



Winchester's Training Campus

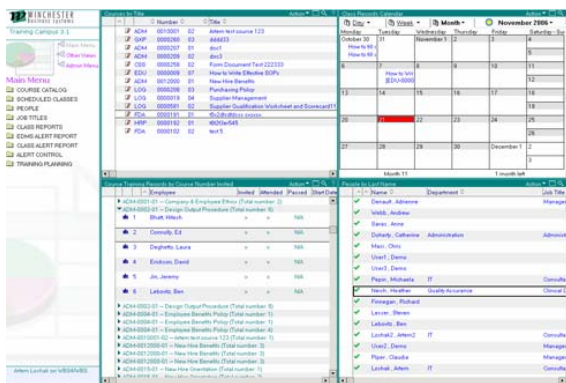
Administrative Software for Life Sciences to Manage the Education and Training Campus

Life Science organizations face new challenges every day. Government regulations coupled with advancing technologies are driving a dynamic range of requirements and expectations. Web-based, online technologies have transformed the management and delivery of education and increasing oversight requires more accurate recordkeeping. Life sciences companies seek a proven, long-term solution—one that can deliver value more quickly across the enterprise.

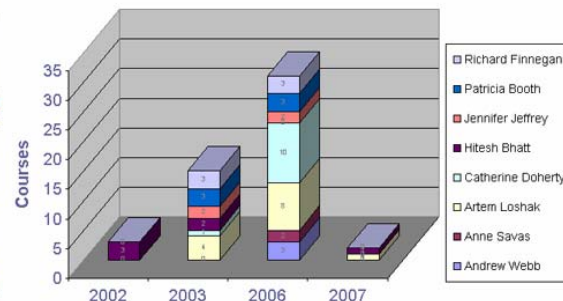
Winchester Business Systems, Inc. (Winchester) answers these challenges with a time-tested, collaborative, enterprise suite, built on proven technology. Rapid implementation and a flexible array of training and technical services work together to help life sciences clients maximize their investment and become compliant more quickly.

A life sciences company's Quality Management System must incorporate assurances that employees are performing functions in accordance with qualifications and according to corporate policies and industry regulations. Mismanagement of employee training records can lead to compliance challenges and deviations. This requires a structured training management system that enables systematic training assignment and follow-up.

The Dashboard allows real-time monitoring of open records as well as the overall state of training compliance.



TRAINING DB - Report - Courses by Employee-Year (Stacked column with a 3-D visual effect.)



Improve Training Management with Winchester's Training Campus.

Introducing Winchester's Training Campus Management System

Winchester delivers an enterprise solution specifically designed to manage the education and training campus.

For life sciences companies, the Training Campus™ edition offers a campus management application essential for life sciences companies, programs or distance learning. Winchester's Training Campus accommodates the management of training records that include external training courses as well. The Training Campus delivers a campus management program that includes the management of courseware, course curricula, course content, instructor and student records, course certification records, "missed class" alerts, course catalogs, course Schedule, and exception reporting. From quality and regulatory affairs management to clinical operations and academic records, users of Winchester's Training Campus find its features to be intuitive and easy to use. The result is faster adoption of the solution—and lower support costs over time.

Winchester's Quality Management Suite and Training Campus enable regulated companies to manage company- or department-wide training policies and requirements using a centralized, fully-automated and completely electronic training campus system.

As part of the Winchester Quality Management Suite, the training campus and reporting is performed in the same Winchester collaborative interface as the other quality and regulatory compliance functions including product complaint management (adWatch-PCM), adverse event reporting (adWatch-AER) electronic document management (paraFILE), corrective and preventive action (adWatch-CAPA), engineering change control (ECC), and compliance management (ComPac-GxP).

Training System Features

The Training Campus is an "Education Management Tool" that maintains a company's training records as well as a training catalog, course schedule, and exception reporting. The Training Campus helps manage training records by class, course, person, job function, and department.

<i>Curriculum Management</i>	Using the Training Campus, your organization can define training curriculum and related training requirements such as classes, SOPs, and other topics that must be completed to satisfy each requisite for any job function or role. Curriculums can vary between sites and divisions as necessary to support your global organization.
<i>Automated Scheduling</i>	Each training requirement may have its own schedule, which dictates when the employee must be re-trained. Enabling a rules-based entry by course provides a flexible means to ensure compliance. Training records are automatically created in the Training Campus for a user when he or she is hired, when training is about to expire, or when a change, such as an SOP change, requires re-training.
<i>Integrated Training Workflow and Tracking</i>	Employees access training requirements from a user friendly dashboard and are notified when training is required and before expiration, so they may update completion of their training tasks. Managers are notified when the requirement has been met, and can review the completed training record and approve or reject it through standard workflow functions.
<i>Escalation</i>	When training requirements are not completed on time, the employee, management, quality assurance, and the training administrator may be notified based on a pre-defined and fully configurable escalation path.
<i>Integrated Document Management System (EDMS)</i>	<p>The Training Campus can be interfaced with the company's Electronic Document Management System. New document revisions in EDMS contain a YES/NO "Training Required Flag" and a YES/NO "Reading Required Flag".</p> <p>If a Document or SOP is updated with spelling edits, perhaps no new training needs to be scheduled for this revision.</p> <p>However, if a document or SOP is updated with new procedures, the YES/NO "Training Required Flag" should be set to "YES", and a new workflow should be initiated to schedule employee training.</p> <p>Document revisions cause automatic e-mail alerts to all managers of employees that require training and/or need to read a document.</p>
<i>Integrated CAPA and Product Complaints</i>	CAPAs and Product Complaints often require that employees be retrained to correct deficiencies or to implement new procedures. Users can specify affected training requirements while creating CAPA and Product Complaint records using adWatch Product Complaint and CAPA System. Once the CAPA or Product Com-

plaint has been completed or approved, Winchester's Training Campus automatically creates new training records and assigns them based on employee job function. Employees are alerted via email and will view training tasks on their Dashboard. The integrated process provides a sure way to reduce deviations and maintain compliance with training program and quality requirements.

Reporting and Trending

The Training Campus provides on-line Dashboards and easy-to-use search tools to ensure visibility and accountability of training tasks and provides the organization with valuable information that may mean the difference between compliance and non-compliance.

Periodic reports – weekly, monthly, annual and “on-demand” – are available to authorized users. Reports can be used to identify gaps in training for individual employees as well as across organizations. Authorized users have the ability to develop “views” and reports as needed.

Exporting views, documents, and data to Microsoft Excel is a built-in feature of the system. New clients often develop information for summary views that capture training gaps specific to departments, divisions, locations, managers, and categories.

Free Text Search

Search the entire database, perform Boolean searches, or search only certain fields, using the Google search engine. The search engine will locate all instances, even in attachments, and highlight the results according to frequency of occurrence.

User Interface

The Training Campus system is "user friendly", allowing intuitive navigation. Views are categorized and sorted by user-defined criteria. Clients often add both “shared” and “private” views and reports during configuration and deployment of the system.

Master Employee Directory

Winchester's Training Campus can be linked to a company's directory of users, e-mail name-and-address book, or active directory. The chosen directory is used as the Master Employee Directory. Person documents in the directory often contain a unique ID number which can be used as the basis for indexing the directory for employee lookups in the Winchester Training Campus.

However, employees who do not have e-mail accounts are often not listed in the active directory. These employees can be imported from other sources as comma-delimited files, structured text files, tabular text files, XML, or from a spreadsheet file.

Scheduled Database Agents

The Training Campus utilizes a scheduled agent – a computer program that is executed on schedule for the module -- that monitors new documents that contain "YES" for the "Training Required Flag" and "YES" for the "Reading Required Flag." The Agent automatically sends notification to managers to schedule training for appropriate employees.

Flagged Employee Re-

Employee Records are flagged for training, based upon training

<i>cords</i>	requirements defined in the employee's "Needs Assessment" tab within each individual's profile document. The Tab denotes data about which training events the employee needs to attend as well as the frequency of the training requirement; e.g. annually, semi-annually, etc.
<i>Job Description Based Assignments</i>	Employee assignments can be made based upon job descriptions and assigned training courses. Once training has been taken, if certification or testing is required for the course, the system will accommodate tracking the employees' scores on such exams.
<i>Reading Documents Requirements</i>	The Training Campus provides the ability to verify that employees have read new revisions of SOP's that do not require additional training. These are defined as "Required Reading" Documents. Verification should occur by capturing "session data", that employee "X" viewed document "X" and entered a password confirming that the new revision has been read. In addition to logging which documents have been read and by which employees, the e-mail notifications are also logged.
<i>Training Course Calendar</i>	The Training Campus publishes a "Training Course Calendar" for scheduled courses, etc. When a user is scheduled to attend a course, the notification is posted in his/her personal calendar as well.
<i>Electronic Signatures</i>	Documents signed to capture training fall within 21 CFR part 11 requirements for electronic signatures. Thus, the system must provide the ability to comply fully with the regulations.

System Security and Regulatory Requirements

The Training Campus provides the highest level of access and security to on-line and on-time event information. Security is customizable and 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 the Training Campus on local machines or on removable media can be assigned various levels of encryption and user authorization privileges.

The Training Campus utilizes Winchester's ComPac GxP Application for compliance with 21 CFR Part 11 Electronic Records and Electronic Signatures.

Training Campus provides the following features

<i>Security</i>	The Training Campus 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.
<i>Audit Trail</i>	Winchester's Training Campus provides a human readable audit trail, at the field level, for each document in the system. Utilizing Winchester's Snapshot technology, the Training Campus tracks the original value of a field, the changed (new) value of the field and records the date, time and originator of the change.
<i>Digital Signatures</i>	By employing a PKI based digital certificate for identification and authentication, the Training Campus 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.
<i>Identity Confirmation</i>	Winchester's Training Campus 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.
<i>Access Logging</i>	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.
<i>Access Control</i>	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.
<i>Validation</i>	The Training Campus can include a tailored software validation protocol database to assist with FDA-mandated requirements for initial validation and change control procedures.

Operational Requirements

Navigation within the Training Campus is meant to be "user-friendly," 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 life sciences and regulated environments.

<i>Best Practices</i>	The Training Campus promotes best practices throughout all business levels.
<i>Configurable</i>	The Training Campus is configurable to meet the specific needs of any life sciences organization. Winchester provides configuration services to help clients fit the Training Campus to their specific environments.
<i>Programmed Agents</i>	The Training Campus automatically triggers programmed actions that ensure that actions and events are promptly followed up.
<i>Remote Operation</i>	The Training Campus 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.
<i>Ease of Use</i>	An intuitive look and feel to screens makes using the Training Campus simple and straightforward. Users are prompted through document development by pop-up menus and internal checks on data integrity. The Winchester Training Campus on-line help system provides detailed user information on all functions of the system.

Technology

The goal is to provide a stable, scalable, and easy to support solution for increasingly complex, multi-campus/division life sciences enterprises. Winchester uses n-tier client-server architecture. Distributed architecture with clustering ensures high availability, scalability, security features, and lower system maintenance costs.

The solution is based on IBM Lotus Notes technology, typically deployed in a centralized environment on multiple application servers, database servers, and Web servers. Client deployment provides secure, centralized access and extends capability to Macintosh[®] computers.

Winchester Services

Winchester professional services available include configuration, implementation, conversion, branded portals to reflect your company's identity, training, and custom report generation.

Winchester's data integration services efficiently integrate third-party "flat files" into Winchester Training Campus' native functionality. The result is industry-leading efficiencies in crucial areas such as student record-keeping.

For ongoing maintenance, Winchester's support services address the lifecycle of your investment. Technical and installation assistance, upgrades, on-line and over-the-web help desks, and other features help ensure smooth running over the long term.

Benefits

Winchester's Training Campus provides these benefits that will help to improve the quality and processes associated with managing your training program:

- **Standardization:** Manage all training records using a one, collaborative database for both employees and management
- **Compliance:** Training records are signed, stamped and accessible for auditing purposes
- **Proactivity:** Training requirements are managed by the system and training tasks are automatically scheduled for employees based on information from the employee's record.
- **Planning:** Plan and schedule courses in advance by frequency, instructor availability, and job description.
- **Flexibility:** Manage and track any type of training process in one system – internal, external, CBT courses. Add and schedule courses, assign instructors and store course materials on an ad hoc basis, as well.
- **Scalability:** Configurable to meet the needs of diverse inter-departmental needs, flexible to support the complexities in a global environment, and powerful enough to support tens of thousands of users.
- **Integration:** Re-training requirements may be initiated directly from CAPA and Document Management System records.



For more information, contact:

Winchester Business Systems, Inc.
304 Cambridge Road
Woburn, MA 01801
United States
<http://www.wbsnet.com>
1-781-503-0200