

MANAGE YOUR DOCUMENTS, CORRECTIVE AND PREVENTIVE ACTIONS, AUDITS IN ONE PLACE!

ENNOV5



**Benefits**

► **Features**

- o User-friendly, graphical mapping of any quality process
- o Fool-proof document control of all formats (HTML, XML, MS Office, PDF)
- o Easy Web access to all your documents, audits and corrective actions
- o Convenient creation of composite documents
- o Reporting tools to simplify analysis and publishing of data
- o Exceeds ISO and FDA requirements

► **IT Architecture**

- o Standard and portable J2EE environment
- o Compatible with all operating systems: Microsoft, Unix, Linux or open source
- o Scalability – Adaptable to any business size
- o Full-Web interface, no need to install software on user's workstation
- o LDAP synchronization with internal e-mail system

**The 100% web-based Ennov solution can be accessed from any internal web page : a single entry point for your Quality Management System Information!**

**Manage Corrective and Preventive Actions : raise a Quality finding and track actions taken. Workflow steps track actions, responsibilities, timing, etc. Workflows are created easily through a graphical drag-and-drop interface.**

**Ennov 5 is an integrated quality management software including document lifecycle, process handling and audit follow-up features.**

Your organization regularly creates, revises, approves and distributes new procedures, raises quality findings and customer complaints, initiates corrective and preventive actions, and schedules and performs periodic audits...

Ennov 5 is the best software solution to optimize these processes, to share information effectively and to drive continual improvement within your business. It has been chosen by 300 discerning clients worldwide, including major companies in the automotive, energy, pharmaceuticals and utility industries.

Ennov 5 presents clearly to your users:

- Documents they must approve or review
- Actions they must take on quality findings
- Audits scheduled in their organization

Real-time measurements of performance to maintain compliance to ISO and FDA standards.

The screenshot displays the Ennov 5 software interface. On the left, a table titled "All CAPAs in Progress by Status" lists various CAPA records with columns for Reference, Title, and status. The main area shows a workflow diagram for "Raising a CAPA" with steps: Manager Appro, QA Dir Appro, Cause Analysis, Action Plan, AP Validation, Action Valid, Efficiency, Closure Appro, and Closure. On the right, a "Description" panel shows details for a CAPA, including status name, description, code, and assignment type.

Reference	Title	Status	Responsible	Category
<b>Manager Appro (4 documents)</b>				
Maint-CAPA-2005-081	Management Proc...			
Maint-CAPA-2005-082	Realization Process/MGPP - Maintenance	H. FAYOL	Manager Appro	H. FAYOL
Maint-CAPA-2005-083	Realization Process/Go to Market/Customer - Mainte	H. FAYOL	Manager Appro	E. DEMING
Maint-CAPA-2005-085	Realization Process/Go to Market/Customer - Mainte	H. FAYOL	Manager Appro	E. DEMING
<b>Causes analysis (1 document)</b>				
PUH-CAPA-2005-047	Support Process/Finance - Production Unit 1	H. FAYOL	Causes analysis -	
<b>Valid of actions (1 document)</b>				
Maint-CAPA-2005-065	Realization Process/Go to Market/Product follow-up -	H. FAYOL	Valid of actions	H. FAYOL Major
=> Maint-CA-2005-066 - 1st corrective action				
=> Maint-PA-2005-067 - 1st preventive action				
<= Maint-CAPA-2005-035 - Support Process/IT - Maintenance				
<b>Efficiency (2 documents)</b>				
Maint-CAPA-2005-035	Support Process/IT - Maintenance	H. FAYOL	Efficiency	H. FAYOL Major
Maint-CAPA-2005-040	Realization Process/Supply the Product/Manufacturin	H. FAYOL	Efficiency	H. FAYOL minor
<b>Final status (4 documents)</b>				
Maint-CAPA-2005-043	Realization Process/Go to Market/Product follow-up -	H. FAYOL	Final status	
Maint-CAPA-2005-048	Support Process/Human Resources - Maintenance	H. FAYOL	Final status	minor
Maint-CAPA-2005-072	Support Process/Quality & Regulatory affairs - Mainte	H. FAYOL	Final status	Major
Maint-CAPA-2005-078	Support Process/IT - Maintenance	H. FAYOL	Final status	Major

## Document Lifecycle

**Document control** – Organize your quality system into different units where the authorized functional user defines the rules for: approval of workflows, approvers and recipients of documents, and confidentiality levels. Document viewing is monitored via electronic return receipts and reminder e-mails.

**Collaborative work** – Users are notified by e-mail whenever they have an action to perform (e.g. approve, revise or view a document). Teams of knowledgeable persons may write documents together using the check-in / check-out feature, or may exchange information in a dedicated forum.

**Ease of access to information** – Documents are indexed according to relevant criteria: by department, by site, by ISO process, by issuer... A full-text search engine enables in-depth browsing of the database. When viewing a document, a user can check all information related to it: who signed it and when, what is the expiration date, if it is being revised...

**Audit trail** – All operations performed in the system are traced in a separate audit trail database. An entry is created with a description of the operation (e.g. change of document status, replacement of a field value by another, creation of a comment...), the name of the user, the date and hour. This database guarantees complete traceability of your documentation management system.

## Quality Processes

**Workflow engine** – A graphical interface allows you to design any type of workflow, however complex. At each stage in the processing, the responsible person enters information in pre-defined fields, then sends the workflow to the next step. The workflow path may be conditional, based on information entered previously. Some fields may be calculated or retrieved from external databases.

**Customizable forms** – Transitioning from paper to electronic forms is often confusing to users. With Ennov 5, integration of HTML forms enables to display a familiar interface, so that users who raise a finding or record a corrective action on the Intranet see a customized lay-out where fields are presented just as displayed in their previous paper forms.

**Global monitoring** – Your organization can have a real-time status of critical quality processes and measurements on quality system's performance. With Ennov 5, you define the quality indicators (number of findings raised for each unit of your business, average processing time for customer complaints) and track your metrics dynamically.

## Audit Follow-up

**Audit scheduling** – Efficiently plan your periodic audit program with an automatic routine that initiates the audit process at predefined dates and sends a timely notification e-mail to all persons involved.

**Declaration of audit findings** – The auditor enters findings and audit results on-line into a customized form, the system then scores each audited area and presents an evaluation of the compliance of your business.

**Corrective / preventive actions** – When audit findings require appropriate actions by responsible persons, parallel corrective action requests may be launched, each following their own workflow. The corrective action for the finding is closed only when all actions have been completed and properly verified.

**Generation of audit reports** – All information entered in the system during the audit period may be consolidated into a report signed by the audit team and approved by the audited unit or site.

## Technical environment

- *Application server: Jboss, WebSphere, WebLogic, Oracle Application Server*
- *RDBMS : Oracle, SQL Server, DB2, MySQL*
- *Client: Internet Explorer, Netscape, Firefox*

## Our clients

AGF Allianz, Alstom, Air Liquide, Aventis, BASF, Cargill, General Electric Energy, Linde Gas, Michelin, Novartis, OMYA, Peugeot, Renault Trucks, Wheelabrator, etc.

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