GRAND AVENUE SOFTWARE
solutions for quality compliance

Quality Management Solution Overview

Grand Avenue Software is an out-of-the-box flexible quality management and compliance solution for medical products companies. Compliance is delivered through the unique combination of web software, proven best practices and workflows, and streamlined solution validation.

Assured Compliance

Easy to Use

Low Cost of Ownership

Process + Workflow + Database + Validation

Saves Time and Money

Business benefits:

- Gets you into compliance fast and keeps you there.
- Provides a high return on investment due to low costs and fast deployment.
- Establishes a solid compliance foundation that supports changes/ growth in your business.
- Delivers for startups, and is scalable to the needs of large organizations.

System Capabilities

- 100% Web-Based

  The system is easy to access, use and administer

- 21 CFR Part 11 Compliance

  The Quality Management solution fulfills requirements for electronic signoff and electronic recordkeeping

- Process Driven

  Built-in workflow notifies people of work to do, tells them how long they have to do it, and reminds users of approaching due dates

- Task Focused

  Users receive the information they need to do the job. Authorization of who can do what, when, and for how long is automatically managed by the application

- Process Metrics

  Charts provide visual status on the performance of important quality processes

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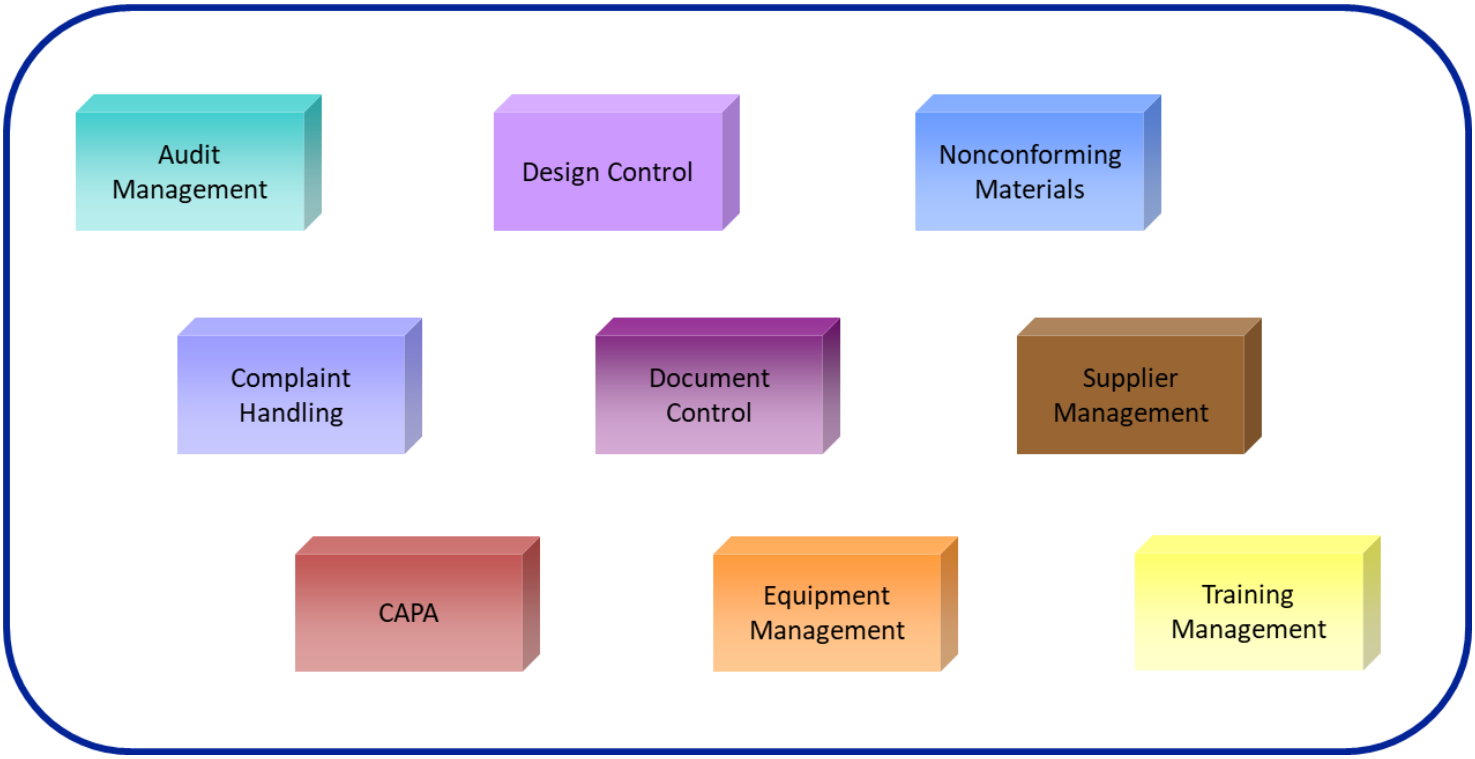

Overview of Functional Capabilities

Audit Management

Manage internal, supplier, and external audits. Record findings, observations, and resolutions. Link to CAPA's.

CAPA

Manage corrective, preventive and continuous improvement requests. Track detailed root-cause analysis and action plans. Perform verification.

Complaint Handling

Capture, track and manage product or service issues. Prioritize, investigate, report, code, and trend complaints.

Design Control

Manage and track design projects through the lifecycle phases. Define and manage deliverables by phase. Maintain electronic Design History File (DHF).

Document Control

Submit, route, review/approve and implement electronic document changes and deviations. Manage electronic documents.

Equipment Management

Define, track and manage equipment, activities, and schedules. Manage calibration, maintenance and qualification activities, and unplanned (ad-hoc, repair) events.

Nonconforming Materials (NCM)

Identify, sort, track, tag and disposition non conforming material. Review/approve proposed dispositions via the NCM Review Board (MRB). Mange disposition work.

Supplier Management

Review and approve suppliers. Manage the Approved Supplier List (ASL). Define, manage, and schedule supplier controls. View summary of related CAPAs, Audits, and Non-conformances.

Training Management

Define and manage training requirements. Mark training complete. Authorize read and understand training. Certify a training requirement. Measure training effectiveness.

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