

## ComplianceManager for Healthcare Industry

*“3 days - we are up and running around the globe... Same promise we deliver to our patients - efficiency and effectiveness.”*



ComplianceManager can benefit healthcare organizations to meet the rising standards of quality and to comply with rigorous regulatory requirements. Regulatory requirements include FDA GxPs and reporting mandates, international drug safety standards, and cross-industry compliance requirements stipulated by laws such as Sarbanes Oxley Act (SOX).

ComplianceManager enables a single compliance and risk management process to ensure compliance with multiple regulations simultaneously. This increases the effectiveness and decreases the cost of compliance for healthcare providers and payers.

ComplianceManager solutions enable companies to gain real-time visibility into various stages of drug development to market including:

- Data and documentation requirement for FDA evaluation of New Drug Application
- Identification, remediation and management of quality issues in drug manufacturing
- Automation of pharmacovigilance processes to record, investigate, and report cases as per the adverse event reporting guidelines

In addition, ComplianceManager solutions for corporate governance, risk management and regulatory compliance enables healthcare organizations to make the shift from isolated compliance initiatives and departmental silos of risk-related information to integrated enterprise-wide governance, risk and compliance strategy.

ComplianceManager can help you to comply with the following internal and external regulatory needs:

→ HIPAA Compliance	→ Internal Audit
→ International Drug Safety Standards	→ Internal Quality Management
→ GXP Requirements	→ Vendor Quality Management
→ FDA Regulations	→ Internal Policies & Procedures
→ SOX	→ Business Continuity Planning
→ Data Protection & Privacy Act	→ FCPA

ComplianceManager includes on-demand modules which can be easily integrated into an entity-wide Governance, Risk & Compliance framework such as Internal Controls, Risk Management, Policy Management, Quality Assurance and Regulatory Compliance. It comes ready with content and best practices templates, access to training content from subject matter experts, and integration of business processes.

## The ComplianceManager Difference

**3-Day Data Migration:** *“In 3 business days - we are up and running around the global.”* ComplianceManager uses patented technology to enable fast migration of existing data into our server while preserving your data’s current format and context.

**50% Audit Reduction:** *“Regulatory audit time cut in half by implementing ComplianceManager.”*

ComplianceManager provides a central repository for data and document retrieval, a clear readily auditable trail with date, time, action and person-stamped, and personalized user access rights to enable an efficient and controlled external audit process.

**100% World Class Security:** *“It’s only one of the two applications we allow offsite hosting – the other vendor has to build an entire mirror hierarchy.”*

ComplianceManager is hosted in a secured, SAS-70 certified environment with dedicated servers to your business. Electronic signatures capability based on robust authentication and authorization infrastructure ensures compliance with industry regulations.

**\$0 IT Investment:** *“...now THAT is a good ROI!”*

ComplianceManager provides an all-in Software-as-a-Service model – there is no addition cost for hosting, implementation, data migration, internal IT costs, and many hidden costs common to similar applications.

**On Demand Modules:** *“100% flexibility – a true on-demand model at my own pace for my evolving needs.”*

ComplianceManager is built with complete flexibility to accommodate your organization needs – you can start with our SOX solution or an individual policy compliance program – each of our solutions can be fully integrated as your needs change.

**1 Dedicated Project Manager:** *“No more struggling with outsourced level-1 helpdesk.... My dedicated project manager is professional, knowledgeable and always available.”* ComplianceManager assigns a dedicated project manager to each project – a professional compliance expert who understands your business and technical needs.

**100’s Management Reports:** *“A myriad of standard management reports and a powerful query to create many more based on my needs.”*

ComplianceManager comes standard with a list of commonly used management reports and a powerful

query builder which enables you to create 100’s more. Graphical dashboards and flexible reports with drill-down capability provide statistics by any data element such as control status, gaps, deficiencies, audit history, retention times at the corporate level all the way down to an individual or a task.

**50% More Affordable:** *“We’ve looked at all the so-called ‘Quadrant 1’ applications ....*

ComplianceManager is at least 50% more affordable than the rest of market.” ComplianceManager is an on-demand solution catered to corporations of all sizes and budgets. Whether you are a Fortune 500 or a pre-IPO small cap, we can deploy a solution that meets your needs.

**Minimal Training Required:** *“Our system administrator was trained in 20 minutes while most users do not require any training time at all... many of whom speak English as a second language!”* ComplianceManager has an intuitive, Microsoft®-like user interface which requires minimal to no training – so your team can be productive at the get-go.

**1 Centralized Automated Update:** *“We only need to update our documents once – no more version control headaches.”* ComplianceManager’s intelligent workflow automatically routes your updates based on pre-defined approval process, through the end-to-end cycle of assessment, remediation, testing, narrative, flowcharts and certification.

**0 Downtime for Upgrades:** *“We came back on Monday morning - and voila! – we got the latest version with the updates at no cost and no downtime.”* All updates and upgrades are performed regularly – and seamlessly. There is no need for online or in-person installation and disruption to your operations – and at zero cost.