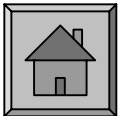


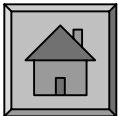
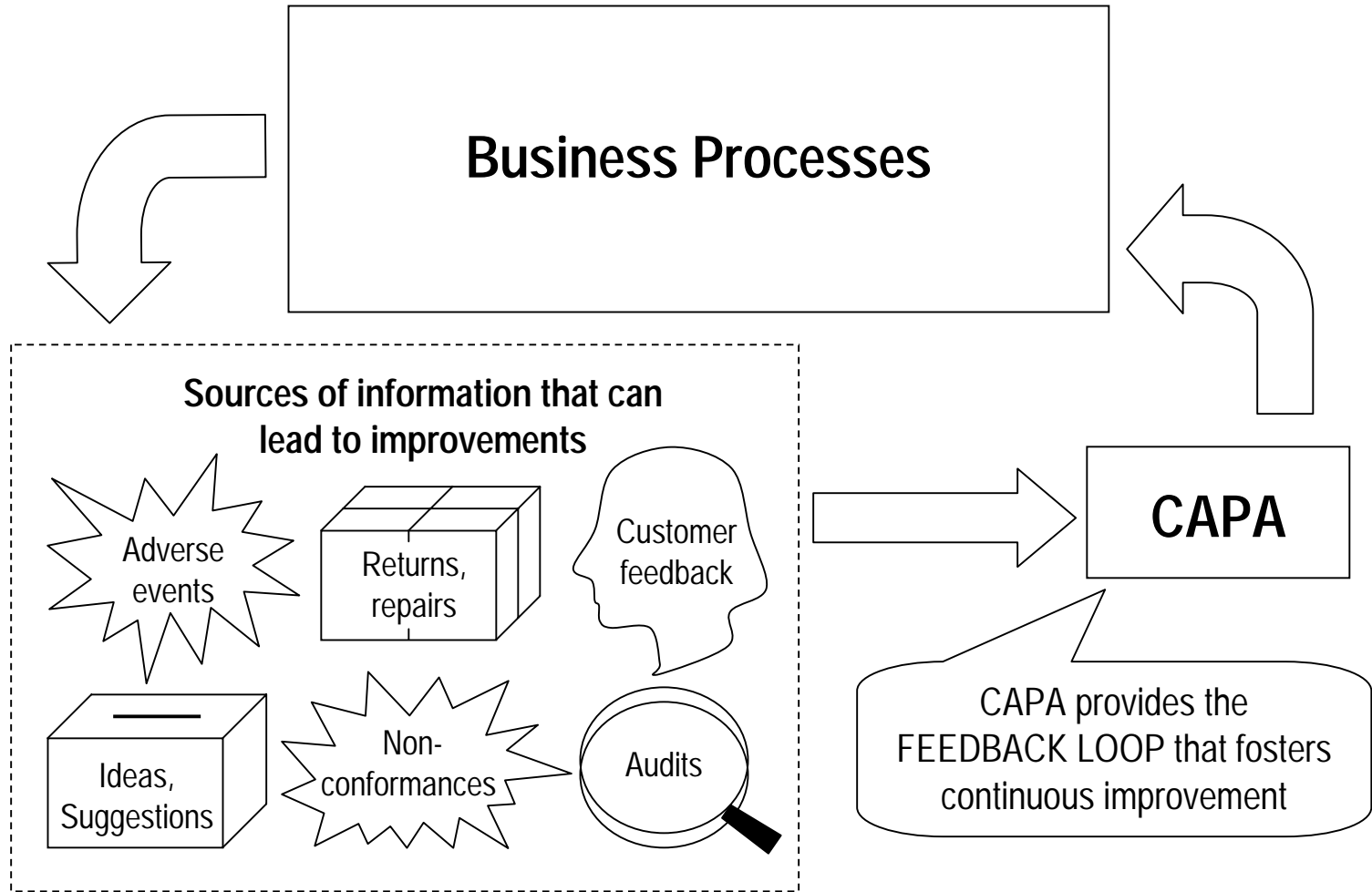
# AcQualis™ – A CAPA Application from Commonwealth Software

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(Corrective And Preventive Action)  
Product Description, October 2007



# The CAPA Feedback Loop



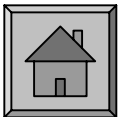
# CAPA's Importance

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 <sup>1</sup> 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 <sup>2</sup>

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.



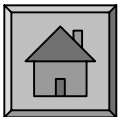
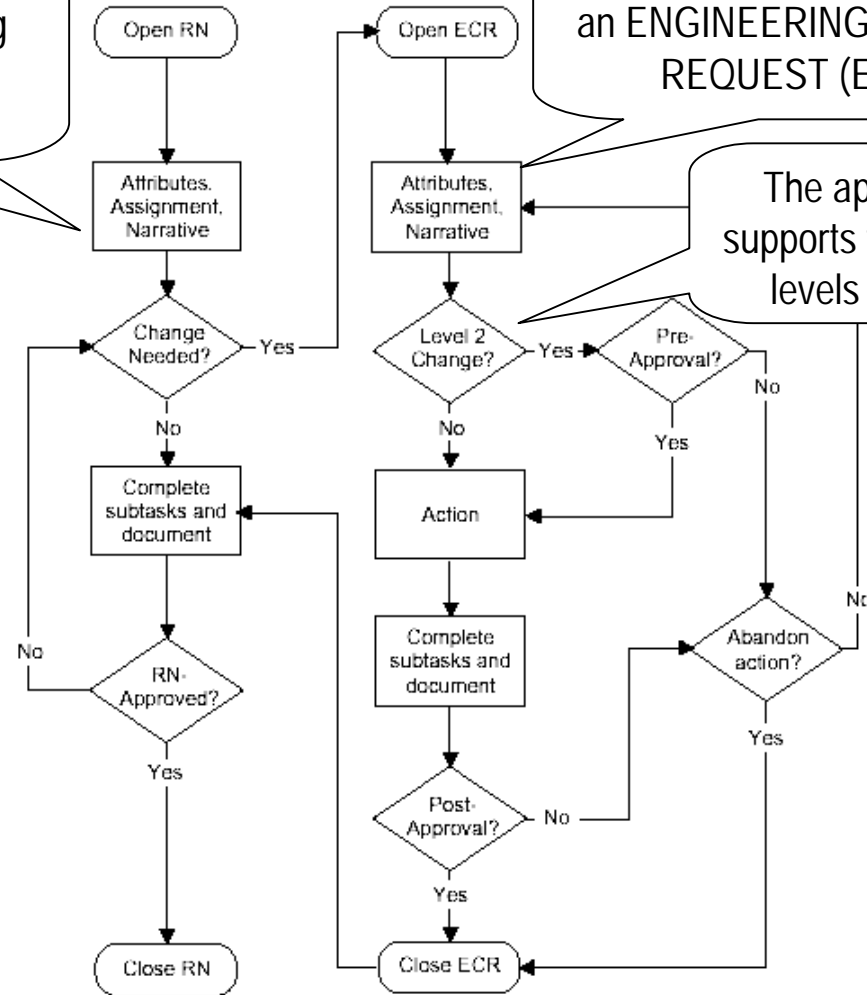
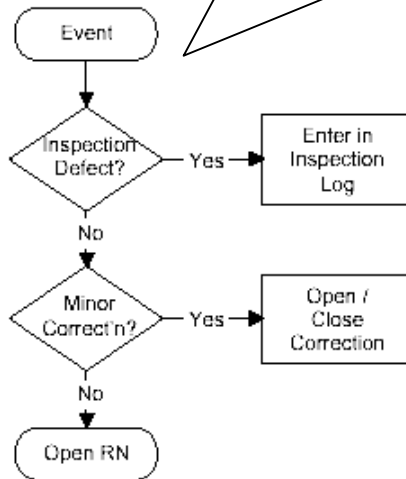
# The CAPA Process

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

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

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

The application supports two distinct levels of ECR.



# The Assembled RN Document

Key status information is 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?

Inventory items from ERP.

**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

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

Attached ECR's and attached documents are here.

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\lib19990412.pdf	<input type="checkbox"/>

**Routing Checklist:**

Description	Required?	Checked by	Date	Done?	Checked by	Date
Vendor (Notify)	<input checked="" type="checkbox"/>	MOBRIEN	01/30/2004	<input checked="" type="checkbox"/>	MOBRIEN	02/24/2004
Employee	<input type="checkbox"/>			<input type="checkbox"/>		
Perf Qual File	<input type="checkbox"/>			<input type="checkbox"/>		
NCL (original)	<input type="checkbox"/>			<input type="checkbox"/>		
Tech Services	<input checked="" type="checkbox"/>	MOBRIEN	01/30/2004	<input checked="" type="checkbox"/>	MOBRIEN	02/24/2004

**Review Date:** 03/01/2004    **Closed by:**    **Date:**    **Signature:** \_\_\_\_\_

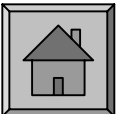
**Signature** \_\_\_\_\_    **Date** \_\_\_\_\_

Signature and date (paper or electronic) go here.

Checklists with names and dates are here.

RN#: 1002

Page 2 of 2

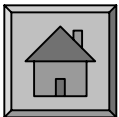


# Distinctive Features

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”

CAPA -- Corrective and Preventive Action (CAPA sample data)

File Options Help

**RN/EC** **CRCT** **LOG** **REPR** **EXIT**  
Review Notification Corrections Inspection Log Repairs Exit

**RN# 1002 -- Review Notification Form**

General | Narrative | Repair Details | Links | Status/Routing

RN ID: 1002 Open Date: 01/14/2004 Topic: Labeling of sterile sleeves  
Status: OPEN Originator: SCARPENTER Resp Party: SCHUNG

Non-conformance? Process/Metric:   
 Customer Complaint? Contact Name: Customer note:   
 Med Device Related?  SEMKO  FDA  Canada  Not Reportable   
 Item Related? 

Item ID	Cat #	Serial/Lot	Description	W/O No	Lock
LB3			Sterile Sleeve	0	Yes
LB3-01			Sterile Sleeve (Pk 20)	0	Yes

 DMR Name:      
 Performance Related? Employee Name:    
 Repair?

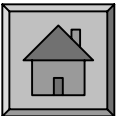
Click the RN/EC button to open a new RN, or to search for and edit existing RNs and their associated ECRs.

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.

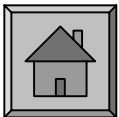


# The Threaded Narrative

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

File Options Help

**RN/EC** Review Notification    **CRCT** Corrections    **LOG** Inspection Log    **RE** Rep...

**RN#1002 -- Review Notification Form**

General | Narrative | Repair Details | Links | **Status/Routing**

Status:

RN Status: **RTC**

Review Date: 03/01/2004    Close Date:

Signed by: **DSE**    Close User:

Routing:

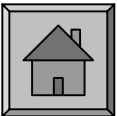
<input checked="" type="checkbox"/> Vendor (Not)	<input checked="" type="checkbox"/> Done
<input type="checkbox"/> Employee	<input type="checkbox"/> Done
<input type="checkbox"/> Perf Qual File	<input type="checkbox"/> Done
<input type="checkbox"/> NCL (original)	<input type="checkbox"/> Done
<input checked="" type="checkbox"/> Tech Services	<input checked="" type="checkbox"/> Done

Shot Printout    Print this RN    Exit this RN

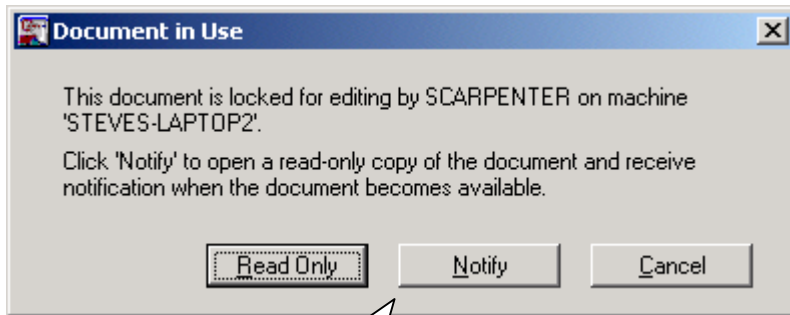
The RN STATUS is changed under the STATUS / ROUTING tab. Configurable document life cycle means that the status identifiers are defined using a STATUS LIST MANAGEMENT screen.

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.

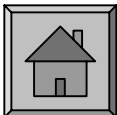
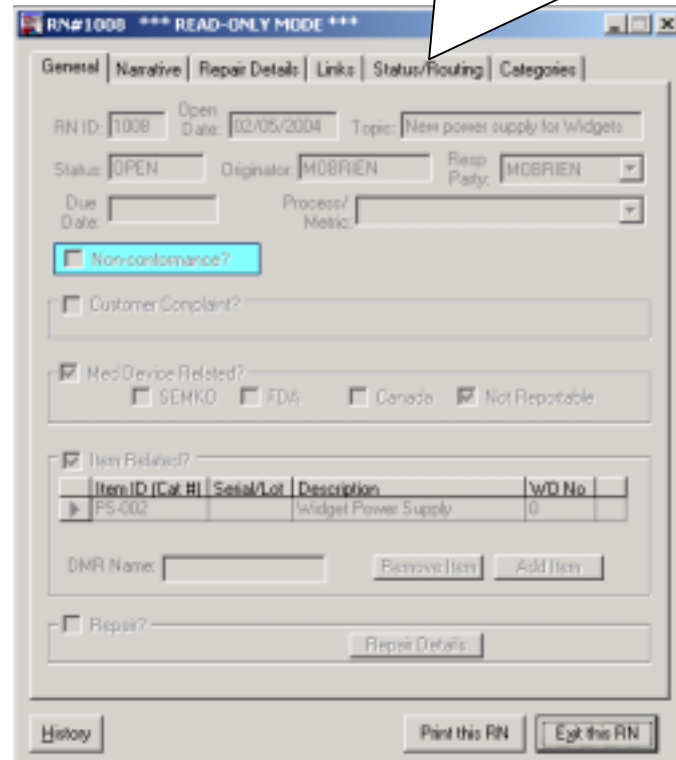


# Document-based Collaboration



Click the NOTIFY button to receive a message when the document becomes available for editing

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



# ECRs and Attached Documents

The screenshot displays two overlapping windows from the CAPA software. The background window is titled 'RN#1002 -- Review Notification Form' and has tabs for 'General', 'Narrative', 'Repair Details', 'Links', and 'Status/Routing'. The 'Links' tab is active, showing a table of Engineering Change(s) with columns for ECR#, Open Date, ECR Topic, Status, and Lock. A single entry is visible: ECR# 1002-01, Open Date 02/03/2004, ECR Topic 'Add "Latex Free" to sleeve labels', Status 'RC READY', and Lock 'Yes'. Below this table is an 'Attached Document(s)' section with a text field containing 'C:\DOCUMENT\vb19390412.pdf' and an 'Open' button. The foreground window is titled 'ECR#1002-01 -- Engineering Change Form' and has tabs for 'ECR Details', 'Narrative', 'ECO Details', and 'Routing/Checklist'. The 'ECR Details' tab is active, showing fields for ECR ID (1002-01), Status (RC READY), Open Date (02/03/2004), Close Date, Topic (Add "Latex Free" to sleeve labels), and Originator (SCHUNG). Below these fields is a table 'Part(s) affected by this ECR' with columns for Old Item ID, Description, New Item ID, and Lock. Two rows are listed: L83 (Sterile Sleeve) and L83-01 (Sterile Sleeve (Pk. 20)). At the bottom of the ECR form is a 'Parts List (BOM) change(s) created by this ECR' section with columns for Parent Item, Old Item, Old Qty, and New Qty. Callouts provide additional context: one points to the 'Links' tab in the RN form, another to the ECR form, a third to the 'Attached Document(s)' field, a fourth to the 'Part(s) affected by this ECR' table, and a fifth to the 'Parts List (BOM) change(s)' section.

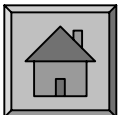
Under the LINKS tab, the RN is linked to its ECR or ECRs and to ATTACHED DOCUMENTS.

The ECR is a comprehensive change support document with its own configurable life cycle and status change rules.

Any Windows document can be linked to an RN here, from where it can be opened in its native application.

Inventory data for affected parts comes from ERP.

A BOM lookup feature generates correction documents for every instance in the ERP system where the affected part is used in an assembly.



# Management

Select Action Form and list type:

After selecting lists and list type, click the ADD or DISDELETE ON/OFF buttons to add or remove items from the Master Checklist.

Control the display sequence by editing the SEQUENCE number.

To preserve compatibility with older documents, a master checklist item MUST NOT be deleted or revised with another description. Its description can be edited for clarity. Or the item can be marked obsolete.

ID	Description	Sequence	Obsolete?
1	Vendor Files	1	No
2	PAR	2	Yes
3	Per # File	3	Yes
4	Employee	4	Yes
5	Per Qual File	5	Yes
6	NCI Journal	6	Yes
7	Tech Services	7	Yes
114	Remaining	114	Yes

**ITEM - Review Notification**

Rating:

<input type="checkbox"/> Vendor (Body)	<input type="checkbox"/> Done
<input type="checkbox"/> Employee	<input type="checkbox"/> Done
<input type="checkbox"/> Per Qual File	<input type="checkbox"/> Done
<input type="checkbox"/> Tech Services	<input type="checkbox"/> Done
<input type="checkbox"/> Remaining	<input type="checkbox"/> Done

Select Document type:

After selecting Document type, click the ADD or DISDELETE ON/OFF buttons to add or remove items from the Master Status List.

Control the display sequence by editing the SEQUENCE number.

To preserve compatibility with older documents, a master status item MUST NOT be deleted or revised with another description. Its description can be added for clarity. Or the item can be marked obsolete.

ID	Status	Sequence	Obsolete
1	OPEN	1	No
111	RTIC	4	No
100	CLOSED	5	No
101	VOID	6	No
87	PRC READY	9	Yes
88	APPROVED	10	Yes
89	COMPLETE	11	Yes

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

Select Document type:

After selecting a DOCUMENT TYPE, add rules one-by-one

Each RULE has one or more STATUSES and one or more CONDITIONS.

Each CONDITION has a SUBJECT, an OPERATOR and if the operator requires one, a PREDICATE.

Multiple conditions are connected by the AND operator. When you need to connect conditions using the OR operator, create separate rules instead, using the same number.

To CREATE A RULE -

1. Select a status and click 'Add Status'
2. Select a Subject and an Operator. If the operator requires a predicate, select one from the list or enter it as a value. When the condition is complete, click 'Add Condition'
3. When the RULE is complete, Click 'Add Rule'

Can't change status to:  When:  is

Can't change status to:  when: (STATUS != DISDELETE) OR (DATE\_TAMP\_OR\_EQUAL\_TO V)

ID	Doc Type	Sequence	Condition	Rule to the Document Type
1	REV_NOTE	1	Can't change status to 'CLOSED' when: DISDELETE REQUIRED, BUT NOT DONE	
4	REV_NOTE	4	Can't change status to 'CLOSED' when: (REVIEW DATE = EMPTY)	

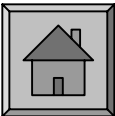
The CHECKLIST manager and its PREVIEW screen create custom to-do lists

**User Involvement Documents**

User	Instance	Date	Device	Instance Start	Doc Type	Document
1	SCAFFENTER	STCNS (LAPTOP)	STCNS (LAPTOP)	6/2/05 5:53 PM	PAR	182
	SCAFFENTER	STCNS (LAPTOP)	STCNS (LAPTOP)	6/2/05 5:53 PM	EDR	182:01

Current Instance:

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.

**AGENDA**

**RN's Ready to Close**

**1008 OPEN** New patient supply for Whiglets 03/02/2014 MCGHEE HNYNYNN  
1009 OPEN Repair of Budget 04/22/14 03/04/2014 TARBON HNNNNNY

**1010 OPEN** Labeling of sterile delivery 03/14/2014 SCHUNG HNYNYNN

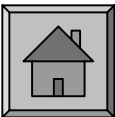
**1011 CLOSED** QTP-91 Glass Tubes 04/22/2014 SCHUNG HNNNYNN

**1012 CLOSED** 25.23 washer not right with 03/23/2014 SMILWC HNNNYNN

**1013 CLOSED** Late shipment for Megacombal 03/23/2014 JFOWLE YYYNYNN

**1014 CLOSED** Whiglet return 03/16/2014 SCHUNG HNYNYNN

**1015 CLOSED** Repair of WA-6550 04/02/2014 SCARPENTER HNYNYNN



# 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.

