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Non Compliance
Non-Conformances   Dissatisfaction

QA-CAPA Solution
Business Content in Business Context

The purpose of a Corrective Action and Preventive Action (CAPA) management system is to identify and investigate existing and potential product and quality problems and assure that appropriate, effective and comprehensive actions are taken to solve them.

Companies in every industry require robust systems to manage two key processes: (1) Their customer claims and (2) Non-conformities to standard operating procedures to achieve, among other things:

- Significant reductions in customer complaints
- Minimize financial risks associated with non-compliance and fines
- Compliance with QA and market regulations
- Maintain detailed control over production costs

Both processes require seamless information sharing, cross-enterprise collaboration, and audit evidence traceability. Despite the critical nature of these areas, most companies address them with paper-based processes, email, spreadsheets, or non-integrated and departmentally focused applications. These "solutions" are also typically not integrated with the companies' core information management systems, causing more inefficiencies and lack of visibility.

The Stratesys QA-CAPA solution brings together **market best-practices** and **best of breed technology** to automate and better monitor these critical business processes. Our solution focuses on simplifying and accelerating the systematic investigation of the root causes of a customer claim or non-conformity, delivering a value added solution to any Quality Management System (QMS) and support compliance with good manufacturing practices (GMP).
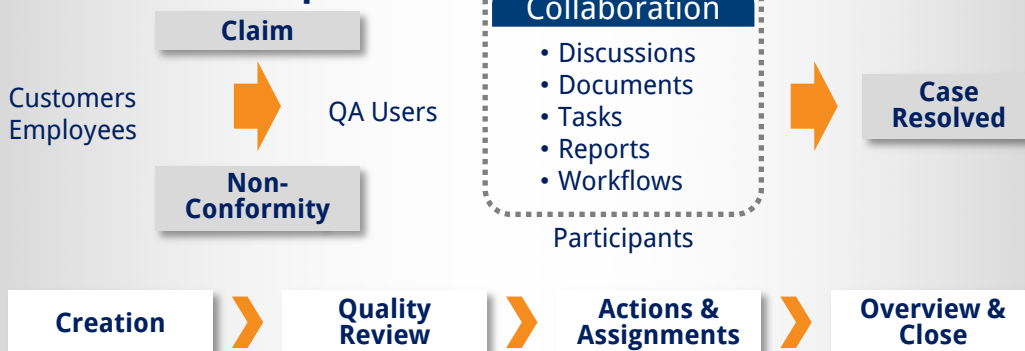
Stratesys has developed a solution that achieves the following:

- **simplify the creation** of a customer claim or process non-conformity
- **dynamically allocate resources** required for each process
- **keep an audit trail of the analysis and resolution of collaborative process** between the QA team and all involved participants
- store all relevant information on a **controlled and secure platform**
- manage a **configurable Quality KPI** dashboard

This solution:
- Enhances efficiency by reducing process costs
- Provides an integrated process view and enhanced management visibility
- Boosts productivity
- Reduces IT TCO

Functional Scope

Customers / Employees → **Claim** / **Non-Conformity** → QA Users

Collaboration
- Discussions
- Documents
- Tasks
- Reports
- Workflows

Participants

→ **Case Resolved**

Creation > **Quality Review** > **Actions & Assignments** > **Overview & Close**

Value Proposition | Return On Investment

Efficiency
- **Elimination of paper** based forms
- **Elimination of content copies** between process participants
- **Control of digital content** attached to the process
- **Minimization of email based communication**

Productivity
- **Automatic traceability** and **KPI management** (excel)
- **Robust cross-platform classification criteria**
- **Template based solution** (automates re-use)
- **Simple GUI for task creation** (dynamic workflow automation)
- **Compliant with QA Norms and Regulations**
- **Secure access to data and content**

TCO
- **Common Master Data**
- **Leverage existing user applications**
- **Reduction of roll-out time** (quick user acceptance)
- **Leverage of existing IT Infrastructure**

Business Goals | KPIs Analysis

Creation

Customers and/or employees create a **Non-Conformity** or a **Claim** and **QA Managers** are notified via:
- e-mail
- Assignments Area (Intranet)

Intranet user
Web Based Forms

Non-Conformity

Claim

Business Information

Attachments

Intranet User
Personal Area

List of User Claims

List of User Non Conformities

User Task QA User Request

Quality Review

Quality user
NC and Claims Review
- Product and Customer
- Agents involved
- Documents
- Mails

Cancellation
Inform Intranet Users

Reject

Approve

- Importance
- Reasons
- Immediate cause
- Root cause

Quality user
NC and Claims Classification

Classification
Importance
Low
<None>
Low
Medium
High

Roles and Users Assigned

Phases / Milestones

Classification

Task and Assignments

Standardized Folder Structures with all Related Content

Business Information

Actions & Assignments

Add: Task

Name:
Assigned To: <Not Assigned>
Start Date: August 26 2012 2 PM
Due Date:
Priority: Medium
Status: Pending
Milestone: <None>
Instructions:
Comments:
Add Content Server Attachment: Browse Content Server
Add Desktop Attachment: Examinar
Categories: Edit
Add Reset

Quality user
Define and Assign Tasks

- Task's name
- Who it is assigned to
- Participants
- Date, Due Date, Priorities, Milestones, Instructions, Contents, Attachments, Categories

Collaborative Tools
- Discussions
- Documents
- Tasks
- Reports
- Workflows

Overview Processes

Overview & Close

- Check that all actions have been fulfilled
- Include additional information (total costs, recovery costs and average closing days)
- Close
- Quality Manager review and approval
- Inform all participants of closed case

Microsoft   OPENTEXT   SAP

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Our Partnership with OpenText

Stratesys is a Select Partner of the OpenText Partner Program for SAP Competence. This status recognizes **Stratesys** as experts in the delivery of **OpenText ECM** for **SAP** solutions to its customers. With this membership, **Stratesys** is committed to maintain up-to-date knowledge through on-going training, certification and blended delivery of services.
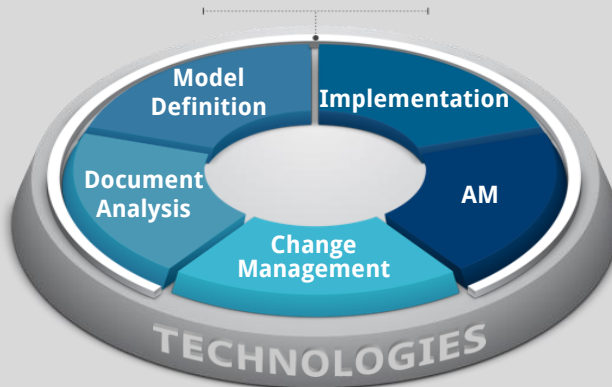
In **Stratesys** we have a deep understanding and wide experience in **OpenText** products that integrate with our clients **SAP** software landscape. Our expertise in design-definition, implementation and support, combined with a specific understanding of vertical requirements such as eCTD and Contract Management, self-service vendor, places **Stratesys** as one of the major players in project execution in this technology.

OPENTEXT Partner
SELECT

We develop IT services implementing OpenText Solutions in several industries

- Energy & Utilities
- Consume Goods
- Telecom & Media
- Retail
- Manufacturing
- Transportation
- Public Sector, Health & Education
- Life Sciences
- Construction & Real Estate
- Banking & Insurance

Core Services

- Model Definition
- Implementation
- Document Analysis
- AM
- Change Management

TECHNOLOGIES

Stratesys is a SAP Service Partner specialized in delivery services for the following SAP Solution Extensions by OpenText:

SAP Invoice Management by OpenText

SAP Document Access by OpenText

SAP Digital Asset Management by OpenText

SAP Extended ECM by OpenText

SAP Document Presentment by OpenText

SAP Employee File Management by OpenText

OCR Option for SAP Invoice Management by OpenText

SAP Archiving by OpenText

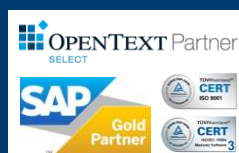**Click on the pictures to learn more about our OpenText customer success stories**

FRV

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SAP COMPETENCE

With the **OpenText Partner Program for SAP Competence**, OpenText relies on partners that clearly differentiate themselves through deep technical SAP expertise from other service providers and consulting firms in the market. SAP Competence partners are highly committed, innovative, and growth-oriented companies with excellent project, industry, and process knowledge.

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