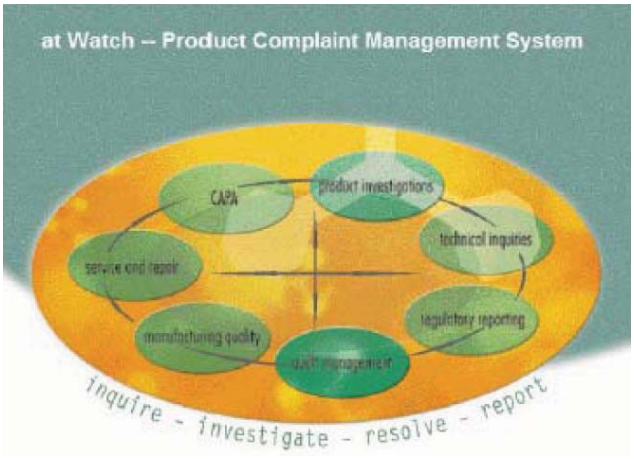
Product Complaint Management System (PCMS)

Effectively Manage Product Complaints Globally

Customer service . . . compliance . . . GxP . . . safety . . . complaints . . . inquiries . . . CAPA program . . . To be compliant and competitive in today's markets where customer service is "king" and the FDA is lurking, your organization needs full participation by all departments – sales, marketing, QA, RA, manufacturing, and technical service. *Atlant's atWatch PCM™* helps organizations capture, distribute, retrieve, and manage product complaints globally — product complaints from any source — manual, computer, or application.

atWatch PCM fosters an environment where document creation, review, and approval can be done collaboratively among individuals.



within and outside the corporation all over the world.

atWatch Product Complaint Management helps a pharmaceutical and/or medical device company:

- Receive, review and evaluate product complaints from customers, physicians, patients, distributors, and other organizations
- Process and document investigations of product complaints by the respective manufacturing site(s)
- Resolve product complaints including the actions necessary to meet customer service goals
- Track all open product complaints to ensure timely resolution Enforce an approval process for each product complaint that complies both with company and regulatory requirements
- Provide access to the product complaint management system by all authorized users inside and outside the organization
- Archive product complaint documents electronically for rapid search and retrieval
- Deliver ad hoc reporting to management for trend evaluation and statistical analysis

atWatch PCM helps you manage both company and regulatory documents associated with an incident.

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

- Inquiries
- Product Complaints
- Adverse Drug Reactions
- Medical Device Reports
- Action Items
- Form Letters
- Shipping Documents
- Failure Investigations
- Corrective Action Requests
- Requests for service calls
- Issues of Materials
- Root Causes
- MedWatch 3500A
- CIOMS
- Periodic Reports
- Corrective And Preventive Action activities
- Call Reports

Why choose Atlant's atWatch PCM Product Complaint Management System? atWatch PCM is:

- Easy to use — with Web-based PCM solution

- Secure — allowing access by only authorized users
- Collaborative – Designed for multiple organizations sites, customers, distributors, patients, health professionals, and internal and OEM manufacturing
- Compliant – helps satisfy 21 CFR Part 11 ?? Accessible – connections from anywhere, at any time
- Configurable – robust and highly- configurable features and functions to meet best practices
- Easy to integrate with existing business systems

atWatch PCM helps you capture product complaints, inquiries, service calls, and CAPA data across the enterprise and provide a collaborative approach to problem solving that includes all departments as part of the process.

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

Atlant's atWatch PCM Software:

Atlant's atWatch PCM software provides the highest level of access and security to online and on-time product complaint information. atWatch PCM facilitates e-business models for product complaint management by supporting a secure intranet and extranet.

atWatch PCM is a Suite — atWatch PCM is a suite of integrated applications designed to assist the Product Complaint Management Team in managing information about product complaints, inquiries, and service calls. atWatch PCM provides an innovative Intranet/Internet-based and client/ server solution to meet a wide-range of pharmaceutical and medical device company business environments.

atWatch PCM components — are integrated to seamlessly exchange data to satisfy multi-organizational needs — sites, customers, distributors, patients, health professionals, and internal and OEM manufacturing.

Best Practices — atWatch PCM promotes best practices throughout all business levels.

Configurable — atWatch PCM components are configurable to meet the specific needs of any service and complaint management organization. IBM Life Sciences and Atlant provides configuration services to help you fit atWatch PCM 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 quality and customer service issues.

Programmed Agents — atWatch PCM automatically triggers programmed actions that lead to a credit memo, debit memo, or a substitute delivery, for example

Code Dictionaries — atWatch PCM contains failure code dictionaries that may be populated by the company. Dictionaries include failure codes, potential root causes, and corrective actions. Codes supplied by the FDA as required on the 3500A are also included. MadDRA and COSTART dictionaries are optionally included for Adverse Drug Reactions.

Complaint Entry and Analysis — atWatch PCM mirrors the workflow of complaint processing from initial notification through investigation, analysis, and resolution.

Automated Adverse Event Reporting — atWatch PCM automatically generates the FDA-approved MedWatch, Baseline, and CIOMS reports from information already in the database. Reports are seamlessly integrated to increase efficiency and accuracy of data.

Customer 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.

Corrective Action — atWatch PCM provides the ability to respond quickly to product quality issues by providing timely customer feedback. Electronic notification with Action Items to all departments is automatically generated.

Software Validation — atWatch PCM includes a software validation database to assist with FDA-mandated requirements for initial validation and change control procedures.

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

Electronic Records and Signatures — atWatch PCM meets and exceeds the requirements for the FDA's 21 CFR Part 11.

Security — atWatch PCM's robust security is a well established benefit of Notes and Domino. Security is customizable, can vary by department and user. Access is governed by an Access Control List.

The regulatory affairs 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 atWatch PCM on local machines or on removable media can be assigned various levels of encryption and user authorization privileges

Remote Operation — atWatch 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. Users can enter data on site or after hours via a laptop. All changes made to documents remotely can be replicated to the Product Complaints Notes databases, thus dramatically expanding accuracy and productivity.

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

atWatch PCM helps you:

- Manage all complaint types across a global organization
- Significantly improve the complaint management process by reducing time-to-resolution
- Streamline communications internally and externally using discussion threads
- Ensure all product complaints are properly documented, FDA commitments tracked
- Share complaint knowledge across the enterprise
- Achieve a faster time-to-compliance with industry standards

atWatch PCM is a Global Clinical Trials Expressway:

atWatch PCM supports continuous improvement by creating a comprehensive database of all planned, current and completed product complaints, inquiries, corrective action requests, and investigations. This data can be used to establish and measure key processes and to implement global standards.

atWatch PCM — is comprised of several integrated modules that work together to form a complete Product Complaint Management System (PCMS). Because of atWatch PCM's open architecture, atWatch PCM can interface with existing company ERP systems). Events recorded in each system can apprise the other system(s) of the completion of the event or that an anomaly has occurred. The functions of the modules that comprise atWatch PCM are briefly described below:

Incident Reporting — Incident reports may be entered or generated by anyone who has access to the system. Entries can be made from the Internet and/or a company's Intranet. Incidents can be inquiries, product complaints, potential product complaints, adverse drug reactions, and medical device reports.

The amount of data collected at the initial entry point is generally limited to the identification of the product, its serial or lot number, when the incident occurred, who is reporting the incident, the name and address of the complainant, and a description of the incident.

The "complaint specialist" or administrator screens the incidents and responds immediately, escalates the incident as an inquiry to a technical specialist, or closes the incident to the Complaint Management component.

The Incident Reporting component retains all queries and answers in a "knowledgebase" for use in the resolution of subsequent incidents.

Accounts & Customers — atWatch PCM interfaces with a company's ERP system to extract and use information about a company's products, customers, shipments. Shipments are managed by either serial number or lot number. Accounts & Customers supplies the other atWatch PCM components with live, online information necessary for selection.

Corrective Action Reporting (CAR) — Corrective Action Reports may be entered or generated by anyone who has access to the system. Entries can be made from the Internet and/or a company's Intranet.

CAR operates in a similar fashion to the Incident Reporting component. If the administrator decides that the CAR has merit, he or she closes the CAR to the CAPA component as an open item.

Form Letters — The atWatch PCM component "Form Letters" contains a repository of form letter templates that are used by the various modules. These templates can contain acknowledgements, "Dear Doctor Letters," and any other tletter templates used within the process. When a template is selected, the generated letter inherits key information from the selected incident, complaint, CAR, CAPA item, or investigation.

Complaint Management — Complaint Management is the primary component of atWatch PCM. Complaint Management accepts incidents as potential complaints fom the Incident component. It also will accept direct entry of a Product Complaint. Workflow steps are automatically adjusted and monitored as a complaint travels through the system. Complaint Management utilizes many forms and documents to manage a single incident. Depending on the type of complaint and your company's policy, ADRs, MDRs, and CIOMS reports can be generated near the end of the workflow cycle.

Complaint Management tracks all incidents as cases. Failure codes are offered for trending and analysis. Complaint Management comes with a comprehensive coding capability. This coding capability allows user companies to maintain failure and other codes in their own dictionaries.

Corrective and Preventive Action (CAPA) — The CAPA component accepts CARs from the CAR Reporting component. An entry in CAPA can include any type of quality issue whether it stems from a product, process, or equipment. Entries can reference already-entered product complaints and other sources. Similar to the Complaint Management component, CAPA has a complete Investigation Worksheet capability. Multiple investigations are allowed for any CAPA item or entry.

MedDRA Dictionary — The MedDRA Dictionary component is used by pharmaceutical companies in coding product complaints and adverse events – depending on company policy. A separate license must be purchased by the company from the vendor of the MedDRA Dictionary in order to use this dictionary.

COSTART Dictionary — The COSTART Dictionary component is used by pharmaceutical companies in coding product complaints and adverse events – depending on company policy. The COSTART Dictionary contents are maintained and updated quarterly by the FDA at www.fda.gov. Updates are downloaded and the contents of the COSTART Dictionary are refreshed depending on company policy.

Query Manager — The Query Manager produces Ad-hoc reports or stored reports across databases and across complaints or CAPA entries. By utilizing the Query Manager an administrator, analyst, or any authorized individual can generate a custom report of information.

Unique Features of atWatch PCM:

Powerful Tools — atWatch PCM integrates product complaint management processes with the extensive functionality of a collaborative groupware application. The resulting atWatch PCM applications deliver functionally rich, comprehensive product complaint management capabilities to the project team.

Remote Operation — atWatch PCM 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. Incidents and CARs may be entered directly utilizing the Internet or the company's Intranet. Company employees may enter data on site or after hours via a laptop. All changes made to documents remotely, can be replicated to the atWatch PCM databases, thus dramatically expanding accuracy and productivity.

E-Mail Freedom — atWatch PCM 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 atWatch PCM processes.

Ease of Use — An intuitive look and feel to screens makes using atWatch PCM simple and straightforward. atWatch PCM users are prompted through document development by pop-up menus and internal checks on data integrity. The atWatch PCM Help database provides detailed user information for the atWatch PCM suite of applications.

Connections to other systems — atWatch PCM helps the company team manage all incidents. atWatch PCM has been connected to many other internally-developed and vendorsupplied ERP systems.

Uploading data and information — Previous product complaint data may currently exist in other systems outside of atWatch PCM. In addition to being able to connect to other systems, direct data can be uploaded into atWatch PCM by applying some simple scripts.

Application Security and Compliance with 21 CFR Part 11

atWatch PCM utilizes Atlant's atComPac Application for compliance with 21 CFR Part 11. atWatch PCM provides the following features

Security — atWatch PCM utilizes the mostcomprehensive security model available to ensure that all information and data is viewed, read, edited, changed, and managed only by authorized personnel.

Audit Trail — atWatch PCM provides a human readable audit trail, at the field level, for each document in the system. Utilizing Atlant's Snapshot technology, atWatch PCM 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, Protocol Manger can apply a digital signature to any electronic record in the system. Once applied, the digital signature will meet the criteria necessary for non-repudiation and identity challenges, and can be considered the legal equivalent of a handwritten signature.

Identity Confirmation — The atWatch PCM 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

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

atWatch PCM has been designed with deliberate simplicity, mirroring the workflow of the clinical and regulatory affairs organizations. A consistent user interface across multiple platforms, coupled with extensive on-line help, makes atWatch PCM intuitively easy to learn and use. Navigation within atWatch PCM 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 clinical trial documentation
- Management of documents through appropriate states of development and approval
- Automated document control
- Consolidation of review and approval history and actions associated with the clinical trial process
- Locking upon completion of controlled records
- Automatic notification and escalation to enforce action items

The centerpiece of atWatch PCM is meta-information — by document. The user is given all relevant information about an product complaint 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.

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

Navigation within the atWatch PCM 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.

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

With Lotus Notes/Domino's technology, remote and mobile users can manage product complaint information using their laptop. Later, new and/or updated information is easily and efficiently replicated to the corporate atWatch PCM database.

atWatch PCM is extremely flexible. It can easily be adapted and customized to meet specific user needs and organizational characteristics.

atWatch PCM is scalable. It can serve a single location or an entire enterprise with global locations. Through replication, data can be synchronized across large organizations.

atWatch PCM has been tested with a wide variety of other applications to further extend its power to other critical functions within the organization including finance and operations. These include: graphics, video, sound, word processing, spread sheets, management reporting, and other database managers.

Deployment Approach

	Deployment Step		
	1	2	3
Focus	- Complaints - Project Team - Complaint administrators - Short Duration	- Incidents - CARs - Trending & Analysis	- Full Deployment - CAPA
Scope	- Configuration - Load Ref DBs - Project Team - Country	- Outside the group incidents - Expanded Team - PT to Train - Region	- Global - End-user Train
Modules	- Accounts & Customers - Form Letters - Complaint Management - Dictionaries	- Incident Reporting - CAR Reporting	- CAPA - Query Manager

Computer Requirements — Minimum

Although not required or essential, Atlant 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 Atlants's clients have decided to install a validated server to house all of their "Regulatory" applications.

Server:

- 800 MHz (minimum) 1.2 GHz to 2.0 GHz (recommended) Pentium Processor or equivalent ?? 1 GB RAM
- If there are remote users, either a modem or Internet connection
- Network connection
- Backup facilities
- 9 GB (minimum) 60 GB (or larger recommended) available hard disk drive
- Operating System: Microsoft Windows NT®, 2000, 2003, XP, Sun Solaris and UNIX, AIX, OS/400, OS/390, Linux

Client for Authoring, Editing, Reviewing, and Approving:

- Microsoft Windows (any variety)
- Network connection
- Remote users need a modem or an Internet Connection
- Pentium 800 MHz with 128 MB or higher
- 2 GB (minimum) of Disk Space, Remote users need an additional 20 GB

Client for Reading atWatch PCM Documents

- Microsoft Windows (any variety)
- Network connection
- Remote users need a modem or an Internet Connection
- Pentium 300 MHz with 64 MB or higher (if using Notes)
- 120 MB of Disk Space for base install — disk space is not required for browser-based use

atWatch PCM operates in a client/server environment and provides an intuitive graphical user interface (GUI). The user that only "reads documents" may choose either an Internet browser or a desktop client. Either GUI makes learning and using atWatch PCM simple and straightforward.

Trusted Technology Partners

Atlant's atWatch PCM software is IBM Lotus Workplace and IBM Lotus Domino Ready.