IBS America develops integrated compliance management solutions to help companies improve corporate governance and achieve sustained adherence to regulations and standards. Since 1982, 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.

WEB-BASED COMPLIANCE MANAGEMENT SOFTWARE

CompliantPro[MD]

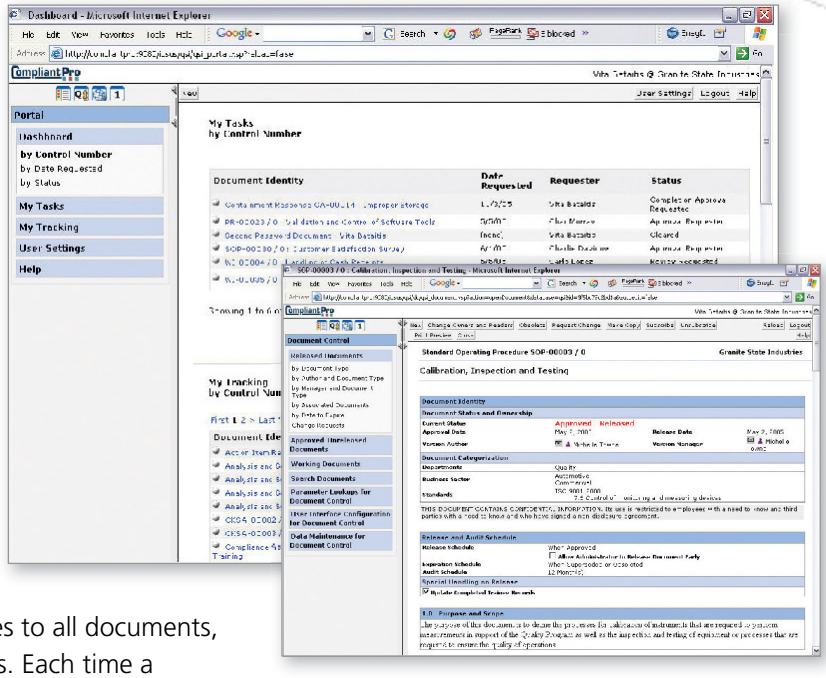
CompliantPro[MD] enables compliance with the FDA's QSR requirements, ISO 13485, and ISO 14971. By leveraging the system's sophisticated features, you can build and maintain safe, effective devices.

Capabilities

- **Corrective and Preventative Actions (CAPA):** Turn requests into actions with CompliantPro[MD] 's integrated CAPA capabilities. Create Corrective Action Requests (CARs) and Preventative Action Requests (PARs) from sources, including customer complaints, audits, NCMRs, internal issues, and suggestions. With real-time tracking, determine the status of an action request at any time.
- **Document Control:** Maintain secure, detailed documentation for products and processes. Build and maintain Device Master Records, Device History Records, and Design History Files. Retain document revisions for the entire life cycle of the product.
- **Enterprise Risk Management:** Perform insightful risk assessments that get to the core of product and process issues. Graphically portray your most significant risks. Set up controls to mitigate product and process problems.
- **Environmental, Health & Safety Management:** Meet the EH&S requirements of the FDA and ISO. Record and assess environmental and occupational hazards throughout the enterprise. Create and monitor controls to reduce the risks associated with these hazards.
- **Customer Complaint Management:** Record, investigate and resolve customer complaints. Track complaints by product, customer and supplier, as appropriate, in order to more quickly identify systemic issues and address them with corrective action.
- **Employee Training & Qualification:** Define training requirements for positions and organizations. Track training requirements, such as Work Instructions, SOPs, certifications, and other training requirements defined by your organization for each employee. Monitor each employee's job qualification information. Automatically notify managers when training deadlines have been missed.
- **Calibration:** Maintain manufacturing equipment and perform traceable calibrations. Create detailed schedules for all your calibration and preventative maintenance activities. For complex pieces of equipment, place components on their own calibration or maintenance cycles.
- **Advanced Product Quality Planning (APQP):** The system enables quality planning during the entire product life cycle. Choose from a number of templates when creating documents such as Process and Product Failure Mode Effects Analysis (FMEAs), Control Plans, and Phase-gate Checklists. Build effective quality management into your product.
- **Incident Reporting:** Comply with the FDA's requirements for MDRs, Corrections, and Removals. Access all the required documentation and file the forms electronically.

CompliantPro

Medical Device



- **Validation:** Our software can be fully validated to 21 CFR Part 11. IBS offers a full range of validation services to simplify compliance.
- **Reviews:** Meeting agendas, minutes and action items are created and tracked for management reviews, design reviews, material reviews, and contract reviews.

Universal System Features

- **Draft Copies and Archives:** Records are maintained of changes to all documents, including CARs, PARs, and NCMRs. Each time a document is submitted or rejected for review, approval or obsolescence, the document is copied to the Draft Copies Archives as a quality record.
- **Mobility:** CompliantPro[MD] is not bound by traditional client-server architecture, so you can log in wherever there is an internet connection. CompliantPro[MD] runs on industry-standard relational databases, email systems, web application servers and directory services.
- **Security:** Password authentication ensures that only authorized individuals access the system. Role-based security allows your organization to control access to specific documents and organizations as needed.
- **Scalability:** CompliantPro[MD] can accommodate organizations of all sizes. It can handle sophisticated taxonomies, manage multiple organizations within a single implementation, and control access according to roles and group membership.
- **Multilingual:** You can configure the user interface to display different languages to different users. Double-byte character sets (e.g., Chinese and Japanese) are fully supported.
- **Configurability:** Use the document configurations provided or choose your own fields and labels and configure your own unique workflow for each type of document. This flexible system adapts to your company's needs.
- **Notifications, Alerts and Escalation:** Users receive alerts about upcoming activities via email. When items become overdue, they are escalated through various levels of management for follow-up actions. Target due dates can be associated with priority codes to establish goals for all types of actions.
- **Rich-text Editing in a Browser:** While other web applications only permit simple text entry, CompliantPro[MD] offers you full functionality as you edit documents from the browser. Change fonts and emphasis of text, and embed images and tables inside fields.

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