

INTRODUCTION

Welcome



Design History Files and Records (Agile PLM)

CLICK THE FORWARD
ARROW TO BEGIN.



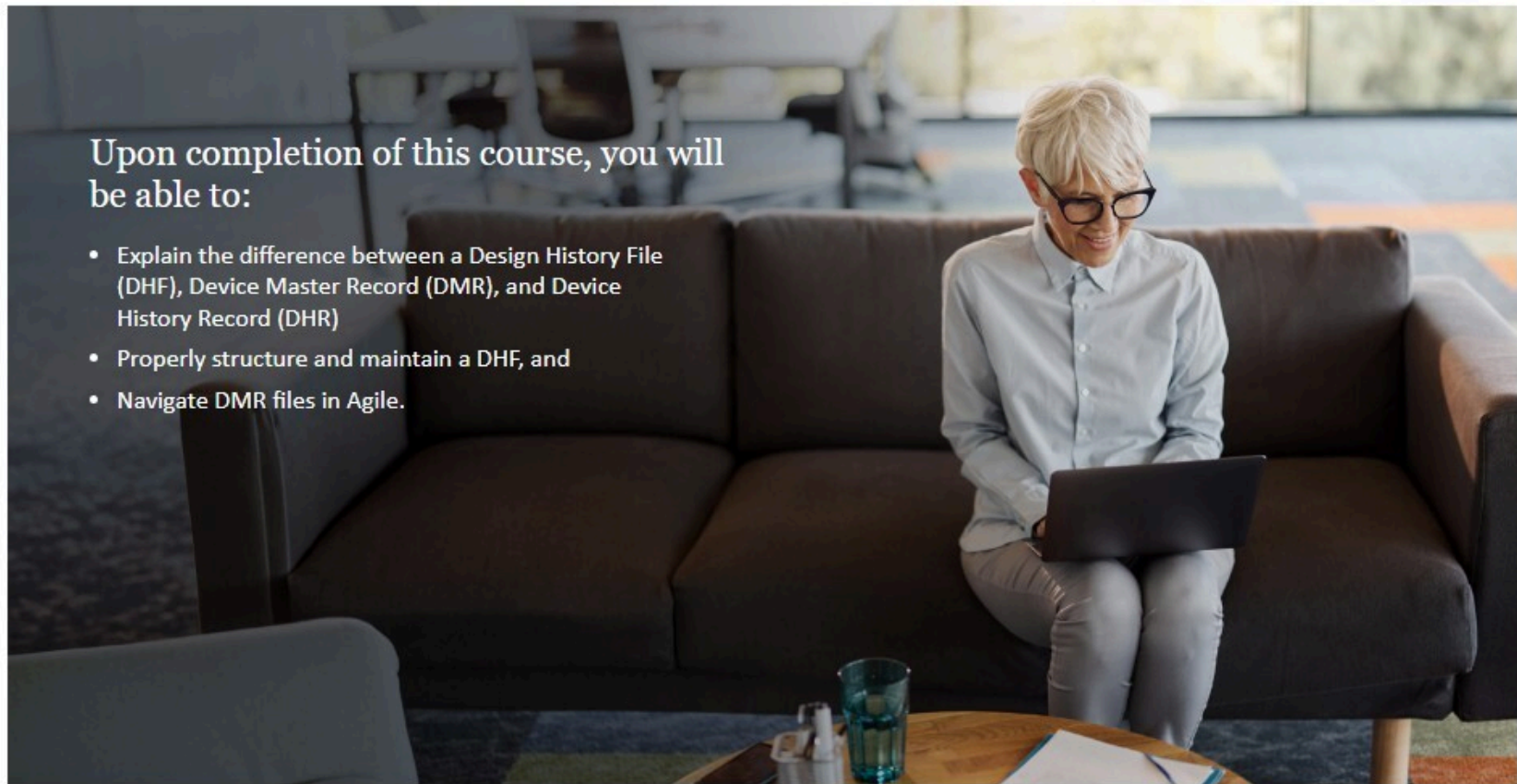
INTRODUCTION

Objectives



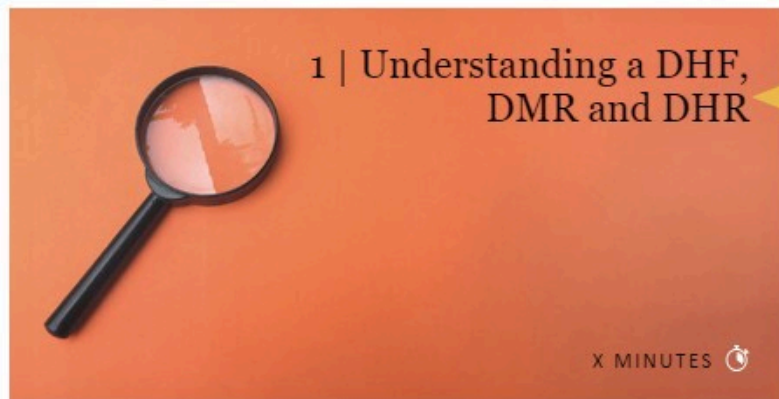
Upon completion of this course, you will be able to:

- Explain the difference between a Design History File (DHF), Device Master Record (DMR), and Device History Record (DHR)
- Properly structure and maintain a DHF, and
- Navigate DMR files in Agile.



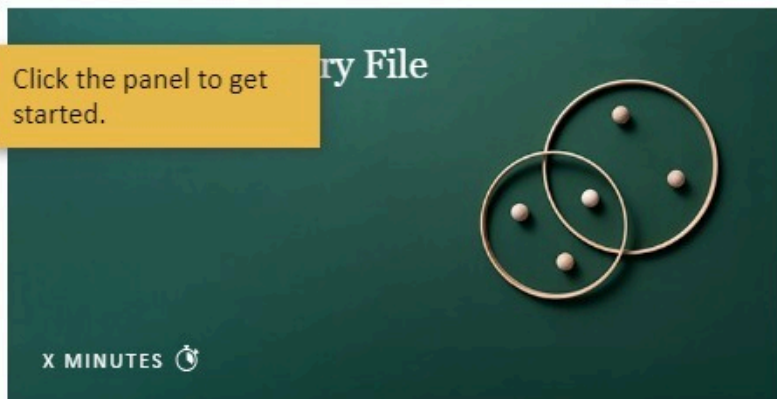
INTRODUCTION

Menu



1 | Understanding a DHF, DMR and DHR

X MINUTES ⌵



Click the panel to get started.

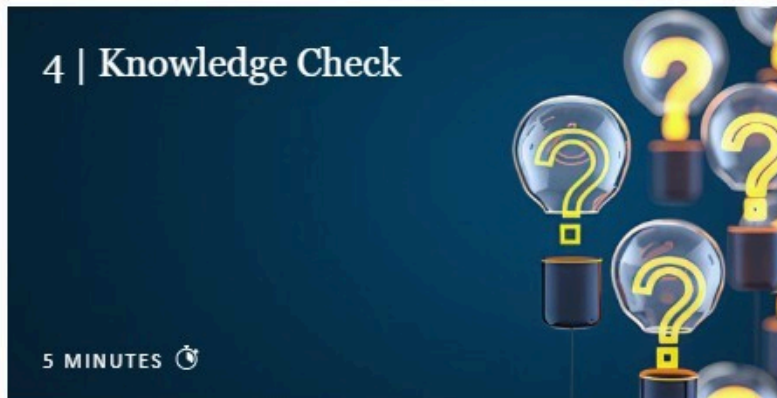
Design History File

X MINUTES ⌵



3 | Device Master Record

X MINUTES ⌵



4 | Knowledge Check

5 MINUTES ⌵



UNDERSTANDING A DHF, DMR AND DHR

Introduction



The creation and maintenance of Design History Files (DHF's), Device Master Records (DMR's), and Device History Records (DHR's) are all critical components of the ADC Design Control process.

These records ensure that our devices are designed and produced according to quality standards, and they provide traceability throughout the device's lifecycle.



UNDERSTANDING A DHF, DMR AND DHR

What is a Design History File (DHF)



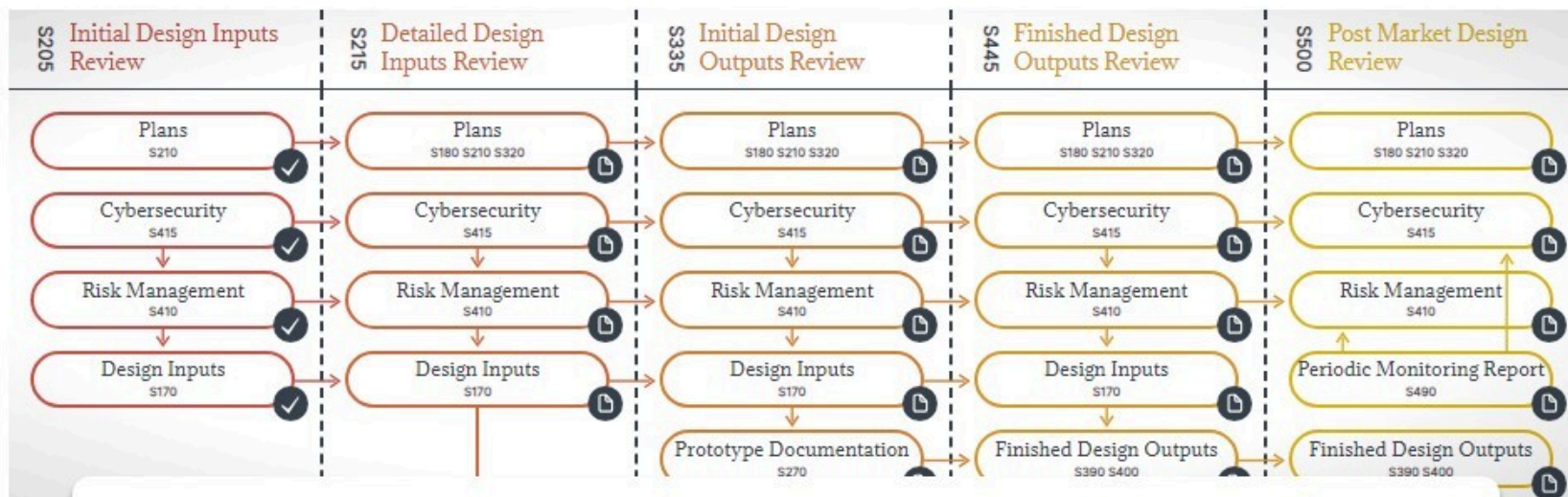
The Design History File or DHF is a comprehensive collection of records that describes the full design and development history of a medical device.

Its purpose is to demonstrate that the device was developed following a structured and controlled process, that all design requirements were met, and that the device is safe and effective for its intended use.



UNDERSTANDING A DHF, DMR AND DHR

What is a Design History File (DHF)



The DHF is initiated once the initial design inputs review is approved and is maintained over the lifecycle of the product.

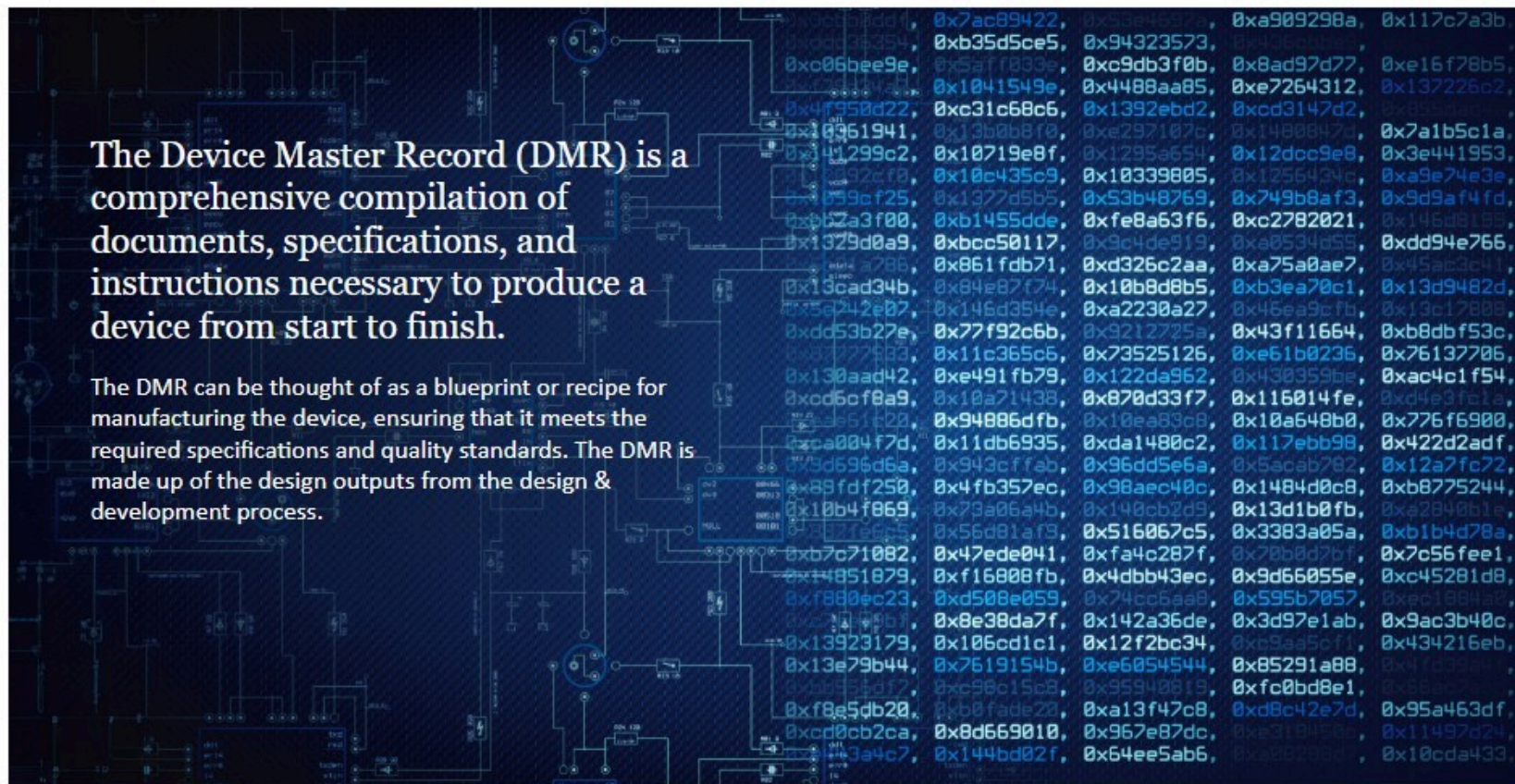
As such, it captures the entire design and development process execution, including design and development planning, design inputs, design outputs, design reviews, verification and validation documentation, design transfer, and design changes. The DHF is a living document, and its records can be maintained in any validated system of record (e.g., Agile PLM).

What is a Device Master Record (DMR)



The Device Master Record (DMR) is a comprehensive compilation of documents, specifications, and instructions necessary to produce a device from start to finish.

The DMR can be thought of as a blueprint or recipe for manufacturing the device, ensuring that it meets the required specifications and quality standards. The DMR is made up of the design outputs from the design & development process.



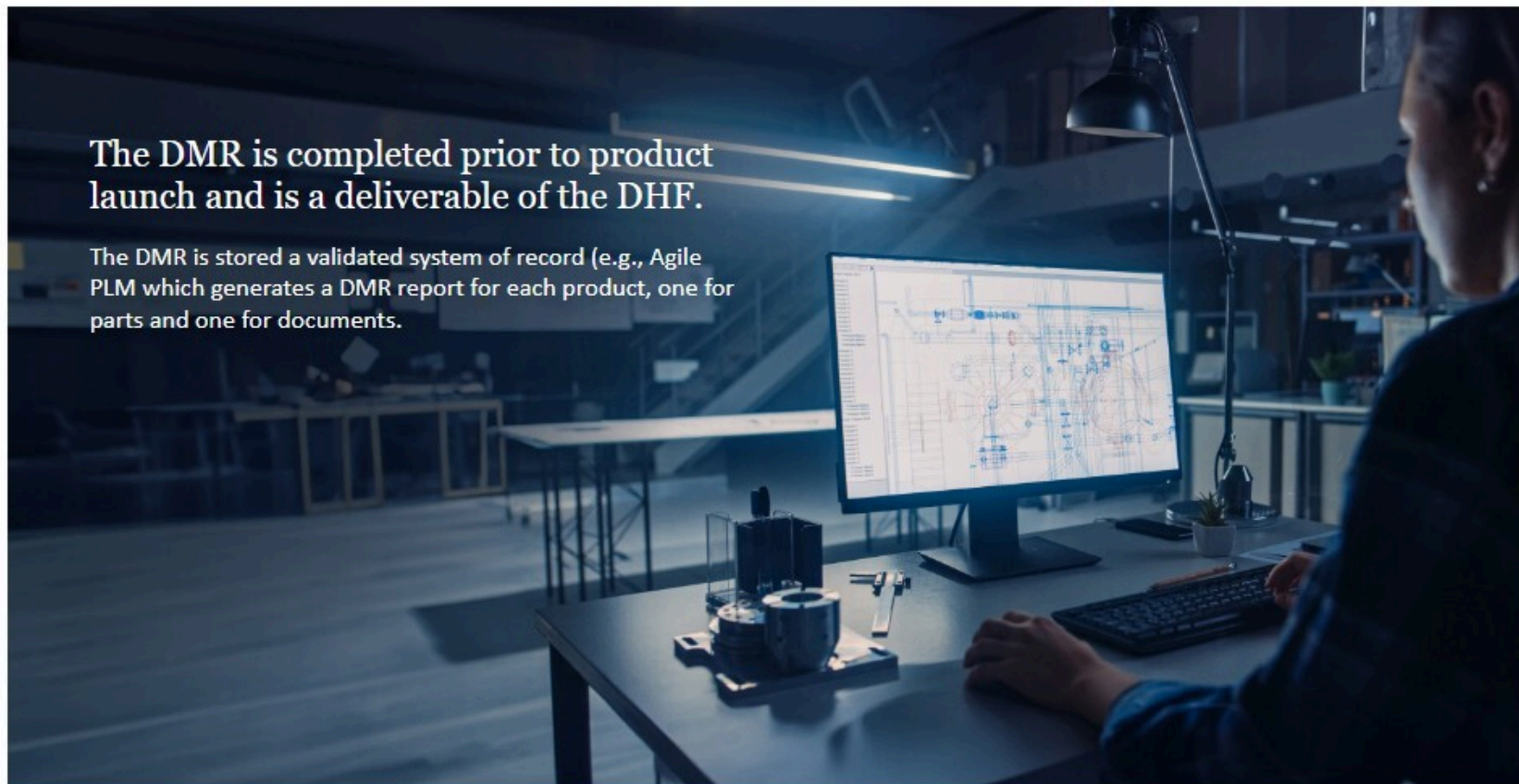
UNDERSTANDING A DHF, DMR AND DHR

What is a Device Master Record (DMR)



The DMR is completed prior to product launch and is a deliverable of the DHF.

The DMR is stored a validated system of record (e.g., Agile PLM which generates a DMR report for each product, one for parts and one for documents.

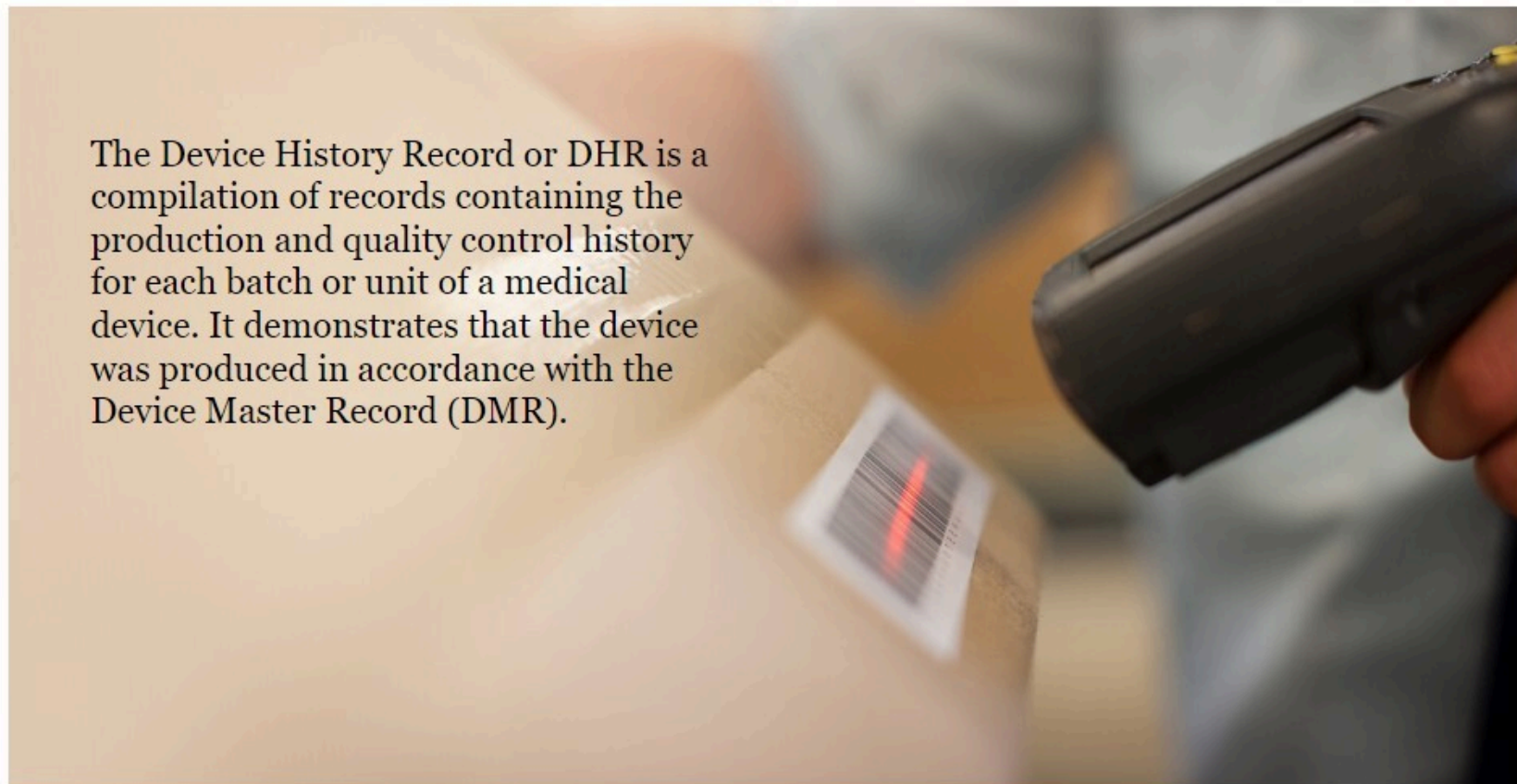


UNDERSTANDING A DHF, DMR AND DHR

What is a Device History Record (DHR)

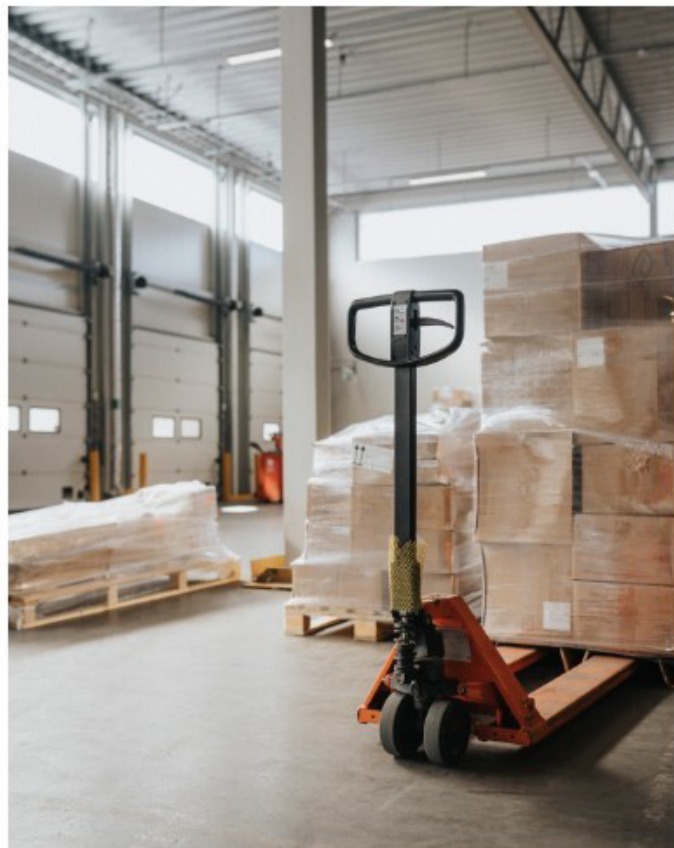


The Device History Record or DHR is a compilation of records containing the production and quality control history for each batch or unit of a medical device. It demonstrates that the device was produced in accordance with the Device Master Record (DMR).



UNDERSTANDING A DHF, DMR AND DHR

What is a Device History Record (DHR)



For a specific batch or unit of device, the DHR typically includes information such as:

- Date of manufacture,
- Quantity produced and released for distribution,
- Acceptance records confirming the device was manufactured according to the DMR.
- Lot or batch number,
- Labelling used, etc.

It is important to note that each may have its own requirements for what is contained in the DHR.





UNDERSTANDING A DHF, DMR AND DHR

Review



Review

Take a moment to review some of the key concepts in this section.

Click the arrow to begin your review.



UNDERSTANDING A DHF, DMR AND DHR

Review



Design History File (DHF)

The Design History File or DHF is a comprehensive collection of records that describes the full design and development history of a medical device.



UNDERSTANDING A DHF, DMR AND DHR

Review



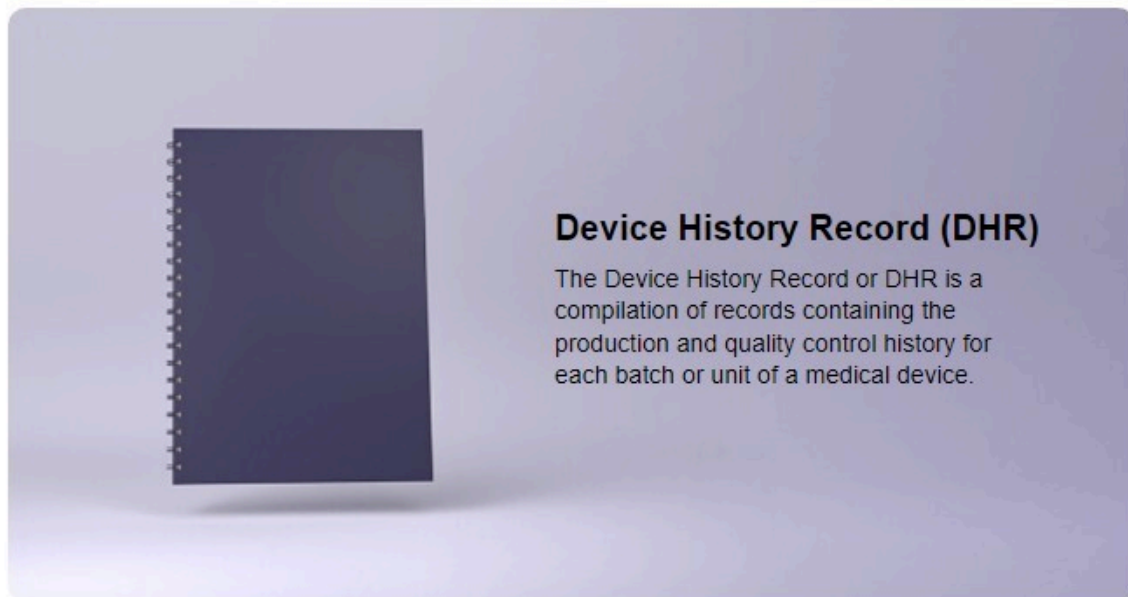
Device Master Record (DMR)

The Device Master Record or DMR is a comprehensive compilation of documents, specifications, and instructions necessary to produce a device from start to finish.



UNDERSTANDING A DHF, DMR AND DHR

Review





UNDE

Re

To check your progress, click
the Menu button



You have completed section 1 of 4

CLICK THE FORWARD ARROW TO CONTINUE LEARNING



DESIGN HISTORY FILE

Creating and Structuring a DHF



For each project, a unique Design History File (DHF) is compiled.

The Development or R&D Program Manager is responsible for compiling the DHF during the Design Control process and ensuring all deliverables in the DHF are appropriately cataloged per 7.3.

Quality Assurance is responsible for verifying the DHF is properly structured, stored, and maintained in the Agile PLM electronic document control system.



DESIGN HISTORY FILE

Creating and Structuring a DHF



Each DHF is structured using the same standard structure and naming convention.

In the case of the design and development of FreeStyle Libre 3, for example, the Development Program Manager assigns the project a file name.

The file name begins with the prefix “DOC,” followed by a 5-digit number. A short descriptor is then added. The descriptor includes the project name followed by the words “Design History File (DHF).”

A DHF includes a single product family. For example, the Libre3 sensor, reader, and application are all part of the same DOC45000 DHF.

7.3T11 : TEMPLATE, PRESENTATION, PERIODIC MC	410	DOC41141-001	DELIVERABLE, S410, RISK MANAGEMENT REPORT, PROJECT 45000 (BOM ONLY)
EC107025 : Update 4.2.300T03 font to Calibri.	415	DOC41853-001	DELIVERABLE S415, CYBERSECURITY RISK MANAGEMENT, PROJECT 45000
4.2.300T04 : TEMPLATE, GENERIC	420	DOC41778	DELIVERABLE S420, TRACE MATRIX, PROJECT 45000, US



DESIGN HISTORY FILE

Creating and Structuring a DHF

The screenshot displays the Design History File (DHF) interface for document **DOC45000-001**. The left sidebar shows a folder tree with 'DHF' expanded, listing various documents. The main area shows the 'BOM' (Bill of Materials) view for the 'Production' project. The BOM table lists sub-projects with their item numbers and descriptions.

Item Number	Item Description
170	DELIVERABLE, S170, DESIGN INPUTS, PROJECT 45000 (BOM ONLY)
180	DELIVERABLES S180, PLAN, DESIGN VERIFICATION AND VALIDATION, PROJECT 45000 US
205	DELIVERABLE, S205, INITIAL DESIGN INPUTS REVIEW, PROJECT 45000
210	DELIVERABLE S210, PLAN, DESIGN AND DEVELOPMENT, PROJECT 45000
215	DELIVERABLE, S215, DETAILED DESIGN INPUTS REVIEW, PROJECT 45000
270	DELIVERABLE S270, PROTOTYPE DOCUMENTATION, US, PROJECT 45000

The subproject deliverables from 7.3 appear as a nested Bill of Materials (BOM) within the DHF.

Each sub-project in the BOM structure has an item number to the corresponds to the sub-project deliverable from 7.3.

For example, Design Inputs is assigned the number 170 and Detailed Design Inputs Review is assigned the number 215.

DESIGN HISTORY FILE

Creating and Structuring a DHF



ACTION PLANS

HISTORY FILE, E

FILE (DHF), LIBR

RE DEFECT TR

BOM

Views: **Base View *** Personalize

Add

Remove

Go To

Expanded Display

More

Save

Cancel

1 Find Num	2 Item Number	Item Description
170	DOC40819-001	DELIVERABLE, S170, DESIGN INPUTS, PROJECT 45000 (BOM ONLY)
180	DOC41332	DELIVERABLES S180, PLAN, DESIGN VERIFICATION AND VALIDATION, PROJECT 45000 US
205	DOC40814	DELIVERABLE, S205, INITIAL DESIGN INPUTS REVIEW, PROJECT 45000
210	DOC45000	DELIVERABLE S210, PLAN, DESIGN AND DEVELOPMENT, PROJECT 45000
215	DOC41480	DELIVERABLE, S215, DETAILED DESIGN INPUTS REVIEW, PROJECT 45000
270	DOC42733-001	DELIVERABLE S270, PROTOTYPE DOCUMENTATION, US, PROJECT 45000
280	DOC43019-001	DELIVERABLE S280, BOM ONLY, DESIGN VERIFICATION, APP/SENSOR, US 45000
320	DOC41615-001	DELIVERABLE, S320, BOM ONLY, DESIGN TRANSFER, PROJECT 45000
335		
370		
390		
400		
410		
415		
420		
455		
455		
455	DOC43146-002	DELIVERABLE, S455, FINISHED DESIGN OUTPUTS REVIEW, CLOSING D&D PLAN, PROJECT 45000

The Development Program Manager assigns a description of the item to each sub-project.














The descriptor begins with the word 'DELIVERABLE'. This is followed by the three-digit item number and the project's name. An example is: DELIVERABLE S210 Design and Development Plan.



BOM

Personalize ▾

There may be separate deliverables for the product cleared in different regulatory regions, e.g., United States (FDA 510k) and the European Union (CE mark)

•	270	 DOC42733-001	DELIVERABLE S270, PROTOTYPE DOCUMENTATION, US, PROJECT 45000
	280	▶  DOC43019-001	DELIVERABLE S280, BOM ONLY, DESIGN VERIFICATION, APP/SENSOR, US 45000
•	320	▼  DOC41615-001	DELIVERABLE, S320, BOM ONLY, DESIGN TRANSFER, PROJECT 45000
•	10	 DOC41695	PLAN, DESIGN TRANSFER, SENSOR COMPONENT MANUFACTURE, ADC WITNEY, PROJECT 45000
•	11	 DOC41695-001R	REPORT, DESIGN TRANSFER, PHASE 1 & 2 PRODUCTION LINE, SENSOR COMPONENT MANUFACTURE
•	20	 DOC42469	PLAN, DELIVERABLES S320, SENSOR KIT, PHASE 2, DESIGN TRANSFER PROJECT 45000
•	21	 DOC42469-001R	REPORT, DELIVERABLES S320, SENSOR KIT, PHASE 2, DESIGN TRANSFER PROJECT 45000
•	335	 DOC42841	DELIVERABLE, S335, INITIAL DESIGN OUTPUTS REVIEW, PROJECT 45000
	370	▶  DOC43020-001	DELIVERABLE S370, BOM ONLY, DESIGN VALIDATION, APP/SENSOR, US 45000
•	390	 DOC42725-001	DELIVERABLE S390, MEMO, DEVICE MASTER RECORD (DMR), PROJECT 45000, FREESTYLE LIBRE 3 US
	400	▶  DOC40960-001	DELIVERABLE, S400, DESCRIPTIVE DESIGN DOCUMENTATION, PROJECT 45000 (BOM ONLY)
	410	▶  DOC41141-001	DELIVERABLE, S410, RISK MANAGEMENT REPORT, PROJECT 45000 (BOM ONLY)
•	415	▶  DOC41853-001	DELIVERABLE S415, CYBERSECURITY RISK MANAGEMENT, PROJECT 45000

DESIGN HISTORY FILE

Maintaining a DHF

FOLDERS

- DHF
 - FS-6
 - LIBREVIEW**
 - Nucleus (CoProd)
 - Gemini
 - LIBRE 3**
 - OmniFad
 - Xceed

Recently Visited

- DOC45000-001 : FILE, DESIGN HISTORY FILE, BOM
- ASM22175-006 : DWG, ASSY, READER, SYSTEM E, :
- PRT45000-003 : ASSY, READER, MG/DL, 45000, US
- 72079-01 : KIT, READER, FREESTYLE LIBRE 3, MG/I
- ASM28985 : DWG, APPLICATOR ASSEMBLY, 45000

DOC45000-001
 Document • FILE, DESIGN HISTORY FILE, BOM ONLY, US, PROJECT 45000
 Rev: F EC101512 Effective From: 06/08/2022 12:00:00 AM PDT to
 Production Incorporated

Views: Base View * Personalize

BOM

Find Num	Item Number	Item Description
170	DOC40819-001	DELIVERABLE, S170, DESIGN INPUTS, PROJECT 45000 (BOM ONLY)
180	DOC41332	DELIVERABLES S180, PLAN, DESIGN VERIFICATION AND VALIDATION, PROJECT 45000 US
210	DOC45000	DELIVERABLE S210, PLAN, DESIGN AND DEVELOPMENT, PROJECT 45000
270	DOC42733-001	DELIVERABLE S270, PROTOTYPE DOCUMENTATION, US, PROJECT 45000
280		DELIVERABLE S280, BOM ONLY, DESIGN VERIFICATION, ADDRESSING THE 45000

Sub-project deliverables in the BOM may be referenced or shared across multiple DHFs.

Similarly, design changes may impact more than one DHF.

For example, the Libre 3 and LibreView products are maintained in separate DHFs but changes to the application or the cloud platform may affect the other product.



DESIGN HISTORY FILE

Review



Review

Take a moment to review some of the
key concepts in this section.

Click the arrow to
begin your review.





DESIGN HISTORY FILE

Review



Responsibility for Compiling the DHF

The Development Program Manager is responsible for compiling the DHF during the Design Control process.





DESIGN HISTORY FILE

Review



Design Changes

Design changes may impact more than one DHF. For example, the Libre 3 and LibreView products are maintained in separate DHFs but changes in one may affect the other product.





DESIGN

Re

To check your progress, click
the Menu button



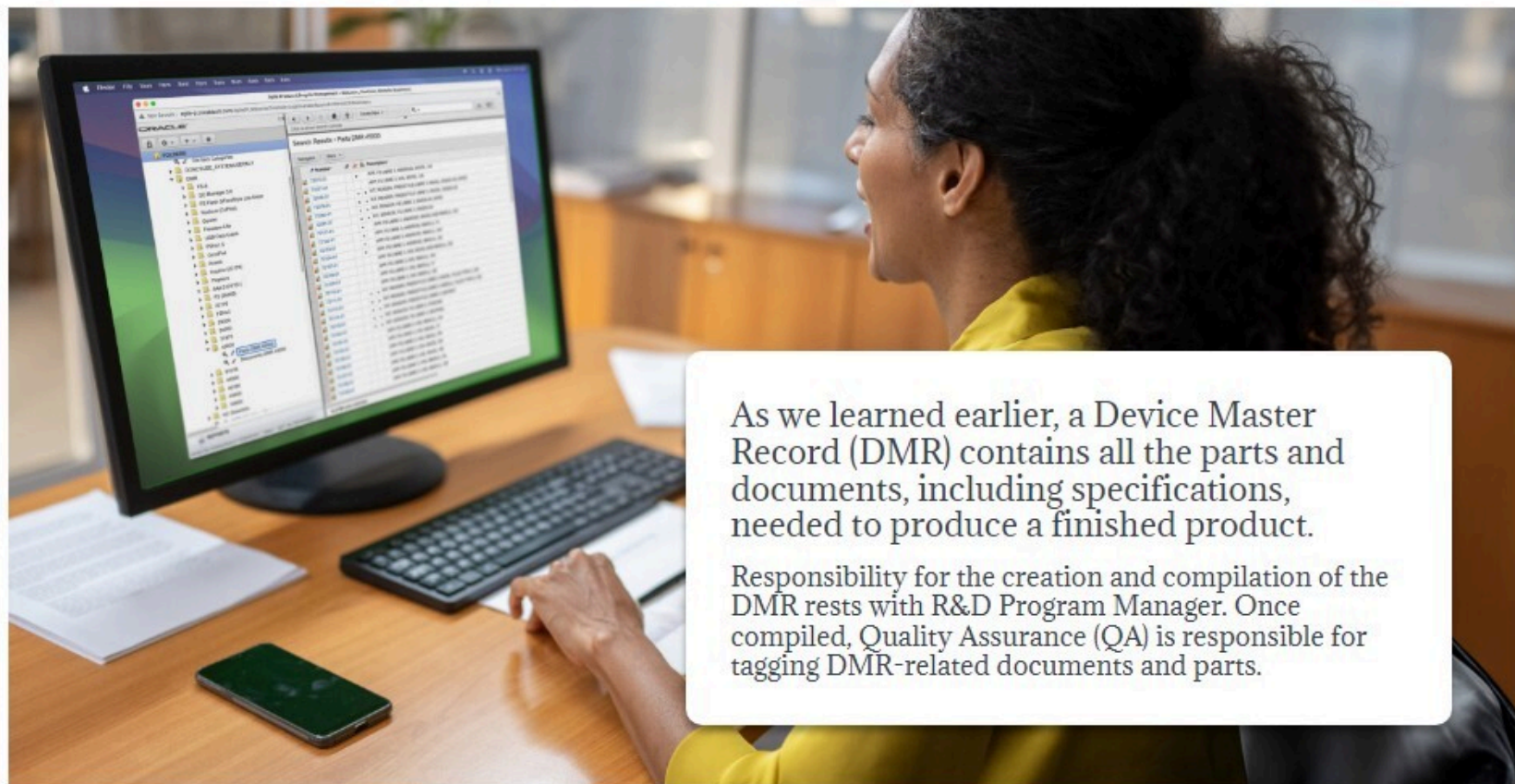
You have completed section 2 of 4

CLICK THE FORWARD ARROW TO CONTINUE LEARNING



DEVICE MASTER RECORD

Creating the DMR



As we learned earlier, a Device Master Record (DMR) contains all the parts and documents, including specifications, needed to produce a finished product.

Responsibility for the creation and compilation of the DMR rests with R&D Program Manager. Once compiled, Quality Assurance (QA) is responsible for tagging DMR-related documents and parts.



Creating the DMR



ORACLE

not Secure | agile-plm.oneapott.com/agile/plmserver/modules/LoginHandler.asp?code=forwardToMainMenu

Click to show search controls

FOLDERS

- Old Item Categories
- DONOTUSE_SYSTEMUSEONLY
- DMR
 - FS-6
 - QC Manager 3.0
 - FS Flash 3/FreeStyle Lite-Meter
 - Nucleus (CoPilot)
 - Gemini
 - Freedom Lite
 - USB Data Cable
 - FSNv1.5
 - OmniFad
 - Xceed
 - Insulinx (22174)
 - Pegasus
 - AA2.0 (25151)
 - P2 (26909)
 - 22175
 - FSNv2
 - 29000
 - 34000
 - 37375
 - 45000
 - Parts DMR 45000
 - Documents DMR 45000
 - 91016
 - 44300
 - 46184
 - 44600
 - 54600
- HC Searches

Navigator More

Number* Description*

To find DMR files go to Global Searches in Agile PLM and click on the DMR folder.

Each uniquely numbered folder is a different DMR for a different product line.



DEVICE MASTER RECORD

Creating the DMR



not Secure | agile-plm.oneapott.com/agile/plmserver/modules/LoginHandler.asp?code=forwardToMainMenu

ORACLE

FOLDERS

- Old Item Categories
- DONOTUSE_SYSTEMUSEONLY
- DMR
 - FS-6
 - QC Manager 3.0
 - FS Flash 3/FreeStyle Lite-Meter
 - Nucleus (CoPilot)
 - Gemini
 - Freedom Lite
 - USB Data Cable
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 - OmniFad
 - Xceed
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 - FSNv2
 - 29000
 - 34000
 - 37375
 - 45000
 - Parts DMR 45000
 - Documents DMR 45000
 - 44300
 - 46184
 - 44600
 - 54600
- HC Searches

Click to show search controls

Navigator More

Number*	Description*
---------	--------------

Each DMR folder contains a 'Parts' DMR and a 'Documents' DMR.



DEVICE MASTER RECORD

Creating the DMR



The Parts DMR contains all the Stock Keeping Units (SKUs) that use that product line DMR.

Search Results • Parts DMR 45000

Number*	Description*
2075-01	APP, FS LIBRE 3, ANDROID, MG/DL, US
2077-01	APP, FS LIBRE 3, IOS, MG/DL, US
2078-01	KIT, READER, FREESTYLE LIBRE 3, MG/DL, EN/ES-US, NFRS
2079-01	KIT, READER, FREESTYLE LIBRE 3, MG/DL, EN/ES-US
2080-01	KIT, SENSOR, FS LIBRE 3, EN/ES-US, NFRS
2081-01	KIT, SENSOR, FS LIBRE 3, EN/ES-US
2101-01	APP, FS LIBRE 3, ANDROID, MG/DL AND MMOL/L, DE
72102-01	APP, FS LIBRE 3, ANDROID, MMOL/L, FI
72103-01	APP, FS LIBRE 3, ANDROID, MMOL/L, NO
72104-01	APP, FS LIBRE 3, ANDROID, MMOL/L, SE
72107-01	APP, FS LIBRE 3, IOS, MG/DL AND MMOL/L, DE
72108-01	APP, FS LIBRE 3, IOS, MMOL/L, NO
72109-01	APP, FS LIBRE 3, IOS, MMOL/L, FI
72110-01	APP, FS LIBRE 3, IOS, MMOL/L, SE
72111-01	KIT, READER, FREESTYLE LIBRE 3, MG/DL, PLUG TYPE C, DE
72112-01	KIT, READER, FREESTYLE LIBRE 3, MMOL/L, PLUG TYPE C, DE
72114-01	KIT, SENSOR, FREESTYLE LIBRE 3, DE/FR/IT
72115-01	KIT, SENSOR, FS LIBRE 3, FI/NO/SV
72164-01	KIT, SENSOR, FS LIBRE 3, DE/FR/NL
72191-01	APP, FS LIBRE 3, IOS, MMOL/L, CH
72193-01	APP, FS LIBRE 3, IOS, MG/DL, IT
72195-01	APP, FS LIBRE 3, IOS, MG/DL, FR
72196-01	APP, FS LIBRE 3, IOS, MG/DL, ES
72197-01	APP, FS LIBRE 3, IOS, MG/DL, BE





DEVICE MASTER RECORD

Creating the DMR



To access the SKUs, click on the Parts folder within any DMR folder.

Then, click on the SKU of interest to open the SKU and see all information.

Oracle AGLIE PONEA

Search Results > 72081-01

72081-01
Part - General - KIT, SENSOR, FS LIBRE 3, ENES-US
Production
Unincorporated

Rev: K EC113148 Effective From: 09/01/2023 12:00:00 AM PDT to Navigator Actions

Title Block Changes * BOM * Manufacturers * Suppliers Relationships Where Used Attachments History

Page Two | General Info | Approval Info | Regulatory Info | Security (System Use Only) | FAI / Mastering

Number*: 72081-01
Part Category*: CAT Level
Description*: KIT, SENSOR, FS LIBRE 3, ENES-US
Product Line(s)*: 45000
Revision Approval Date: 09/01/2023 10:21:51 AM PDT
Effective Date: 09/01/2023 12:00:00 AM PDT
Lifecycle Phase: Production
Part Type: Part - General
Last Incomp Date:
Site*: US
Item Group(s):
Race Model:

Page Two

General Info

Part Classification:
Source Code*: C=Custom Purchased Part/Assy
UOM*: EA





DEVICE MASTER RECORD

Creating the DMR



The screenshot displays the 'Creating the DMR' interface. On the left is a file tree with the following structure:

- FS Flash 3/FreeStyle Lite-Meter
- Nucleus (CoPilot)
- Gemini
- Freedom Lite
- USB Data Cable
- FSNv1.5
- OmniFad
- Xceed
- Insulinx (22174)
- Pegasus
- AA2.0 (25151)
- P2 (26909)
- 22175
- FSNv2
- 29000
- 34000
- 37375
- 45000
 - Parts DMR 45000
 - Documents DMR 45000
- 91016
- 44300
- 46184
- 44600
- 54600
- HC Searches

At the bottom left are 'REPORTS' and 'NAVIGATOR' buttons. The main area on the right is titled 'Page Two | General Info | Approval Info | Regulatory Info | Security (System Use Only) | FAI / Mastering'. It contains the following fields:

- Number*: 72081-01
- Part Category*: CAT Level
- Description*: KIT, SENSOR, FS LIBRE 3, EN/ES-US
- Product Line(s)*: 45000
- Revision Approval Date: 09/01/2023 10:21:51 AM PDT
- Effective Date: 09/01/2023 12:00:00 AM PDT
- Lifecycle Phase: Production

Below these is a callout box with the text: 'Each SKU is tagged as DMR under General Info and is the top level DMR item.'

The 'General Info' section is expanded, showing:

- Part Classification:
- Source Code*: C=Custom Purchased Part/Assy
- UOM*: EA
- DMR/QSR*: DMR (highlighted with a blue circle)

At the bottom right are navigation arrows.

DEVICE MASTER RECORD

Creating the DMR



FOLDERS

- Old Item Categories
- DONOTUSE_SYSTEMUSEONLY

Search Results » 72081-01

72081-01

Part - General • KIT, SENSOR, FS LIBRE 3, EN/ES-US

Production
Unincorporated

Rev: K EC113148 Effective From: 09/01/2023 12:00:00 AM PDT to ...

Navigator Actions

Title Block Changes * BOM * Manufacturers * Suppliers Relationships Where Used Attachments History

BOM

Views: Base View * Personalize

Add Remove Go To Expanded Display More

Item Number	Item Description
ASM29500-601	DWG, ASSY, SENSOR KIT, AUTO PACK, 45000
DOC29500-300	SPECIFICATION, KITPACK, SENSOR STERILE AND NON-PYROGENIC, FLEX, 4410
DOC38486	SPECIFICATION, LIBRE/LIBRE PRO SENSOR KIT PALLETIZING INTERNATIONAL P.
DOC41782-18	EXPIRY ADJUSTMENT = 18 MONTHS FROM END OF CURRENT MONTH
DOC42715-104	PACKLINE SKU CONFIGURATION, D1 ASIC US, 45000 FOR -104
DOC42927-026	SOFTWARE RELEASE FILES, VERSION 1.4.2.30, PROJECT 45000 PDU
PRT26906	LABEL, FREESTYLE LIBRE, REIMBURSEMENT, 40 X 20MM
PRT31516-300	KIT PACK, CONSUMABLES, FLEX AUSTIN
PRT41790-105	CARTON, SENSOR KIT, FS LIBRE 3, W/READER, EN/ES-US
PRT45880-002	INSERT, SENSOR KIT, FS LIBRE 3, W/READER, EN/ES-US
PRT28985-306	ASSY, APPLICATOR, FLEX, FR4, D1, US, 45000

Each SKU contains a Bill of Materials (BOM).

You will find all the parts that report into the SKU under the BOM tab on the SKU's title page. In this example, the assembly ASM29895 reports into a part, and the part reports into the SKU. So, the assembly, the part, and the SKU are all DMR.





DEVICE MASTER RECORD

Creating the DMR



Lower-level parts are also DMR if they report into parts or assemblies that report to the SKU.

Search Results » 72081-01

72081-01
Part - General - KIT, SENSOR, FS LIBRE 3, EN/ES-US
Production
Unincorporated

Rev: K EC113148 Effective From: 09/01/2023 12:00:00 AM PDT to ...

Navigator Actions

Title Block Changes * BOM * Manufacturers * Suppliers Relationships Where Used Attachments History

BOM Views: Base View * Personalize

Add Remove Go To Expanded Display More Save Cancel

Item Number	Item Description
ASM29500-601	DWG, ASSY, SENSOR KIT, AUTO PACK, 45000
DOC29500-300	SPECIFICATION, KITPACK, SENSOR STERILE AND NON-PYROGENIC, FLEX, 4410
DOC38486	SPECIFICATION, LIBRE/LIBRE PRO SENSOR KIT PALLETIZING INTERNATIONAL P.
DOC41782-18	EXPIRY ADJUSTMENT = 18 MONTHS FROM END OF CURRENT MONTH
DOC42715-104	PACKLINE SKU CONFIGURATION, D1 ASIC US, 45000 FOR -104
DOC42927-026	SOFTWARE RELEASE FILES, VERSION 1.4.2.30, PROJECT 45000 PDU
PRT26906	LABEL, FREESTYLE LIBRE, REIMBURSEMENT, 40 X 20MM
PRT31516-300	KIT PACK, CONSUMABLES, FLEX AUSTIN
PRT41790-105	CARTON, SENSOR KIT, FS LIBRE 3, W/READER, EN/ES-US
PRT45880-002	INSERT, SENSOR KIT, FS LIBRE 3, W/READER, EN/ES-US
PRT28985-306	ASSY, APPLICATOR, FLEX, FR4, D1, US, 45000
ASM28985	DWG, APPLICATOR ASSEMBLY, 45000
DOC41782-06	EXPIRY ADJUSTMENT = 06 MONTHS FROM END OF CURRENT MONTH
PRT29556	TRAY, PDU, 45000





DEVICE MASTER RECORD

Creating the DMR



The screenshot shows the 'Creating the DMR' interface. On the left is a file tree with folders like 'FS Flash 3/FreeStyle Lite-Meter', 'Nucleus (CoPilot)', 'Gemini', 'Freedom Lite', 'USB Data Cable', 'FSNv1.5', 'OmniFad', 'Xceed', 'Insulinx (22174)', 'Pegasus', 'AA2.0 (25151)', 'P2 (26909)', '22175', 'FSNv2', '29000', '34000', '37375', '45000', '91016', '44300', '46184', '44600', '54600', and 'HC Searches'. Below the tree are 'REPORTS' and 'NAVIGATOR' buttons. The main area is titled 'Page Two | General Info | Approval Info | Regulatory Info | Security (System Use Only) | FAI / Mastering'. It contains a text field 'Number*: ASM28985' and a callout box with the text: 'Some lower-level parts may not be labeled DMR under General Info even though they are.' Below this are fields for 'Item Group(s):' and 'Base Model:'. The 'General Info' section is expanded, showing 'Part Classification:', 'Source Code*: C=Custom Purchased Part/Assy', 'UOM*: EA', and 'Proprietary for Int:'. A blue-bordered box highlights the text 'DMR/QSR*: N/A'.

Page Two | General Info | Approval Info | Regulatory Info | Security (System Use Only) | FAI / Mastering

Number*: ASM28985

Some lower-level parts may not be labeled DMR under General Info even though they are.

Item Group(s):

Base Model:

Page Two

General Info

Part Classification:

Source Code*: C=Custom Purchased Part/Assy

UOM*: EA

Proprietary for Int:

DMR/QSR*: N/A





DEVICE MASTER RECORD

Creating the DMR



The screenshot displays the 'Where Used' tab in the Design History Files and Records application. The left sidebar shows a folder structure with 'FOLDERS', 'Old Item Categories', 'DONOTUSE_SYSTEMUSEONLY', and 'DMR'. A callout box on the left explains that to check if a part is DMR, one should go to the 'Where Used' tab to see where the item is referenced by other items. It notes that in the example, the part reports to the SKU, indicating it is DMR, even though its General Info is not tagged DMR.

The main window shows the part 'ASM22175-006' with the title 'Production' and 'Incorporated'. The 'Rev: A' is selected, and the 'Effective From' date is 'MC06748'. The 'Where Used' tab is active, showing a list of items that reference the selected part. The table below lists these items, including their item numbers, revisions, and descriptions.

Item Number	Rev	Description
PRT29918-004	1	ASSY, READER, SYSTEM E, ALGO GEN 3, MG/DL, NAI 12 HRS, 22
PRT45000-001	C	ASSY, READER, MMOL/L, 45000, DE
PRT45000-002	C	ASSY, READER, MG/DL, 45000, DE
PRT45000-003	A	ASSY, READER, MG/DL, 45000, US
PRT45000-004	A	ASSY, READER, MG/DL, 45000, US, NFRS
PRT45000-005	1	ASSY, READER, MMOL/L, 45000, CA
PRT45000-006	A	ASSY, READER, MG/DL, 45000, DE, AT
PRT45000-007	A	ASSY, READER, MMOL/L, 45000, DE
PRT45000-008	A	ASSY, READER, MG/DL, 45000, BE
PRT45000-009	A	ASSY, READER, MG/DL, 45000, ES, IT
PRT45000-010	A	ASSY, READER, MMOL/L, 45000, NL, NO, SV
PRT45000-011		ASSY, READER, MG/DL, 45000
PRT45000-012	A	ASSY, READER, MG/DL, 45000, FR



DEVICE MASTER RECORD

Creating the DMR



The screenshot shows the 'Production' record for part PRT45000-003. The left sidebar lists folders including 'DMR' and various item categories. The main panel displays the part details, revision history, and a 'Where Used' table.

72079-01 » PRT45000-003

PRT45000-003
Part - General • ASSY, READER, MG/DL, 45000, US

Production
Unincorporated

Rev: A MC07613 Effective From: ... to ... Navigator Actions

Title Block Changes BOM * Manufacturers * Suppliers Relationships Where Used Attachments History

Where Used Pending Changes Where Used

Views: Base View * Personalize

More

Item Number	Rev	Description
72079-01	C	KIT, READER, FREESTYLE LIBRE 3, MG/DL, EN/ES-US

If you want to modify a part, you first need to check if it reports to a SKU. Remember if the part reports to a SKU, it is part of the DMR.

If the part reports to a SKU, any modification requires approval according to the design change process per 7.3W06. If the part does not report to a SKU, the part may be modified without using the design change process and may be modified using the change control process.





DEVICE MASTER RECORD

Review



Review

Take a moment to review some of the
key concepts in this section.

Click the arrow to
begin your review.





DEVICE MASTER RECORD

Review



Agile PLM

An electronic DMR is maintained in a validated system of record, like the Agile PLM system.



DEVICE MASTER RECORD

Review





DEVICE MASTER RECORD

Review



Modifying Parts in a DMR

If you want to modify a part, you first need to check if it reports to a SKU. If the part reports to a SKU, any modification requires approval according to the design change process per 7.3W06.





DEVIC

Re

To check your progress, click
the Menu button



You have completed section 3 of 4

CLICK THE FORWARD ARROW TO CONTINUE LEARNING



KNOWLEDGE CHECK

Introduction



The Knowledge Check that follows consists of 5 questions. You must score 80% or higher to successfully complete this course.

WHEN YOU ARE READY, CLICK THE KNOWLEDGE CHECK BUTTON.

KNOWLEDGE CHECK



KNOWLEDGE CHECK

Assessment



1

Which of the following can be thought of as a blueprint or recipe for manufacturing a device?

1 | Design History File (DHF)

2 | Device Master Record (DMR)

3 | Device History Record (DHR)

NEXT

1

2

3

4

5



KNOWLEDGE CHECK

Assessment



2

The _____ typically includes information such as the date of manufacture, lot or batch number, labelling used, etc.?

1 | Design History File (DHF)

2 | Device Master Record (DMR)

3 | Device History Record (DHR)

NEXT

1

2

3

4

5



KNOWLEDGE CHECK

Assessment



3

Which of the following captures the entire design and development process execution?

1 | Design History File (DHF)

2 | Device Master Record (DMR)

3 | Device History Record (DHR)

NEXT

1

2

3

4

5



KNOWLEDGE CHECK

Assessment



4

The sub-project deliverables in the Bill of Materials (BOM) of a Design History File may be referenced or shared across multiple DHFs.

1 | True

2 | False

NEXT

1

2

3

4

5



KNOWLEDGE CHECK

Assessment



5

If you want to modify a part that is in a Device Master Record, you first need to?

1 | Ensure the part has a corresponding Device History File.

2 | Update the Documents DMR.

3 | Check if it reports to a SKU.

SUBMIT

1

2

3

4

5





Where to Get Help



MANAGER OR SUPERVISOR

If you have questions or concerns about an activity or interaction, the best place to start is with your manager or supervisor.

Course Resources



TRANSCRIPT

Click [here](#) for a full transcript of the course

