Operational QMS

2022

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EQUMAS

Several of EQUMAS' core features include, inter alia:

- All-in-one quality management
- Unified data model
- Adaptive document building process
- Integrated record generation
- Smart AI platform

Manufacturing requires complex administration and infrastructure to support it. Yet, most existing platforms lack key features, forcing users to fill in the gaps with paper-based operations, thus lead to serious complications, because paper-based operations are prone to error and data loss. Their ad-hoc nature makes it difficult to analyze data and spot problems. In manufacturing, this can potentially create costly or even life-threatening problems.

Our solution, EQUMAS OQMS, designed and developed with manufacturing focus, integrates every aspect of the production process into a single smart platform. It handles all data and actions, from employee training to deviation detection, to submitting documents to the FDA.

Ultimately, this approach creates a smarter, safer, more efficient, and fully compliant way to operate. Our unique, all-in-one smart platform is enabled with bona fide AI functionality that can detect mistakes before they are made, allowing users to operate with lower levels of deviations.

All-in-one Quality Management

QMS Operational Quality Management System

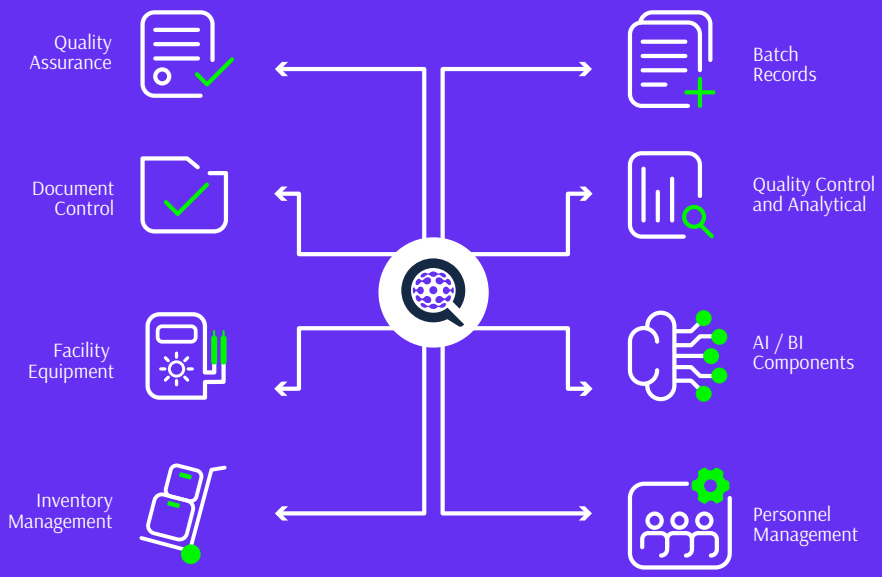
Many small and medium sized manufacturing companies still use paper for their operations. Not only is this practice outdated, it is also inefficient and unsafe. Storing records on paper creates many deficiencies resulting in errors and data loss.

Businesses are hesitant to modernize due to the perceived high cost of digitalization. Typically, they can't adopt just one new platform- they have to pay for and implement several separate applications to do their job. Even then, constant updates and bug fixes lead to never-ending maintenance worries.

Some businesses partially digitalize, while leaving other parts of their operations paper-based. This approach leads to significant disconnection in their overall operations, making room for all sorts of errors. It also makes it more difficult to analyze data, because disparate information sources create difficulties in information integration.

Our EQUMAS OQMS platform solves these problems with its flexibility, adaptability, and interconnected modular design. EQUMAS can add and subtract its various features, much like mobile apps, so you can get the right mix of programs that you need. Instead of juggling many different systems, you only need to use one system in order to handle your quality management while staying compliant.

Our Solution



Our software architecture contains a data layer, a service layer, and a design pattern. Having separate data and service layers means that you can keep your data while changing the overall functionality of the platform- you can plug in and plug out systems while keeping your data intact.

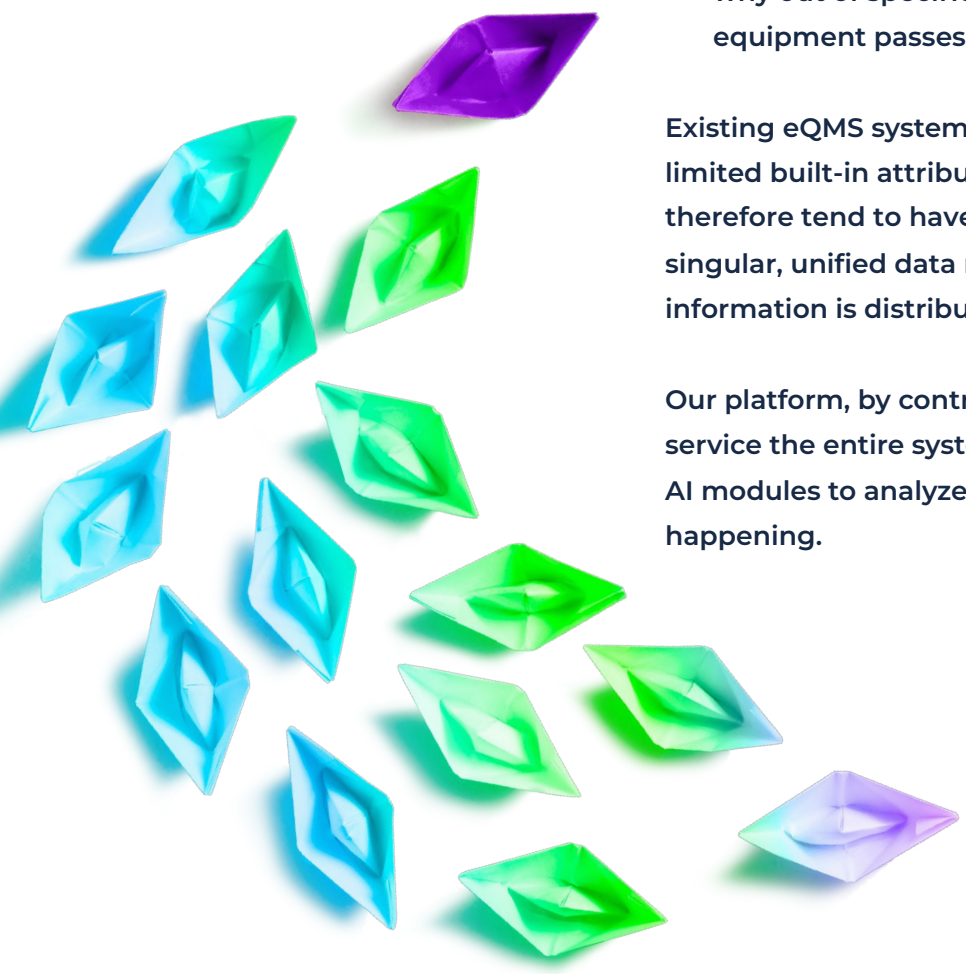
Having a microservices architecture means that different programs can easily be pluggedin like Lego bricks. Instead of multiple separate programs with different structures, you get a unified platform that can handle all of your needs. For example, if you have an ERP, you can bypass the existing inventory module and plug it into our system.

With this approach, you can digitize your operations the way you see most fit for your needs, adapting the EQUMAS OQMS to your specific operational needs.

One Data Model for Good Manufacturing Practice (GMP)

Quality assurance and continuous improvement play a significant role in GMP production. However, many features of the process can behave unexpectedly and be difficult to understand. It can be hard to tell:

- why certain deviations take longer.
- why certain procedures cause more deviations.
- where improvements can be made.
- why out of specification (OOS) happens even though equipment passes calibration services.



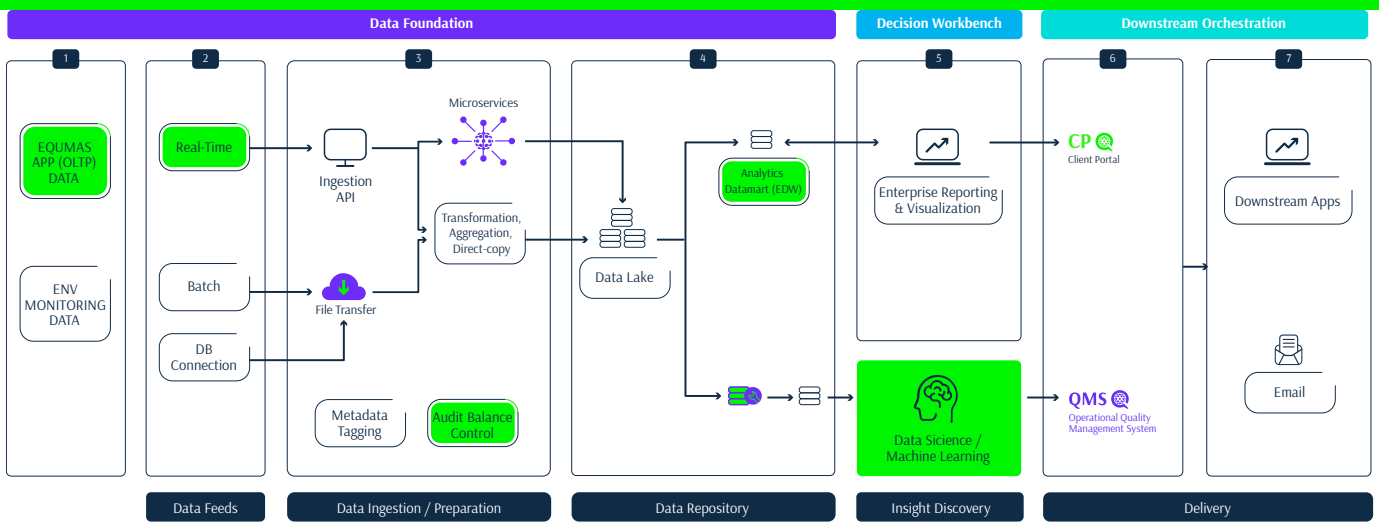
Existing eQMS systems or paper-based operations have limited built-in attributes for machine analysis, and therefore tend to have a poor functionality. They lack singular, unified data models for AI to analyze, because their information is distributed across multiple modalities.

Our platform, by contrast, uses one integrated data model to service the entire system. This allows us to plug in additional AI modules to analyze the data and understand what is happening.

Our Solution

Our unique data model governs over 1500 business attributes that cover every aspect of the operational process. With this unique data model, we are reinventing the collecting and auditing approach.

This solution pulls data from multiple systems and loads it into a single data lake. This way, the application can identify bottlenecks and gather information, without having to look at multiple sets of data.



Adaptive Document Building Process

In most GMP operations, production and quality assurance is still paper-based. Most existing digital solutions are not flexible and cannot adapt to different manufacturing functions. Adapting these solutions to quality assurance tends to be complicated and counterproductive.

Additionally, when customers need changes in these shelf-ready solutions, the existing programs simply cannot adapt. Instead, customers find they have to change their operations to fit the software, wasting time and resources in constructing a system that is prone to errors.

Our unique document building approach puts customers in the driver's seat. It adapts to your operational needs, making EQUMAS OQMS fit the unique properties of your operations. This minimizes and reduces business interruptions during digitalization, streamlining your entire process. Our platform simply fits into the gaps and weak points of your existing system.

Another common manufacturing problem is the need to communicate in real time: adding comments, initiating deviations, and more. Our platform enables cross-team real-time communication, facilitating greater intra-operational capability.

Our document building technology is further enhanced with templates that can be easily adapted to regulatory submission formats, such as eCTD. This means you don't have to take any extra steps to prepare data for regulatory submission, saving you precious time that can be put into other aspects of your business.

Our Solution

Our unique document building approach puts customers in the driver's seat.

With the flexibility of the Design Pattern technology, combining various software technologies, our solution provides you with the flexibility you need. Using an html interface, users can easily create dynamic do-it-yourself forms by dragging and dropping components. Each document can be saved as a template. This allows teams to build off of their previous work and maintain consistency.

With this approach, EQUMAS OQMS can:

- Decide where to cut the process
- Accelerate document creation
- Ease FDA submission
- Facilitate real-time communication

Integrated Record Generation

EQUMAS focuses on heavily regulated industries, like biological production and manufacturing. This type of GMP production has complex inner workings, many of which are sensitive and must not be done incorrectly. Each internal component must be independently managed and maintained, but all must be integrated for the final release, and all must go through the same quality assurance process.

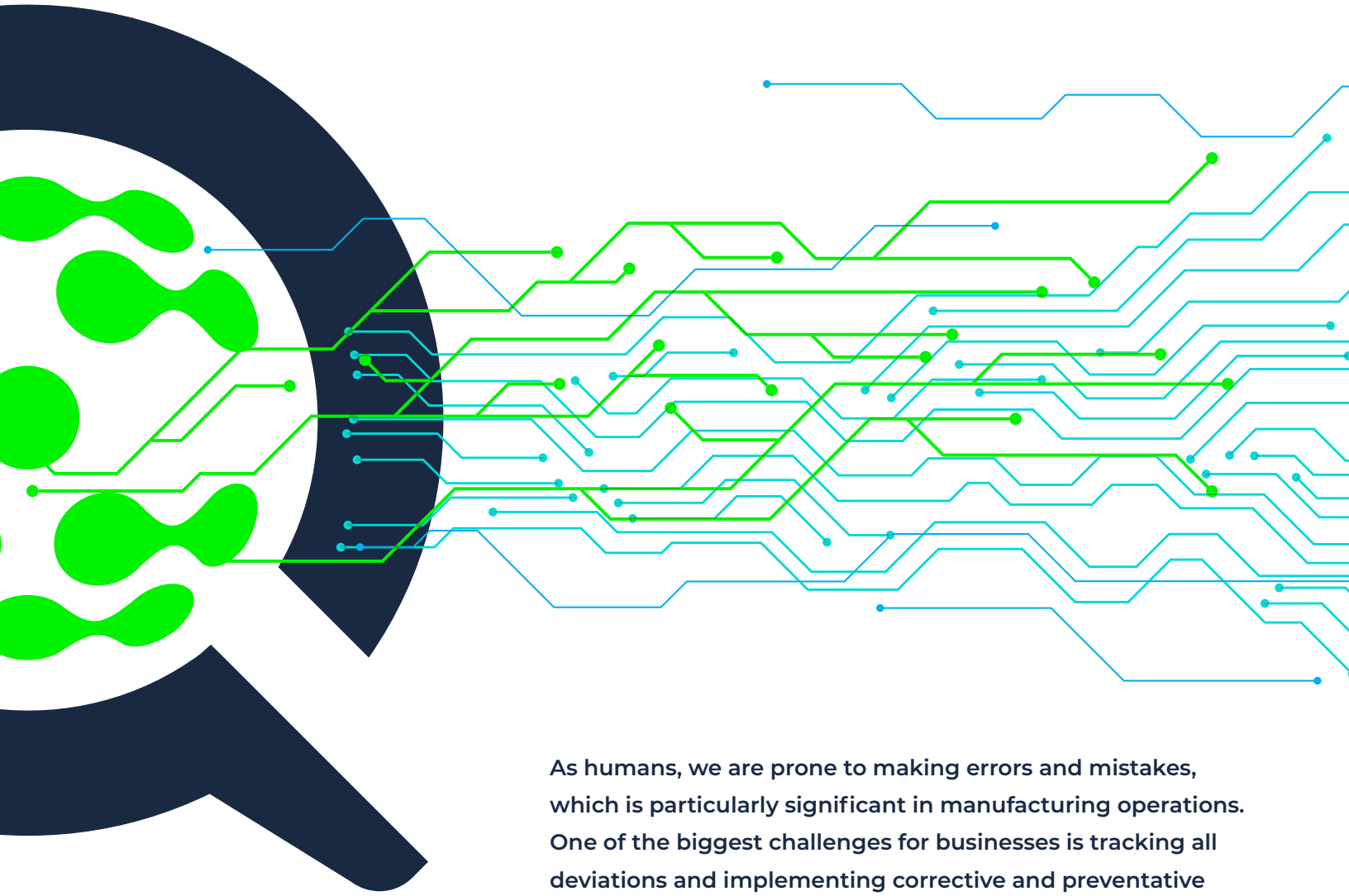
Most existing electronic QMS platforms do not capture all of these independent components; they do not control inventory, equipment, personnel, and QA, all in one place. Therefore, most existing production companies still rely on paper, setting themselves up for errors and mishandling. Our approach creates interconnected modules that allow for independent inputs and controls, and also integration when necessary.

Our Solution

With our approach, users can apply conditions and controls to multiple aspects of an operation independently. This reduces the chances of deviations and other non-compliance issues at the final product release stage. For example, our solution can:

- Force users to complete qualification trainings prior to performing their manufacturing job tasks.
- Forbid utilization of expired materials.
- Trigger calibration / maintenance events before they are due.

Smart Platform



As humans, we are prone to making errors and mistakes, which is particularly significant in manufacturing operations. One of the biggest challenges for businesses is tracking all deviations and implementing corrective and preventative actions to prevent the same deviations from occurring again.

Most existing eQMS and paper systems passively maintain deviation records. They do not actively help workers find bottlenecks and identify problems. Our system employs a next-generation AI solution. It looks ahead to prescribe actions when encountering incidents.

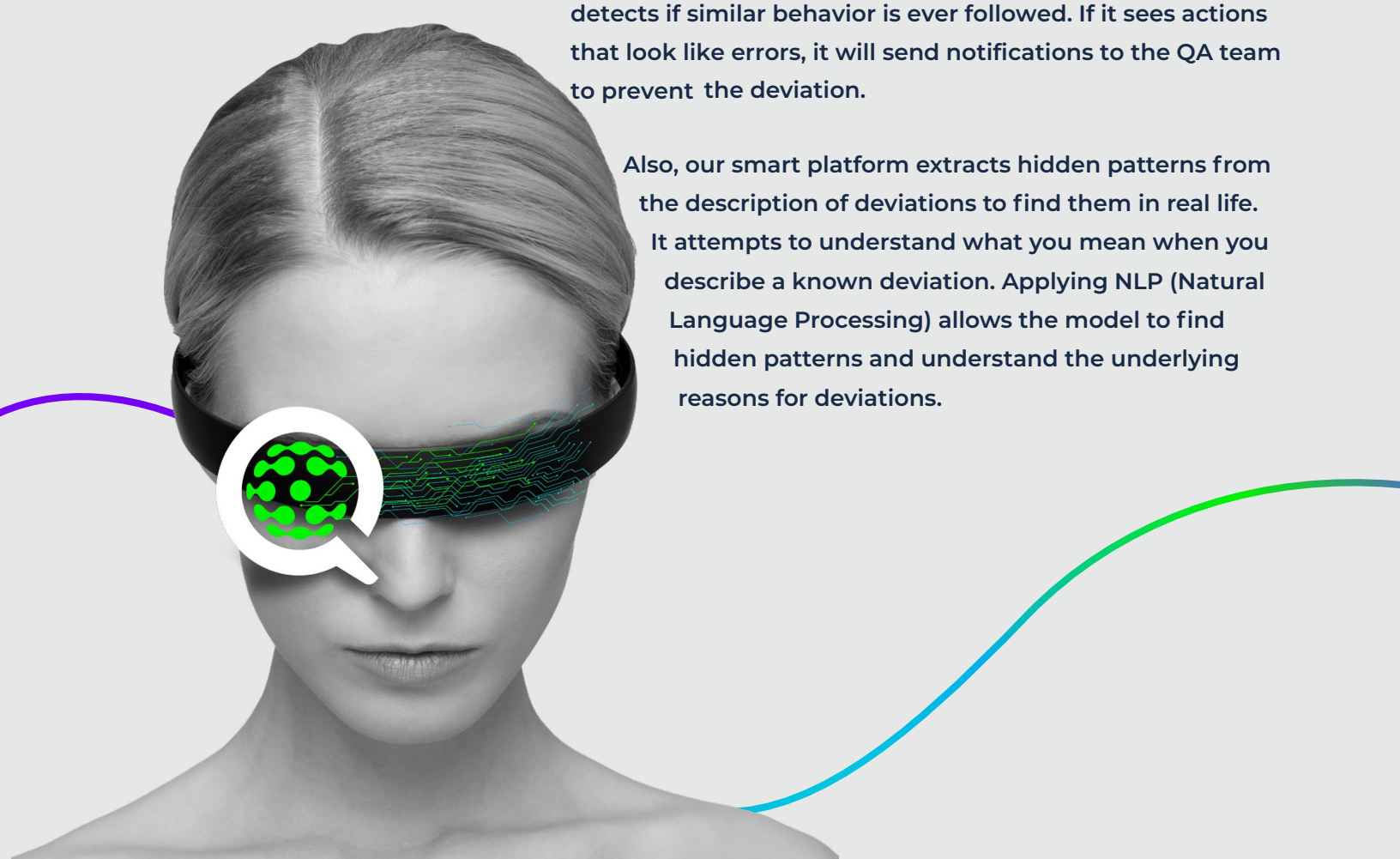
Our Solution

We have perfected our AI models to perform well when trained, even on small data sets. Once certain conditions are met, the AI takes action. An embedded chat bot (Q-friend) sends an automated message to inform the Quality Assurance team about potential deviation risks before they occur.

Deviations can happen anywhere, and at any time. That is why it is crucial to have one data model that can access all of the information about the entire system; hence our one data model for GMP. Our model tracks the deviation lifecycle, collecting over 1500 data points to train the AI.

Once the AI model is trained, it learns from errors and detects if similar behavior is ever followed. If it sees actions that look like errors, it will send notifications to the QA team to prevent the deviation.

Also, our smart platform extracts hidden patterns from the description of deviations to find them in real life. It attempts to understand what you mean when you describe a known deviation. Applying NLP (Natural Language Processing) allows the model to find hidden patterns and understand the underlying reasons for deviations.



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We look forward to understanding
your operation and QMS needs.

Request a demo!

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