

# Winchester Business Systems

## *Moving Life Sciences Forward*

### Winchester's Expertise

- Clinical Trials Management
- Consulting Services
- Adverse Event Reporting
- Document Management
- Part 11 Compliance
- Regulatory Affairs Reporting
- Product Complaint Management

### In Partnership with

- IBM Corporation
- RSA Security
- Clinical Providers Consortium
- Regulatory Affairs  
Professional Society
- Drug Information Association

**Winchester Business Systems, Inc.**  
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### Mission

To offer life science companies the highest quality, most technologically-advanced business solutions and procedures to address their unique requirements. Utilizing our clinical expertise and the latest technology, we provide collaborative tools to accelerate clinical research, project management, and regulatory oversight.

### The Right People. The Right Solutions.

Established in 1989, Winchester Business Systems, Inc. is a leader in providing software and implementation services to life science companies worldwide. The Winchester consulting team has over 50 years of collective experience with regulatory requirements and clinical workflow. Coupled with our understanding of the latest groupware technologies, we streamline business processes to more effectively utilize and support an organization's most important resource, its people.



Winchester software has helped over 500 pharmaceutical, biotechnology, and medical device companies successfully conduct clinical trials, track product safety, and manage regulatory documents in support of their product development efforts.

### Clients

Winchester Business Systems' clients include Bayer, Pfizer, Novartis, Olympus Medical Systems, Averion Inc, Sigma-Tau Pharmaceuticals, MDS Pharma Services, FUJIFILM Medical Systems, Philips Medical, RRD International, Dov Pharmaceutical, and Johnson & Johnson.

## Products

**adWATCH-AE - Adverse Event Reporting System**  
adWATCH-AE gives the medical professional a fast and effective means of generating and managing Adverse Event Reporting (AERs).

**adWATCH-CAPA - Corrective and Preventive Action**  
adWATCH-CAPA helps organizations capture, distribute, retrieve, and manage corrective action requests and preventive action requests globally and in real-time.

**adWATCH-PCM - Product Complaint Management System**  
adWATCH-PCM helps organizations capture, distribute, retrieve, and manage product complaints globally and in real-time.

**ComPac GxP - Part 11 Compliance Module**  
ComPac GxP is an out of the box set of tools that can be integrated into Domino systems to achieve 21 CFR part 11 compliance.

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

**Investigator Portal - Clinical Collaboration Module**  
The Investigator Portal is a software module that makes it easier for sites, sponsors and CRO partners to collaborate on trials.

**paraFILE - Electronic Repository**  
paraFILE is an Electronic Document Management System (EDMS) that can be tailored to fit your enterprise and each departmentally different EDM requirement.

**Protocol Manager - Clinical Trial Management System**  
Protocol Manager is a collaborative Clinical Trial Management System (CTMS) that helps manage time-critical information, regulatory documents, budgets, and schedules about investigators, patients, clinical trial staff, and all related components of a clinical trial.

**HATS - Health Agency Tracking System**  
Health Agency Tracking manages queries and corresponding responses between pharmaceutical companies and the respective worldwide Health Agencies.

## Consulting Services

**Winchester Business System's consulting services** offers clients the skills and industry knowledge to implement a successful solution. Along with offering consulting services to complement a solution, we also offer specific engagements to address life sciences industry needs.

**FDA Compliance Planning**  
Winchester specialists work with the regulatory team to bring systems and procedures into compliance with major FDA regulations including 21 CFR Part 11, Sarbanes-Oxley, and HIPAA.

**CTMS Planning Study**  
A two week engagement during which Winchester professionals work with the project team to put clients on the right track to implementing a CTMS.

## ACTION Methodology

Winchester's strategy to improve business processes is based on Information Engineering. ACTION is a systems lifecycle methodology that promotes client involvement during development and implementation. ACTION ensures that the solution fits the client's needs. Users come to the system with a sense of ownership and involvement that can significantly reduce training and acclimation periods, improve quality and productivity and increase the return on investment.



## ACTION

A Practical Approach to  
Systems Implementation

**A**nalysis and Prototyping

**C**oordination of Disciplines

**T**raining & Education

**I**mplementation Planning

**O**n-Line Planning

**N**ew System Deployment

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