*A **Review Notification** document initiates an action by a Review Committee. Engineering Change documents must begin as an RN. Narrative fields contain theaded discussions like "blogs."*

WORKFLOW

To present the lowest barrier possible for entering matters of concern into CAPA, AcQualis™ empowers anyone in the organization to open an RN. There are no required fields except those that are set automatically (originator, date of entry).

As resolution proceeds, multiple users contribute to the narrative, enable and complete checklist items and fill in the fields. As the RN moves toward completion, the Rules Engine applies more requirements to each phase until at closure the document is fully defined and compliant.

When RNs are presented to committees for review, the Print to Word features can assemble data

The completed RN document, ready to be signed digitally or in ink.

quickly into agenda or minutes documents for distribution and for display on a projector screen.

Each RN concludes as a signed document, either a paper document signed in ink or a PDF (Portable Document Format) document signed digitally in conformance with FDA's standard-setting regulation *21CFR Part 11*. Once completed, digitally signed RNs are separate and no longer dependent on the AcQualis™ environment. [11-07]
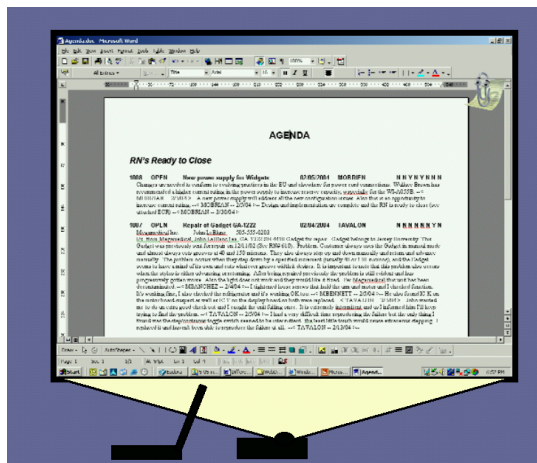
During meetings, use a projector to mark up the agenda/minutes document or AcQualis™ itself.

AcQualis™

CAPA-centered Quality Software for Medical Devices

- **Manages CAPA forms, engineering changes, inspection logs and document corrections**

- **Casts a wide net and presents a low barrier for capturing critical information**

- **Links to your ERP system**

- **With unique collaborative features, helps people work interactively and arrive at meetings better prepared, saving money and reducing risk**

Commonwealth Software has developed PC-based systems in the areas of scientific research, manufacturing and government for more than 16 years.

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COMMONWEALTH
SOFTWARE

www.commonwealthsoftware.net

OVERVIEW

COMMONWEALTH SOFTWARE has completed a commercial release of its ACQUALIS™ CAPA (*Corrective and Preventive Action*) software for medical device manufacturers. Although newly commercialized, ACQUALIS™ is a highly mature multiuser system in daily operation for more than six years. Its unique collaborative features have been instrumental in raising the level of participation and the quality of documentation for teams resolving CAPA issues.

Design of this system grew from the special role CAPA plays in medical device risk management. CAPA is of paramount importance to the FDA.

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

INTERLOCKING FORMS

The ACQUALIS™ system manages a database, hosted under Microsoft SQL Server 2005, built from several types of documents:

- **Review Notification** (RN) forms – CAPA forms that trigger a committee review
- **Engineering Change** requests / Engineering Change orders
- **Corrections** to drawings, bills-of-materials and other critical documentats
- **Inspection Log** entries
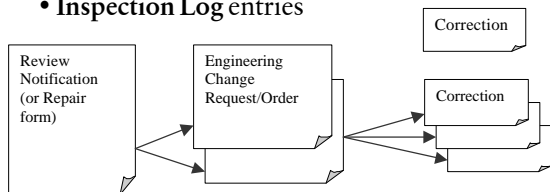
The containing form with its large buttons can display any number of ACQUALIS™ documents simultaneously.

Here a single RN document is displayed along with two of its dependent Engineering Change documents.

*The Correction form at the bottom shows a correction to the master bill-of-materials table in the ERP system as required by ECR #1008-01. Dependent Correction forms can be generated automatically when a user clicks the **Auto Fill** button.*

Correction forms can also be free-standing.
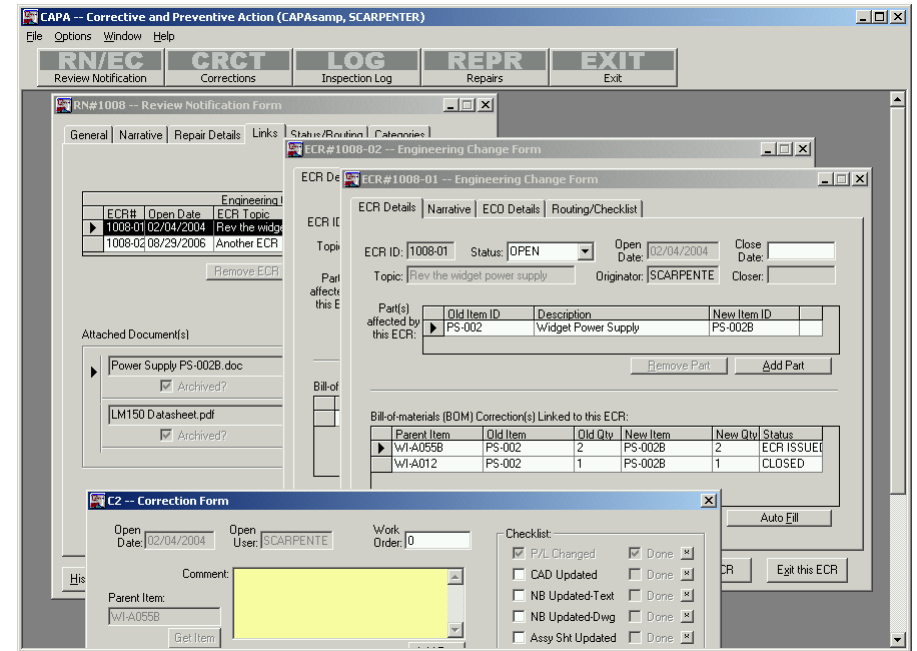
The central CAPA document (RN) is more than just a non-conformity form. It functions as a multi-ported, instantly accessible *suggestion box* which everyone in the organization is empowered to use, whenever there's an opportunity to identify a potential improvement in a process or product.

An RN can't be closed until its dependent Engineering Change(s) are closed and other required actions are done. An Engineering Change can't be closed until its dependent Correction(s) are closed.

DOCUMENT MODEL

Unlike other systems built simply as a database, ACQUALIS™ has a rich document model hosted within its secure database. It has several unique features to enhance collaborative productivity:

- **Threaded narratives** – work like a "blog" or threaded discussion and identify contributions from each participant with name and date, showing vividly how an issue was tackled and resolved. Comments are composed in a separate window with spell checking.
- **Rule-managed document life cycle** – a rules engine allows administrators to specify the stages a document goes through and the rules that govern when it's ready for the next stage.
- **Configurable checklists** – configurable at the administrative level to specify the contents of a checklist and at the document level to specify that a checklist item is required for the current document.
- **Document-style concurrency** – several users can view a document while only one may edit it – read-only users are notified when the document becomes available for editing.
- **Two-stage attached documents** – Documents from any Windows application can be attached in an active stage where they are editable from any workstation having the host application, and an archived stage where they can be read but not changed.
- **Indelibility** – a complex of user-interface and security elements that can be summarized by the term "indelibility"