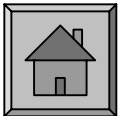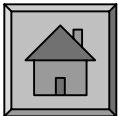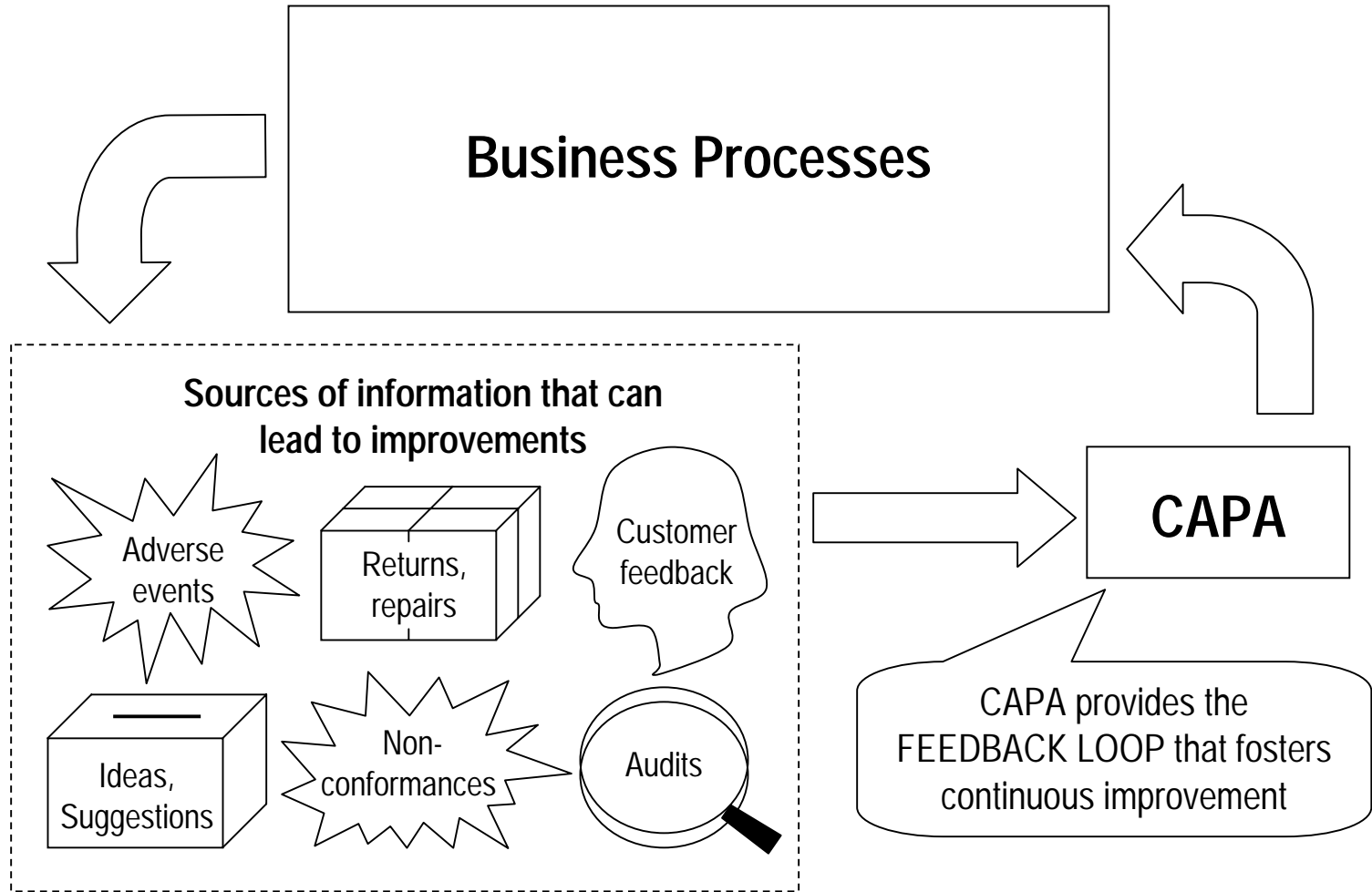# AcQualis™ – A CAPA Application from Commonwealth Software

(Corrective And Preventive Action)

Product Description, October 2007

COMMONWEALTH
S O F T W A R E

The CAPA Feedback Loop

Business Processes

Sources of information that can lead to improvements

Adverse events

Returns, repairs

Customer feedback

Ideas, Suggestions

Non-conformances

Audits

CAPA

CAPA provides the FEEDBACK LOOP that fosters continuous improvement

CAPA's Importance

CAPA is of paramount importance to the FDA. According to FDA documents:

- CAPA accounts for 30-50% of FDA-483 forms issued for non compliance [1] and

- CAPA is the only one of the four major subsystems the FDA tracks that must always be included in a Level 1 ("Abbreviated") inspection [2]

[1] *QSIT Validation Document*, 3/18/99, chapter titled "G2A Increase Focus FDA 483."

[2] The four subsystems are: "Management Controls", "Design Controls", "Corrective and Preventive Actions (CAPA)", "Production and Process Controls (P&PC)". FDA Program document 7382.845 "Inspection Of Medical Device Manufacturers" completed 9/30/04, Part III page 1.
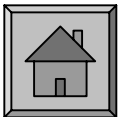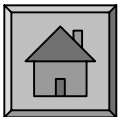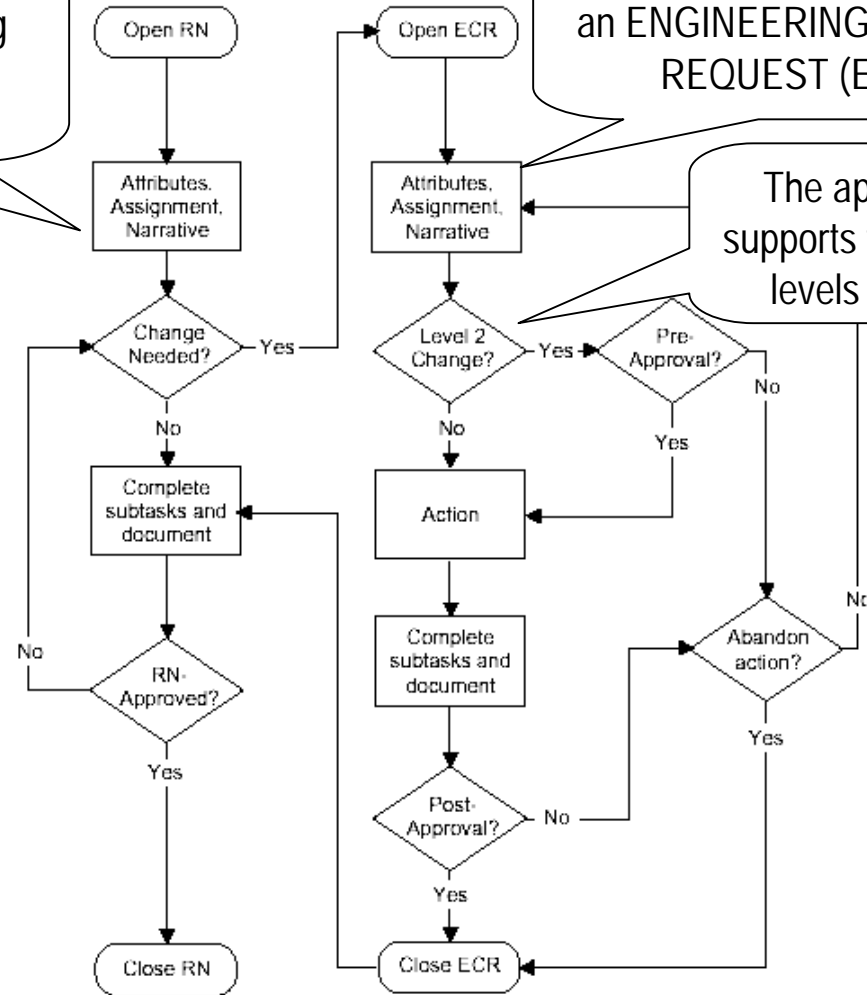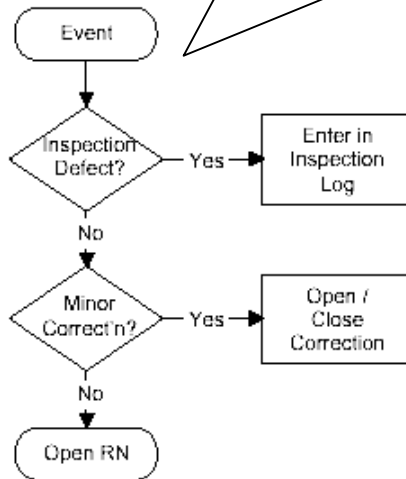
The CAPA Process

Anyone can open a REVIEW NOTIFICATION (RN) to bring an idea or concern before a Review Committee.

If a change is needed, open an ENGINEERING CHANGE REQUEST (ECR).

The application supports two distinct levels of ECR.

The Preliminary flow chart shows how the INSPECTION LOG and CORRECTIONS divert minor errors from the full CAPA process

Open RN

Attributes, Assignment, Narrative

Change Needed? — Yes

No

Complete subtasks and document

No

RN Approved?

Yes

Close RN

Open ECR

Attributes, Assignment, Narrative

Level 2 Change? — Yes

No

Pre-Approval?

No

Yes

Action

Complete subtasks and document

Post-Approval? — No

Yes

Abandon action?

No

Yes

Close ECR

Event

Inspection Defect? — Yes → Enter in Inspection Log

No

Minor Correct'n? — Yes → Open / Close Correction

No

Open RN

The Assembled RN Document

Key status information is here.

Attached ECR's and attached documents are here.

Inventory items from ERP.

Signature and date (paper or electronic) go here.

Checklists with names and dates are here.

The threaded narrative fields, which identify the contributions of each participant like a "blog" or threaded discussion, appear here.

REVIEW NOTIFICATION

RN#: 1002   Originator: SCARPENTER   Date: 01/14/2004   Topic: Labeling of sterile sleeves

☐ Non-Conformance?   Status: RTC   Responsible Party: Process:

Institution: Megamedical Inc.   Customer: Lucy Falwell   Phone: 050-555-3654

☐ Customer Complaint?
   Contact: Note:

☑ Medical Device Issue?
   ☐ SEMKO Reportable?   ☐ Canada Reportable?   ☐ FDA Reportable?   ☑ Not Reportable

☑ Item Related?   DMR:

Item ID	Serial/Lot	Description	Work Order
L83		Sterile Sleeve	0
L83-01		Sterile Sleeve (Pk 20)	0

☐ Performance Related?

☐ Repair?

Reason:

Lucy Falwell from Megamedical called from an OR where she is attending a Widget-based surgical case. At the beginning of the surgery it is mentioned that the patient is latex sensitive and the subject of whether the sterile sleeves contain latex or not is brought up. After reviewing the contents of the label no conclusion could be drawn then Megamedical contacted us.

No mention of latex free could be found here at WidgetCo on the sterile sleeves (M7-22) spec sheet sent by Acme.

Lucy decided to continue the case using the Widget in manual mode instead of using the power assist just to be on the safe side. She asked that we find out about the exact composition of the sleeves and whether they contain latex or not.
--< SCHUNG -- 1/14/04 >--

Solution:

A letter was sent by Acme stating that the sleeves are indeed latex free. They are constructed of elastoflex film for the endpiece and polyethylene film for the body.

Open ECR to add "latex free" onto the sleeves label.
--< SCHUNG -- 2/3/04 >--

RN#: 1002

Revised labels L745B and L745-01B now read "LATEX FREE" prominently in the upper right corner,
--< ESAMUELSON -- 2/10/04 >--

Engineering Changes:

ECR ID	Date	Topic	Status
1002-01	02/03/2004	Add "Latex Free" to sleeve labels	RC READY

Attached Documents:

Document	Archived?
C:\DOCUMENT\tib19990412.pdf	☐

Routing Checklist:

Description	Required?	Checked by	Date	Done?	Checked by	Date
Vendor (Notify)	☑	MOBRIEN	01/30/2004	☑	MOBRIEN	02/24/2004
Employee	☐			☐		
Perf Qual File	☐			☐		
NCL (original)	☐			☐		
Tech Services	☑	MOBRIEN	01/30/2004	☑	MOBRIEN	02/24/2004

Review Date: 03/01/2004   Closed by: Date: Signed

Signature _____   Date _____

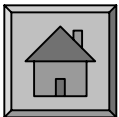RN#: 1002   Page 2 of 2
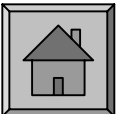
Distinctive Features

Commonwealth Software's approach to building CAPA software is distinctive and depends on an expressive DOCUMENT MODEL with unique team-oriented features:

- "Indelibility"
- Threaded narratives
- Rule-based document life cycle management
- Configurable checklists
- Document-based collaboration control

Team-oriented features enhance collaboration: employees use the system frequently and arrive at meetings prepared to handle issues thoroughly and efficiently.

Opening an RN; "Indelibility"

Click the RN/EC button to open a new RN, or to search for and edit existing RNs and their associated ECRs.

Implementing the concept of INDELIBILITY, data already entered cannot normally be changed by a later user.

Under the GENERAL tab, key categorization checkboxes lead to blocks of category-specific data.

Inventory numbers and descriptions come from a live connection to the organization's ERP system.

The long printout format gives a complete rendering of the RN document.
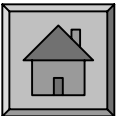
The Threaded Narrative

Under the NARRATIVE tab, threaded narratives with name and date for each comment tell vividly how the issue was tackled and resolved.

Users compose comments in a separate window where spell-checking is available.

The COPY button loads the entire narrative (both segments) and customer data into the Windows clipboard for pasting into an agenda or other report.
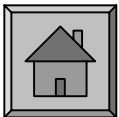
Statuses, Rules and Checklists

The RN STATUS is changed under the STATUS / ROUTING tab. Configurable document life cycle means that the status identifiers are defined using a STATUS LIST MANAGEMENT screen.

Each change of status is validated using a set of STATUS CHANGE VALIDATION RULES. Rules are developed using a RULES MANAGEMENT screen.

CONFIGURABLE CHECKLISTS are managed at the document level by clicking the REQUIRED box. They are configured system-wide using the CHECKLIST MANAGEMENT screen. Name and date are recorded for each checkmark made.

Document-based Collaboration

The READ-ONLY view of a document shows very clearly by its appearance that it's not enabled for modification, the same as a CLOSED document
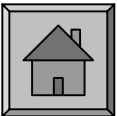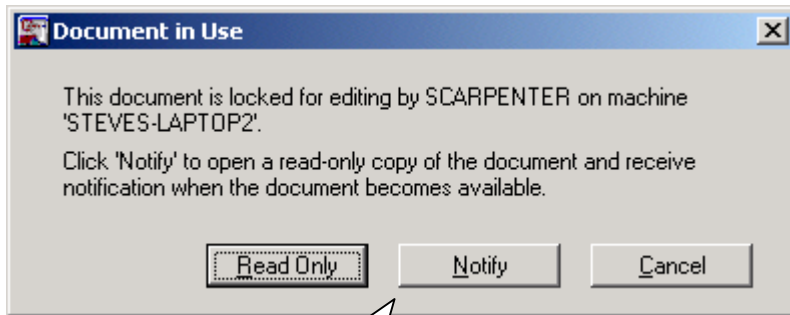
Click the NOTIFY button to receive a message when the document becomes available for editing

ECRs and Attached Documents

Management

Document LIFE CYCLE and STATUS CHANGE RULES screens give you control over process flow.

The CHECKLIST manager and its PREVIEW screen create custom to-do lists

USER management screens let you manage accounts, view user activity and disconnect sessions when needed
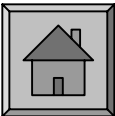
Informing the Committees

Using the PRINT to WORD options, the team can quickly assemble RN data into agenda or minutes documents for distribution to the Review committees.

During the meeting, use a computer projector to mark up the agenda / minutes or CAPA itself.
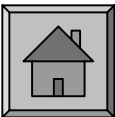
Additional Features

- **Reporting –** Open relational database structure gives authorized users unlimited reporting options.

- **Searches –** A highly capable but easy-to-use search feature builds queries optimized to the AcQualis™ data structure.

- **Corrections –** Correction documents expedite management of simple document errors or bill-of-materials changes.

- **Inspection Log –** Facilitates entry of inspection events into the data and their analysis.

- **Repairs –** All (or a subset) of the items returned for repair can be routed through the application's repair feature, identifying returned items as a highly productive source of product-improvement ideas.

- **Background Saves –** Entries are periodically saved to the local hard drive to limit loss of work during network or power failure.