



Quality Management System

Effectively Manage Quality Documents

Winchester's Quality Management Systems (QMS) help organizations capture, distribute, retrieve, and manage quality assurance-related documents globally -- documents from any source -- manual, computer, or application.

Winchester's QMS fosters an environment where document creation, review, and approval can be done collaboratively among individuals within and outside the corporation all over the world.

*Customer service . . . compliance . . .
GxP . . . safety . . . complaints . . .
inquiries . . . CAPA program . . .
document management . . . training
records . . . engineering changes . . .
regulatory correspondence . . .*

The centerpiece of Winchester's Quality Management System (QMS) is meta-information -- by document. The user is given all relevant information about a particular function 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.

Winchester's QMS philosophy supports continuous improvement by creating a comprehensive database and repository of all planned, current and completed documents.

QMS helps clients manage the operational and regulatory documents associated with a specific function.

QMS helps the individual user develop and manage relevant documents and to collaborate with the requisite and appropriate other client personnel.

QMS integrated applications enable users to create, collaborate, take action, review, approve, re-release, track, and control documents including:

- Training records
- Engineering change requests
- Corrective action requests
- Preventive action requests
- Product complaints
- Adverse events
- Health agency correspondence
- Standard operating procedures

QMS addresses the documentation, workflow, and communication needs of the entire client quality assurance team, including:

- Design Engineering
- Manufacturing Engineering
- Manufacturing Operations
- Quality Assurance
- Regulatory Affairs
- Marketing & Sales
- Human Resources

QMS-managed data can be used to establish and measure key processes and to implement global standards.

Winchester's design for QMS is comprised of several integrated modules but individually-deployed that work together to form a complete QMS. Events recorded in each module can appraise the other modules(s) of the completion of the event or that an anomaly has occurred. The functions of the modules that comprise QMS are briefly described in this section

To be compliant and competitive in today's markets where customer service is "king" and the health agencies are lurking, your organization needs full participation by all departments -- sales, marketing, quality assurance, regulatory affairs, manufacturing, and technical service.

Seven individual modules comprise the Principal Architecture of Winchester's Quality Management Systems (QMS) for Life Sciences companies:

1. Electronic Document Management System (paraFile™)
2. Training System
3. Engineering Change Control (ECC)
4. Product Complaint Management (adWATCH-PCM)
5. Adverse Event Reporting (adWATCH-AER)
6. Regulatory Correspondence Tracking
7. Corrective and Preventive Action (adWATCH-CAPA)

Electronic Document Management System

(EDMS) – Winchester's EDMS is called Winchester's **paraFILE™**. paraFILE is an electronic document management system that may be configured to fit Olympus Germany's requirements. paraFILE helps users capture, author, edit, distribute, retrieve, and manage electronic documents globally--documents from any computer source or application.

Training System – Winchester's Training system helps manage client's training records as well as a training catalog, course schedule, and exception reporting. The training system manages training records by class, course, person, job function, and department.

Engineering Change Control (ECC) – Winchester's Engineering Change Control (ECC) module of its QMS is a suite of integrated applications designed to assist the engineering team in managing information about engineering-controlled documents as well as engineering changes. Its components are often interfaced with client product structure systems (bills-of-materials), item masters, and electronic drawing repositories.

Product Complaint Management System

Product Complaint Management system is a module of QMS. The Product Complaint Management module of Winchester's QMS will help client's customer service and quality assurance capture, distribute, retrieve, and manage product complaints globally -- product complaints from any source -- manual or computer. Winchester's Product Complaint module fosters an environment where document creation, review, and approval can be accomplished through collaboration among individuals within and outside the corporation all over the world.

Adverse Event Reporting System – The Adverse Event Reporting system is a module of QMS. Winchester's Adverse Event Reporting module helps clinical operations, pharmacovigilance, quality assurance, and regulatory affairs manage and report adverse events that occur during clinical trials. Winchester's Adverse Event Reporting module gives the reporter at a clinic, hospital, or investigative site a fast and effective means of generating and managing Adverse Event Reports (AERs) and reporting to regulatory departments and government agencies.


Regulatory Correspondence Tracking System


The Regulatory Correspondence Tracking system is a module of QMS. The Winchester Regulatory Correspondence Tracking module is a suite of integrated applications designed to assist the Regulatory Affairs Team in managing information about regulatory-sensitive documents. The Regulatory Correspondence Tracking module will initially be an "extension" of the previously deployed document management system. Regulatory Correspondence Tracking module is configurable to fit clients' requirements for a Regulatory Correspondence Tracking Management solution.


Corrective and Preventive Action (CAPA)


The Winchester CAPA system is a module of QMS. Corrective Action Requests would be entered or generated by anyone who has access to the system. Entries can be made from the Internet and/or the client's Intranet. The CAPA module would operate with an Incident Reporting component. If the administrator decides that the corrective action request (CAR) has merit, he or she closes the CAR to the CAPA component as an open item.


Winchester's QMS provides the highest level of access and security to on-line and on-time quality management information. QMS facilitates e-business models for quality document management by supporting a secure intranet and extranet.


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


 **QMS 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** -- QMS promotes best practices throughout all business levels.


 **Configurable** -- QMS components are configurable to meet the specific needs of any service and complaint management organization. Winchester provides configuration services to help you fit QMS to your specific environment.

 **Analytical Tools** -- Powerful analytical tools are included in QMS to provide you with the reporting and trending you need to anticipate quality and customer service issues.


 **Programmed Agents** -- QMS automatically triggers programmed actions that lead to a overdue document alert, delayed or delinquent workflow action, or a substitute delivery, for example


 **Code Dictionaries** -- QMS contains failure code dictionaries that may be populated by the company. Dictionaries include failure codes, potential root causes, and corrective actions. For clients that possess a MedDRA license, MedDRA and COSTART dictionaries are optionally included for Adverse Drug Reactions.


 **Complaint Entry and Analysis** -- QMS mirrors the workflow of complaint processing from initial notification through investigation, analysis, and resolution.


 **Automated Adverse Event Reporting** -- QMS 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** -- QMS 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** -- QMS includes a software validation protocol and scripts to assist with health agency-mandated requirements for initial validation and change control procedures

 **Global Access to Current information** -- Customer Service, Quality Assurance, Regulatory Affairs, Marketing, and Manufacturing have access to critical data as the document -- request, complaint, service, engineering change, and document change -- is being processed and resolved. Enterprise-wide replication ensures up-to-the-minute information is available across all locations, worldwide

 **Electronic Records and Signatures** -- QMS meets and exceeds the requirements for the FDA's 21 CFR Part 11.

 **Remote Operation** -- QMS 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 appropriate Notes databases, thus dramatically expanding accuracy and productivity.






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


Application Security and Compliance with 21 CFR Part 11


QMS utilizes Winchester's ComPac GxP Application for compliance with 21 CFR Part 11. QMS' 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 QMS on local machines or on removable media can be assigned various levels of encryption and user authorization privileges. QMS provides the following features:

-  **Security** -- QMS 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** -- QMS provides a human readable audit trail, at the field level, for each document in the system. Utilizing Winchester's Snapshot technology, QMS 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 hand-written signature.
-  **Identity Confirmation** -- The QMS authentication module (ComPac GxP) 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 ComPac GxP 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 (ComPac GxP), 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).

QMS helps you:

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

Why choose Winchester's Quality Management System? Winchester's QMS is:

- Easy to use -- with Web-based input 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 the FDA's regulation 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

Winchester's QMS helps you capture product complaints, inquiries, service calls, CAPA, engineering change requests, and electronic documents data across the enterprise and provide a collaborative approach to problem solving that includes all departments as part of the process.

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

For more information, call or visit our website:

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