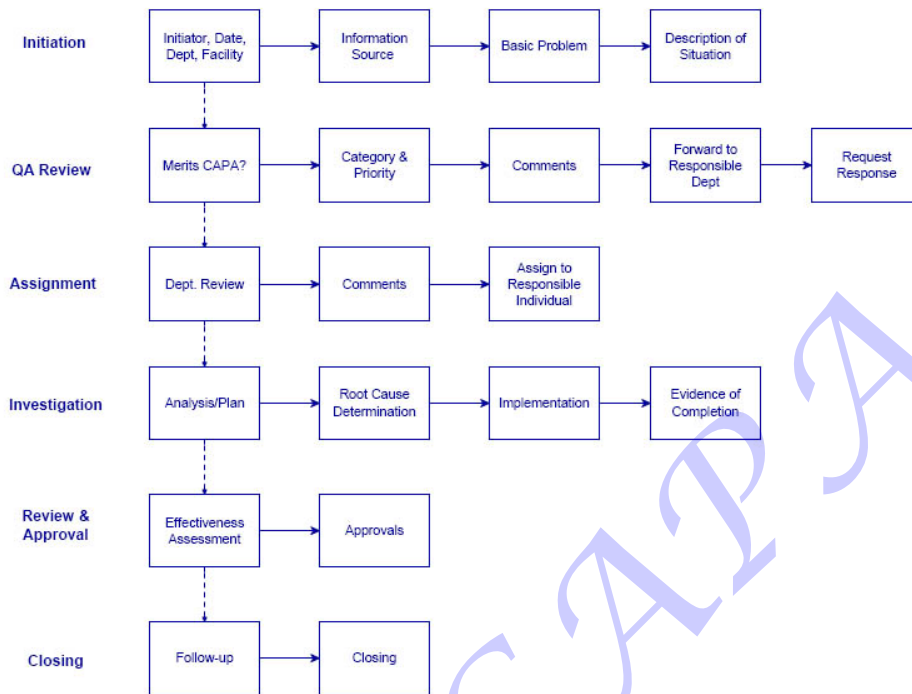


InfoCAPA (v.9)

Web-based Corrective and Preventive Action and Nonconformance Software

Corrective and Preventive Action Flow Diagram

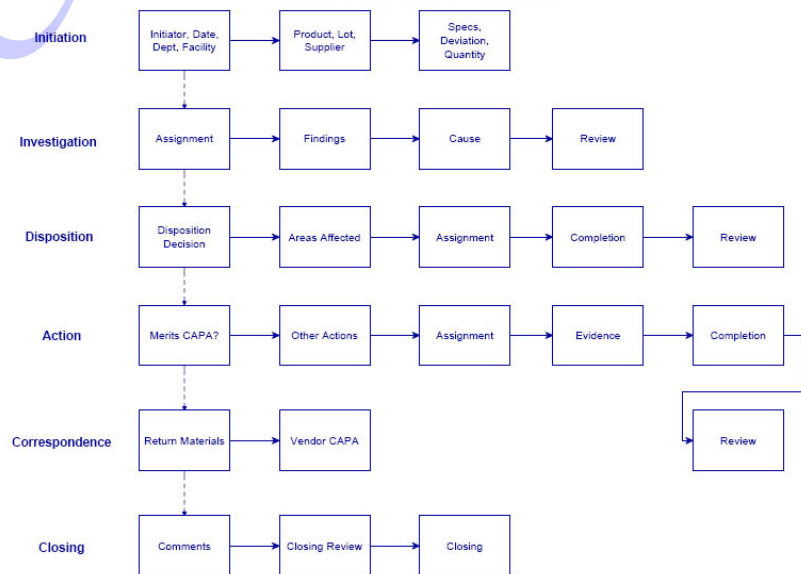


Web-based platform
Workflow rules
Drill-down reports
...And much more

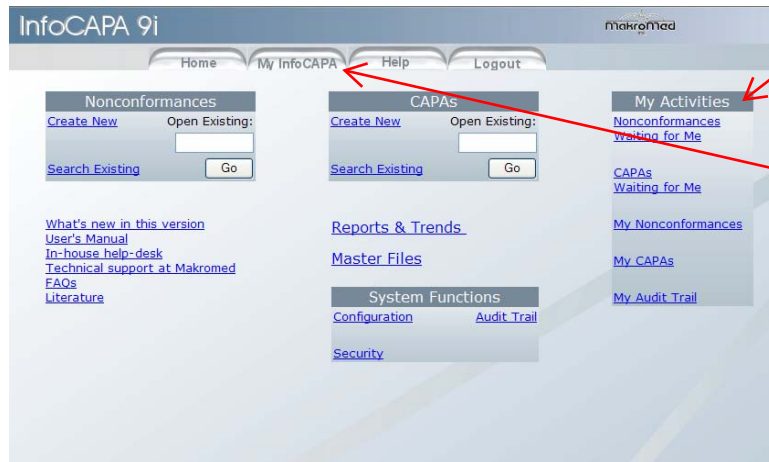
Advantages of InfoCAPA software:

- Allows users in medical device, pharmaceutical, and biotech industries to collect all of the information related to corrective and preventive actions and nonconformances in one centralized location.
- Built-in reports and trends allow for streamlined reporting of information for audits, management review, and more.
- Business rules allow you to control inter-dependencies of activities, email alerts, and critical data capture.
- Compliance with 21CFR Part 11, including electronic signatures, full audit trail, secured data access, and data integrity.

Nonconformance Flow Diagram



InfoCAPA 9i includes a long list of new features:



a. Dashboard of My Activities allows a user to focus on relevant and pending activities.

b. My InfoCAPA allows end users to configure personal options above and beyond the system configuration set up by the administrator.

c. New configurable workflow logic that allows you to define and control the rules of engagement and inter-dependencies of activities.

d. New email notifications, including notifications for coordinators and initiators and time-based reminder notifications.

e. Enhanced closing conditions to ensure that critical data is captured before the files are closed.

f. Full Nonconformance module, including product, deviation, investigation, disposition, action, correspondence, and closing.

g. QA Review of CAPA's, including Priority categorization.

h. CAPA root cause analysis.

i. CAPA implementation phase, with ability to enter multiple action items.

j. CAPA effectiveness assessment and follow-up.

k. Ability to void CAPA and Nonconformance records.

l. Security privileges to reopen closed records to add additional information. Reopen History is captured, including the reason for reopening.

Investigation can not be completed without documenting the evidence of completion.

Completed investigation can not be edited.

Department approval can not be performed before completing the investigation.

Investigation can not be edited after department approval.

QA Assessment can not begin until after the department approval of the investigation.

When an incomplete investigation becomes these many days old:

When a CAPA is ready for QA assessment

When the follow-up is not completed by due date

When the follow-up is completed

When an open CAPA becomes these many days old:

QA Assessment must equal approved

Effectiveness Assessment must be filled in

Follow Up Requirement can not be blank

If no Follow Up is required, Justification must be filled in

If Follow Up is required, then Follow Up assignment can not be blank



m. Record status displayed on CAPA and Nonconformance form and report.

n. Expanded reporting and trending module, including drill-down reports that allow you to open a record of interest by clicking on a link directly on the report.

CAPAs Log						
December 15, 2006 09:20:45 AM						
InitDt>=02/01/2000 and InitDt<=12/08/2006						
CAPA No.	Date	Results	Priority	Info Source	Description	Root Cause
000001	08/26/2005	Accept	Low	Customer Complaint	Labels are being afixed at an angle.	Design
000002	08/29/2005	Accept	Medium	Internal Audit	Training records are not complete.	Design

And More...

You can rest assured that we will keep your CAPA system up-to-date and ahead of the underlying regulations and quality standards.

**We Practice What We Preach!
We Are ISO 13485 Certified.**