

DHF-BASED PROJECT MANAGER



OBJECTIVE

DHF-based Project Manager manages new product development design projects, activities and content with creation of the device design history file to satisfy regulatory standards and good manufacturing practices for design control.

OVERVIEW

DHF-based Project Manager offers improved visibility of the design (development) process to the organization. It helps accomplish zero delays by linking product development data to design project execution and maintains procedures to control the design of the device to ensure that specified design requirements are met. **DHF-based Project Manager** becomes the central hub for collecting all information from requirements to risks to final design in an easy to navigate design history file. **DHF-based Project Manager** assures a well-organized Design History File (DHF), context completeness via visual cues that communicate which deliverables are included in the DHF, and its approver signatures. **DHF-based Project Manager** provides tools for design controls and risk management to flow and blend together early in product development.

CAPABILITIES

Project Management

Design project management becomes data-driven by being linked with the product portfolio and the design content that regulatory agencies demand.

Design History File Management

DHF-based Project Manager uniquely accomplishes zero delays in design projects by linking product development data to design project execution. It dramatically increases productivity globally by executing design projects with real-time design information via automated synchronization of a project's status in terms of overall schedule, phases, gates, and resources and design artifacts to the DHF. This automated synchronization allows the design teams to focus on high-value activities rather than tracking down design status.

The DHF provides dynamic links to related documents and data for improved visibility into related business processes, assigns design activities and task assignments with details. A consolidated summary view can be created of the product DHF for all related design projects, signatures of approvers, and related records (such as Parts) to assure compliance. Easily view and compare baseline "DHF Snapshots", capturing the status of the design history file at specific times in the design project lifecycle.

Key Benefits:

- Manage design projects, activities and content with creation of the design history file.
- Aggregate regulatory content into a traceable DHF to confidently handle future audits and submissions.
- Design input and output traceability to ensure that the intended design satisfies all product requirements.
- Coordinate design project scope, schedule and resources to deliver the product portfolio.
- Ensure all identified risks are mitigated using Hazard Analysis, included in the DHF.
- Manage design evolution accuracy and efficiency of product record maintenance.

Hazard Management

Control measures are the key to identifying ways to mitigate and reduce your product's risks to acceptable levels. **DHF-based Project Manager** provides a complaint workflow and risk management throughout the product lifecycle from scales of severity, probability and risk acceptability matrix. Hazards traceability is available from individual design projects, establishing automatic traceability of hazards with design input and mitigating hazards by associating new requirements to the design.

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