



GRAND AVENUE SOFTWARE
solutions for collaborative intelligence

Design Control Solution Highlights

- Model and manage the design process for your company
 - Phases
 - Phase names
 - Sequence of phases
- Assign a Project Manager for each project
- Initiate work assignments to people regarding the deliverables
- Append files, information and evidence to the deliverables within each phase
- Document reviews within each phase as needed:
 - Technical reviews
 - Deliverable reviews
 - Projects reviews
- Conduct electronic phase review and approval when deliverables are completed in a phase
- Define and maintain the electronic Design History File (DHF) online in real time
- Measure and track project and phase status
- Send tasks and emails automatically to individuals informing them of work to do
- Maintain all information along with the associated reviews and approvals online by project
- Part of an integrated suite of modules that provide a robust quality management system including Corrective Action (CAPA), Complaint Handling, Non-Conforming Materials (NCM), Document Control and Training Management

Design Project Example: Deliverables in Phase I Concept Analysis

Manage Design Project	
Project ID	Market Buster
Project Description	New product that will bust open an new market for the company.
Project Manager	Schmitz, Ron (RonS)

Phase I Concept Analysis	Phase II Design Inputs	Phase III Design Outputs	Phase IV V & V	Phase V Market Transfer
Phase Name	Phase I Concept Analysis			
Phase Description	Cross-functional team review and analysis of proposed design concept			
Phase Status	Current			

Deliverables

Edit	Deliverable Name	Deliverable Description	Status	Tasks In Progress	Documentation
Edit	Program Initiation Memo	A memo approving the use of company time and resources to perform an analysis of the design concept.	Complete		Program initiation memo from management.
Edit	Market Analysis	A preliminary analysis of the market potential, market/profit rates, competitive forces, product positioning, projected sales/selling price, reimbursement, distribution channel, etc.	In Progress		2007, A (Product Brand Study)
Edit	Engineering Analysis	A study of the technology that must be developed, acquired, or licensed to develop the design. Include an opinion of the feasibility of the design and IP position.	In Progress	Turner, Tina (TinaT) - 5/25/2006	
Edit	Manufacturing Analysis	An assessment of the design's manufacturability.	In Progress	Carson, Johnny (JCarson) - 8/15/2006	
Edit	QA/Regulatory Analysis	QA/Regulatory and clinical strategy defining product classification, product family, domestic (PMA, IDE, 510K) and Outside U.S. (OUS) (Design Dossier/Technical File) submission requirements.	Not Started		

Screen Capture: Deliverables in Phase I Concept Analysis

The Project ID and Project Description at the top of this page provide information to the Project Manager about this specific project. The tabs below that show the phases of this project. The Project Manage may move from one phase of the project to another by clicking on the different tabs.

The tab for Phase 1 is currently selected in the screen capture. The middle and lower portions of the screen show the deliverables in Phase 1. The status column indicates whether work has been done or is still ongoing for each deliverable. Documentation that has been uploaded for a deliverable is shown on the right side of the screen in the Deliverables table.