peak avenue

PERMANENT QUALITY IMPROVEMENT THROUGH eQMS

OPTIMIZED QUALITY MANAGEMENT

How to find the right eQMS solution for your company and successfully implement it

Content

1 Introduction

High-quality products and services not only ensure customer satisfaction, but also a company's success. However, to offer high-quality products or services you need good quality management system (QMS), which defines the set of well-established processes, procedures, and policies put in place to ensure that products meet quality standards.

And only good quality management can reliably ensure the quality of products and processes along the value chain, reliably.

This is where eQMS comes in, simplifying certain quality management processes and optimizing them. An eQMS analyzes, documents, monitors and controls work processes to avoid errors in the long term. In addition, the data which is collected is used to identify opportunities for improvement.

As in most cases, an eQMS is set up using individual modules that support various quality processes, such as initial sampling or complaints processing. If the individual modules are seamlessly integrated and share data, you get a powerful closed control information system that can be used for active process optimization.

Why you need a eQMS for product development

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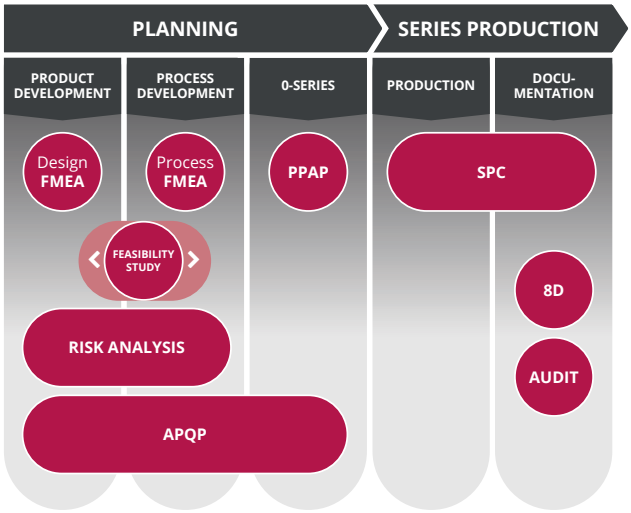
Every company wants its products and services to be of high quality and as flawless as possible. To achieve this objective, possible failures should ideally be eliminated during the product creation process.

An eQMS can support quality assurance in every phase of the product creation. As a rule, there is a separate module for each phase (e.g. for APQP, FMEA, complaints management, etc.), which efficiently supports each phase and greatly simplifies work processes.



The individual modules should not only work independently but they should also be linked and communicate with each other. In this case, all data is stored in a central location which each module can access when needed. This results in an eQMS that can consistently and reliably be used for the continuous optimization of products and processes.

The extent to which a company deploys the full range of features and functionalities of an eQMS depends on each company and the multidisciplinary team it supports. In many cases eQMS are available in modules which can be switched on as needed. Each individual module has its own advantages, which is discussed in more detail below. Please note, however, that the modules are far more extensive and have more advantages than we will list here.

Requirements management and feasibility study

The basis for finding the highest quality at the lowest cost is through the efficient advance quality planning. For this reason, a feasibility study is carried out to check whether the desired product can even be produced in accordance with the requirements management and feasibility study.

With a software-based feasibility study, you can create a digital catalog of questions for your own production/suppliers. Central data storage and central access enable smooth communication across the engineering and/or quality team working on the product. As they progress, comments, changes or additions – in essence, everything the team works on can be viewed at any time, is easy to follow and is always up to date. For a better overall overview, you can use checklists that are stored with each project and production phases, which simplifies the processes, and also saves you time and resources.

Why you need a eQMS for product development

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Advance product quality planning: APQP

APQP (Advanced Product Quality Planning) is used for continuous project management. The main aim is to avoid errors to optimize quality and improve compliance with all project deadlines, including delivery dates.

Digital APQP provides a complete project overview, which forms the basis for the successful start of series production(?) on a planned date. All project-related data (sub-projects, schedule, and cost overviews, etc.) is stored in a central location.

Detailed and structured documentation provides a clear overview. This allows deviations or problems to be identified at an early stage and countermeasures to be implemented.

Failure mode and effects analysis: FMEA

The FMEA is used to prevent failures and is intended to avoid product or process failures before they occur instead of having to rectify them afterwards. Traditionally, an Excel spreadsheet is often used to create FMEAs, but software-based FMEAs can considerably simplify many work processes.

A good digital FMEA will offer ready-made modules that make creating an FMEA quick and easy. Responsibilities for tasks can be assigned directly to team members, making it quick and easy to identify upcoming activities.

A great FMEA module is one linked to the inspection plan and the action and complaint management module, which allows repeat errors to be identified and avoided, knowledge to be retained, and products and processes to be optimized.

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Inspection planning and inspection equipment management

Preventing failures and detecting deviations is not just a matter for FMEA. Only the interaction of several components, such as inspection planning, inspection equipment management and the actual inspection, results in continuous and consistent quality assurance during product development.

An eQMS provides an exceptional advantage because data is stored centrally and component modules are all linked so failures are detected quickly and appropriate actions are assigned or initiated. The digital representation of all processes means that upcoming tasks, inspections and their results are clearly visible.

Initial sample inspection report

The initial sample inspection report checks whether in-house manufactured or supplied parts conform to the required quality, are free of defects and meet the required specifications. Close cooperation between customer and supplier as well as clear and well-functioning communication are essential for successful implementation.

The main advantage of a digital initial sample inspection report is that all processes are organized, fast and transparent. The drawings can be easily edited and updated, and target values can be read out electronically and transferred to the measuring machine. The measuring machine then supplies the actual values to the initial sample inspection report.

The central saving of all data also ensures simplified and smooth communication and an up-to-date status that can be viewed by all parties involved at any time.

Why you need a eQMS for product development

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Incoming and outgoing goods inspection and In-process inspection (SPC)

During the **incoming goods inspection**, it is essential to ensure that the delivered parts are flawless. Any quality defects that are already present on the incoming goods will otherwise affect the entire production process and reduce the overall quality of the product.

The reliability history of a supplier should determine how often their deliveries are subject to random sampling and inspection.

With a digital eQMS, the procedure for sampling and dynamization can be defined in the inspection plan to optimize the inspection effort. The random samples can be triggered automatically via an interface to the ERP or PPS system.

If the eQMS is also linked to the supplier evaluation module, it is easy to see which partners offer consistent quality and are particularly reliable. This makes it easier to select a suitable supplier.

In the event of deviations, the In-process inspection (SPC) can be used immediately to determine suitable measures and internal complaints.

To ensure that the customer receives their goods in the expected quality, an **outgoing goods inspection** is carried out to detect any failures or deviations.

Various methods and techniques are available in a eQMS for the final inspection. If a failure or deviation is discovered, it can be processed directly as a complaint and an error analysis can be initiated.

Why you need a eQMS for product development

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Complaints management

An effective complaints management system is characterized by a quick response and smooth processing when a problem or complaint arises.

Complaints can be created, processed and tracked quickly and easily using software-based complaint management. With the help of already integrated and proven methods (e.g. 8D), the complaint management tool provides you with optimum support for error analysis and problem solving and allows you to plan the necessary measures immediately afterwards.

The central database helps to ensure that identical or similar complaints are quickly identified and points directly to the appropriate solution. By linking with the other modules (e.g. APQP, FMEA, etc.), you obtain a continuous quality control loop.

How to find the right eQMS for your company

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To find the right quality management software for your company, thorough preparation is necessary. This is the only way to select the system that really meets your requirements from the wealth of offers available in the market. To make it easier to compare the various eQMS and their modules, you need to define all the important requirements in advance:

Define your requirements for the eQMS

You can only find the right product if you know exactly what you want and need. To simplify this point, collect all the important figures, data, and facts about your company. For example, think about which locations the eQMS should support, and which interface languages should be available accordingly.

Include the individual departments and note their requirements for the future eQMS. In addition to the company-specific requirements, also consider the industry-specific requirements and certification standards. To ensure a smooth integration, you should also consider the existing IT infrastructure.

What functions should the eQMS have?

Once you are clear about what your company requires from the new software, the next step is to look at the features you need from the future quality management system. Choose which functions and modules are particularly important to you.

MODULAR STRUCTURE

A modular structure is ideal for a eQMS , which can be flexibly expanded in the future and adapted to your requirements. This type of structure enables you to start with only those features that are necessary for your processes and to expand them at any time as required.

CENTRAL DATABASE

The advantage of a central database is that all master data, drawings, and process-related data are stored and versioned in one place. This creates seamless documentation, and all processes and changes can be traced at any time. It is also recommended that the eQMS guarantees data consistency. This means that all eQMS modules access the same the same up-to-date data.

To track modifications between the individual versions, all technical changes should also be documented automatically.

How to find the right eQMS for your company

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INTERFACES

When selecting a eQMS, consider whether it can connect to your ERP or MES system. It is an enormous advantage if master data can be managed via a central interface. Feedback from the eQMS via a bidirectional interface should also be possible.

To transfer measured values smoothly into the eQMS, it makes sense if measuring machines and electronic measuring equipment can be integrated without any problems.

INTEGRATED DRAWING

Some eQMS offer features that allow the import and ballooning of a technical drawing, which often contains important product specifications. This important time-saving feature has many other benefits specially when the software identifies the characteristics and requirements and links them to the technical drawing. This means that the drawing can be used at any time throughout the eQMS for further process steps. By versioning the technical drawing, changes can be easily mapped in the system and tracked at any time.

APPLICATION OF THE PDCA PRINCIPLE

Ideally, the entire eQMS should apply the Plan-Do-Check-Act (PDCA) principle in all modules. Under this principle, not only are individual processes planned, carried out and improved, but there is also a feedback flow (e.g. complaint data in the FMEA), which helps increase the quality of future products.

Make sure that the experience gained is recorded in the central database. In this way, you build up an internal knowledge store for your company, which you can use to continuously improve your products.

CENTRALIZED ACTION MANAGEMENT

Centralized action management has many advantages: If it accesses all modules that contain actions, you get an optimal overview of all actions as well as their status to easily track progress.

By analyzing actions and progress performance you can optimize resources and schedules to improve productivity.

If deadline monitoring is actions, reminders or warnings are automatically generated which helps keep the quality and engineering teams on track.

How to find the right eQMS for your company

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GOOD COMMUNICATION

Fast, simple, and clear communication along the entire supply chain is particularly important for maintaining the quality of your products. For this reason, a web-based communication platform via the eQMS is a great advantage.

This means you always have a good overview of all processes and agreements and can not only contact your suppliers quickly and easily, but also involve them directly in quality processes and actions.

EVALUATION AND ANALYSES

Pay attention to the analysis options offered by the eQMS. If, for example, it can evaluate key fault areas from the collected data, you can take targeted countermeasures to remedy faults.

What about customized reports? Ideally, templates for standard reports (e.g. 8D) are part of the eQMS, and you can also create company-specific templates yourself.

CREATE A REQUIREMENTS CHECKLIST

A requirements checklist for your eQMS is where you record all the requirements and functions that are important for your company. It contains all the decisive criteria regarding the functionality of the individual eQMS modules.

With a checklist, you can keep track of the key aspects and compare the different eQMS more easily.

You can find out more about the requirements specification and how to create a checklist in the next chapter.

The creation of a requirements checklist

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A requirements checklist is indispensable for a successful eQMS project. The checklist not only makes it easier for you to select a suitable eQMS easier, but it also shows what you should expect from the future software.

To get the best product fit for your needs, it is also important to add to the requirements checklist all other relevant information, such as the current status or starting point of your eQMS, and a list of “nice to have” features and functionality for the future software.

The creation of such a checklist is now considered indispensable for software projects. Take the opportunity to describe your individual requirements for the software in detail and in a targeted manner. However, make sure that it is clear which expectations must be met and which are optional. Only then can your eQMS project be implemented realistically.

Create the requirement checklist at an early stage

You should prepare the checklist as early as possible in the project planning. On one hand, this will make it clear what you need, which will help you select a suitable provider more easily. Secondly, the selected provider can refer directly to your checklist when responding to your proposal.

It is quite possible that your list of requirements will change over time and only gradually become clear what your actual requirements are.

If your eQMS is a particularly comprehensive project, we recommend that you consider taking on the requirement checklist as a separate project.

The creation of a requirements checklist

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10 guiding questions for the successful creation of specifications

Preparing a requirement checklist seems more complicated than it is. However, there are several aspects that should be taken into consideration to make it as detailed as possible. Below we have listed some questions that you can use as a guide for creating your checklist:

1. WHAT IS THE CURRENT STATUS?

Describe your current situation and how the project idea came about. What problems are you facing? Are you pursuing a long-term corporate strategy that needs to be considered? Why is there a need for action?

2. WHAT ARE YOUR OBJECTIVES?

What do you want to achieve with the eQMS project? How do you want to measure your success? Make your goal measurable with fixed key figures. What are the dates and deadlines that must be met during implementation? If you set interim targets or milestones, you can see whether you are on the right track.

3. HOW ARE INDIVIDUAL PROJECT PHASES OR MILESTONES ORGANIZED?

By dividing your project into phases and defining milestones, you can maintain a better overview of your project progress. Create clear phases with measurable milestones. The Specific, Measurable, Assignable, Realistic, and Time-bound (SMART) principle can help you with the formulation.

4. WHAT IS THE PRODUCT DESCRIPTION?

Only eQMS whose modules are fully interlinked and which is not an isolated solution is truly effective. Describe which components you need, and which systems are already in use and should be replaced or linked. Also consider possible modules or systems that could become more important in the future.

5. WHERE IS THE EQMS USED?

Clarify the framework conditions under which the product will be used. In which departments will the eQMS be used? Describe where the software is to be implemented and do not forget that the users must be trained accordingly.

The creation of a requirements checklist

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6. WHAT ARE YOUR FUNCTIONAL REQUIREMENTS?

What functions should your eQMS modules have? Distinguish which functions are necessary and which are optional. What should diagrams and reports look like and what are your documentation requirements? A sketch of the technical basics could also be helpful.

7. WHAT NON-FUNCTIONAL REQUIREMENTS DO YOU HAVE?

In addition to the functional requirements, the non-functional components must also be considered. What expectations do you have in terms of maintenance? Would it be possible to expand or change the software? What user interface do you envision? Who should be responsible for operating the system? What is the scope of any external support?

8. WHAT SHOULD BE INCLUDED IN THE DELIVERY SCOPE?

At this point, describe exactly what you expect in the delivery scope and what you do not want. By when should the finished eQMS be delivered? It is also important to determine which components may be supplied by other providers. In this case, requirements and compatibility must be checked.

9. WHAT OPEN POINTS STILL NEED TO BE CLARIFIED?

There are always changes during a planning process. Determine how decisions are made in the project and how changes find their way into the requirement checklist. Also make a note of which questions are still open and will only be clarified over time and who is responsible for them.

10. WHICH ACCEPTANCE CRITERIA AND QUALITY REQUIREMENTS SHOULD BE DEFINED?

Determine how the project will proceed. Which tasks fall under the responsibility of the project management, and which fall under the project team ? Which committees should progress be reported to? How will success be monitored and who is responsible for monitoring success? This is also the place to define the quality conditions.

> Creating a requirements checklist is an extensive task and not always easy. Nevertheless, you should not do without one under any circumstances that contains everything important as clearly and comprehensibly as possible. A well-drafted requirements checklist is the best chance of getting what you really need in the end.

What a specification should contain

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The specification is the contractor's response to the client's requirements checklist. In the functional specification the contractor defines the requirements from the client's checklist and describes in detail the framework within which concrete implementation is possible.

A good functional specification can support the smooth implementation of eQMS . Once the client has accepted the specification, the implementation can be carried out by the contractor.

9 points that belong in a well-defined specification sheet

By defining specific objectives and the type and scope of the desired eQMS, you can secure yourself and your contractual partner. Each party therefore knows what is expected and what service is to be provided. That's why the specifications sheet should contain all relevant information for implementation.

Based on the requirement checklist, a functional specification should contain the following:

1. GOAL DEFINITION

As the client, you have defined your objectives in the requirement checklist. At this point, the contractor should confirm whether your objectives are feasible or whether they need to be re-defined into realistic and achievable objective. The software provider should also state which of the stated requirements the product will not fulfill. This will clarify the agreed deliverables between you and your contractual partner.

2. PROJECT PHASES AND MILESTONES

The contractor can agree and confirm the goals and milestones you have specified or make suggestions for changes. In this case, they will explain why a different structure makes sense from their point of view. An in-person conversation can be very helpful for this purpose.

3. PRODUCT OVERVIEW AND PRODUCT ENVIRONMENT

At this point, an overview of the main features of the product should be recorded. This also includes the product environment, which lists which operating systems and databases are already available. In the technical product environment, the software provider lists the specific conditions under which the product will be used. This includes Hardware, software, and interfaces as well as information on which other applications the product will be linked to.

What a specification should contain

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4. DATA PROCESSING

In this part of the specification, the software provider describes which data is processed and how. The description is split into two parts: a more simple non-technical explanation, and a technical version. Ideally, the explanations are presented graphically using diagrams and models to make them easier to visualize and understand.

5. LOCATIONS WHERE THE SOFTWARE IS TO BE USED

As the client, you have already determined in which departments of the company the software is to be used, in which areas of activity it is required and in which process step it is to be implemented. The contractor takes these specifications and adds technical details as required.

6. FUNCTIONAL REQUIREMENTS

In the requirement book, you described exactly which requirements and functions you expect from the eQMS and which functions are optional. At this point, the software provider should describe in detail which of these functions the eQMS contains and how they are implemented. In addition, the corresponding access rights and roles are defined.

7. NON-FUNCTIONAL REQUIREMENTS

All requirements that are not related to functionality are recorded here, such as legal issues, prescribed standards, or maintenance regulations. In addition, the user interface of the eQMS and its usability can be presented here.

8. SCOPE OF DELIVERY

Under this point, the software provider can describe the scope of the service and the date in which it is to be delivered. Ideally, your wishes from the requirements checklist should be have been fully met. Nevertheless, you should check carefully whether the scope of delivery meets your requirements.

9. ACCEPTANCE CRITERIA

Based on the requirement checklist, the quality requirements of the eQMS are defined here, including any test runs which must be carried out before acceptance in order to ensure a smooth introduction of the software.

> After successfully creating a requirements checklist and the functional specification, the most difficult steps have already beed acomplished. At this point, you know what you want and have agreed with the provider the scope of delivery and have chosen the eQMS. The next step is the introduction of the eQMS into your company.

What you should consider for a successful eQMS implementation

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The successful implementation of a eQMS depends on much more than the mere purchase, installation, and configuration of the software. To achieve a sustainable solution, you should systematically approach the entire project from start to finish.

Our experience has shown us where failures are repeatedly made, what is forgotten or where expectations are simply too high. We have put together some helpful tips to help you successfully implement your eQMS:

Tips for software implementation

THE ANALYSIS

Before you start looking for the right eQMS, you should take the time to carry out a comprehensive analysis of the current situation. It is often clear where there is potential for improvement, but not what optimization should look like in concrete terms. You should therefore carry out a comprehensive cause analysis. Collect various pieces of information from all stages of the current product life cycle and analyze the origin of the problems. Only when you know which tool is required can you eliminate the problem and determine what an optimization should look like.

THE SMART PRINCIPLE

The most important thing in any project is to have clearly defined goals. This is often not so easy. That's why the SMART rule is particularly suitable for setting the right goals. With this principle, you formulate specific, measurable, attractive, realistic, and time-bound goals.

You should also create a roadmap, which you can use for regular check-ups to determine whether you are still on the right track. Under no circumstances should you neglect to draw up a detailed specification sheet. This makes your wishes and requirements clear and thus provides a reference point for the right solution concept.

RESOURCE AND CAPACITY ALLOCATION

However well-designed, the software can only be truly successful if it is operated by someone who is familiar with it. For this reason, it is important that you also think about training the relevant employees and ensure that all users involved are familiar with the operation and methods of the software according to their areas of responsibility.

What you should consider for a successful eQMS implementation

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The same applies to the eQMS project itself: You need a project team that is well versed in the relevant topics. Make sure that your employees either can incorporate the additional work into their day-to-day routine or, if necessary, give them time off to do so. This prevents too much pressure being applied on the project team and allows them to concentrate better on the core issues at hand.

COMMUNICATION

No matter what it's about, communication is usually the be-all and end-all! This also applies to the eQMS project. Of course, it is particularly important to talk to the eQMS supplier about what you want and how possible problems can be solved, but you must not forget your own employees!

To achieve good acceptance of the upcoming changes, you should inform your employees about the background and objectives of the software project at an early stage. Keep them up to date on any progress or changes.

To give the whole process a structure, you should plan meetings and determine who should receive what information and when. For a better overview, keep a record of the exchange of information.

THE DOCUMENTATION

Even if it may seem unnecessary, the documentation of a project is a basic component that should not be ignored. It happens time and again that the person responsible for a project changes or new employees join the team during the ongoing process. When the project documentation is complete and available, the relevant people can quickly familiarize themselves with the project, thereby preventing possible delays.

To ensure that the documentation is as detailed and easy to understand as possible, consider which documents are advantageous for quickly getting to know the project.

THE SUPPORT

Don't be afraid of external support. Nobody expects you to have detailed knowledge of all areas of the eQMS project – especially if it is something completely new. Also consider the amount of time you will have to invest in the project and the other tasks that will be left undone instead. If the effort required to familiarize yourself with the new project on your own is too high, the help of an external specialist can be extremely worthwhile.

An external expert can not only provide you with advice, they can also provide an outside perspective to ensure that you don't lose sight of the actual goal. In addition, most software suppliers also offer helpful and supportive services such as workshops and training courses.

What you should consider for a successful eQMS implementation

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THE EXPECTATIONS

Remember that eQMS alone cannot solve all problems, but only serves as a tool for problem solving and process optimization. Always question routine processes critically and find out how they can be optimized with the help of the eQMS.

Furthermore, you should not place all the burden on the shoulders of your software supplier. Stay in communication with the supplier and maintain a partnership-based relationship. This means that you will work closely together and solve any problems that may arise through open and friendly interaction.

You should also expect problems! Rarely does everything run like clockwork – in most cases, obstacles arise from time to time, but these can usually be overcome and do not immediately put the entire project at risk. It is always better to start with a solution that is not quite flawless and to continuously develop and adapt it than to wait for a perfect solution that may not even exist.

It is therefore best to try to keep your expectations as realistic as possible to avoid disappointment and stay calm if things don't go quite as planned.

> The digitalization of quality management and the resulting introduction of a eQMS are the first major steps towards simplifying processes and optimizing the quality control loop. If everything is well thought out from the outset and the various demands and requirements are precisely defined, the successful introduction and use of your eQMS will ensue.

Your path to successful eQMS implementation

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As the industry leader in eQMS, PeakAvenue supports companies in optimizing their quality processes. Our modular software solution offers customers worldwide specialized standard software for daily business and production processes. Through regular further development of our software solutions, we ensure close integration with users from the field and their needs.

With the digital transformation to Industry 4.0, you achieve a return on investment from day one! Utilize valuable data, e.g. from your initial sampling and action management, to identify optimization potential in your value chain – transparently, consistently, and globally accessible.

Increase your competitiveness by improving processes along the supply chain.

How is your quality management?

Use the QR code below to arrange your free eQMS consultation with one of our experts and find out what optimization potential exists in your quality control processes!

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