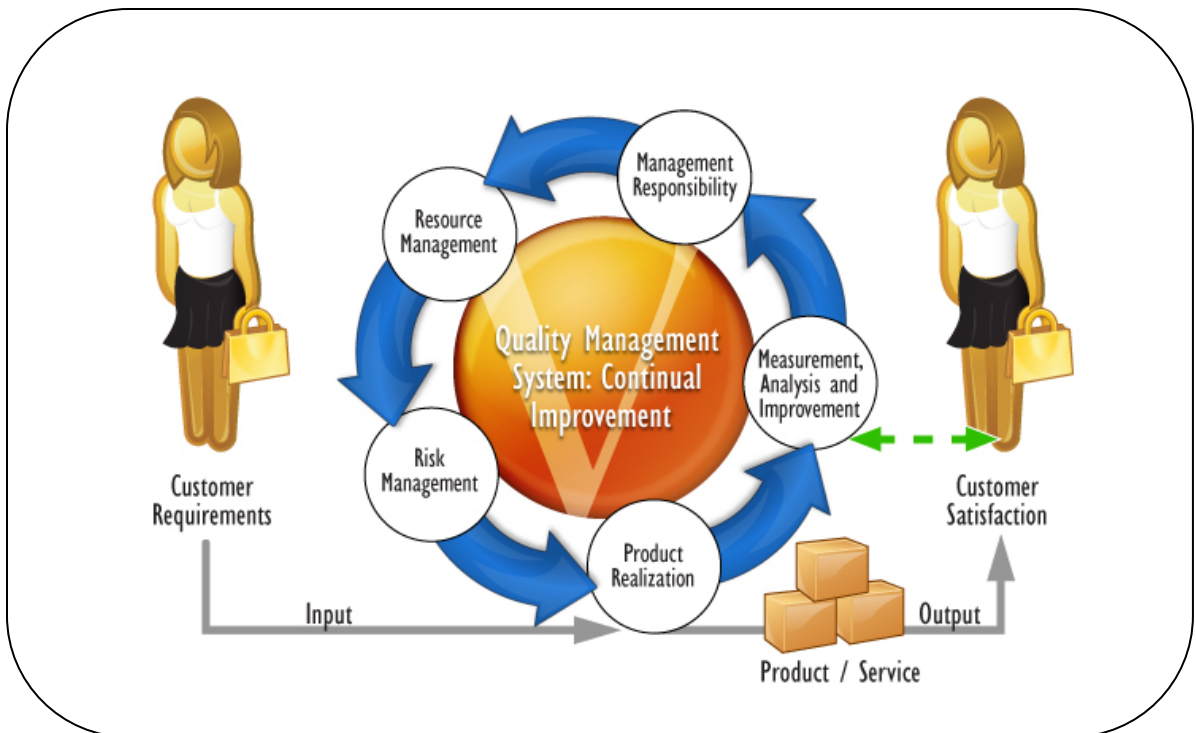




The Art of Compliance



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Regulatory and business compliance systems utilizing a process-centric methodology can produce extraordinary benefits to an organization. Continuous improvement, enhanced executive oversight, faster response times and reduction of administrative overhead are the direct benefits of an electronic compliance system with rich workflow, document management and electronic form capabilities.

Compliance systems are largely based upon the premise of relating business strategy to business processes to explicit instructions on how to perform specific tasks, all within the culture of the organization. Once the key processes are defined, requirements for audit trails, oversight, training and documented evidence are developed to meet the standards.

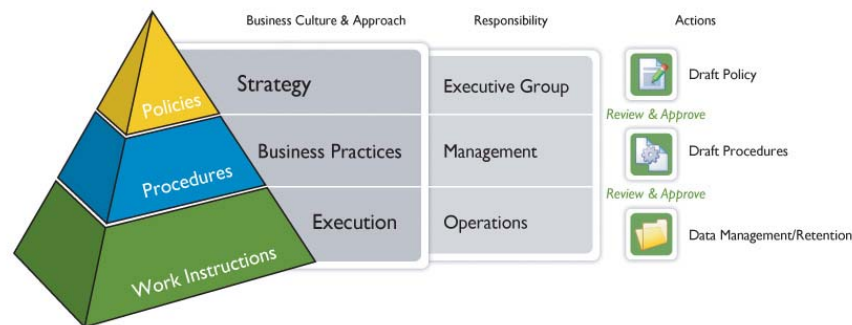


Figure 1 The Compliance Pyramid for document processes.

The compliance system requires continual refinement of processes for efficiency and regulatory changes, while competitive forces and personnel changes demand flexibility. Therefore, an effective support system incorporates the following attributes:

- Lifecycle management of all core documentation.
- Training and training record management for all employees.
- Form based processes with conditional routing based upon information/events.
- Record management with configurable retention rules.
- Access to audit trails for inquiries or reviews.
- Administrative oversight for process owners.
- Role based access to information.
- Support of hierarchical process flows and assignment of rights and workflow to organization job titles (to support attrition and job changes).

Modern document management platforms provide this breadth of capability within a web based environment. Configuration can be established by subject matter experts and may not require IT Professional support; even for the set-up of advanced workflow routings.

These systems can be further enhanced by adding customer, suppliers or other stakeholders to the overall compliance infrastructure. Integrating the external stakeholders into the full process flow brings greater satisfaction, greater customer retention and further reduces costs by collective participation.

Auersoft is a leading provider of modern compliance tools. Each compliance implementation is unique based upon the organizational culture and their interpretation of the standards. The selected platform must be capable of complementing the organization yet provide the means to enhance productivity.

For example, consider the breadth of an ISO900X or ISO13485 implementation. The normative standards cover the full range of organizational activities from product/service fulfillment to varying levels of risk management. In the case of ISO13485 or FDA regulated industries, compliance determines the ability of the organization to deliver product.

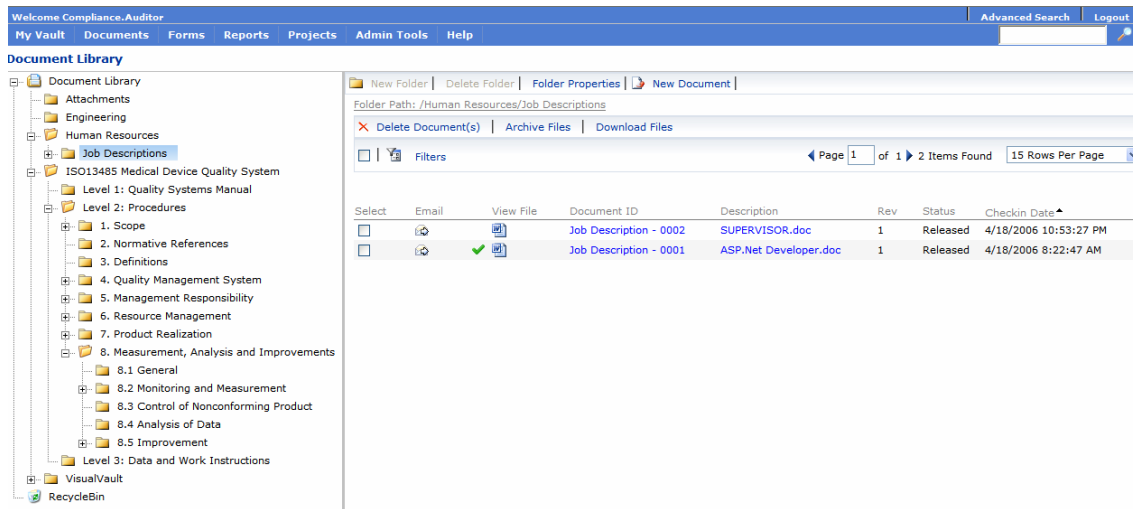


Figure 2 The document taxonomy for ISO Quality Management Systems.

The standards define requirements for documentation and taxonomy of procedures, work instructions and evidence of process management. Organizations often store their data in similar, yet unique ways that need to be supported.

Document control often involves the controlled release and change management of procedures and work instructions, and support of the training function per the standard. VisualVault can automate these functions

by establishing release workflow rules at the folder/sub-folder level and configuring training at the document level.

These standards also define requirements for several key processes:

- Corrective Actions
- Preventive Actions
- Internal Audits
- Suggestions for Improvement
- Engineering Change
- Non-Conforming Materials
- Deviation Reports
- Supplier CA
- Customer Complaints
- Returned Materials
- Customer Survey
- Credit Authorization

These processes are generally operated as form based processes. VisualVault provides sample forms and editing tools to change layout and field options and a flexible workflow engine to enable:

- Workflow routing
- Data capture
- Electronic signatures (meets 21 CFR 11 requirements)
- Audit trails for user inputs through field level changes (a Change Log that meets the intent of FDA electronic records keeping and used for clinical studies)
- Document associations to provide a single view of all related content
- Oversight dashboards for administrators to monitor all activity

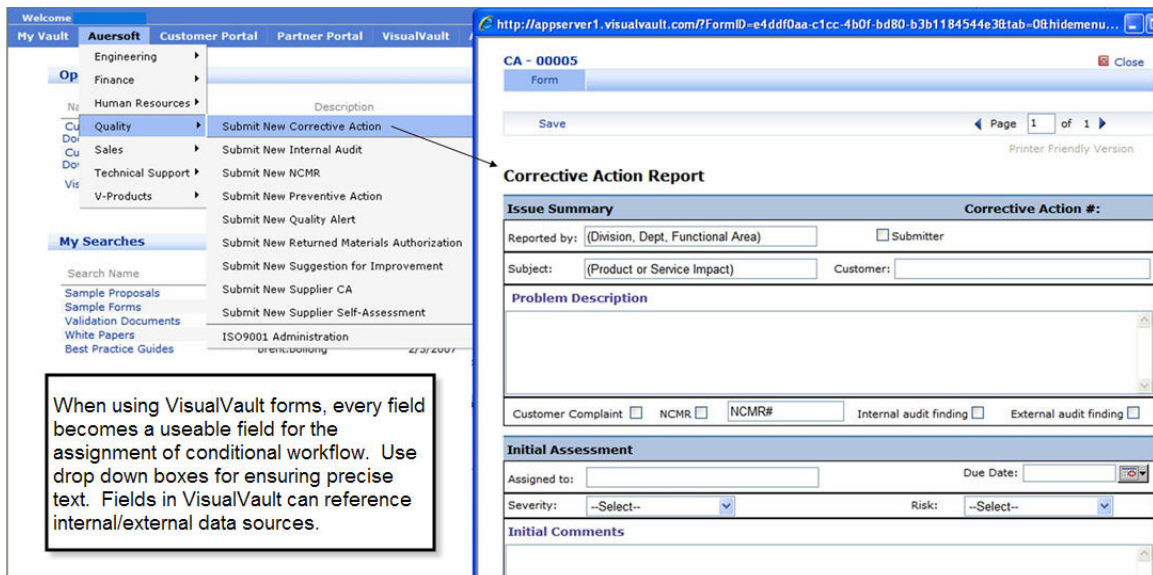


Figure 3 An example of a VisualVault Corrective Action form. In this case the main menu was modified to provide ease of access for system users.

Every document, folder, form, form dashboard and saved search can be thought of as an object to which security can be defined. To arrange content and simplify navigation, administrators in VisualVault can create their own

custom pages and configure menu navigation. With other simple features such as the ability to add logos to the top of each screen or define CSS (cascade style sheet) properties, the organizational look and feel can be created in VisualVault without compromising functionality or validation. With these abilities, the full compliance capability of VisualVault can meet and reflect the organization culture.

By leveraging the art of compliance, expect to reduce administrative overhead by the equivalent of two full time clerical workers for every 100 users upon transition from a paper based system to an electronic system. Customer satisfaction metrics consistently show improvement when on-line information access is provided to external stakeholders. Providing employee fingertip access to key documents, specifications or client related information allows issues to be handled on demand.

Choose your compliance system partner wisely. While technology is one part of the solution, a configurable system that meets the demands of the regulatory standard as well as the organizational culture will provide the greatest return on investment and highest levels of satisfaction. Exceeding expectations and satisfying clients is the essence of a successful quality system.

