improving quality is an investment in a secure future.

Audit supported by versiondog

The data management system versiondog supports you in answering the following questions when it comes to an audit:

- How can companies efficiently prepare for an audit?
- How can the audit documentation and follow-up (which are at least as important as the audit itself) be carried out effectively within a short period of time?
- How can suggestions for improvement be documented and how can one keep track of their scheduled implementation?

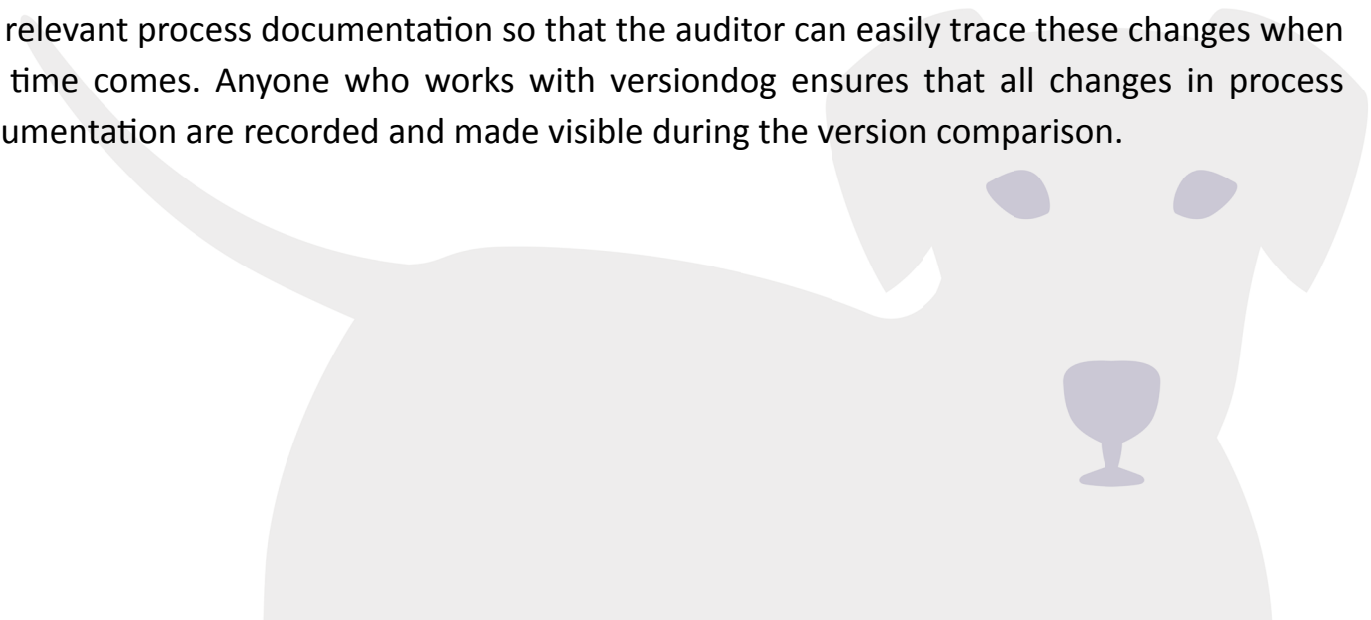
With versiondog, users can fulfil three key tasks:

- Data backup
- Versions control
- Documentation of version changes

The versiondog software is installed on a central server at the company and allows users to set up different levels of authorisation for all workers (internal, external, and auditors). Each worker receives a user client that they can use to download all data from the server, provided they have the required authorisation.

All of the documents required for an audit are managed in an archive on the server. With versiondog, changes will never go unnoticed, and all of the documents needed for the audit are available at a central location.

If workers make changes to certified processes at the company, then they must also change the relevant process documentation so that the auditor can easily trace these changes when the time comes. Anyone who works with versiondog ensures that all changes in process documentation are recorded and made visible during the version comparison.



That is how versiondog supports you during an audit:

- The auditor can clearly see WHO changed a process, WHEN they changed it and WHY the change was made. This means they can easily check whether or not the process described in the documentation is reflected in reality.
- versiondog goes one step further and shows the auditor the entire life cycle of a process in the company via a simple analysis.
- The benefit of versiondog lies in the fact that the auditor can draw conclusions regarding the quality development of production processes. This is because versiondog is designed not only to work with regular documents, but also to backup, version and document changes to software programs from the field of automated production and to take FDA and GMP requirements into account.

The standard features of versiondog provide support for quality management in the following ways:

- Maintaining Excel lists is time-consuming and inefficient. With versiondog, change management for Excel lists is fully automated and documented.
- The Windows file manager does not automatically meet audit requirements. versiondog, on the other hand, keeps track of who made changes to a document and when the change was made (across the entire life cycle of a document).
- Without proof that the two-person rule has been adhered to, the auditor will not be satisfied with process changes. versiondog allows users to implement and provide proof of the two-person rule during the versioning process.

If an auditor knows that a company uses versiondog to monitor all changes to its data, then he/she will take a different attitude to the auditing process and place more emphasis on the audit results, thus increasing efficiency and satisfying the main aim of an audit: to improve quality in the company. Documentation that would otherwise be very difficult to trace is now simple, without being an unnecessary distraction. When it comes to documentation, traceability and clarity are crucial for all subsequent steps…

Because if it isn´t documented, then it didn´t happen!

About AUVESY

versiondog from AUVESY (AUtomated VErsioning SYstems) is the world‘s leading version control & data management system for automated production. The company continues to grow steadily as it has since it was founded in 2007.

With a team of around 65 employees and 15 International Sales Partners, AUVESY has more than 700 customers in 40 countries and across the board of industry.

Hundreds of versiondog systems are right now safeguarding customers‘ data, simplifying their data management and helping them optimise their workflow.

versiondog- For more efficient production

versiondog is the leading version control and data management software solution for automated production. It makes tracking changes and safeguarding data significantly more efficient.

versiondog brings order and clarity where project data needs to be continually changed and made available from a central source. The increased safety, security and certainty provided by this software system quickly results in measurably increased productivity. versiondog makes it easy for you to optimise the interplay between all your different types of robots, controllers, field devices, drives, programming languages, file formats and software applications.

This data management system gives you ultimate data traceability, minimising your risks and costs, and saving you time and effort.

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