



GRAND AVENUE SOFTWARE

solutions for collaborative intelligence

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 complete solution validation.

Assured compliance

Easy to use

Low cost of ownership

Process + workflow +
database + validation

Saves time and money

Business benefits:

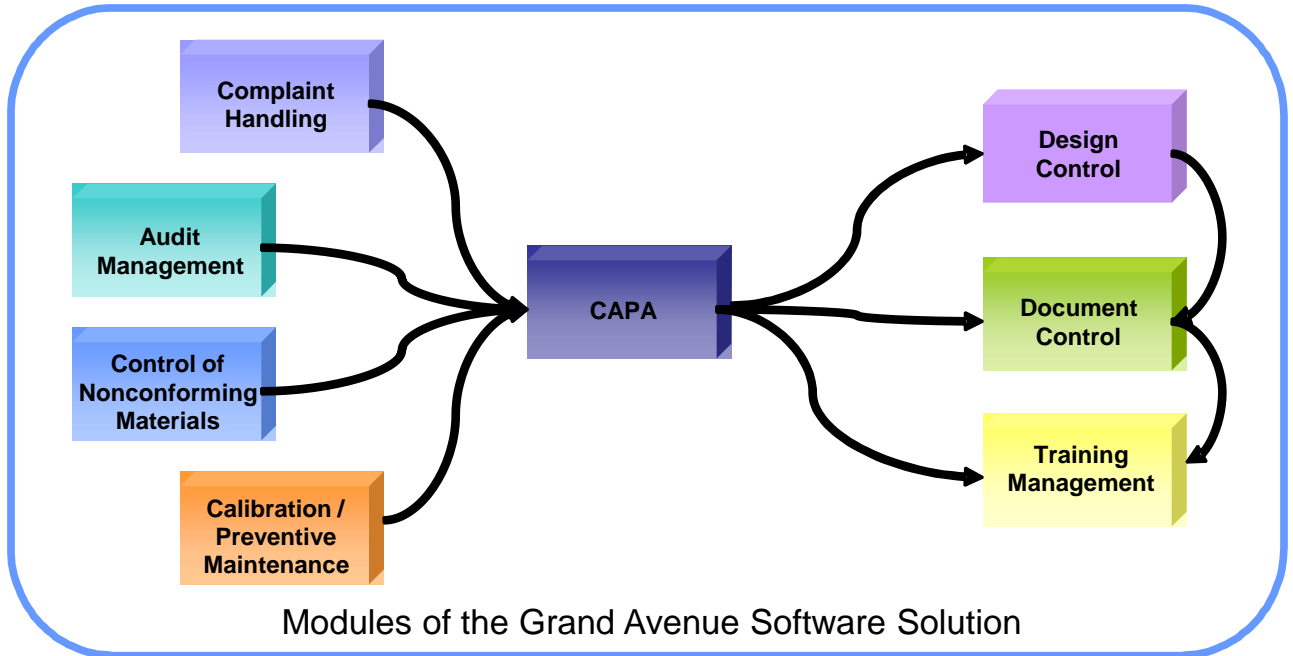
- Gets you into compliance fast and keeps you there.
- Provides a high return on investment due to low costs and fast deployment.
- Establishes a solid compliance foundation that supports changes/growth in your business.
- Delivers for startups, and is scalable to the needs of large multi-nationals.

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 record keeping
- Process Driven
Built-in work flow 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.
- Complete Validation
The entire solution is fully validated at all times
- Process Metrics
Visual gauges on the dashboard provide status as to how the processes are performing



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Overview of Functional Capabilities

Complaint Handling

- Issue capture, complaint prioritization, investigation, reporting, coding, trending

Audit Management

- Tracking of findings, observations, resolutions, creation of audit check lists

Nonconforming Materials

- Identification, sorting, tracking, disposition of materials, MRB reviews, tag creation, costs

CAPA

- Corrective, preventive and continuous improvement requests, prioritization and backlog management, detailed root-cause and action plan tracking, short and long term verification

Design Control

- Tracking of inputs, outputs, verification and validation protocols, reviews, DHF

Document Control

- Change impact assessment, online approvals, verification of change implementation

Training Management

- Assignments, sign off of tasks, records of needs and requirements, measured effectiveness

Calibration / Preventive Maintenance (in development)

- Equipment definition, schedule for calibration and maintenance, ad-hoc events, integration with CAPA and NCM, reports