

CANEA ONE

Corrective and Preventive Action (CAPA) Best Practices Guide



Quality system regulation (QSR) in North America requires establishing a corrective and preventive action (CAPA) process for most firms selling food, biological, and medical related products.

Although FDA has always expected regulated industries to perform corrective and preventive actions, establishing a unified CAPA system also makes good sense for most businesses, especially those looking to focus on continuous process improvements. Additionally, FDA inspections and ISO audits are a significant part of manufacturing businesses. Year after year, FDA reports data from inspections. And year after year, companies receive FDA 483 inspectional observations for “lack of or inadequate procedures” for CAPA.

FDA requirements for CAPA are defined in 21 CFR Part 820.100 Corrective and Preventive Action

(a) Each manufacturer shall establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for:

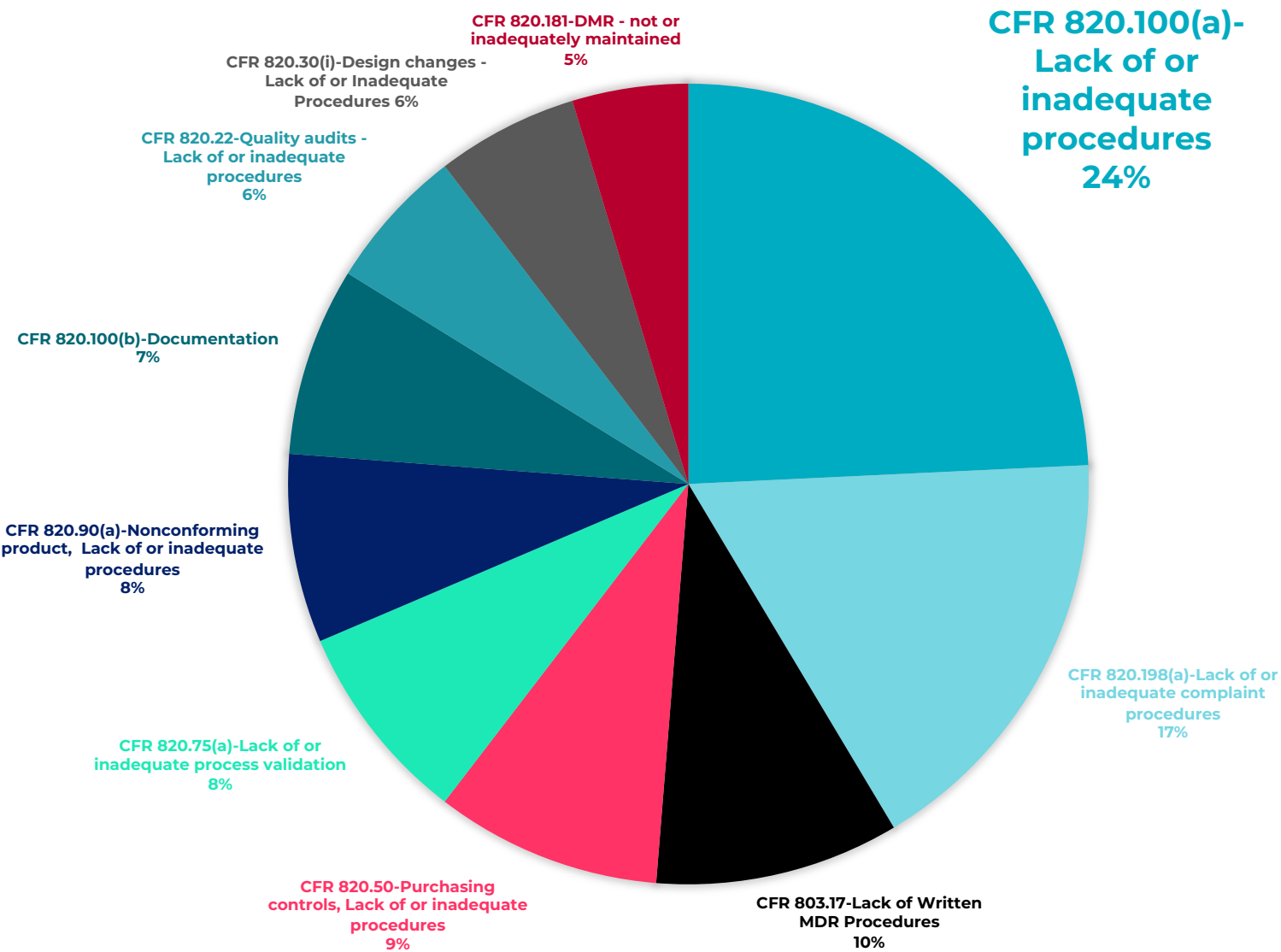
1. Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems. Appropriate statistical methodology shall be employed where necessary to detect recurring quality problems;
2. Investigating the cause of nonconformities relating to product, processes, and the quality system;
3. Identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems;
4. Verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device;
5. Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;
6. Ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems; and
7. Submitting relevant information on identified quality problems, as well as corrective and preventive actions, for management review.

(b) All activities required under this section, and their results, shall be documented.

FDA Inspection Data (Devices Chart)

Every year many organizations are screened by FDA...

and an overwhelming percentage of findings are typically related to “procedures for corrective and preventative action have not been established” or “procedures for corrective and preventive action have not been adequately established” or even that “corrective and preventive action activities/and/or results have not been documented”. In fact, the largest percentages for all FDA control products usually revolve around lack of or inadequate procedures in general.



To avoid these issues several well documented best practices can be deployed by your organization to proactively address this problem.

Some of the items listed in this document are obvious, others may provide some insight on how best to ensure your procedure is not inadequate and finally, others will require some technical insight with advanced techniques being deployed. However, for the most part, virtually any organization regardless of size and scale can build in the necessary approach to avoid some of the typical FDA citations.



Common best practices that can improve your operational standing:

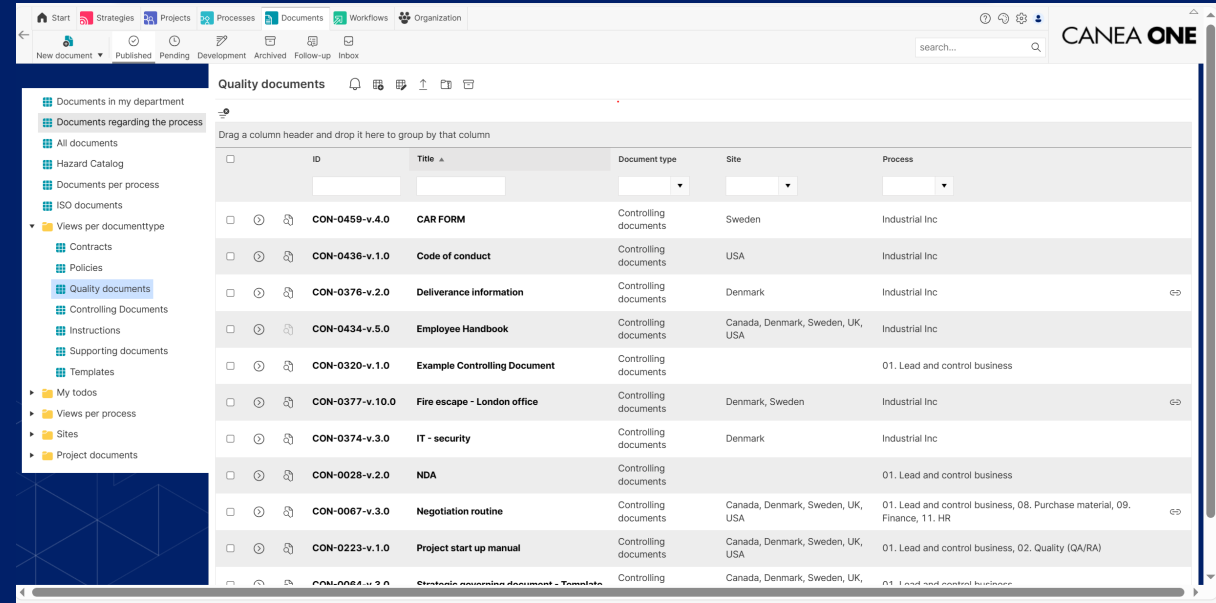
1. Clearly establish your approach through systematic policies and procedures
2. Manage quality events and data sources effectively
3. Maintain process consistency & timelines
4. Incorporate risk-based prioritization
5. Ensure proper Root Cause Analysis (RCA) techniques are utilized
6. Utilize cross-functional teams and keep them well informed
7. Implement actions and track results

1 Clearly establish your approach through systematic policies and procedures

A firm's CAPA processes should be carefully planned and documented with clear policies, guidelines, and procedures. All critical CAPA items resulting from investigations—or from continuous improvement projects—should be tracked in a centralized system. It is important to maintain information for FDA purposes in all internal audit reports, supplier audit reports, or management reviews. The firm should also define in a company's SOPs which items should be elevated to a CAPA request and who will make the final decisions. The final approval on whether an official CAPA request should be opened should be made by an experienced Quality Manager. Use of a Quality Review Board (QRB) may also be effective and useful in larger organizations with many product lines and departments. All QSR requirements mandate that companies have staff with the training, knowledge, and experience for the job. This staffing includes experienced Quality Assurance (QA) professionals who will manage and maintain the CAPA system for future evolution.

- ✓ Establish a clear policy along with Standard Operating Procedures, ensure that the staff is trained and is aware of your CAPA policy.
- ✓ Create the appropriate level of authority and governance, for instance a Quality Review Board (QRB) may be necessary for approvals and oversight.
- ✓ Ensure that the CAPA procedure is tied to other relevant inputs and processes like audit, root cause, investigations, complaints, and deviation management.
- ✓ Maintain a database or tracking system for proper follow-up and visibility.
- ✓ Make sure that all relevant departments within the firm are identified and can contribute to the process.
- ✓ Remember to incorporate preventive action into your overall quality management system.

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The screenshot displays the CANEA ONE software interface. The top navigation bar includes tabs for Start, Strategies, Projects, Processes, Documents, Workflows, and Organization. Below this, a search bar and a 'New document' button are visible. The main content area is titled 'Quality documents' and features a table with columns for ID, Title, Document type, Site, and Process. The table lists various documents such as 'CAR FORM', 'Code of conduct', 'Deliverance information', 'Employee Handbook', 'Example Controlling Document', 'Fire escape - London office', 'IT - security', 'NDA', 'Negotiation routine', and 'Project start up manual'. A sidebar on the left provides a hierarchical view of the system's structure, including 'Documents in my department', 'Documents regarding the process', and 'Views per document type'.

ID	Title	Document type	Site	Process
CON-0459-v.4.0	CAR FORM	Controlling documents	Sweden	Industrial Inc
CON-0436-v.1.0	Code of conduct	Controlling documents	USA	Industrial Inc
CON-0376-v.2.0	Deliverance information	Controlling documents	Denmark	Industrial Inc
CON-0434-v.5.0	Employee Handbook	Controlling documents	Canada, Denmark, Sweden, UK, USA	Industrial Inc
CON-0320-v.1.0	Example Controlling Document	Controlling documents		01. Lead and control business
CON-0377-v.10.0	Fire escape - London office	Controlling documents	Denmark, Sweden	Industrial Inc
CON-0374-v.3.0	IT - security	Controlling documents	Denmark	Industrial Inc
CON-0028-v.2.0	NDA	Controlling documents		01. Lead and control business
CON-0067-v.3.0	Negotiation routine	Controlling documents	Canada, Denmark, Sweden, UK, USA	01. Lead and control business, 08. Purchase material, 09. Finance, 11. HR
CON-0223-v.1.0	Project start up manual	Controlling documents	Canada, Denmark, Sweden, UK, USA	01. Lead and control business, 02. Quality (QA/RA)
CON-0000-v.0.0	Strategic business document - Tenetets	Controlling	Canada, Denmark, Sweden, UK, USA	01. Lead and control business

Store and manage all controlling documents within your eQMS with the ability for formal approval, security controls, automated distribution, read receipts and electronic signature.



2 Manage quality events and data sources effectively

Proper identification and tracking of quality events and data sources are critical to a CAPA system. Companies should identify all the potential inputs that they will use to uncover existing problems as well as potential problems. Having the processes linked would be ideal and ensure that your approach is comprehensive and avoids any potential gaps. Among these inputs they could include acceptance activities, complaints, FDA-483 observations or warning letters, nonconformances or deviations, process monitoring data, and calibration and preventive maintenance records. Don't forget other potential events like internal, external, supplier, or third-party audits, and customer or employee feedback via complaint tracking.

- ✓ Identify all quality events and potential inputs to your CAPA process.
- ✓ Build in specific decision gates or formal CAPA submissions procedures.
- ✓ Ensure that completed CAPA actions are connected back to the quality event for proper closure and lessons learned.



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NC-1206 Missing proper documentation regarding temperature Save case Attached files (1) Export

Initiate Non-Conformity Non-Conformity Investigation

Title* Missing proper documentation regarding temperature

General information

Non-Conformity description *

The laboratory failed to maintain proper documentation of the temperature and humidity conditions in the storage area for sensitive reagents, as required by industry standards.

Non-Conformity initiation Process

Non-Conformity area QMS

Non-Conformity towards QMP

Elements for N-C Search/Add...

Role assignment

Non-Conformity investigator Tina Johansson

Product Bandages

API

Component/OEM

Article number 9-273

LOT/Serial number 47930

Add Disposition

Drag a column header and drop it here to group by that column

ID	Date put to quarantine	Description	Disposition approver	Disposition of products	Closed date	Phases
DIS-1207	10/30/2023	the laboratory will immediately implement a corrective action plan to ensure compliance with documentation requirements	Anders Andersson	Use with concession		

Audit - Choose type if N-C came from an audit

Audit type Internal audit

Non-Conformity classification Minor

Attachments

Attach file

Filename	Changed by	Changed
Corrective action plan.docx	Felicia Lindström	10/23/2023 9:14 AM

Manage all quality events including deviations, nonconformities, and complaints in your eQMS solution, with automated workflows.

3 Maintain process consistency & timelines for effective control

Within your documented procedures or within your system the specific CAPA occurrences should be tracked with key dates related to approval and resolution. These statistics are important for evidence that your process is responsive and addressing the concerns that have been identified. These deadlines or timelines should be documented in your procedures with clear roles and responsibilities identified for all team members involved. In addition, companies must ensure that all necessary data is being captured. Electronic systems must be 21 CFR Part 11 compliant with proper tracking of data and archiving. Employees should be trained to immediately notify the QA department when they deviate from an established procedure, work instruction, or batch record. In addition, firms must ensure that QA is notified immediately about major issues.

- ✓ Maintain one consistent source of truth for all your documented records.
- ✓ Ensure that timelines and approvals are tracked for responsiveness.
- ✓ Make sure roles and responsibilities are clearly outline and the staff is trained on their involvement or how they can contribute to the process.
- ✓ Identify notification procedures so that QA is made aware of potential problems and quality events that would trigger CAPA investigations.

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The screenshot displays the CANEA ONE software interface for a CAPA record titled "CAPA-588 CAPA wrong colour IN MRI". The interface includes a navigation bar with tabs for "Parent", "DEV 584 Wrong colour in pr.", "Approval of investigation", "Countermeasures", and "QA Response". The "Countermeasures" tab is active, showing a table of actions. The table has columns for Title, Action type, Description of action, Action responsible, Expected implementation date, Effectiveness verification plan, Description of implementation, Expected verification date, Result of verification, Phases, and ID. Two actions are listed: "Calibration" (Corrective action) and "Software Update" (Preventive action). Below the actions table, there is a "Records" section with a table showing a log of actions. The log has columns for ID, Log, Logged by, and Date. One record is shown: "REC1210" with the log "Two actions has been registered", logged by "Felicja Lindström", and dated "10/23/2023 11:41 AM". At the bottom, there is an "Attached files & document" section showing a file named "Corrective action plan.docx" changed by "Felicja Lindström" on "10/23/2023 11:42 AM".

Title	Action type	Description of action	Action responsible	Expected implementation date	Effectiveness verification plan	Description of implementation	Expected verification date	Result of verification	Phases	ID
Calibration	Corrective action	Ensure that the MRI machine is properly calibrated to accurately represent colors in the images. Recalibrate the system as needed to prevent color distortion.	Olivia Smith	10/30/2023	Absence of color-related complaints from patients and healthcare providers. Consistent and accurate color representation in MRI images. Successful completion of peer reviews with no color-related issues identified.	Recalibrated the system to prevent color distortion	10/25/2023			ACT-1209
Software Update	Preventive action	Check if the issue is related to the software used for image processing and visualization. If so, update the software to the latest version or apply patches if available.	Thomas Brandner	11/28/2023						ACT-1208

ID	Log	Logged by	Date
REC1210	Two actions has been registered	Felicja Lindström	10/23/2023 11:41 AM

Filename	Changed by	Changed
Corrective action plan.docx	Felicja Lindström	10/23/2023 11:42 AM

Your eQMS should give you the ability to assign clear organizational responsibility with specific due dates or expected completion dates.



4 Incorporate risk-based prioritization into your decision-making process

Risk management is a critical component of CAPA and quality management in general. Building your understanding of risk management principles and techniques is the first step. The second step is to implement techniques related to risk assessment and identification, which is essentially evaluating impact and severity of the quality event against the potential reoccurrence, into your overall CAPA procedure. Once the risk assessment is complete the next step involves scoring the risk and using the information to help inform your decision making. Risk scores and assessment can also help prioritize which investigation gets handled first. Other factors to consider would be deploying specific evaluation criteria for determining risk severity, i.e., product related, process related, supplier related, etc.

- ✓ Build a better understanding of risk management techniques and risk-based decision models.
- ✓ Update or implement risk-based assessment tools into your CAPA procedure.
- ✓ Use risk scores to help prioritize your CAPA investigations.
- ✓ Embed root cause analysis techniques to help expand your understanding of the quality event that triggered the occurrence.



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RISK990 Production Disruptions Save case Attached files (1) Export

Registration Classification

Felicia Lindstrom
Currently editing
Creator

< 1/2 >

Title* Production Disruptions

Risk

Registration

Description *

If deliveries of subpar or delayed raw materials or components occur, it can lead to production disruptions and impact the company's ability to deliver goods on time.

Date of registration 10/18/2023

Classification * Work environment

ISO-Standard ISO 14001

Risk area Staff

Name/content Search/Replace...
4.2 Environmental policy X

Location USA

Area Los Angeles

Process 05. Manufacture products

Process level 2 05.02. Manufacture prod...

Risk Assessment

Risk likelihood 3 - Likely

Risk Consequence 4 - Major Shortfall

Risk Value 12

		Consequence				
		Regligible 1	Minor 2	Moderate 3	Major 4	Catastrophic 5
Likelihood	5 Almost certain	Moderate 5	High 10	High 12	High 12	High 12
	4 Likely	Moderate 4	High 8	High 12	High 12	High 12
	3 Possible	Low 3	Moderate 6	High 9	High 12	High 12
	2 Unlikely	Low 2	Moderate 4	Moderate 6	High 8	High 10
	1 Rare	Low 1	Low 2	Low 3	Moderate 4	Moderate 5

Risk manager * Helen Smith

Risk comment To address this risk, it's important to establish a stringent supplier evaluation process and incoming material quality control.

Attach file

Filename	Changed by	Changed
Risk Checklist.xlsx	Felicia Lindstrom	10/18/2023 3:33 PM

Develop risk-based assessments models to improve decision making and prioritization.

5 Ensure proper Root Cause Analysis (RCA) techniques are utilized

Determining root cause is one of the most critical elements related to effective quality management, especially as it relates to CAPA. Many organizations fail to conduct in depth root cause analysis, very often they simply restate the problem statement / issue description and capture this as the root cause. There are many effective root cause analysis techniques and those could be covered in a separate document all together, but the most important thing is to provide some initial guidance to your team and allow for the process to implement the right approach. Some organizations will use the 5 why's technique for drilling down to the root cause and this is an effective tool, while others would rather conduct fish-bone diagrams, or some organizations conduct routine Failure Mode and Effects Analysis (FMEA). FMEA however, could also compliment your RCA approach or even help prevent occurrences from occurring so that is a good preventative technique to consider outside of your reactive CAPA process.

- ✓ Each CAPA investigation should either be proceeded with or completed with a root cause analysis (RCA) to ensure completeness.
- ✓ Build in flexibility to allow for multiple techniques but recommend or establish at least one standard approach to use for your team.
- ✓ Provide continuous training and guidance on how to conduct RCA to your staff.
- ✓ Maintain records and documentation for proper traceability and compliance.



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The screenshot displays the CANEA ONE software interface for a Root Cause Analysis (RCA) form. The form is titled "5Y-8115-v1.0 Root cause dev 960" and includes a "Create new version" button. The form is divided into several sections:

- Parent:** DEV-960 Deviation in machi..
- Document Information:** Document title: Root cause dev 960, Created date: 2022-11-16, Document ID: 5Y-8115, Version: 1, Case ID: , Case title: , Performed by: Patrik Bergwall, Date completed: .
- 5 WHYS ROOT CAUSE ANALYSIS:** This section is divided into two main columns: "DEFINE THE PROBLEM" and "CORRECTIVE ACTION TO TAKE".

The "DEFINE THE PROBLEM" column contains a grid of boxes for the 5 Whys analysis. The first row is labeled "PRIMARY CAUSE" and the subsequent rows are labeled "CONTRIBUTING PROBLEM". Each box contains the text "Why is it happening?". The "CORRECTIVE ACTION TO TAKE" column contains a grid of boxes for corrective actions. Each box contains the text "Corrective action performs with sub-case".

At the bottom of the form, there are buttons for "Read mode" and "Download PDF".

Incorporate templates for root cause analysis as additional documentation, files can be automatically linked to cases.

6

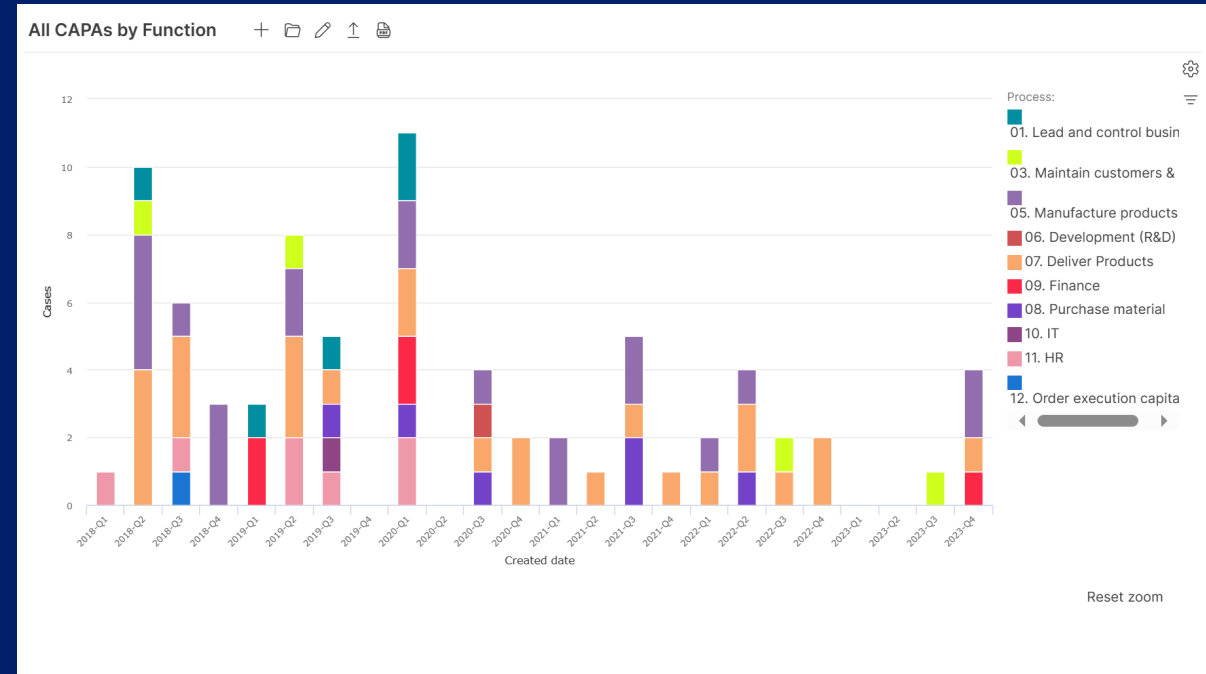
Utilize cross-functional teams and keep them well informed

A true CAPA investigation should touch all relevant departments and functions within the organization. One recommended best practice is to establish a cross-functional team to review and discuss issues that may be solid candidates for a CAPA as part of the submission process. Sometimes organizations will establish a management review board (MRB) which is comprised of representatives from quality, regulatory, operations, and engineering departments. The MRB should meet frequently, and review issues related to customer feedback, complaints, audits, nonconformances, etc. Your system should also allow for these relevant departments to be assigned to the CAPA and ensure approval or review is completed for the process to move to the next phase.

Once a CAPA is issued, remember that it is a project that will require resources and dedication. All too often CAPAs are not treated with equal status and importance as other initiatives in the company, such as research or product development. This is one of the reasons why CAPAs tend to linger and effectively fail to address the underlying problem.

- ✓ Identify departmental roles and policies associated with CAPA.
- ✓ Within your CAPA procedure, establish clear guidance on department notification and how approvals will be conducted.
- ✓ Establish a structured cadence so that departments are consistently engaged, regular meeting cycles, weekly or bi-weekly for instance are recommended.
- ✓ Distribute completed reports and analyses to all department roles so that visibility is ensured.
- ✓ Prioritize CAPA as a small project so that proper resources are committed.

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Track and manage dynamic attributes related to your CAPA investigations including the functional department.



7

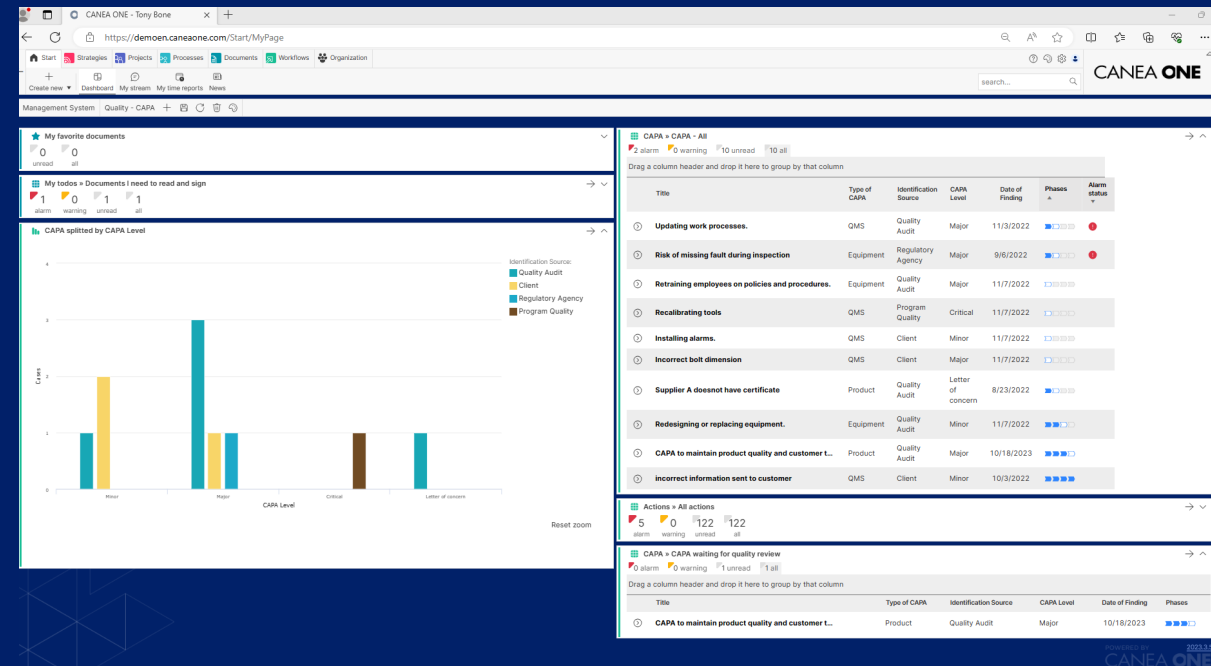
Implement actions and track results for measured effectiveness

Once actions are determined the most critical element to understand is the specific measurement data that will be used to ensure the action is successfully implemented. Data results should be gathered within the appropriate timeframe to ensure effectiveness. These measurements statics will need to be verified by the review board and the results should be documented in your system of record, attached to the CAPA and/or the originating quality event. Accompanying reports should be developed and produced for all stakeholders including FDA and other executive committees when appropriate. Ideally the organization should use its database system or other official data source to produce regular updates and keep track of timelines. Use of dashboards and tracking tools are highly recommended. Not completing CAPA investigations and clearing out actions could result in an FDA warning and would require additional oversight.

- ✓ Actions should include documented data measurement criteria for verification purposes.
- ✓ Assigned resources to actions should have the ability to track all relevant attributes and post their documentation to the official record source.
- ✓ Verification dates should be established so that completion occurs in a timely manner.
- ✓ Incorporate dashboard reporting tools or similar tracking mechanisms for overall process visibility.



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Create dynamic dashboards with instant tracking of CAPA action items with follow-up dates, automated alerts, and warnings for quick user follow-up.



CANEA **ONE** supports your organization's ability to plan, implement, monitor, and reach new heights in operational excellence... within any industry or sector.

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health care

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Gotland

Gävle kommun

MÖLNDALS
STAD

Region
Östergötland

Region
Värmland

kry

Food & beverage

Bergendahls
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GLASS

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Skåne
mejerier

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