

Productivity Improvement Comes From More Than Just A Medical Device History File

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Presentation Outline

- Where we Started with eDHF
- System/Process Modifications
- Requirement Tracing
- Conclusion
- Desired Teamcenter Enhancements
- Q & A

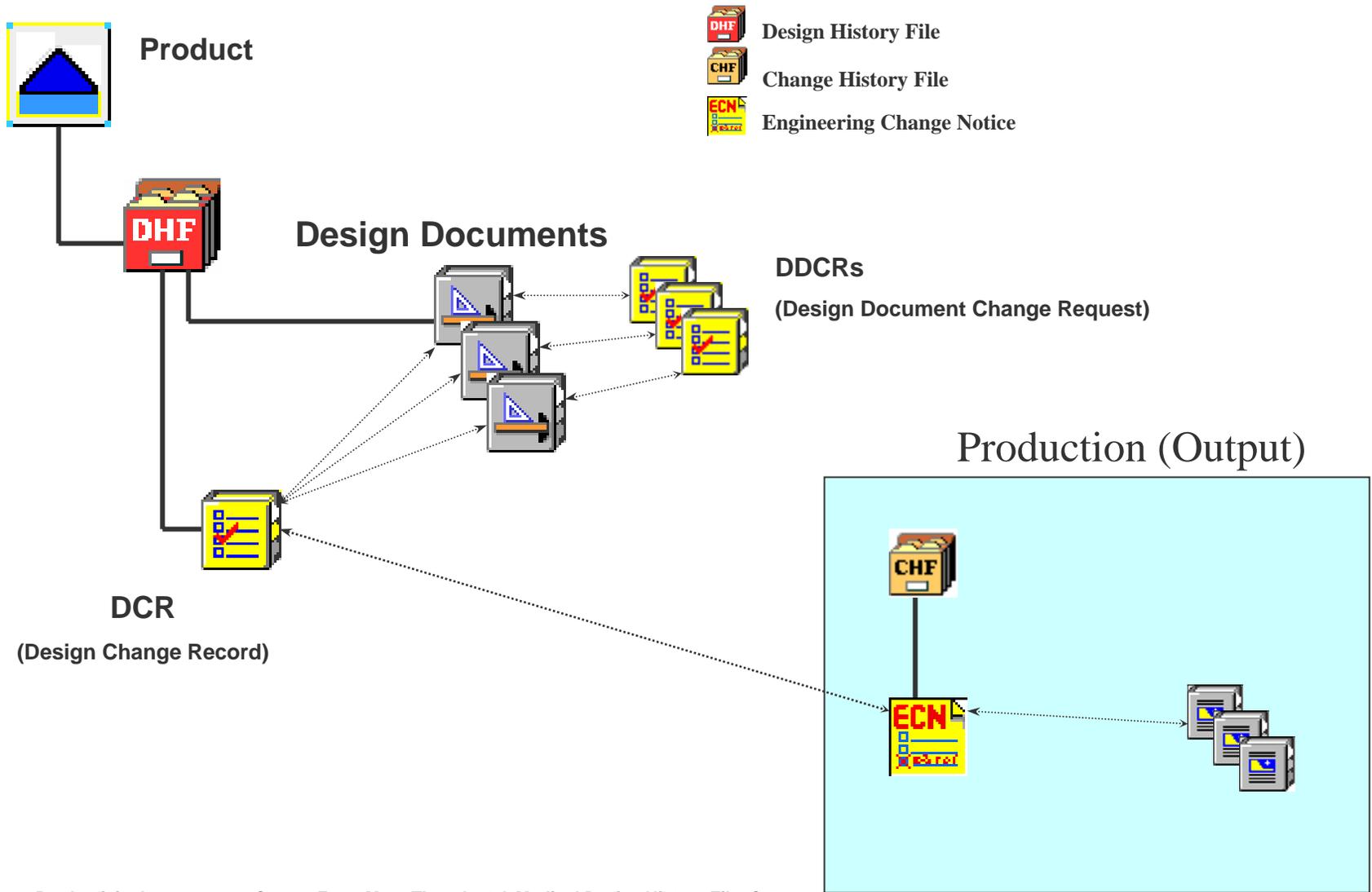
DHF Document Categories

- **Inputs** (Design History File)
 - **Planning**
 - **Design Input**
 - **Design Reviews**
 - **Risk Management**
 - **Design Changes**
 - **Design Verification**
 - **Design Validation**
 - **Design Transfer**
- **Outputs** (Device Master Record Index)
 - **Design Output**
 - Engineering & Mfg. Documentation
 - (Mechanical Models , Electrical, software, Labeling, Mfg. Processes)

Input Documentation

- Documents
 - Project Plans
 - Verification Plan
 - Software Design
 - Design Review Minutes
 - User Needs
 - Product Requirements
 - Detailed Design Specifications
 - Risk Analysis
 - Verification Protocols
 - Verification Reports
- Change Records
 - Design Change Record
 - Design Document Change Record

eDHF With Relations



Initial Document Release Process

Design Change Record

Submit



Final Review

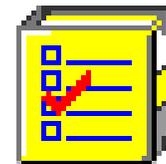
Last Years Planned Release Process!

Approval

Creation



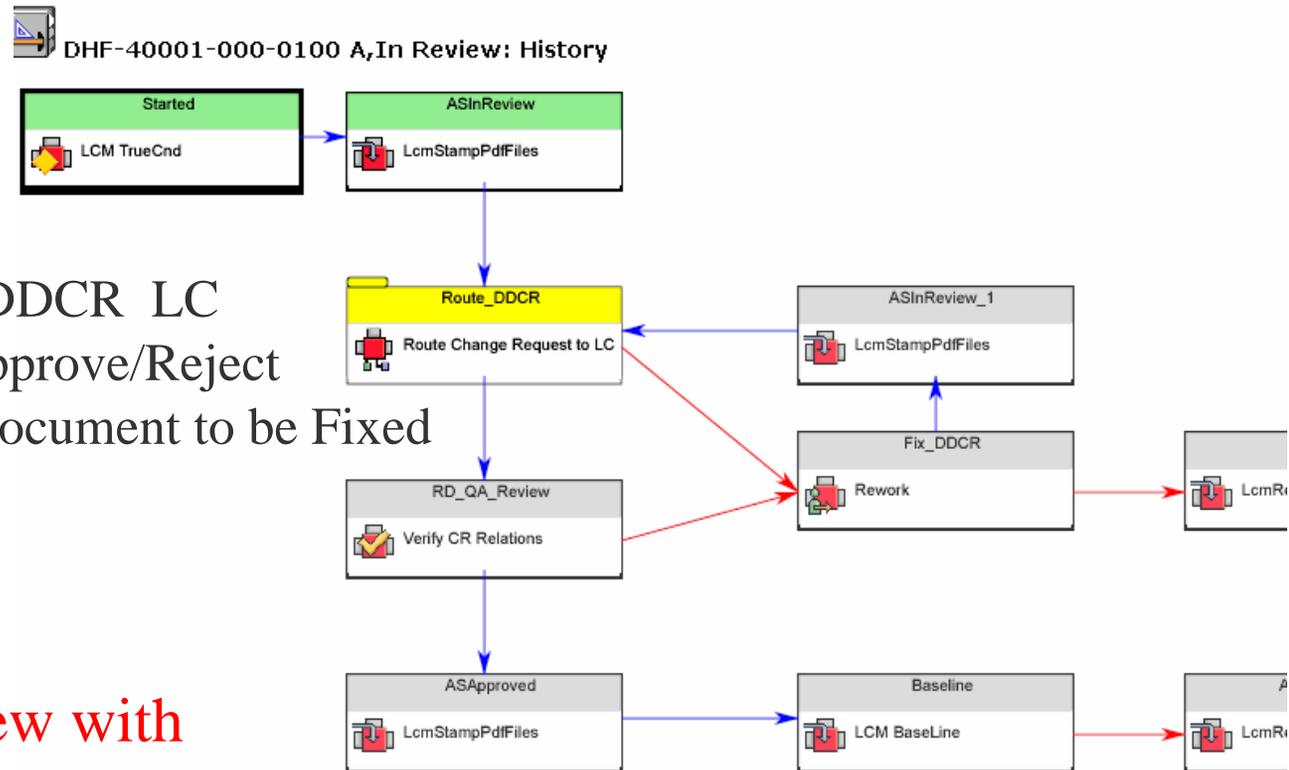
Design Document



Design Document Change Request

First Document Life Cycle

Paper oriented paradigm for the first electronic process



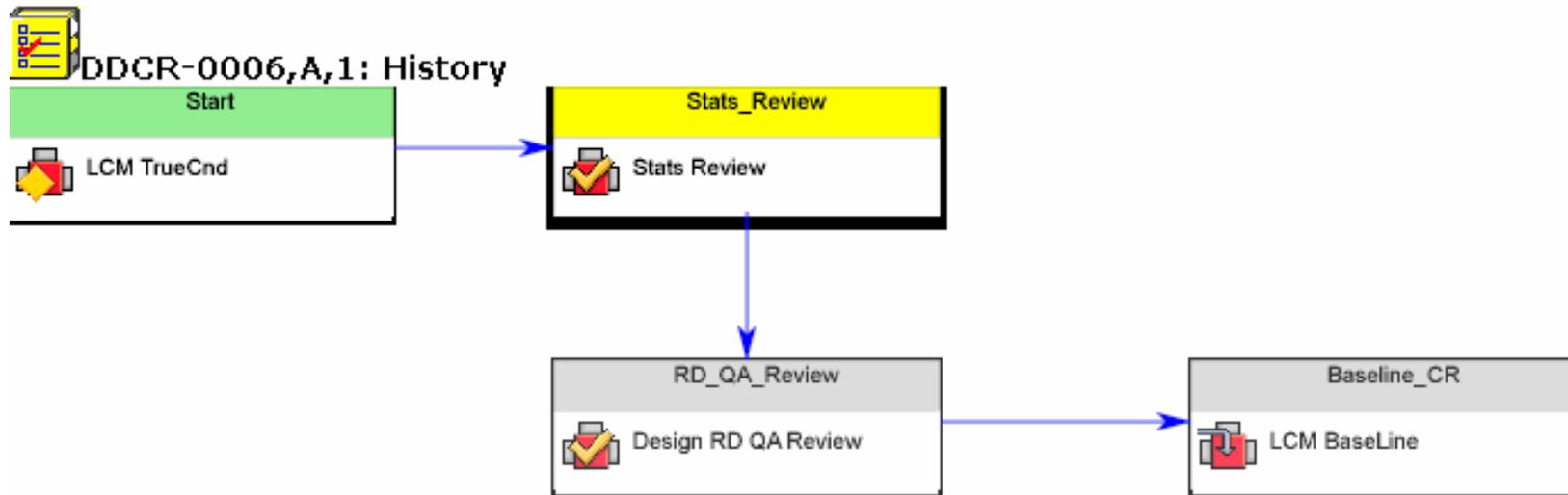
- Stamps PDF Files
- Routes Document To DDCR LC
- All Reviewers must Approve/Reject
- One Rejection sends Document to be Fixed
- QA Review**
- Document Approval

**Replace QA review with
system check**

Rev A, In Review - Stamped On: 04/29/2005 - Effective On: - Confidential - Page 2 of 5

Life Cycle Per Document Type

Users wanted more flexibility for selecting Roles!



Current Work
Select one assignment to work on.

<input type="checkbox"/>	Name	Description	Assignment	Assignment
<input checked="" type="checkbox"/>	DDCR-0006,A,1	DDCR-0006,A,1	Esig Stats Review	Request
<input type="checkbox"/>	DDCR-0005,A,1	DDCR-0005,A,1	Esig Stats Review	Request

You have 16 assignments in this Work List.

Signature Matrix

Roles

Document Types	Initiator (Submitter)	Systems Director R & D	System Development Manager	SW Director	SW Program Manager	SW Engineering Mgt	SW Configuration Mgr	R & D Manager	Program Manager	Systems & Assay Integration Mgr	SI Manager	SW Test Manager	M&D Manager
Planning													
Alpha Plan										X	X		
DD Plan													
Design Review Practice					X								
Feasibility Plan													
Feasibility Test Plan											X		
Issue Reporting Practice						X							
Marketing Plan													
MD Project Plan													X
MD Development Plan													X

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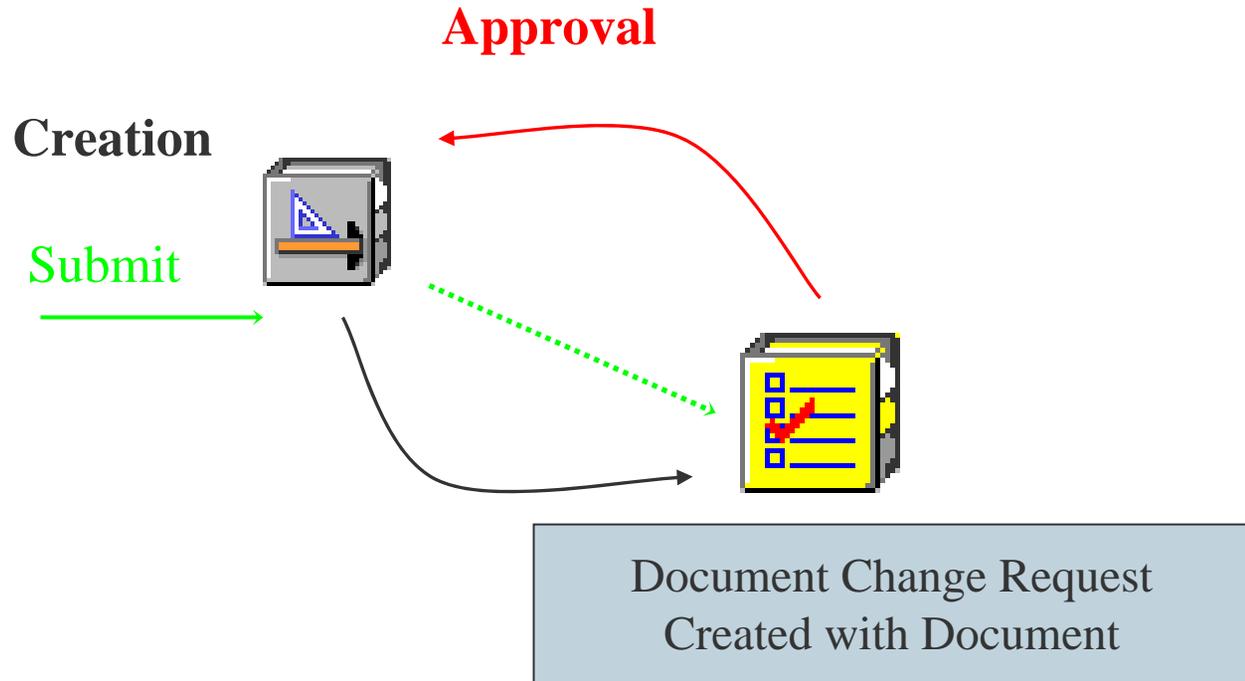
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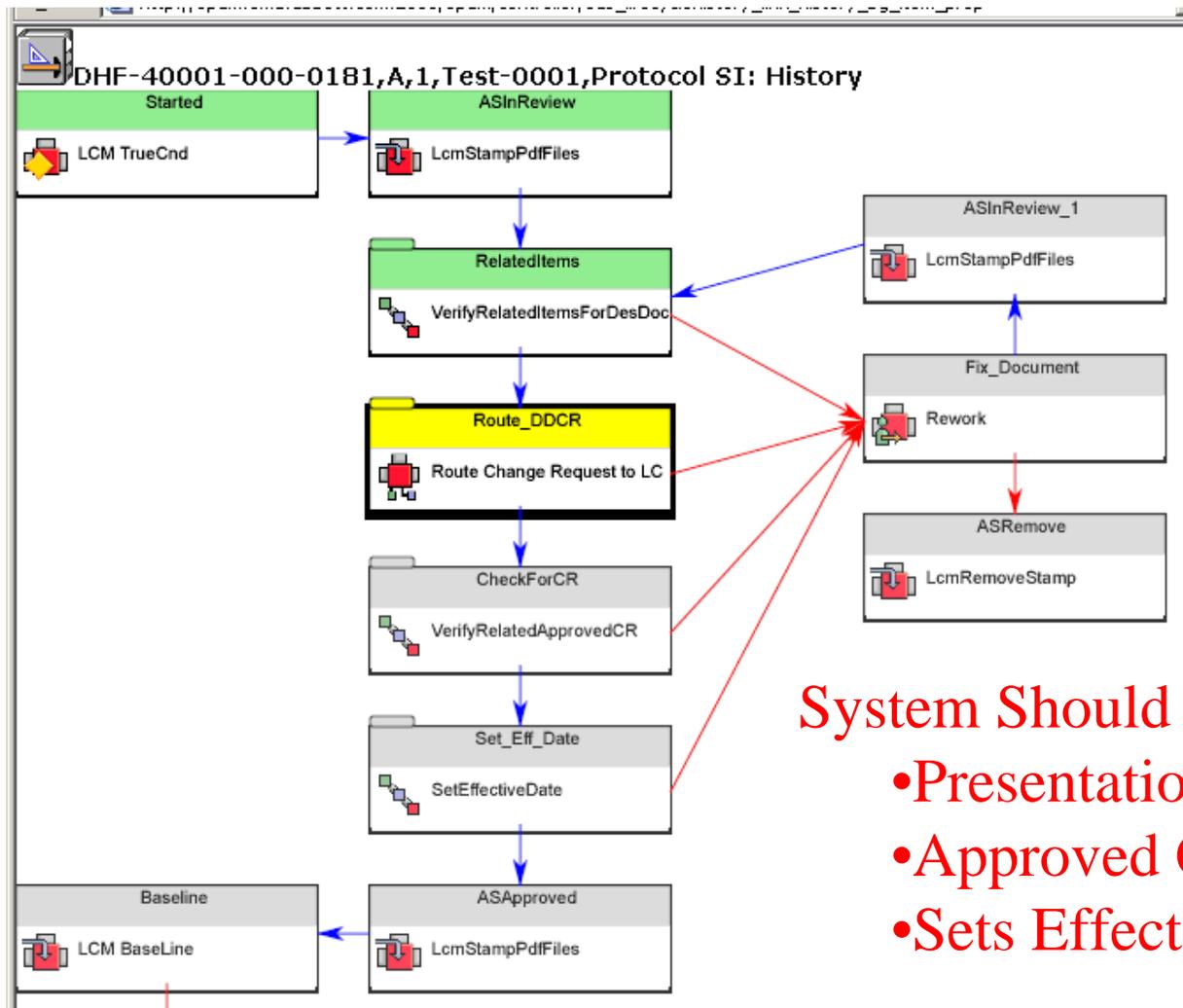
Present Document Release Process

Users Wanted Simple Way to Manage Change!

Design Document



New Document Life Cycle



System Should Perform Checks

- Presentation File Present
- Approved Change Object
- Sets Effectivity Date

One Review Step For Change Record

The screenshot shows a web browser window titled "Lifecycle History - Microsoft Internet Explorer provided by Abbott Laboratories". The address bar contains the URL: http://epdm.ema.abbott.com:2005/epdm/controller/eds_lifecyclehistory_link_history_bg_item_prep. The main content area displays a workflow diagram for "DDCR-0713,A,1,In Review: History". The diagram consists of three stages connected by downward arrows:

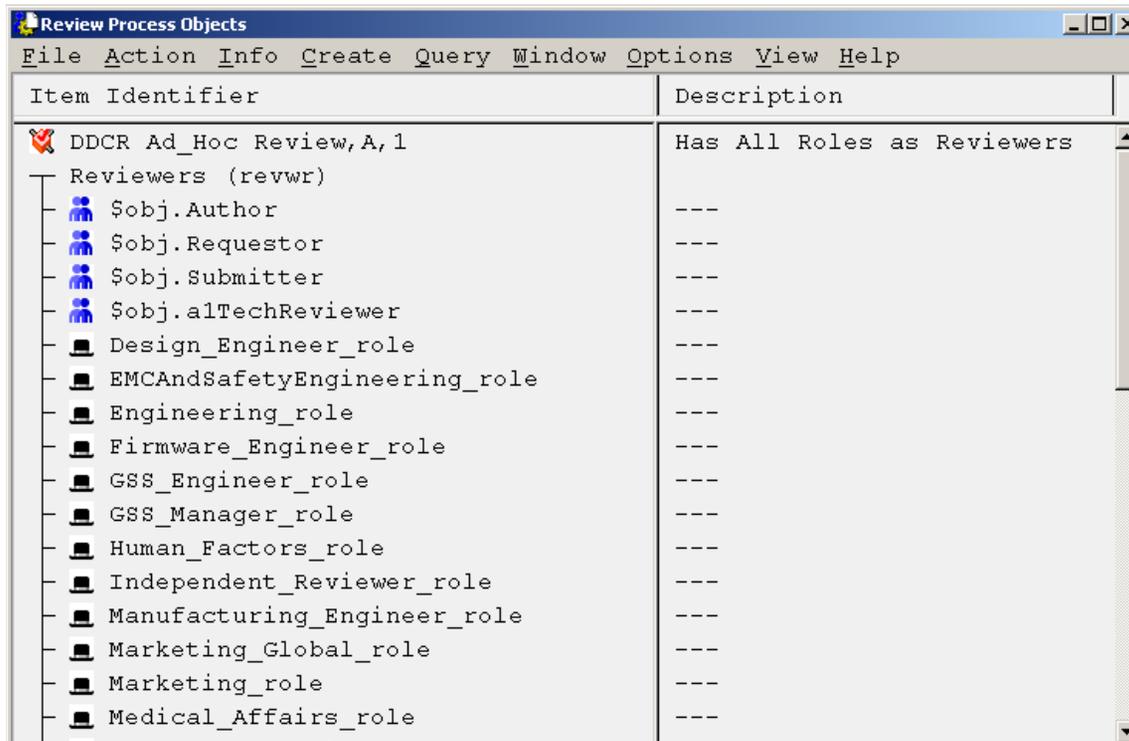
- Start_LC** (green box) containing "LCM TrueCnd".
- DDCR_Review** (yellow box) containing "DDCR Ad_Hoc Review".
- Baseline_CR** (grey box) containing "LCM BaseLine".

Below the diagram is a table with the following columns: User ID, Action Taken, Assignment, Signoff Date, and Comments.

<u>User ID</u>	<u>Action Taken</u>	<u>Assignment</u>	<u>Signoff Date</u>	<u>Comments</u>
lindbda		Submitter Signature		
lindbda		Submitter Signature		
\$obj.Submitter	None	Esig Initiator Review		
IndependentReviewer_SI_Role	None	Esig Independent Reviewer SI		
RD_QA_Instrument_role	None	Esig RD QA Instrument Review		
Statistics_role	None	Esig Statistics Review		

One Step review for all Document Types

Reviewer List



The screenshot shows a window titled "Review Process Objects" with a menu bar (File, Action, Info, Create, Query, Window, Options, View, Help) and a table with two columns: "Item Identifier" and "Description". The table lists various roles under the "DDCR Ad_Hoc Review, A, 1" item, including "Reviewers (revwr)" and a list of specific roles like "Sobj.Author", "Sobj.Requestor", etc., each with a description of "----".

Item Identifier	Description
DDCR Ad_Hoc Review, A, 1	Has All Roles as Reviewers
Reviewers (revwr)	
Sobj.Author	----
Sobj.Requestor	----
Sobj.Submitter	----
Sobj.alTechReviewer	----
Design_Engineer_role	----
EMCAndSafetyEngineering_role	----
Engineering_role	----
Firmware_Engineer_role	----
GSS_Engineer_role	----
GSS_Manager_role	----
Human_Factors_role	----
Independent_Reviewer_role	----
Manufacturing_Engineer_role	----
Marketing_Global_role	----
Marketing_role	----
Medical_Affairs_role	----

All Roles associated with Review Step with Conditions

Ad-Hoc Selection of Roles

DHF-40001-000-0119,B,5,iLC-SD-0000001,Supplemental Design Document

Assignment Properties Files Related Items Reviewers Roles ACL Summary

Roles

- Systems_Engineer_role
- Marketing_role
- Author_On_CR_role

Add Remove

Add Roles To Review List

DHF-40001-000-0119,B,5,iLC-SD-0000001,Supplemental Design Document:
Assign Roles: Add

Select the roles you want to add to the roles list

Roles

- Systems_Director_RD_role
- SystemAssayIntegrationMgr_role
- Project_Manager_SI_Test_role
- Systems_Development_Mgr_role
- SW_Director_role
- SW_Program_Manager_role
- RD_Manager_role
- MD_Manager_role
- Systems_Engineer_role
- SW_Engineer_role
- OLH_Manager_role
- IndependentRev_Firmware_role
- Marketing_Global_role
- Marketing_role
- Human_Factors_role
- Author_On_CR_role

Reviewer Condition

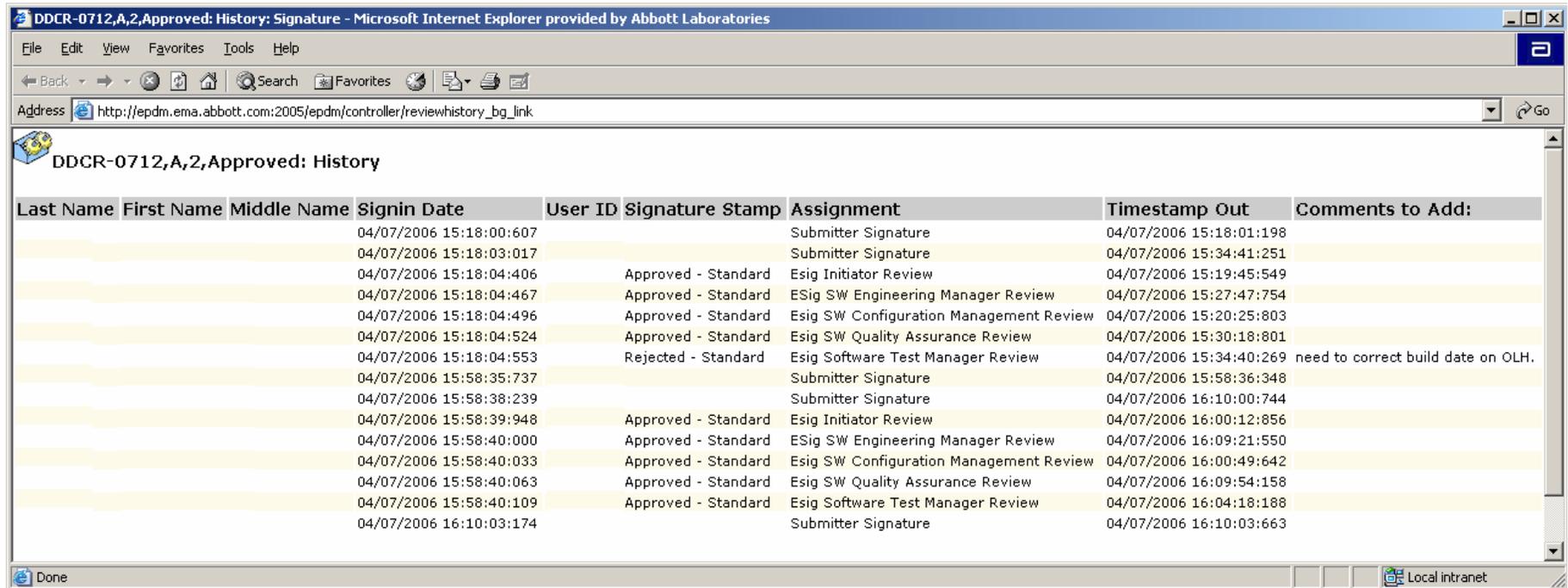
Condition

```
ABT_Rev_ProgramManager(obj,env,actr,hist) :=  
  (  
    'Program_Manager_role' INLIST $obj.alRoleList  
  )  
  OR  
  (  
    $obj.Type = 'SW Verification Plan' OR  
    $obj.Type = 'Verification Plan'  
  )  
  ;
```

Reviewer Condition Determines if:

- Has Role been selected for signature
- Is a Signature Required by Business Policy

Signature History



DDCR-0712,A,2,Approved: History: Signature - Microsoft Internet Explorer provided by Abbott Laboratories

Address: http://epdm.ema.abbott.com:2005/epdm/controller/reviewhistory_bg_link

DDCR-0712,A,2,Approved: History

Last Name	First Name	Middle Name	Signin Date	User ID	Signature Stamp	Assignment	Timestamp Out	Comments to Add:
			04/07/2006 15:18:00:607			Submitter Signature	04/07/2006 15:18:01:198	
			04/07/2006 15:18:03:017			Submitter Signature	04/07/2006 15:34:41:251	
			04/07/2006 15:18:04:406		Approved - Standard	Esig Initiator Review	04/07/2006 15:19:45:549	
			04/07/2006 15:18:04:467		Approved - Standard	ESig SW Engineering Manager Review	04/07/2006 15:27:47:754	
			04/07/2006 15:18:04:496		Approved - Standard	Esig SW Configuration Management Review	04/07/2006 15:20:25:803	
			04/07/2006 15:18:04:524		Approved - Standard	Esig SW Quality Assurance Review	04/07/2006 15:30:18:801	
			04/07/2006 15:18:04:553		Rejected - Standard	Esig Software Test Manager Review	04/07/2006 15:34:40:269	need to correct build date on OLH.
			04/07/2006 15:58:35:737			Submitter Signature	04/07/2006 15:58:36:348	
			04/07/2006 15:58:38:239			Submitter Signature	04/07/2006 16:10:00:744	
			04/07/2006 15:58:39:948		Approved - Standard	Esig Initiator Review	04/07/2006 16:00:12:856	
			04/07/2006 15:58:40:000		Approved - Standard	ESig SW Engineering Manager Review	04/07/2006 16:09:21:550	
			04/07/2006 15:58:40:033		Approved - Standard	Esig SW Configuration Management Review	04/07/2006 16:00:49:642	
			04/07/2006 15:58:40:063		Approved - Standard	Esig SW Quality Assurance Review	04/07/2006 16:09:54:158	
			04/07/2006 15:58:40:109		Approved - Standard	Esig Software Test Manager Review	04/07/2006 16:04:18:188	
			04/07/2006 16:10:03:174			Submitter Signature	04/07/2006 16:10:03:663	

A 21 CFR – Part 11 Signature history is needed for Thin Client

Electronic Signoff

- On Step Concurrent Document Sign-Off
- Use Life Cycle to Check for Key Objects
- Last Signature Defines Effectivity
- Unique Change Record For Document
- Rejection Goes Back to Submitter
- Submitter Can Select Additional Roles

Linking Requirements

Managing

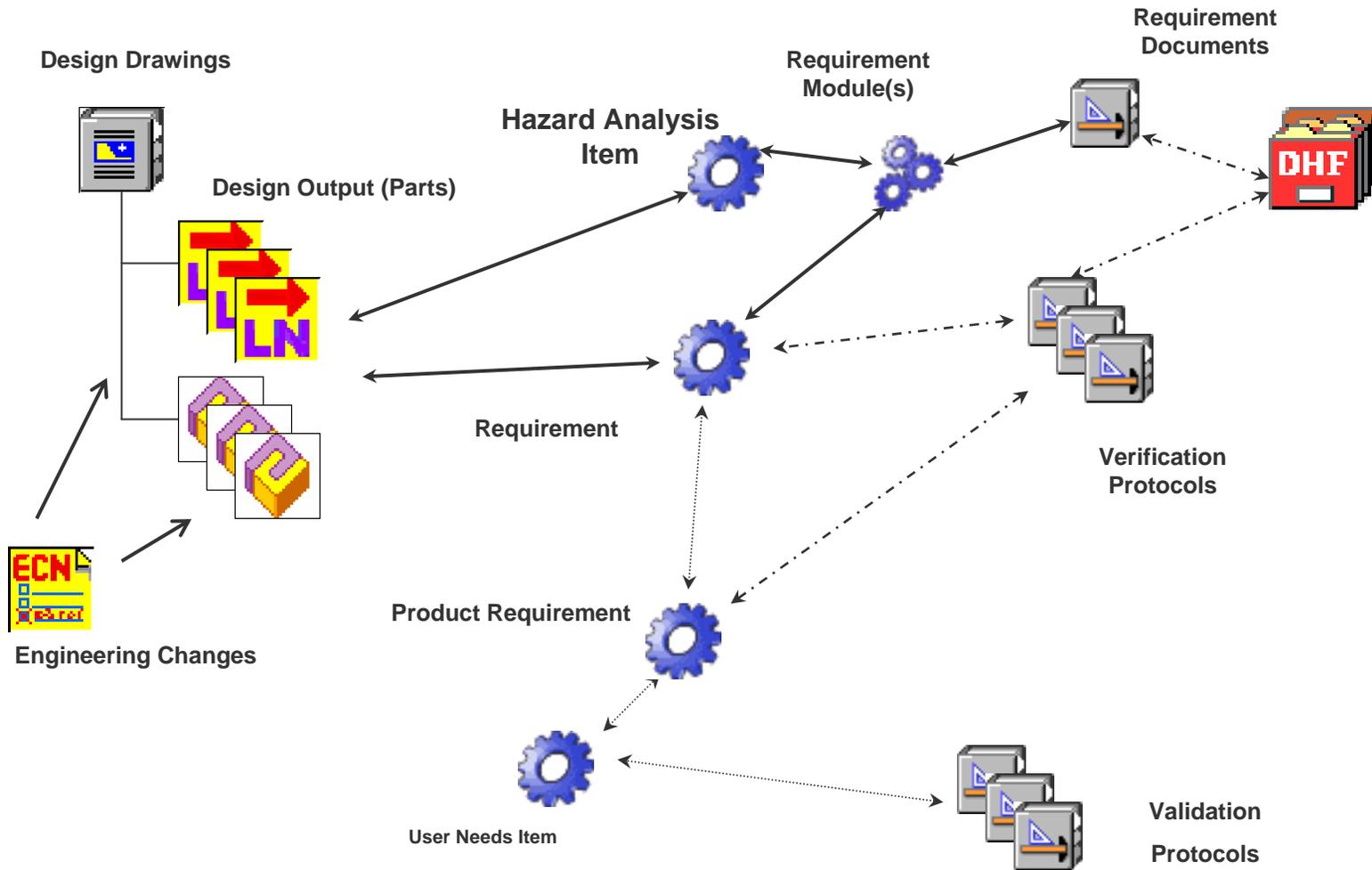
Design

To

Product



Product Trace Information



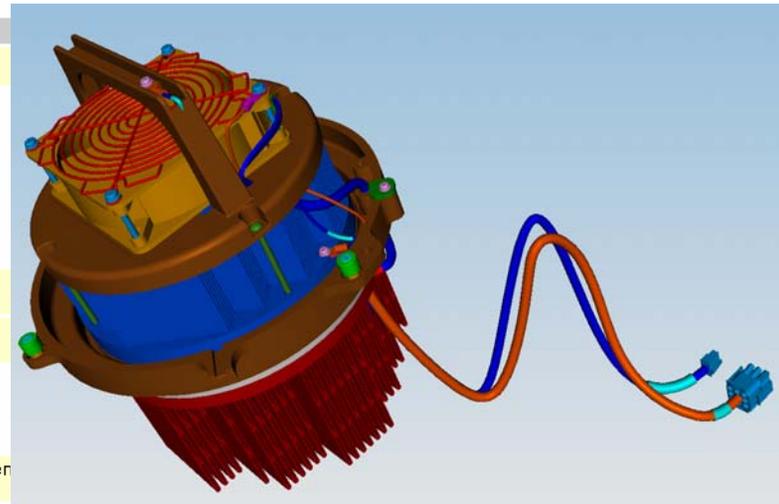
EPDM Part and Related Items

 **97180-105,D,Released,ASSY_ REAGENT COOLER**

Assignment | Properties | BOM | Files | Related Items | Reviewers | ACL | Configuration | Summary

Name	Description			
 97180-105,D,Released,ASSY_ REAGENT COOLER				
 <i>Is Used By Parts</i>				
 <i>Uses Parts</i>				
 <i>Supersedes</i>				
 <i>Is Described By</i>				
<input type="checkbox"/>  MM 97180-105 D,Released,Model				
<input type="checkbox"/>  S 97180-101 E,Released,Specification				
 <i>Is For Item Master</i>				
 <i>Part Affected by</i>				
<input type="checkbox"/>  30184-023_-1	Product Release/Improvement [NA]			
 <i>Has DOORS Requirement</i>				
<input type="checkbox"/>  153_ REAGENT COOLER	153	DOORS Object	Working	
 <i>Is Requirement For</i>				
<input type="checkbox"/>  97180-105,D,Released,ASSY_ REAGENT COOLER		Part	Released	
<input type="checkbox"/>  DHF-40002-000-0095_A,2,iLC-DV-042,Protocol SI	PROCESS PATH WARM-UP INNER AND OUTER TRACKS	Design Document	Approved	
<input type="checkbox"/>  DHF-40002-000-0122_A,1,iLC-DV-044,Protocol SI	SYSTEM WARM-UP AND READINESS	Design Document	Approved	
<input type="checkbox"/>  DHF-40002-000-0163_A,1,iLC-DV-079,Protocol SI	REAGENT COOLER	Design Document	Approved	
<input type="checkbox"/>  DHF-40002-000-0249_A,2,iLC-DV-070,Protocol SI	ROBUSTNESS TO TEMPERATURE AND HUMIDITY	Design Document	Approved	
 <i>DOORS Object child of</i>				
<input type="checkbox"/>  172,DDR Sample and Reagent Handling	172, Handling	DDR Sample and Reagent	DOORS Object	Working

3 items in the Attached Files List.



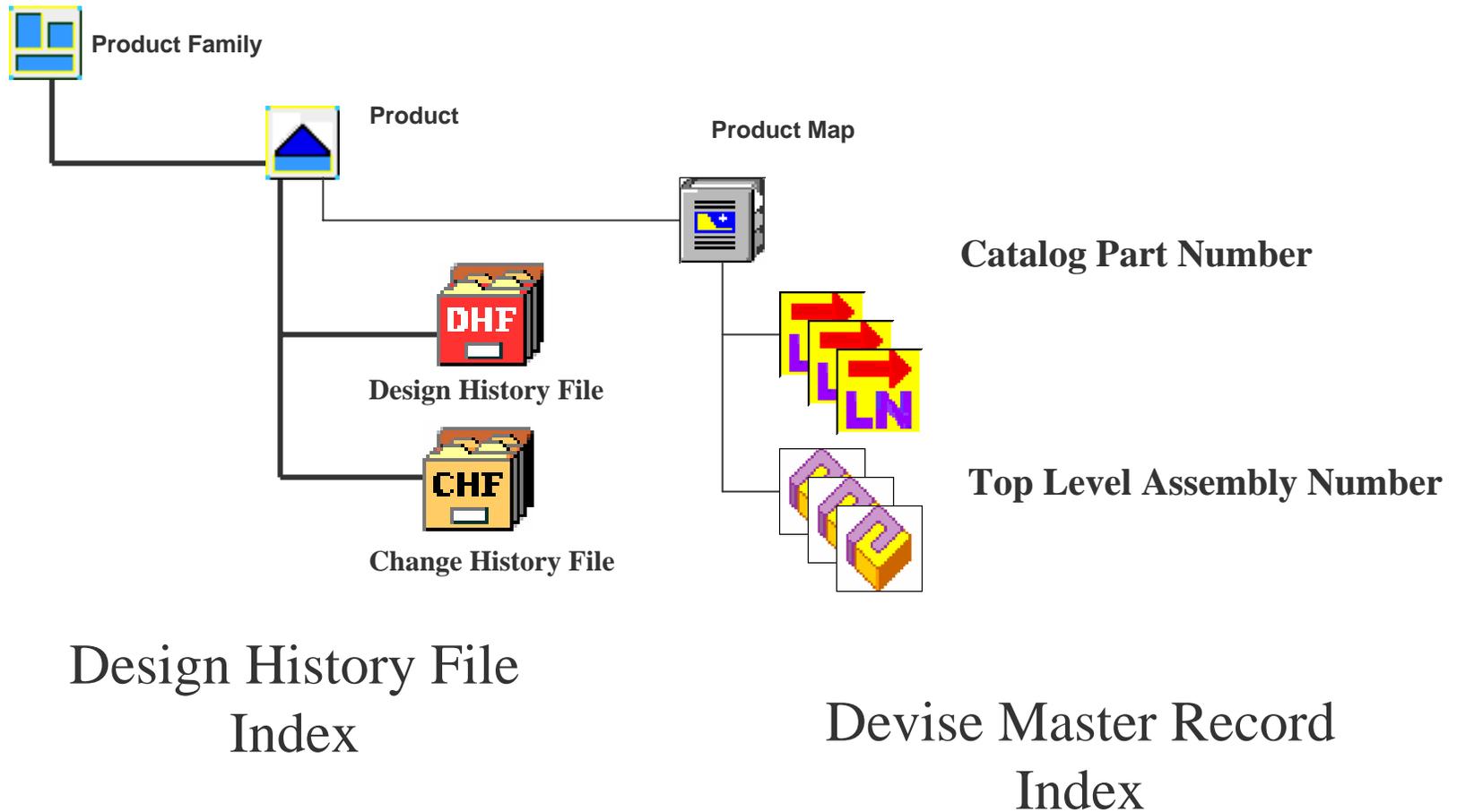
Requirements Perspective

	Sample and Reagent Handling DDR	EPDM Links	Background
SRH183	5.1.5.4 Altitude		
SRH184	The system, with the SRH Subsystem present, shall be capable of operating throughout the altitude range of -100 feet below sea level to 8,500 feet above sea level. (646)	DesDoc DHF-40002-000-0258,A,2,iLC-DV-069,Protocol SI ABT_Vault	NOTE: "Operating" is as a 5 day run of 100 t day with no error who can be attributed to th environmental conditi
SRH186	5.1.5.5 EMC Requirements		

Username: Exclusive edit mode

Requirement System Should Provide Full Trace
User Needs → Validation Test Cases/Output

Product Data Structure



DHFi/DMRi Reporting Must be Available

Conclusion:

- Teamcenter is Providing a Working eDHF
 - Uses Office Automation Tools
 - Electronic Forms
 - Electronic Signature
 - Signature History
 - Real Time Maintenance of Indexes
 - Trace Matrix..... Links Inputs to Outputs
 - DHFi.....Design History File Index
 - DMRi.....Device Master Record Index

Desired Teamcenter Enhancements

- Full Name Signature History
 - Filters For Approval Signatures Only
- Design History File Index
- Device Master Record Index
- Electronic Signature
 - Default Role Selection (By Document Type, etc)
 - Ad-Hoc Role Selection (21CFR- Part 11 History)
 - Ad-Hoc User Selection (21CFR- Part 11 History)
- Show Default List of Approvers
- OOTB DHF Classes /Functions