



IBS America develops integrated compliance management solutions to help companies improve corporate governance and achieve sustained adherence to regulations and standards. Since 1993, we have delivered our systems and services to thousands of companies worldwide. IBS America is one of the very few compliance software companies certified to ISO 9001.

CLIENT/SERVER-BASED COMPLIANCE MANAGEMENT SOFTWARE

QSi System for FDA Document Control



The QSi System for FDA Document Control provides all the templates and examples needed to complete a well-structured Quality Manual and to create Procedures, Work Instructions, Specifications, Quality Plans and Process Description documents. Features include multi-level access security, FDA compliant electronic signatures designed using the guidelines of 21 CFR Part 11, revision control and automated document status updates. Document review and approval workflow across the network can be either sequential or parallel. Activities associated with every document are automatically recorded in the History section. Document archiving of approved documents is automatic and an optional Draft Documents area automatically provides an audit trail that documents time-sequenced development and modification of documents.

Operational Controls

For maximum efficiency, QSi System provides controls for every aspect of the operation, including: electronic signatures with up to two back-up approver selections for each approver, customer-definable numbering options, automated alpha or numeric choices for versioning, user definable text headers for all documents, document review and audit scheduling, automated status tracking of each document and templates and examples needed to create, approve, control and distribute a well-structured Quality Manual, and complete Procedures, Work Instructions, Quality Plans, Specifications, Form Control and Process Description Documents. Documents can be sent to up to 18 approvers for review and final approval with a numbering system of up to 99,999. Process Control forms and General Process Change Management allow you to easily make the transition to process oriented business structures.

Process Controls

Beyond operational controls, controls are in place to monitor the process of tasks. Back-up approvers receive automatic notification when documents are not approved by primary approvers within user-definable time periods. Missed deadlines for document approvals, document change requests and document audits can be escalated to up to three levels of management. There are automatic electronic notifications and distribution of documents upon approval. The controls enforce predefined document audits with automatic notification to document owners of impending audit dates. There is user-definable release scheduling of approved documents to allow for training and the automatic updating of training records prior to document release.

For multi-site installations, duplicate document numbering alerts are sent. To ensure accuracy, final approval messages are sent with "comments" capability and there is an option to notify associated (linked) document owners of changes or new releases. The system allows users to display all documents associated with each individual document for easy access and management.

Draft Documents

Automatically provides an audit trail that documents time-sequenced development and modification of documents.

Security Controls

These controls provide selectable approver allowances with seven levels of database security. Process security prevents documents from being modified in the final approval process. There is selective read access restriction on a per document basis, and if a document is edited, there is an automatic status change alert. The use of dual passwords is required for all document reviewers and approvers. Electronic signatures automatically record date, time and time zone. Password sizes and time-outs are selectable by the system Password Administrator.

Process Workflow

There is a choice of two approval processes: review and final approval. With the flexible workflow, serial or parallel approval is selectable for each document. Upon final approval, documents automatically move and replace earlier versions in the Released Documents module.

Every released document is automatically archived and stored. Users can define the release dates for approved documents to allow for training.

