



CAPA SIMPLIFIED

THREE-STEP TO SIMPLER, MORE EFFECTIVE QUALITY

An eBook Guide to Help Mid-market Companies in Regulated Industries Improve their Quality and Ensure Compliance

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INTRODUCTION



Let's face it. The volume and complexity of quality regulations isn't lessening—and there's nothing to suggest it will get easier to comply anytime soon. Whether you manufacture medical devices, pharmaceuticals, food products, jet engines, or automotive parts, tracking, identifying and resolving quality related incidents or events is critical to your business.

But how do you do it and where do you begin?

This eBook provides a short overview of key CAPA concepts, followed by a practical three-step guide to help show you how to implement a modern, simple and effective CAPA system.

OVERVIEW: KEY COMPONENTS

Effective CAPA management involves four main components: 1) Identification 2) Correction 3) Corrective Action and 4) Preventive Action. If you are missing any one of these four critical components, your CAPA system will be deficient or incomplete.

1 IDENTIFICATION



We see an issue

2 CORRECTION



We correct it

3 CORRECTIVE ACTION



We investigate it

4 PREVENTIVE ACTION



We stop it

OVERVIEW: CLOSED-LOOP CAPA



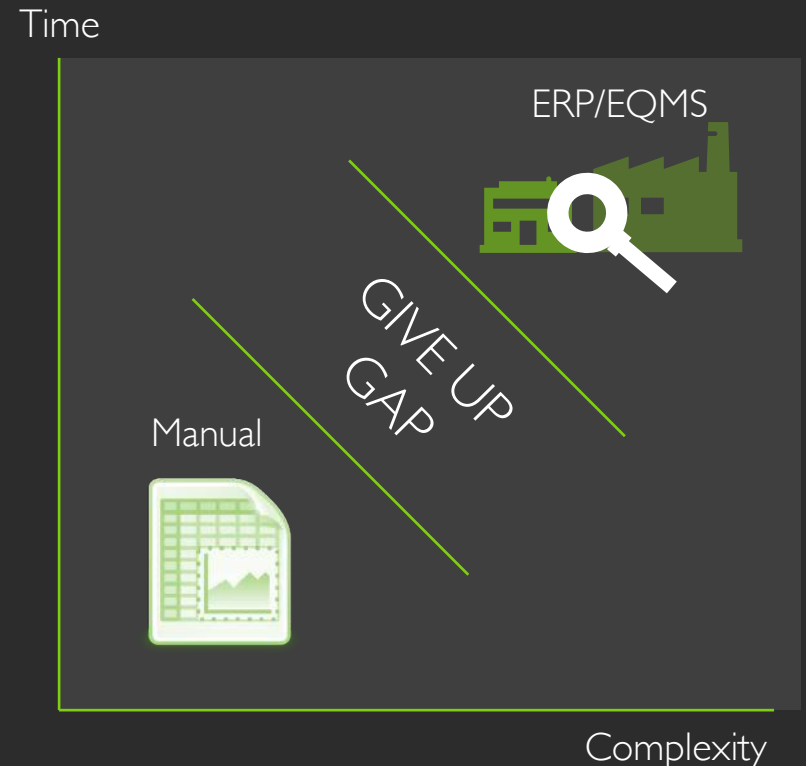
Experts agree that a centralized, closed loop CAPA system is most efficient and effective. A closed-loop CAPA system is simply a set of connected data and steps that form the basis of a quality management ecosystem.

By centralizing and automating these components, you'll be able to identify and respond to quality events sooner, reduce quality costs and improve production quality.

OVERVIEW: TECHNOLOGY

For most companies, the practicality of implementing a heavy enterprise CAPA system has simply been prohibitive. It's too expensive. It's too complicated. It takes too long. As a result, most companies give up and resort back to manual systems.

A new generation of agile cloud-based solutions have emerged, providing businesses with a faster, simpler alternative to bloated enterprise software deployments. Agile and fast, the solutions can be configured and re-configured by non-technical end users. Because of their configurability, users can also start simple and build out additional functionality over time, often starting with CAPA management.



OVERVIEW: CORE ELEMENTS

While the degree of complexity can vary greatly between organizations, the basic elements of an effective CAPA system and solution breaks down into three core areas. 1) Collecting quality data accurately and efficiently. 2) Analyzing that data to identify incidents or events that demand attention or action. 3) Taking the appropriate actions to correct or prevent those incidents or events.

ACQUISITION



FAST, SIMPLE COLLECTION

Structured forms using mobile devices, tablets, phones.

ANALYSIS



REAL-TIME VISIBILITY

Data instantly centralized in one place; Real-time reporting.

ACTION



STREAMLINED WORKFLOW

Automated workflows and task assignments. Triggered instantly.

THREE STEP CAPA SOLUTION

1 Centralized Data



2 Real-time Discovery



3 Automated Action

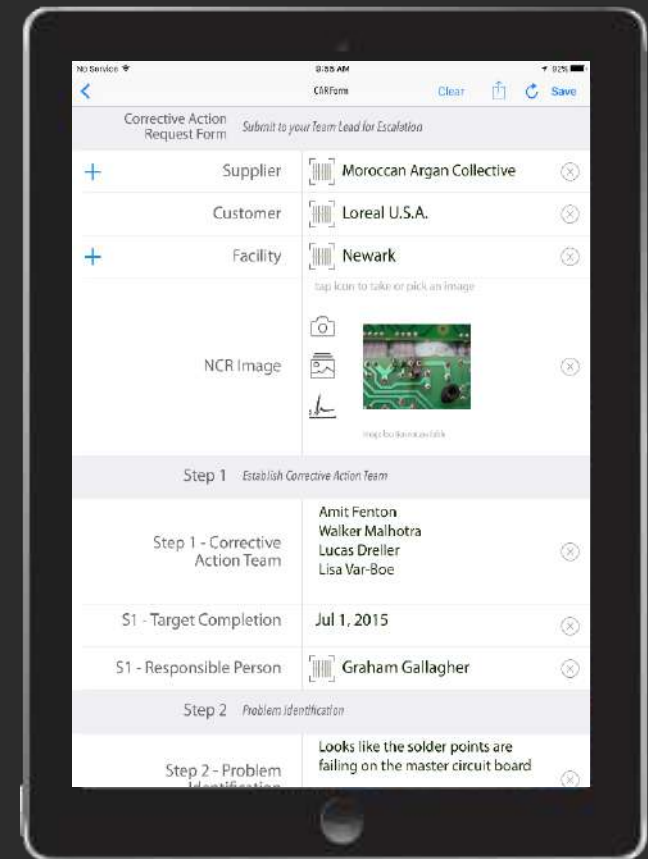


STEP I: CENTRALIZED DATA

Create a Centralized CAPA System

The first step is to begin centralizing all your critical quality data into one place, eliminating overlap between sites, departments or even individual workers. Instead of writing data on a paper form and re-entering it manually, enter it directly into a centralized system. That way, your data is captured accurately and instantly, regardless of location.

Cloud-based systems simplify data centralization, by providing secure access to enter or retrieve data from anywhere, anytime on virtually any device. As a result, you can extend your CAPA system from front-line employees on the production line or in the field to managers and supervisors back at headquarters.

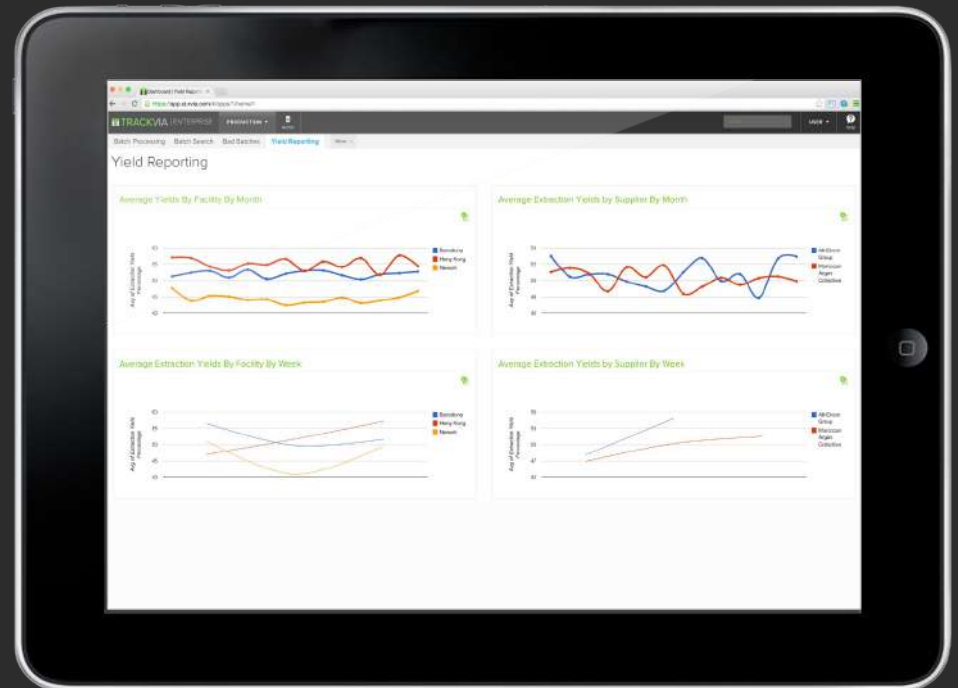


STEP 2: REAL-TIME DISCOVERY

Identify & Analyze Incidents in Real-time

With all your data centralized in one place, you can now begin to identify and analyze incidents or events as they happen versus waiting for end-of-day, weekly or monthly reports.

Centralized reporting also helps close the loop on your CAPA process, providing timely and accurate reporting insight into the effectiveness of your QC checks and actions before, during and after their implementation.

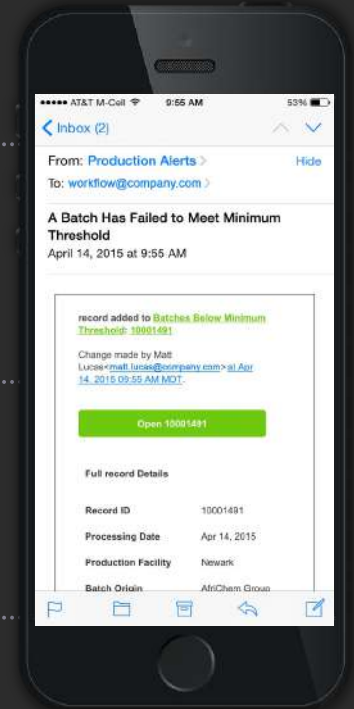


STEP 3: AUTOMATED ACTION

CAPA and Continuous Improvement

Once an incident has been identified and verified, why wait to take corrective or preventive actions? Configurable workflow capabilities allow you to instantly assign tasks to departments, groups or individual workers.

You can also schedule alerts and workflows around deadlines or ongoing investigations, thereby providing increased visibility and accountability across the organization at all levels.



CONCLUSION

Effective CAPA management is no longer a nice-to-have, but rather a must-have in today's highly regulated and competitive world. Having a system—any system—is a good first step. But having a closed-loop CAPA system provides better results.

Next-generation cloud-based solutions are making it faster and easier to centralize and streamline this critical process, helping reduce cost of quality, increase production efficiency and ensure accountability and regulatory compliance.



ABOUT TRACKVIA

TrackVia is the leading mobile quality and process management solution that can be fully configured to fit your unique manufacturing workflows.

TrackVia's detailed dashboards and live-data reporting give you enhanced visibility into your operations and its unrivaled mobile capabilities make it easy for employees to enter data, scan barcodes, capture signatures, and collaborate on any iOS or Android device.

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