Electronic Design History File:Automatic Regulatory Compliance in Medical Device Industry through PLM Application

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ABSTRACT

Medical device manufacturers face the same intense competition that other manufacturers face, but with the added burden of having to plan, develop, test and produce in an environment rigidly controlled by regulatory requirements.

To meet regulatory mandates, medical device manufacturers must be able to provide, upon request, documentation supporting the entire product lifecycle, from concept through execution. For many companies, this means maintaining hardcopy records of all related product information. And with a paper-based system of record-keeping, this requirement adds a huge burden to an already formidable task. With an electronic system of record-keeping, medical device manufacturers could ease this burden by streamlining processes and automating record-keeping. By using an electronic system that both links Product Development and Quality System Regulations, and automates the task of capturing records, companies can focus on innovating, accelerating time-to-market, and improving their audit results.

This white paper presents an over view of how Teamcenter For Medical device Industry(TcMDI) ,a fully integrated PLM solution for medical device industry provides Electronic design history file technology to help medical device manufacturers to improve performance of several critical business processes including regulatory compliance, quality systems management, detailed design, change management and requirements management.

Since the white paper is based on PLM solutions to Medical Industry it makes reference to the PLM and Medical Industrial terminology it assumes that the target audience is familiar with their general meanings.

1. INTRODUCTION

In today's competitive marketplace medical devices manufacturers face a larger challenge by having to comply with strict regulatory requirements. FDA-required design controls force companies to integrate quality systems regulations with product development

Section 820.30 of the Quality System Regulation (FDA's 21CFR Part 820) defines Design History File (DHF) as a compilation of records which describes the design history of a finished device. DHF contains or references all the records necessary to demonstrate that the design was developed in accordance with the approved design plan and the requirements of the device.

For many medical device manufacturers, the process of keeping paper based records adds a significant burden. Not only is this process slow, but it is also costly in terms of the amount of time spent filing and searching these records.

An electronic-based system of record-keeping can help manufacturers 'hardwire' compliance into their systems by automating the process of capturing records ensuring better audit results.

Teamcenter for Medical Devices manages a Design History File which can be created and maintained by authorized users. It assists Product Managers to define a Stage/Gate process in managing product development including planning, change

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management and reporting. This feature allows the product manager to define a Product Lifecycle with defined tollgates in a configurable product definition template.

2. DESIGN HISTORY FILE: DEFINITION AND CONCEPT

Design History File is a compilation of documentation that describes the design history of a finished medical device. The design history file, or DHF, is part of regulation introduced in 1990 when the U.S. Congress passed the Safe Medical Devices Act, which established new standards for medical devices that can cause or contribute to the death, serious illness, or injury of a patient.[1] Prior to this legislation, U.S. Food and Drug Administration (FDA) auditors were limited to examining the production and quality control records of the device.

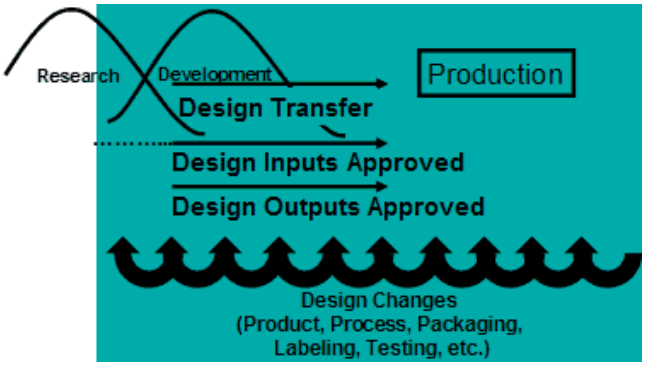

Figure 1: Design History File

2.1 Regulation Requirements

Medical device companies that want to sell products in the United States must first be granted permission by the US Food and Drug Administration (FDA).

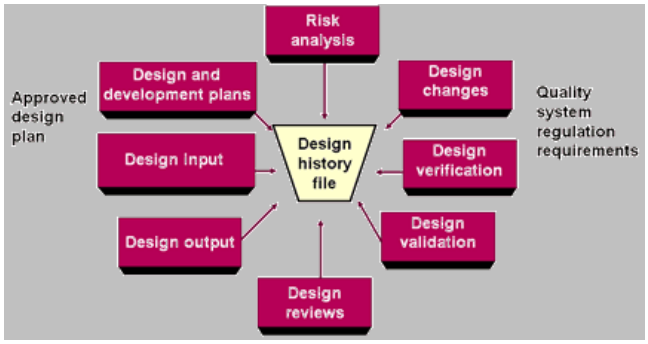

Figure 2: Regulation Requirement of DHF

To obtain permission, companies must comply with several laws from the US Code of Federal Regulations (CFR), the most prominent of which is 21 CFR Part 820–Quality Systems Regulations. Part 820 defines the important concepts of design control and quality records. Under this regulation, medical device manufacturers are required to document the entire design process from cradle-to-grave. To be compliant, companies must create a Design History File (DHF) comprised of the following sections:

- Design planning
- Design inputs
- Design outputs
- Design reviews
- Design verification
- Design validation
- Design transfer

2.2 Design History File Factors

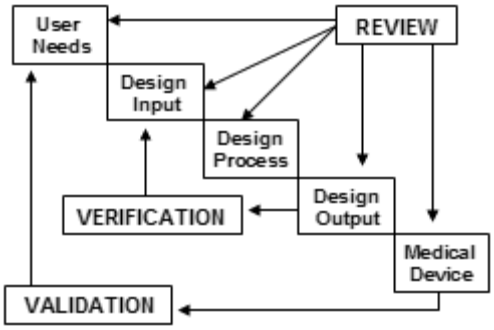

Figure 3: Design and Development Activities

2.2.1 Design and Development Planning

CFR Part **820.30(c)** states that:

- Each manufacturer shall establish and maintain plans that describe or reference the design and development activities and define responsibility for implementation.
- The plans shall identify and describe the interfaces with different groups or activities that provide, or result in, input to the design and development process.
- The plans shall be reviewed, updated, and approved as design and development evolves.

Design Planning enables management to exercise greater control over the design and development process by clearly communicating policies, procedures, and goals to members of the design and development team, and providing a basis for measuring conformance to quality system objectives.

2.2.2 Design Input

CFR Part **820.3(f)** states that:

- Each manufacturer shall establish and maintain procedures to ensure that the design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the user and patient.

Design input means the physical and performance requirements of a device that are used as a basis for device design

2.2.3 Design Output

CFR Part 820.30(d) sates that:

- Each manufacturer shall establish and maintain procedures to ensure that the design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the user and patient

Design output means the results of a design effort at each design phase and at the end of the total design effort. The finished design output is the basis for the device master record. The total finished design output consists of the device, its packaging and labeling, and the device master record.

2.2.4 Design Review

CFR Part 820.30(e) states that:

- Each manufacturer shall establish and maintain procedures to ensure that formal documented reviews of the design results are planned and conducted at appropriate stages of the device's design development.

Design review means a documented, comprehensive, systematic examination of a design to evaluate the adequacy of the design requirements, to evaluate the capability of the design to meet these requirements, and to identify problems.

2.2.5 Design Verification

CFR Part 820.30(f) states that:

- Each manufacturer shall establish and maintain procedures for verifying the device design. requirements.
- Design verification shall confirm that the design output meets the design input requirements

Design Verification means confirmation by examination and provision of objective evidence that specified requirements have been fulfilled.

2.2.6 Design Validation

CFR Part 820.30(g) states that

- Each manufacturer shall establish and maintain procedures for validating the device design.
- Design validation shall be performed under defined operating conditions on initial production units, lots, or batches, or their equivalents.

Design validation means establishing by objective evidence that device specifications conform to user needs and intended use(s).

2.2.7 Design Transfer

Figure 4: Design Transfer

CFR Part 820.30(h) states that

- Each manufacturer shall establish and maintain procedures to ensure that the device design is correctly translated into production specifications.

Design Transfer process translates the device design into production. It includes the process validation activities, which are performed during production to demonstrate through objective evidence that the manufacturing process produces device that meets its specifications.

2.2.8 Design Changes

CFR Part 820.30(i) states that

- Each manufacturer shall establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation

Design Changes involves **change control** procedure to re-verify and re-validate the design.

2.3 Correlation with Quality Management System for Medical Devices

There is no specific requirement in ISO 9001 or ISO 13485 for a design history file. However, in order to market a medical device in the United States, a manufacturer must comply with the U. S. Food and Drug Administration (FDA) quality system regulation, which requires a design history file.
Product documentation required by Canada, Europe, and Japan contain certain elements of the U. S. FDA design history file requirements without requiring all the elements to be compiled in a file.

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Figure 5: Quality Management Subsystems

ISO 13485 section 4.16, Control of quality records correlates the Section 820.30 of the Quality System Regulation (FDA's 21CFR Part 820)

ISO 13485:1996 Specifies, in conjunction with the application of ISO 9001, the quality system requirements for the design/development and, when relevant, installation and servicing of medical devices

ISO 13485 sections 4.16 Control of quality records clearly specifies the following records should be maintained and established

- Records relating to design and development inputs
- Records of the results of design and development reviews and any necessary actions.
- Records of the results of design and development verification and any necessary actions.
- Records of the results of design and development validation and any necessary actions.
- Records of results of the review of design and development changes and any necessary actions

FDA's Design History File also requires the same design records to be compiled.

2.4 Industrial Benefits:

The primary beneficiary of the device history file is the Medical device manufacturer.

For example, in one case, a microprocessor-controlled entreats feeding pump was reported to be behaving erratically in the field. Some of the symptoms pointed to software problems. But the manufacturer admitted that they did not possess a copy of the software source code for the product. The software had been developed by a contractor who had delivered only a master EPROM (memory chip) which was duplicated by the manufacturer to install the software in each machine. The contractor had subsequently withdrawn following a contractual dispute, leaving the manufacturer with no rights to the source code developed by the contractor, and no practical way to maintain the software. For this and other reasons, the product was the subject of a mandatory recall and all known units were collected and destroyed.

This is admittedly an extreme case, but many similar cases have been documented in which the manufacturer lacked design information necessary to validate a design and maintain it throughout the product life cycle. This occurs for the most innocent of reasons-contracts expire, companies reorganize, employees move on to new projects or new jobs. Even when the designer is available, he or she may forget why a particular decision was made years, months, or even weeks before.

Since design decisions often directly affect the well-being of device users and patients, it is to the manufacturer's benefit to maintain the design history file which forms a basis for the product design.

3. MANAGING DESIGN HISTORY FILES

There are no requirements on the location or organization of the design history file. In some cases, especially for simple designs, the designer will assemble and maintain the entire design history file. For larger projects, a document control system will likely be established for design documents, and these files will likely be maintained in some central location, usually within the product development department.

Based on the structure of the product development organization, more or less extensive controls will be required. For example, company policy should state unequivocally that all design history documentation is the property of the manufacturer, not the employee or contractor. Design and development contracts should explicitly specify the manufacturer's right to design information and establish standards for the form and content of design documentation. Finally, certain basic design information may be maintained in a single project file in a specified location. This may include the following:

- Detailed design and development plan specifying design tasks and deliverables.
- Copies of approved design input documents and design output documents.
- Documentation of design reviews.
- Validation documentation.
- When applicable, copies of controlled design documents and change control records.

3.1 Paper Based System

Many design engineers maintain laboratory note books which are typically retained in the engineers' personal files. In addition, the design history may include memoranda and electronic mail correspondence which are stored at various physical locations. Quality system plans applicable to a development project may reside in the quality assurance department, while the chief engineer may be responsible for maintaining design and development plans. These diverse records need not be consolidated at a single location. The intent is simply that manufacturers have access to the information when it is needed. If

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a manufacturer has established procedures for multiple filing systems which together satisfy that intent, there is no need to create additional procedures or records.

However, because a paper based system is a manual process, it is very difficult and time consuming to capture the reason behind all design decisions. As a result, it is not uncommon for important product design information to be missed. In addition, records can be misfiled, information may be changed incorrectly, and often entire records go unified.

3.2 Electronic Process for Managing Design History Files

Automated, electronic solutions can help medical device companies better manage their design history file (DHF).
In an electronic system, files are stored in a central repository rather than in disparate file systems. Design data's can be automatically captured when files are checked into the repository in an ordered approach using a hierarchical folder structure. Furthermore, files are automatically linked to relevant
records, ensuring all records are accurately captured. This process also provides full traceability, from design through production.

3.2 Benefits of an Electronic DHF System:

Typical benefits of moving from a paper-based to an electronic DHF system include:

- **Improved productivity**–By automating the filing of records and enabling easy electronic searches, workers spend less time filing and searching records, and more time developing products.
- **Better compliance**–By automating the filing of DHF an records, you ensure that all records are captured, changes are accurately made to all relevant records, and all required records are easily accessible. All of this leads to faster FDA approval and better audit results.
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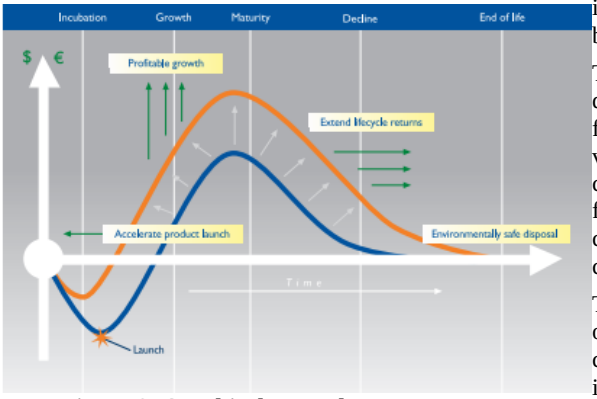

Figure 6: Graphical Records

- **Faster time-to-market**–Automating processes and hardwiring compliance ensures that you get your product to the marketplace faster, where it can start helping customers sooner and generate important revenue earlier.

4. TEAMCENTER EDHF SOLUTION

TCS and Siemens PLM Software have developed Teamcenter for Medical Device Industry (TcMDI), a fully integrated PLM solution for medical device industry. The solution combines compliance management, traceability and reporting capabilities to help medical devices manufacturers address strict quality and regulatory requirements, increasing competition and demanding time-to-market pressures.

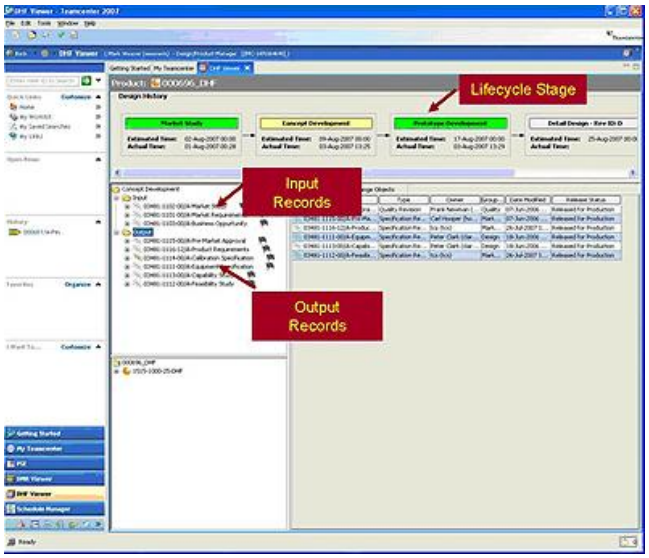

Figure 7: Teamcenter DHF Interface

Teamcenter provides the foundation for managing a static DHF (sDHF) and an electronic (eDHF). It is a business goal to treat the static and electronic DHF as similar as possible. Where there are differences they will be identified as sDHF and eDHF. The indicator DHF is used when the design and behavior refers to both.

The purpose of the sDHF is to make the existing paper DHF documentation available in electronic form. The sDHF provides a framework for collecting, storing and finding the electronic versions of the documents currently managed in paper format for current and past projects. The sDHF will differ in organization from the paper DHF. The revisioning feature will be used to capture revisions instead of separate sub-chapters for previous and current versions.

The purpose of the eDHF is to support the electronic construction of the DHF within Teamcenter as an eventual replacement for the current paper process. The main difference in the daily behavior is that with the sDHF PDF versions of the paper documents will be attached, while in the eDHF will have original document source, such as MS Word. There are also differences in the approval process between the static and electronic DHF's.

The deployment of Teamcenter provides a mechanism for:

- An electronic location for documentation related to a DHF

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- A foundation to reach a common DHF organizational structure
- Controlling the lifecycle of the Design and Development Plan
- An accessible R&D wide electronic location for DHF's.
- Robust management DHF related documents and drawings with electronic signatures, dynamic watermarking and rendering to a secure format such as PDF.

- Records of the device master those are automatically captured and rendered when you associate DHF documents to your product.

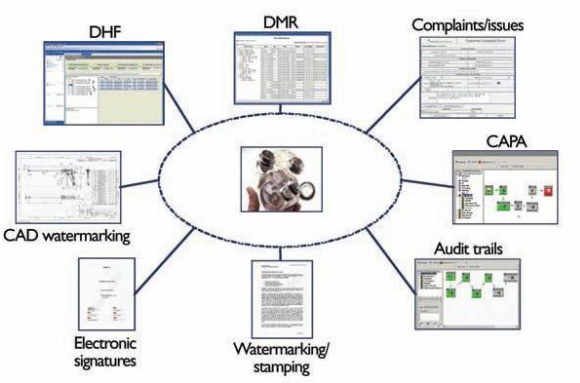


Figure 8: Teamcenter Electronics solutions for Medical device compliance

- Robust and highly functional change management of base Teamcenter to address and track device design issues and complaints including automatic triggering of CAPA

4.1 DHF Structure

The framework for the DHF is a template that follows 21CFR 820.30 sections for the organization of the design control information. There is a preset structure provided in the tool. The user can generate a new DHF which will automatically generate the structure shown in the table below. The user has the capability to create and remove sub-structure to meet the needs of the specific DHF to be created.

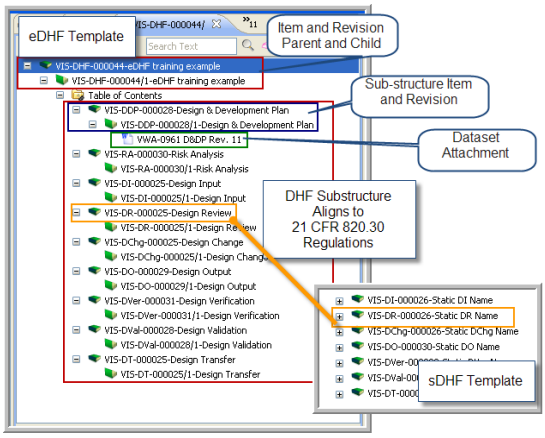


Figure 9: Teamcenter DHF Structure

There is a template for the sDHF and a template for the eDHF The eDHF template should be used when the design history file is created for a new project. The sDHF template should be used when existing project documentation is being moved to an electronic format

4.2 DHF Lifecycle

Teamcenter allows the DHF item to go through 3 states of its life cycle.

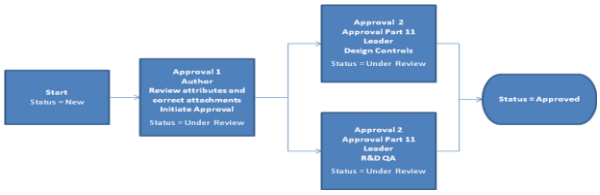
New: This is the status assigned to any New DHF item. All new device design documents begin life in the 'New' state.

Under Review: This status will be placed on a DHF and associated design documents when the author initiates the workflow activity to have the design documents reviewed.

Approved: The system will asign this status once all approvers have reviewed and completed the workflow activity to approve the design documents. The eDHF will require Part 11 Signature actions from multiple group leaders. The sDHF signature can be completed by the same individual provided the user has the appropriate role assignments

4.3 DHF Workflow approval Process

The first task in the approval process is to perform an administrative review to verify attributes and file attachments. The second task is a technical review with a Part 11 compliance signature after a content review is carried out. Finally, once the system detects the Part 11 Compliance signature, it automatically sets the item's status to 'Approved'. These tasks may be performed by the same person (with appropriate privileges) or as separate actions by multiple approvers.



4.4 Teamcenter Functionalities to Manage DHF

The following sections describe the functionalities available for the management of the DHF in Teamcenter for Medical Devices.

4.4.1 Monitoring Product Development at any stage through DHF Viewer

DHF Viewer allows user to view and monitor every phase of Product Development Process.

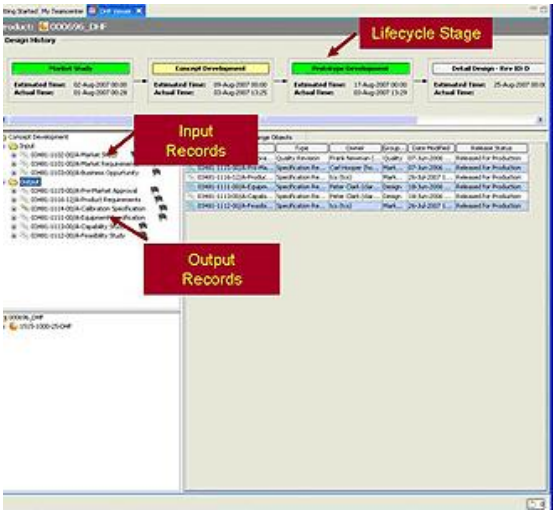


Figure 10: DHF Viewer

DHF viewer consists of 4 parts as stated below:

4.4.1.1 Product Phase Panel:

This panel displays the different phases in the life cycle of a product. The phases of a particular product depend on the product line it belongs to. The product line of a product is set in the master form of the DHF item. The product phase panel displays the estimated dates for all the phases and the actual completion date for the completed phases. The color of a phase depends on the state of that phase. The following are the list of colors (states) that a phase can have.

Green - Completed Phase

Orange - In Process Phase

White - Working phase

Grey - Phases that are yet to start.

When a phase is selected in the phase panel, the color of the phase is changed to yellow

4.4.1.2 Product Phase Documents Tree:

This panel displays all the input and the output documents associated with the current selected phase.

4.4.1.3 Sub DHF Tree:

This panel displays all the DHF items associated with the current product. These can be any DHF items that belong to any of the sub-assembly of the product.

4.4.1.4 Properties Panel:

This panel has two tabs, Properties tab and the Change Objects tab. The properties tab displays the properties of the documents displayed in the product phase documents tree. The change objects tab displays all the change items associated with the documents displayed in the product phase documents tree.

4.4.2 Set estimated dates for the DHF

This functionality allows user to set estimated date of completion for each stage in product life cycle.

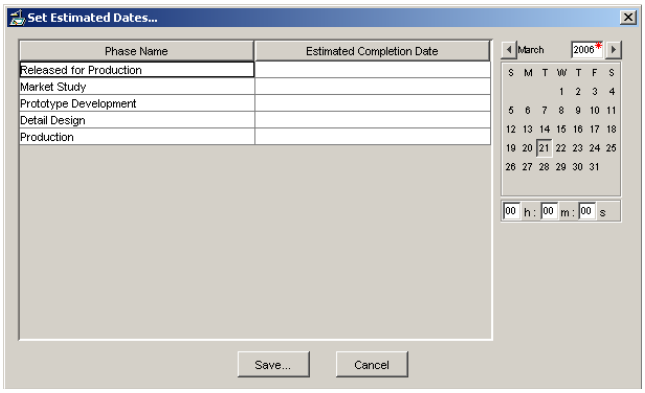


Figure 11: Set Estimated date dialogue

4.4.3 Associating a document to a DHF

If a user has write access to modify DHF association, he/she can add input /output documents to the DHF.

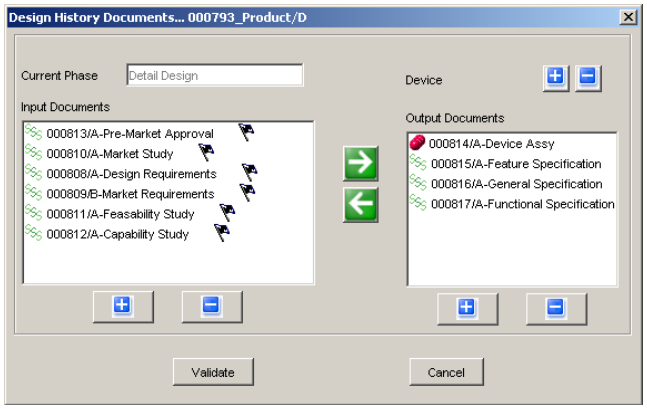


Figure 12: Associating Document To DHF

4.4.4 DHF Validation

DHF validation enables a user to verify if a phase in the product life cycle is complete by checking for the mandatory documents as specified by the DHF product definition file.

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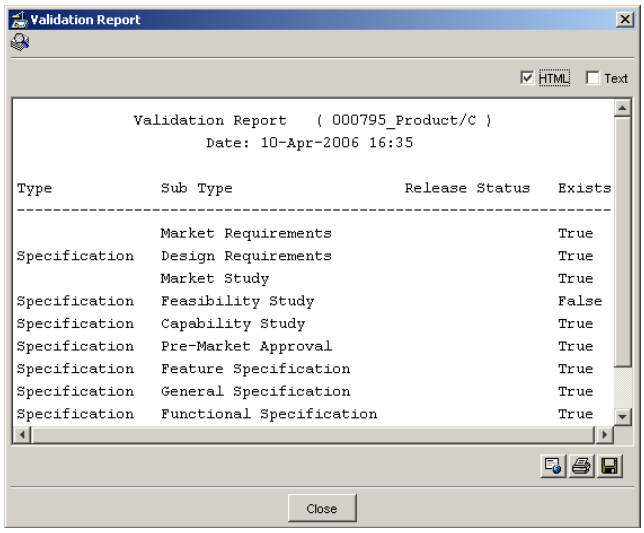

Figure 13: DHF Validation Report

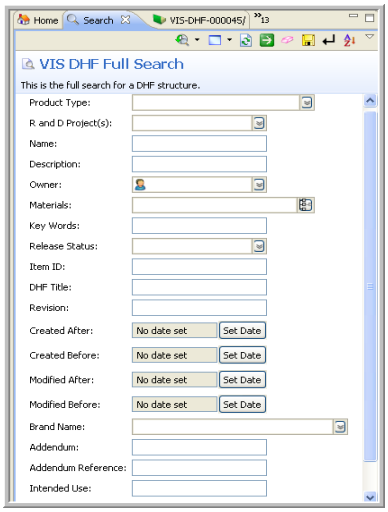

Figure 14: DHF Search

4.4.5 Revise DHF Revision

A DHF item is revised when a phase in the life cycle of a product is complete and the next phase is to be started

If the latest revision of the selected DHF item is a released revision then a new DHF revision is created. The input documents of the old revision will be carried to the new revision. Some of the output documents from the old revision are moved to the input of the new revision based on the rules set by the system administrator. The output documents under the old DHF revision that does not match the rules will be carried to the new DHF revision as output documents

If the latest revision of the selected DHF is not a released revision then no new DHF revision is created. The output documents from the previous released DHF revision will be carried to the working revision as input documents based on the rules set by the system administrator.

4.4.6 DHF Search

The search function is a global function of Teamcenter.

The search feature enables users to search DHF's based on a specific set of attributes.

4.4.7 DHF Report Generation

A HTML dynamic report can be generated for the DHF. This report provides the information about the various phases of the product, the documents associated with the phases, the changes associated with the documents and the estimated and actual dates of completion of each phase

Design History File

Product: 000795_Product
Date: 10-Apr-2006 16:38

Phase Name	Estimated Date	Actual Date	Owner	Validation Status
Market Study	26-Mar-2006 00:00	14-Feb-2006 16:31	Raghavender Kurapati	Success
Concept Development	24-Mar-2006 00:00	14-Feb-2006 16:31	Raghavender Kurapati	Not Validated
Prototype Development	13-Mar-2006 00:00	14-Feb-2006 16:32	Raghavender Kurapati	Not Validated
Concept Development	24-Mar-2006 00:00	14-Feb-2006 16:32	Raghavender Kurapati	Success
Prototype Development	13-Mar-2006 00:00			Success
Detail Design	03-Mar-2006 00:00			
Production	06-Mar-2006 00:00			

Phase: Market Study

Input Documents				
Object	Type	Owner	Release Status	Change
Ouput Documents				
Object	Type	Owner	Release Status	Change
000809/A-Market Requirements	Specification Revision	Raghavender Kurapati (ragha)	Approved for Pre-Release	
000808/A-Design Requirements	Specification Revision	Raghavender Kurapati (ragha)	Approved for Pre-Release	
000810/A-Market Study	Specification Revision	Raghavender Kurapati (ragha)	Approved for Pre-Release	

Phase: Concept Development

Input Documents

Figure 15: DHF Report

4.4.8 DHF Audit Report Generation

DHF audit report will contain the details of all the events related to DHF Items

MDI DHF Audit Report

Aug 29, 2006 Tuesday

Search Criteria Used

Object	Type	Event	Event Objects	Event Date	User	Phase Name
000023/A	DHF	Remove	000006	26-Aug-2006 15:41	Himaja	Market Study
000023/A	DHF	Add	000007/A	26-Aug-2006 15:41	Himaja	Market Study
000004/F	DHF	Move To Input	000022/A	28-Aug-2006 19:17	Himaja	Detail Design
000004/A	DHF	Move To Output	000001_DMR/A	25-Aug-2006 17:57	Himaja	Market Study
000004/D	DHF	Move To Output	000008/A	26-Aug-2006 14:29	Himaja	Prototype Development

Figure 16: DHF Audit Report

5. SUMMARY

Teamcenter for Medical Devices facilitates comprehensive program lifecycle management, which in turn results in faster design cycles, accelerated time to regulatory agency approval, fewer design and submittal iterations and lower costs for design, development, manufacturing, testing and tracing.

Teamcenter facilitates this strategic approach by tracking all of the product data that pertains to product development activities performed by a medical devices OEM (original equipment manufacturer) and its suppliers. By integrating compliance management into a complete product lifecycle, Teamcenter virtually eliminates manual data entry, improves data accuracy and reduces the costs of both compliance and non-compliance.

Teamcenter's EDFH solution helped the OEM in achieving their business objectives along following parameters:

- 80% cost saving in device components without compromising on quality
- 10% cost saving in device cost
- Alignment with future global supply chain strategy .

6. ACKNOWLEDGMENTS

[1] Siemens PLM Software – www.siemens.com/teamcenter

[2] Tata Consultancy Services- www.tcs.com/offerings

[3] Rajesh Pudota -Rajesh Pudota/HYD/TCS.

[4] Soumya Ranjan Rout- Ranjan Soumya/KOL/TCS.

[5] Ranjan Banerjee- Ranjana Banerjee/KOL/TCS

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