

paraFILE<sup>TM</sup>

## Managing Documents on a Global Basis

Technology is a strategic issue that directly impacts a pharmaceutical's competitive advantage. The management of and greater access to knowledge is the principal concern of Winchester Business Systems. Today's organizations need a series of groupware-based, interfaced modules providing wider availability of knowledge.

## Other Pharmaceutical Systems available from WBS

adWatch — adverse events reporting system

Protocol Manager — clinical trials protocol management system

Health Agency Tracking and Safety — agency query and response system

paraSALE — contact and project/engagement management system

electronicLABOOK — time stamping discoveries as they occur

## About Winchester Business Systems

WBS is differentiated by its superior pharmaceutical industry experience. WBS professionals have direct line management and consulting experience in every segment of clinical trials, regulatory affairs, and quality assurance.

WBS provides leadership and technical knowledge to complement the client organization's expertise.

**Our Goal.** To meet and exceed the expectations of our pharmaceutical clients.

**Our Mission.** To provide our clients with the highest quality, most efficient technology for solving their business problems.

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 Premier Partner

# paraFILE™

paraFILE document management designed specifically for the pharmaceutical, biotech, and medical device industries.

paraFILE helps users collaborate and manage documents quickly and efficiently with the right level of security.

The goal of paraFILE is to help pharmaceutical, biotechnology, and medical device companies manage the huge volume of data associated with the drug and device development processes. paraFILE fosters an environment in which document creation, review, and approval is collaborative among authors, approvers and reviewers within and outside the corporation worldwide.

The centerpiece of paraFILE is meta-information — by document. The user is given all relevant information about a document in the way the authoring, editing, and filing process is performed — step by step, action by action — all summarized in one location. Detail information about any document is immediately available via imbedded views. All managed documents are “full-text indexed” to provide for optimal searching.

## Documentation management needs addressed by paraFILE:

- NDA submissions
- SOP's
- Clinical trial protocols
- Data clarification tracking
- Quality assurance
- Research and development
  - Lab notebooks
  - Test data
- Government agency inquiries and responses
- Departmental documents
  - Patents
  - Legal agreements
  - Contracts
  - Business partnering arrangements
  - Marketing agreements
- Product Change Control

**AUTHOR**

**RE**

**CHANGE**

**paraFILE**  
DOCUMENT LIFE CYCLE

**ARCHIVE**

**DISTRIBUTE**

**PUBLISH**

paraFILE  
document management  
designed specifically for the pharmaceutical,  
biotech, and medical device industries.

## Features of paraFILE

**VIEW**

**REVISE**

**APPROVE**

- Consistent user interface — providing the same user interface whether for ad hoc inquiry or production purposes
  - Searchability — attribute and full-text search allows users to find relative content across and within all documents and their attachments
  - Complete audit trail — a chronologically arranged history allows users to see dates, times and activities associated with each document, providing a complete lifecycle review.
  - Check in/check out — maintains document integrity during editing without blocking access to document viewers. This ensures that readers are always accessing the latest approved document.
  - Versioning — effectively manages and maintains revisions as distinct versions of a document. Users see the latest version of a document unless otherwise authorized.
  - Seamless Integration — automatic connection to ODMA-supported desktop applications as well as Microsoft Word and Excel.
  - Mobile use for distributed enterprise — the same, rich functionality is available to users with laptops and remote PC's.
  - Tailorability — the ability to customize paraFILE to a company's unique workflow without complex programming

### Built-in Workflow Speeds Up the Approval Process

- Allows electronic notification of reviewers
- Maintains workflow status; informs administrator when tasks have not been performed within timeframes
- Restructures workflow to coincide with changes in review and approval process

### Give Users What They Need Without Compromising Your Company's Intellectual Assets

- Maintains document integrity from authoring through the approval process
- Stores annotations and comments associated with documents created during review process while maintaining the authenticity of the original document.
- Controls user access and authenticity
  - 2-level password system.
  - 7 different permission levels
- Permits access to field portions of documents by role authorization