

## Product Life Cycle Management

Enterprise information boundaries are disappearing as corporations open their networks to allow external access by manufacturing partners to internal systems. In today's competitive and regulatory environment, managing all of the assets, people, and documents that comprise an engineering change is essential.

**Winchester's Engineering Change Control<sup>™</sup>** manages time-critical information, regulatory documents, and schedules about all related components of an engineering change. Winchester's ECC is the award-winning computer software system which satisfies a company's need for an Engineering Change Control System.

The "bundle" offered by IBM Life Sciences described in this document is meant to provide the client with the correct hardware, software, and deployment services to meet the requirements for an ECC system.

The bundle is comprised of four components:

1. Engineering Change Control
2. IBM Server
3. Lotus Workplace Components
4. Consulting support services

### Winchester's Engineering Change Control Software:

Engineering and product information boundaries are disappearing as pharmaceutical and medical device companies open their networks to allow external access to internal documents. In today's regulatory environment with access via the Internet, securing these open networks, systems, and applications is essential.

Winchester's Engineering Change Control software provides the highest level of access and security to on-line and on-time engineering information. Engineering Change Control facilitates

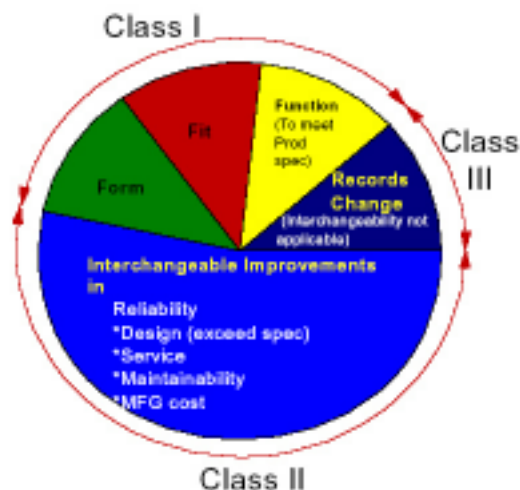
e-business models for engineering change management by supporting a secure intranet and extranet.

Engineering Change Control is a suite of integrated applications designed to assist the engineering team in managing information about engineering controlled documents. It is a configurable solution. Winchester provides configuration services to fit Engineering Change Control to your specific environment.

Engineering Change Control allows enterprises to obtain and maintain control over product, process, and equipment changes.

Managing all documents electronically - bill of materials, manufacturing specifications, item masters, routings, drawings, manufacturing processes and equipment - is a manufacturing company's first concern in developing an enterprise requirements planning system that works - a system that is used to plan, control and effectively utilize all of the resources employed to produce products.

### Change Classes and Interchangeability



Winchester Business Systems' Engineering Change Control (ECC) system provides a centralized Engineering Document Management System that may be used as a template to establish a standard for unique company environments. ECC is a customizable Lotus Notes/Domino-based Product Configuration Management solution. Winchester provides customizing services to fit ECC to specific environments.

The critical processes directly supported by the Engineering Change Control System include:

- Change Control Board workflow
- CCB Meetings
- ISO 9000/14000 and OSHA Safety Compliance
- Drawing mark-ups
- Effectivity dates
- Engineering Change Administration
- Engineering Change Requests
- Action Items
- Approval Routings
- Interfaces to ERP, MRP, and CAD/CAM
- Cost Estimating
- Manufacturing effectivity
- Tracking ECRs into ECO's & ECN's
- Implementation Planning and Distribution
- Disposition Planning
- Change Testing & Prototyping in Preproduction

ECC users may work from their desks, from their homes, and while they travel. ECC is web-enabled to include customers, suppliers, consultants, and others designated by the enterprise to have access. ECC connects to many existing systems ranging from CAD/CAM, ERP, TO MRP, to act as the true workflow tool and front-end to those systems.

### **Engineering Change Control is a Global Change Control Expressway:**

**Engineering Change Control** is comprised of several integrated modules that work together to form a complete Engineering Change Control System (ECCS). Because of **Engineering Change Control's open architecture**, Engineering Change Control can interface with a company's ERP systems, complaint management systems, and maintenance 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 Engineering Change Control are briefly described below:

**Change Request Processing** — Manages the workflow for:

- Products - design engineers request and process changes to products, parts, raw materials, assemblies, fabrications, ingredients and recipes
- Processes - manufacturing engineers request and process changes to manufacturing processes with the same emphasis as Engineering Change Requests
- Equipment - manufacturing, industrial, and maintenance engineers request and process changes to manufacturing/production equipment.

**Bill-of-Material Maintenance** — Provides the single-source of records to describe the parts list for every product, assembly, and component.

**Change Control Board** — Ensures that the processing of a change request for product, manufacturing process, and equipment changes are addressed by cognizant company personnel in a timely fashion.

**Dynamic/User Controlled Tables** — Offers company tailoring of the workflow and checklist tables without program changes.

**Engineering Change Administration** — Ensures that people remain in charge of the processes.

**ISO 9000/14000 and OSHA Compliance** — The appropriate emphasis is placed on process, product quality and environmental safety issues throughout the entire change control process.

**Action Items** — As a by-product of the approval process, the Engineering Change Administrator is provided the ability to develop action plans and steps and make assignments to members of the Change Control Board members.

**Approval Routings** — Automatically routes all three types of change requests to the appropriate departments and members of the Change Control Board for processing and, where appropriate, their approval.



### **Interfaces to MRP, ERP, and CAD/CAM Systems**

— To ensure consistency of information among a company's operating systems, the master files can be interfaced to the Engineering Change Control system.

**Cost Estimating** — As a change is passed through the process, pertinent cost estimates for material, labor and overhead are calculated. Detailed and summary cost information is then available to the approving authorities.

### **Change Testing & Prototyping in Preproduction**

— Records both summary and detail testing of a change before it is placed on line.

**Tracking ECRs into ECO's & ECN's** — Tracks information regarding the current (and potential) status of a change as it progresses through the Engineering Change Control procedure and system.

**Implementation Planning** — Provides a single information gathering point for all of the pertinent information needed for developing a plan to implement a change. Includes the facility to track the implementation project as it progresses.

**Disposition Planning** — Facilitates plan development for the disposition of affected items.

**Manufacturing Effectivity** — Plans when the change should be implemented or become effective. The system provides for a specific:

- date or date range the change is effective,
- product serial number the change should first affect,
- range of serial numbers the change should affect, or
- customer order that should be affected by the change.
- customer order that should be affected by the change

**Prerecorded Minutes of CCB Meeting** — Provides tracking of meeting minutes and development of "action item" assignments.

**Deviation Authorizations** — Provides an option to issuing a permanent engineering change. Allows for temporary fixes due to a lack of materials. Requires processing appropriate approvals.

### **Electronic Record and Signature Compliance** —

Meets requirements for FDA's 21 CFR Part 11.

### **Unique Features of Engineering Change Control:**

**Powerful Tools** — Engineering Change Control integrates change management processes with the extensive functionality of a collaborative groupware application. The resulting Engineering Change Control applications deliver functionally rich, comprehensive change control management capabilities to the project team.

**Remote Operation** — Engineering Change Control 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 Engineering Change Control database, thus dramatically expanding accuracy and productivity.

**E-Mail Freedom** — Engineering Change Control 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 Engineering Change Control processes.

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

**Connections to other systems** — Engineering Change Control helps the engineering team manage configuration changes. Other computerized systems may be used to manage other data elements of a product. Engineering Change Control has been connected to many other internally-developed and vendor-supplies systems. Popular system types include: ERP systems, MRP systems, Standard Operating Procedure (SOP) systems, and document management systems.



**Uploading data and information** — Reference data may currently exist in other systems outside of Engineering Change Control. In addition to being able to connect to other systems, direct data can be uploaded into Engineering Change Control by applying some simple program scripts.

## Application Security and Compliance with 21 CFR Part 11

Engineering Change Control utilizes Winchester's ComPac GxP tool set for compliance with 21 CFR Part 11. Engineering Change Control provides the following features

**Security** — Engineering Change Control 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** — Engineering Change Control provides a human readable audit trail, at the field level, for each document in the system. Utilizing Winchester's Snapshot technology, Engineering Change Control 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 Manager 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 Engineering Change Control 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. During the initial authentication of a session, the identity of a user is determined by the presence of that person's "private key" and the associated password for that private key. In subsequent authentications, a separate password tied to the private key is required.

**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. Utilizing the module, it is also possible to further restrict actual access to the database and provide power users the ability to update security without giving them full "DBA" or manager permissions to the system.

**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

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

Engineering Change Control has been designed with deliberate simplicity, mirroring the workflow of the engineering, manufacturing, and quality organizations. A consistent user interface across multiple platforms, coupled with extensive on-line help, makes Engineering Change Control intuitively easy to learn and use. Navigation within Engineering Change Control 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 engineering change environments.

These features include:

- Linked subsystems with bi-directional cross referencing of stored 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 engineering change process
- Locking upon completion of controlled records
- Automatic notification and escalation to enforce action items

Engineering Change Control is extremely flexible. It can easily be adapted and customized to meet specific user needs and organizational characteristics.

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

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

Engineering Change Control 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 — Oracle, DB2, SAS, and Documentum included.

### For more information, contact:

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## Computer Requirements — Minimum

Although not required or essential, Winchester 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 Winchester'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 Engineering Change Control 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

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

### Trusted Technology Partners

Winchester's Engineering Change Control software is IBM Lotus Workplace and IBM Lotus Domino Ready.

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