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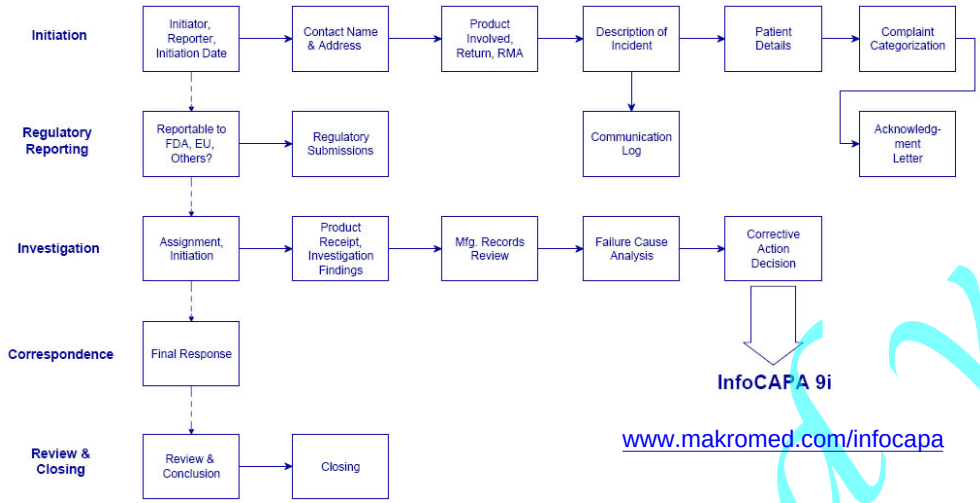
InfoMed (v.9)

Web-based Complaint Handling Software



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

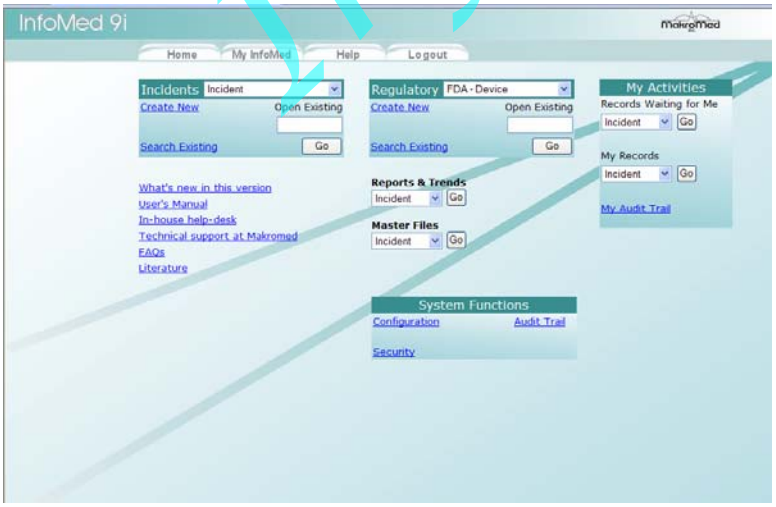
InfoCAPA 9i

www.makromed.com/infocapa

Advantages of InfoMed complaint handling software:

- Allows users in medical device, pharmaceutical, and biotech industries to collect all of the information related to customer complaints 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.

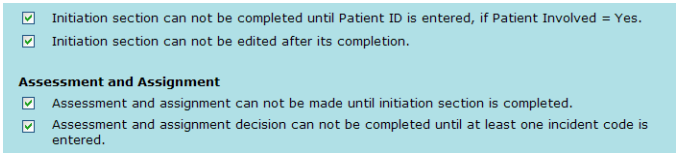
InfoMed 9i includes a long list of new features:



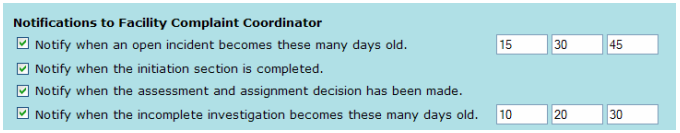
a. Dashboard of My Activities allows a user to focus on relevant and pending activities.

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

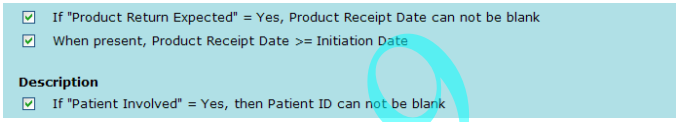
c. New configurable workflow logic that allows you to define and control the rules of engagement and inter-dependencies of activities.



d. Improved email notifications, including facility-level notifications for coordinators and time-based reminder notifications.



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



f. Expanded Product section, including received condition and final disposition.

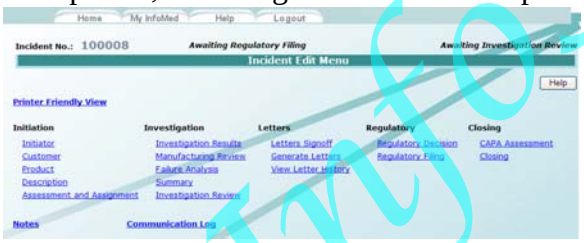
g. More detailed Patient information captured at the Incident level, including age, weight, implant date, explant date, etc.

h. Failure Cause.

i. Ability to create and save Draft and Final versions of customer letters.

j. Ability to void Incident records.

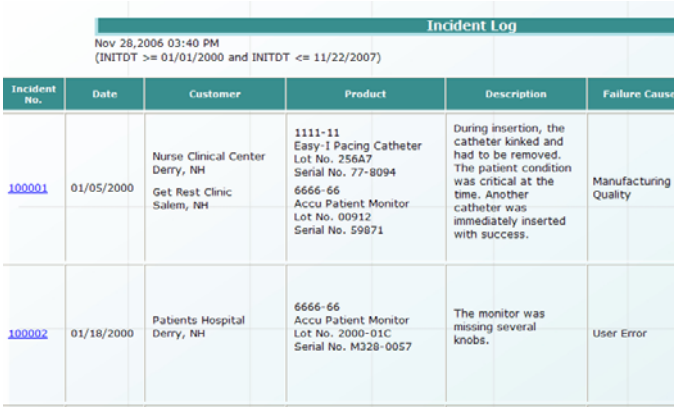
k. Security privileges to reopen closed records to add additional information. Reopen History is captured, including the reason for reopening.



l. Incident and Regulatory status displayed on incident form and report.

m. Expanded reporting and trending module, including Threshold report and Incident rate trends.

n. Drill-down reports allow you to open a record of interest by clicking on a link directly on the report.



Incident Log

Nov 28,2006 03:40 PM
(INITDT >= 01/01/2000 and INITDT <= 11/22/2007)

Incident No.	Date	Customer	Product	Description	Failure Cause
100001	01/05/2000	Nurse Clinical Center Derry, NH Get Rest Clinic Salem, NH	1111-11 Easy-I Pacing Catheter Lot No. 256A7 Serial No. 77-8094 6666-66 Accu Patient Monitor Lot No. 00912 Serial No. 59871	During insertion, the catheter kinked and had to be removed. The patient condition was critical at the time. Another catheter was immediately inserted with success.	Manufacturing Quality
100002	01/18/2000	Patients Hospital Derry, NH	6666-66 Accu Patient Monitor Lot No. 2000-01C Serial No. M328-0057	The monitor was missing several knobs.	User Error

o. Optional Service and RMA modules.

InfoMed v.9.has all these new features and is now web-based! In addition, all the important features our users have come to expect are carried forward from the previous version, such as the following:

a. MDR submissions using FDA Form 3500A (MedWatch)
- FDA approved MedWatch form
- built-in library of all FDA-mandated MedWatch codes
- auto-generation of MedWatch numbers per FDA format
- provision for multiple manufacturing facilities
- ability to handle supplemental information through follow-up submissions
- attachment page/s for text overflow

c. Baseline Reports for products.

d. World-wide regulatory submissions for EU MDV, Canada's TPP, Australia's TGA, and Japan's adverse event reporting.

e. Documented history of regulatory submission deliberations.

f. Due reports for regulatory submissions.

And More…

a. Enhanced filtering of data, allowing user selection of combination of conditions. For example, display complaints of specific nature, on a specific product, in a given territory, within a specific time period.

b. MedWatch records are assigned the reference number when they are ready to be submitted rather than at creation, thereby eliminating skipped reference numbers when it is determined that the event is not reportable after the MedWatch record has already been created.

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

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