Corrective and Preventive Action System (CAPA)

Product & Services Bundle for

Atlant's atWatch CAPA™

Atlant Systems, Inc. (781)325 - 8157 team@atlantsystems.com

Effectively Manage CAPAs Globally

According to regulations, all companies that come under the purview of the FDA are required to establish a Corrective and Preventive Action (CAPA) program within their company. The ultimate objective of the regulations is for each company to achieve the highest-level of quality.

Corrective Action and Preventive Actions are required quality measures that must be maintained as outlined in the FDA's 21 CFR 820.100 and 21 CFR 211.180 regulations as well as in ISO 8402.

Integrating corrective / preventive action CAPA system processes enterprise-wide has always been an important part of any life sciences corporate quality system.

The purpose of a CAPA report is to ensure that the root cause of any problem is addressed and that current or future problems will be alleviated or prevented.

No topic is of more consequence to life sciences companies than the consistent and proper use of a CAPA system. The company's CAPA systems can also serve as the cornerstone of cost reduction and process improvement efforts. It will likely lead to regulatory action if the company fails to implement a proper CAPA system besides preventing the company from leveraging these tools.

Corrective action and preventive action problems are dealt with strictly during FDA systems-based inspections. FDA Form 483 observations and warning letters published on the FDA's Web site make this statement obvious. According to the FDA, 30 percent to 50percent of all 483s are directly due to CAPA non-conformances.

Atlant's atWatch CAPA system Provides the Tools

Atlant's atWatch CAPA helps the company by providing a fast and effective means of generating reports and managing quality problems, non-conformances, and corrective / preventive action requests.

atWatch CAPA also helps a company achieve compliance with the FDA's regulation 21 CFR part 11, *"Electronic Records; Electronic Signatures* ."

Atlant's atWatch CAPA allows quality management, inspection personnel, customer service and repair, product complaint specialists, and other life sciences professionals to produce and file corrective action / preventive action reports for investigation, root-cause analysis, and the development of a proper implementation plan to achieve the desired quality level. They accomplish this task by simply filling in standardized forms, electronically on user-friendly screens.

Atlant's atWatch CAPA not only generates the reports, but can also file them in predetermined databases and direct them to the attention of the proper recipients.

Atlant's atWatch CAPA integrates seamlessly with Atlant's atWatch CPM, Product Complaint Management system. atWatch CAPA has often been interfaced to a company's Enterprise Resource Planning System (ERP) and other Customer Service Systems.

Atlant's atWatch CAPA helps a life sciences company:

- Receive, review and evaluate CAPA reports from customer service and repair, in-process inspectors, finished goods inspector, receiving inspection, and manufacturing.
- Process and document investigations of CAPA reports by the respective parties.
- Assist in determining root causes.
- Develop implementation plans for corrective and preventive actions.
- Track all open CAPA events to ensure timely resolu- tion and action.
- Enforce an approval process for each CAPA report that complies both with company and regulatory requirements.
- Provide access to the CAPA management system by all authorized users inside and outside the organization.
- Archive CAPA documents electronically for rapid search and retrieval.
- Deliver ad hoc reporting to management for trend evaluation and statistical analysis.

Atlant's atWatch CAPA helps you manage both company and regulatory documents associated with an CAPA report.

atWatch CAPA integrated components enable users to create, review, approve, release, track, and control documents including:

- Corrective Action Reports
- Field Action Requests
- Non-Conformance Reports
- Action Items
- Call Reports
- Form Letters
- Lab Reports
- Follow ups
- Investigations – external and internal
- Implementation Plans
- Trending Reports
- Information Requests

Atlant's atWatch CAPA helps you capture CAPA events data across the enterprise and provide a collaborative approach to problem solving that includes all relevant departments as part of the process.

Atlant's atWatch CAPA provides a closed-loop mechanism for initiating, implementing, and verifying the effectiveness of changes resulting from the exception experience.

The Centerpiece of Atlant's atWatch CAPA

The centerpiece of Atlant's atWatch CAPA is meta-information -- by document. The user is given all relevant information about an CAPA event in the way the authoring, editing and filing process is performed - step by step, action by action - all summarized in one location. More detailed information about any document is immediately available via imbedded views.

Atlant's atWatch CAPA has been designed with deliberate simplicity, mirroring the workflow of the quality management and safety organizations. A consistent user interface across multiple platforms, coupled with extensive on-line help, makes Atlant's atWatch CAPA intuitively easy to learn and use.

Navigation within the Atlant's atWatch CAPA system is simple. The design of the integrated modules leads the user through steps to click on buttons or icons that automatically forwards them through the appropriate workflow.

Atlant's atWatch CAPA employs user-controlled tables for almost every checklist-driven entry. Modification of checklists and tables are under the control of the CAPA database administrator, not the IT staff.

With the latest in collaboration technology, remote and mobile users can personally manage CAPA information using their laptop. Later, new and/or updated information is easily and efficiently replicated to the corporate Atlant's atWatch CAPA database.

Atlant's atWatch CAPA is scalable. It can serve a single location or an entire enterprise with global sites. Through replication, data can be synchronized across large organizations.

Atlant's atWatch CAPA has been tested with a wide variety of other applications to further extend its power to other critical functions within the organization including manufacturing and engineering. These include: graphics, video, sound, CAD/CAM, word processing, spread sheets, management reporting, and other database managers -- Oracle, DB2, SAS, SAP included.

Compliance:

Atlant's systems engineering experience provides the perfect foundation on which to build dependable, consistent, secure, accurate and attributable Internet-based applications conforming to all GxP requirements for Data Integrity, System Reliability, Management Control, and Auditable Quality.

Atlant's atWatch CAPA is designed to be in full compliance with International Conference on Harmonization and Good Clinical Practices (ICH-GCP), 21 CFR Part 11 Electronic Record and electronic signatures and FDA's "Guidance: Computerized Systems Used in Clinical Trial."

Interfaces:

Atlant's atWatch CAPA integrates seamlessly with Atlant's Product Complaint Management system.

Atlant's atWatch CAPA automatically performs error correction between the user's input and history. On a more complex level, Atlant's atWatch CAPA can automatically test a report for any gross variation from established history.

If, for example, a reporter records a CAPA effect that has never been associated before with a particular company product, assembly, ingredient, raw material, or manufacturing process, then Atlant's atWatch CAPA will alert the user that something is very unusual in this particular report.

Once the AER is complete, CAPA alerts the quality management team electronically via an action item. The action item is automatically sent through e-mail with a link brings the recipient(s) directly to the appropriate report.

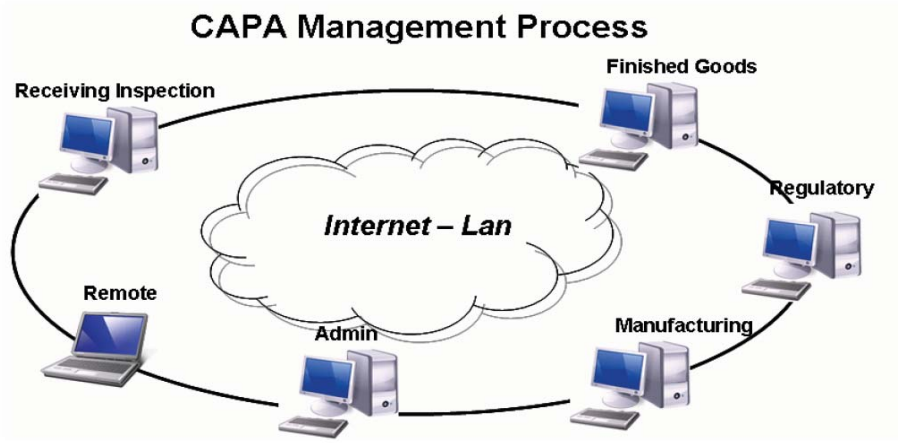
The CAPA event is now available to all authorized users for review and action. Atlant's atWatch CAPA manages the process flows that take place within the organization to alert the appropriate and assigned personnel.

Atlant's atWatch CAPA Software:

Atlant's atWatch CAPA software provides the highest level of access and security to on-line and on- time CAPA event information. Atlant's atWatch CAPA facilitates e-business models for CAPA event management by supporting a secure intranet and extra-net.

Atlant's atWatch CAPA - is comprised of several integrated modules that work together to form a complete CAPA system. Because of Atlant's atWatch's open architecture , Winchester's ad- Watch CAPA can interface with existing company ERP, customer service and repair, and product complaint systems. Events recorded in each system can apprise the other system(s) of the completion of the event or that an anomaly has occurred.

Atlant 's atWatch CAPA components - are integrated to seamlessly exchange data to satisfy multi-organizational needs - sites, patients, health professionals, and internal and external clinical trial partners.



CAPA -
Atlant's atWatch CAPA mirrors the workflow of CAPA event processing from initial notification through investigation, analysis, and resolution.

Automated Investigation - Atlant's atWatch CAPA automatically generates the necessary investigation action requests from information already in the database. Reports are seamlessly integrated to increase efficiency and accuracy of data.

Best Practices - Atlant's atWatch CAPA promotes best practices throughout all business levels.

Configurable - Atlant's atWatch CAPA components are configurable to meet the specific needs of any life sciences manufacturing organization. Atlant provides configuration services to help you fit Atlant's atWatch CAPA to your specific environment.

Analytical Tools - Powerful analytical tools are included in atWatch to provide you with the reporting and trending you need to anticipate CAPA event issues.

Programmed Agents - Atlant's atWatch CAPA automatically triggers programmed actions that ensure that CAPA events are promptly followed up.

Correspondence and Notification Forms letter library provides the ability to send customized letters at predetermined times or on an as-needed basis during the investigation and resolution. Powerful merge-mail facility allows departments to send multiple customized letters.

Software Validation - Atlant's atWatch CAPA includes a software validation protocol database to assist with FDA-mandated requirements for initial validation and change control procedures.

Global Access to Current Information - Manufacturing Operations, Customer Service, Quality Assurance, and Regulatory Affairs have access to critical data as the CAPA event is being processed and resolved. Enterprise-wide replication ensures up-to-the-minute information is available across all locations, worldwide

Electronic Records and Signatures - Atlant Systems' atWatch CAPA meets and exceeds the requirements for the FDA's 21 CFR Part 11.

Remote Operation - atWatch CAPA allows remote users to participate in many functions of the system via dial-up, intranet, or extranet. Requests for actions and process notifications appear in the recipient's electronic mail box, regardless of what e-mail system they use. Users can enter data on site or after hours via a laptop. All changes made to records and documents remotely can be replicated to the CAPA system, thus dramatically expanding accuracy and productivity.

Ease of Use - An intuitive look and feel to screens makes using Atlant's atWatch CAPA simple and straightforward. Users are prompted through record and document development by pop-up menus and internal checks on data integrity. The Atlant's atWatch CAPA Help system provides detailed user information on all functions of the system.

Unique Features of Atlant's atWatch CAPA:

Powerful Tools - Atlant's atWatch CAPA integrates CAPA processes with the extensive functionality of a collaborative groupware application. The resulting Atlant's atWatch CAPA applications deliver functionally rich, comprehensive CAPA event management capabilities to the project team.

E-Mail Freedom - Atlant's atWatch CAPA interfaces with all known e-mail systems. Action items and document workflow tracking make free use of the users' e-mail. However, e-mails are kept external to the Atlant's atWatch CAPA processes.

Connections to other systems - Atlant's atWatch CAPA helps the company team manage all incidents. Atlant's atWatch CAPA has been connected to many other internally-developed and vendor- supplied ERP systems.

Uploading data and information - Previous CAPA event data may currently exist in other systems outside of Atlant's atWatch CAPA. In addition to being able to connect to other systems, direct data can be uploaded into Atlant's atWatch CAPA by applying some simple scripts.

Application Security and Compliance with 21 CFR Part 11

Atlant's atWatch CAPA robust security is a well established benefit of the platform. Security is customizable, can vary by department and user. Access and user roles are governed by an Access Control List.

The CAPA administrator can specify users by name, by groups, and even by "roles" (i.e., Dept. Manager, Regulatory Affairs Manager, IT Staff, etc.). Even personal "replica copies" of Atlant's atWatch CAPA on local machines or on removable media can be assigned various levels of encryption and user authorization privileges.

Atlant's atWatch CAPA utilizes Winchester's atComPac Application for compliance with 21 CFR Part 11.

Atlant's atWatch CAPA provides the following features.

Security - Atlant's atWatch CAPA utilizes the most-comprehensive security model available to ensure that all information and data is viewed, read, edited, changed, and managed only by authorized personnel.

Audit Trail - Atlant's atWatch CAPA provides a human readable audit trail, at the field level, for each document in the system. Utilizing Atlant's Snapshot technology, Atlant's atWatch CAPA tracks the original value of a field, the changed (new) value of the field and records the date, time and originator of the change.

Digital Signatures - By employing a PKI based digital certificate for identification and authentication, atProtocol can apply a digital signature to any electronic record in the system. Once applied, the digital signature will meet the criteria necessary for nonrepudiation and identity challenges, and can be considered the legal equivalent of a hand-written signature.

Identity Confirmation - The Atlant's atWatch CAPA authentication module (atComPac) meets the guidelines set forth by the FDA for subsequent saving or signing of records in both a new session and in a continuous session.

Access Logging - Access to an application can be logged using the atComPac tool set. When a user enters the database, the event is captured, the termination of that session is also captured and a log is written with the length of time of each session.

Access Control - One of the challenges in a regulated environment is to produce a 21 CFR part 11 audit trail of the access and permissions changes to an application. By utilizing the access control module (atComPac), a full audit trail is written showing the access changes, the previous levels and/or roles and subsequent changed levels and/or roles.

Web Authentication - The web based version of the tool allows a web form to capture all changes in the audit trail and perform full authentication at the saving of a record.

Reason for Change - Many key fields within a system should require a user to enter a reason for change when updating those values. The system allows the database manager to define fields that require a reason for change.

Rules Based Configuration - By default all fields within the database are audited. The configuration module allows the database manager to define rules for auditing as well as to select certain fields for exclusion, and direct where the audit trail is to be stored (internal or external to the current database).

Ease of Use

Atlant's atWatch CAPA incorporates powerful groupware technology for collaboration and information exchange. By enabling people to access and modify the same documents, Atlant's atWatch CAPA allows team members to work independently while sharing a common database.

Atlant's atWatch CAPA has been designed with deliberate simplicity, mirroring the workflow of the quality and regulatory affairs organizations. A consistent user interface across multiple platforms, coupled with extensive on-line help, makes Atlant's atWatch CAPA intuitively easy to learn and use.

Navigation within Atlant's atWatch CAPA is very easy, using buttons and icons that automatically forward users through the appropriate workflow.

The system provides a wide range of features that simplify the workflow management of clinical trial environments.

These features include:

- Linked subsystems with bi-directional cross-referencing of CAPAs
- Management of records and documents through appropriate states of development and approval
- Automated record and document control
- Consolidation of review and approval history and actions associated with the CAPA process
- Locking upon completion of controlled records
- Automatic notification and escalation to enforce action items

Computer Requirements - Minimum

Although not required or essential, Atlant Systems recommends:

> *"Computer applications that are required to be in compliance with and require validation according to FDA's 21 CFR Part 11, Electronic Records Electronic Signatures, should not be placed on the same server as other applications that need not be compliant."*

Generally, most of Atlant's clients have decided to install a validated server to house all of their "Regulatory" applications.

Trusted Technology Partners

ACTION Deployment Phases for Adverse Event Report Management