Document & Record Control For Medical Devices

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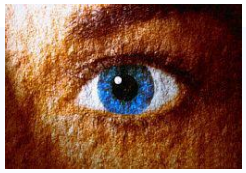
Quality & Regulatory Consultant

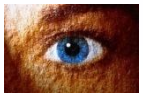
PROCESS VISION

DOWN TO EARTH QUALITY SERVICES

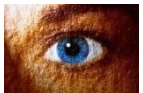


Content

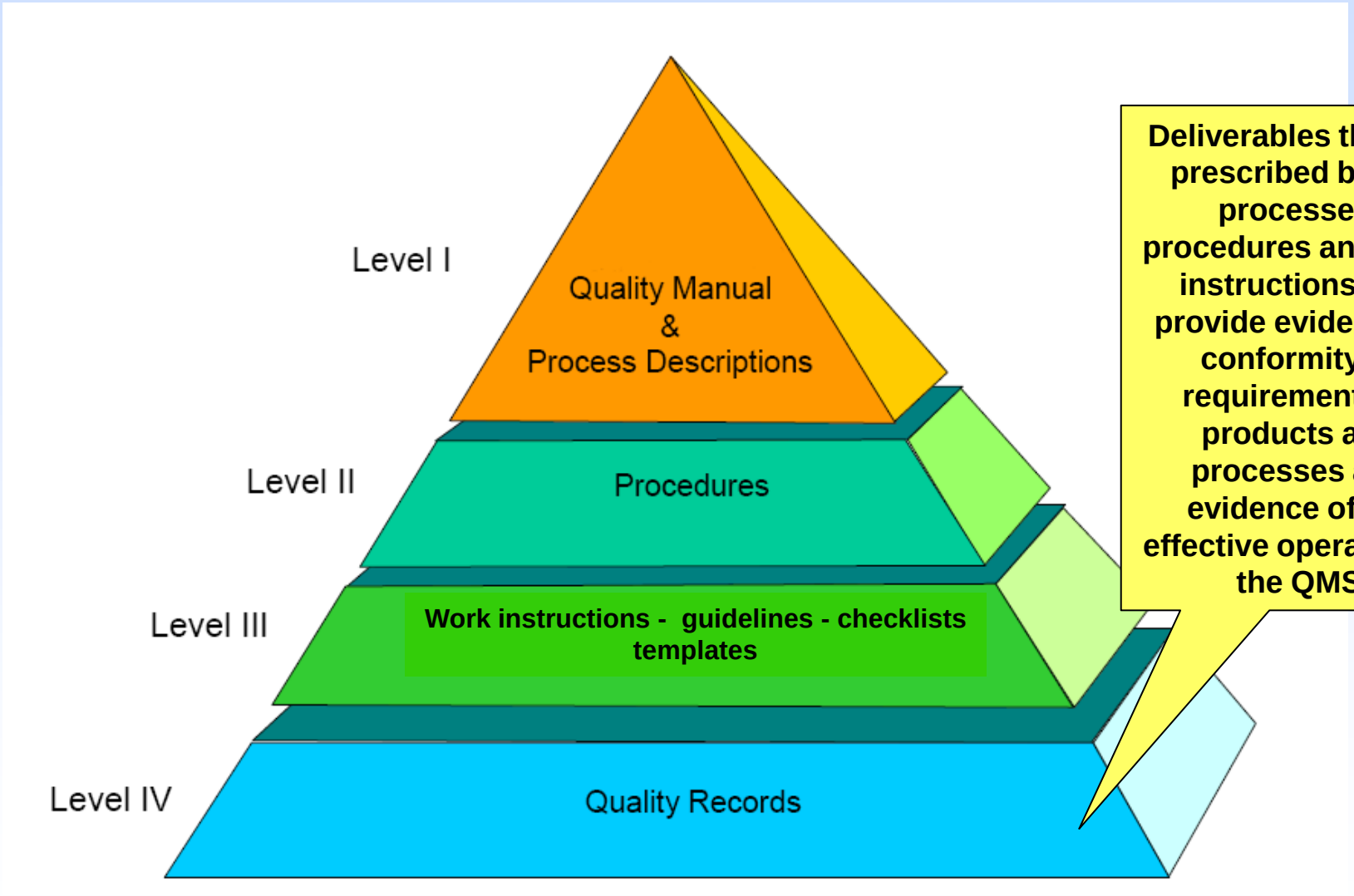
- Quality Management System requirements
- Good Documentation Practices
- Tooling
- How to continue

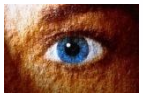


Quality Management System requirements



Start at the basic: Architecture QMS





Traceability QMS

Process

↑

Ref 1
To which process does a procedure belong?

Procedure

Ref 2
Which templates has this procedure

↓

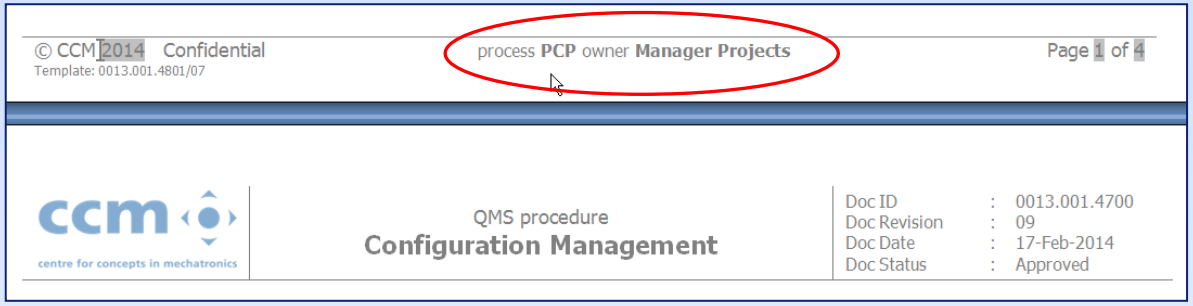
Template

↑

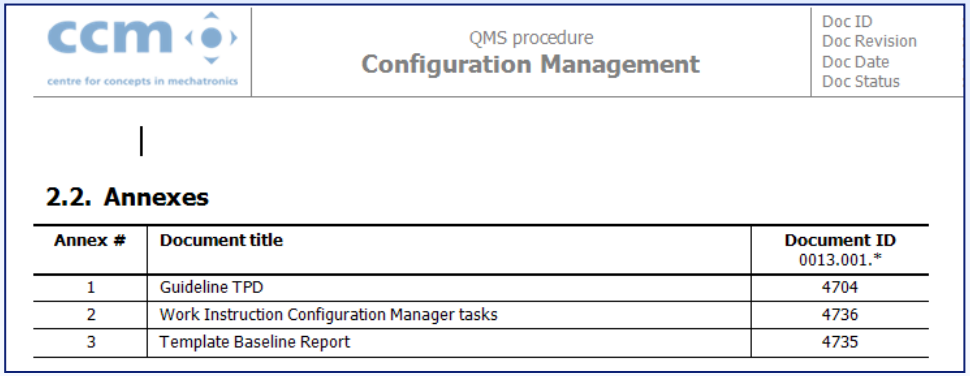
Ref 3
From which template is this record?

Quality Record

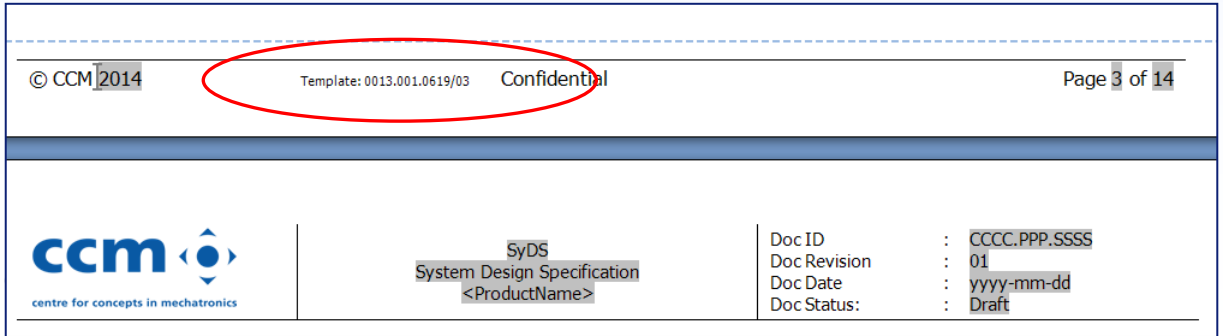
Ref 1: Example of a procedure that refers to its process (and owner)

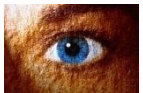


Ref 2: Example of a procedure that refers to its templates, guidelines,.....



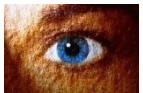
Ref 3: By using the latest released template (id+version), reference 3 is assured





Quality Records

- Device specific records:
  - Design History File (DHF)
  - Device Master Record (DMR)
  - Device History Record (DHR)
- Non specific device records:
  - Quality System Records (QSR)
    - 820.20 (c) Management review records
    - 820.22 Audit records
    - 820.25 Training records
    - 820.72 Calibration records
    - 820.100 CAPA records
    - 820.198 Complaint records



ISO 13485 requirements control docs/records

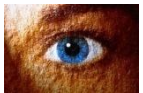
Controlled Documents

- Readily Identifiable
- Legible
- Readiliy Retrievable
- Defined retention period
- Review & approve
- Change control
- Versioned

Records

- Readily Identifiable
- Legible
- Readily Retrievable
- Defined retention period
- Review & approve if needed
- Audit trail
- No versioning

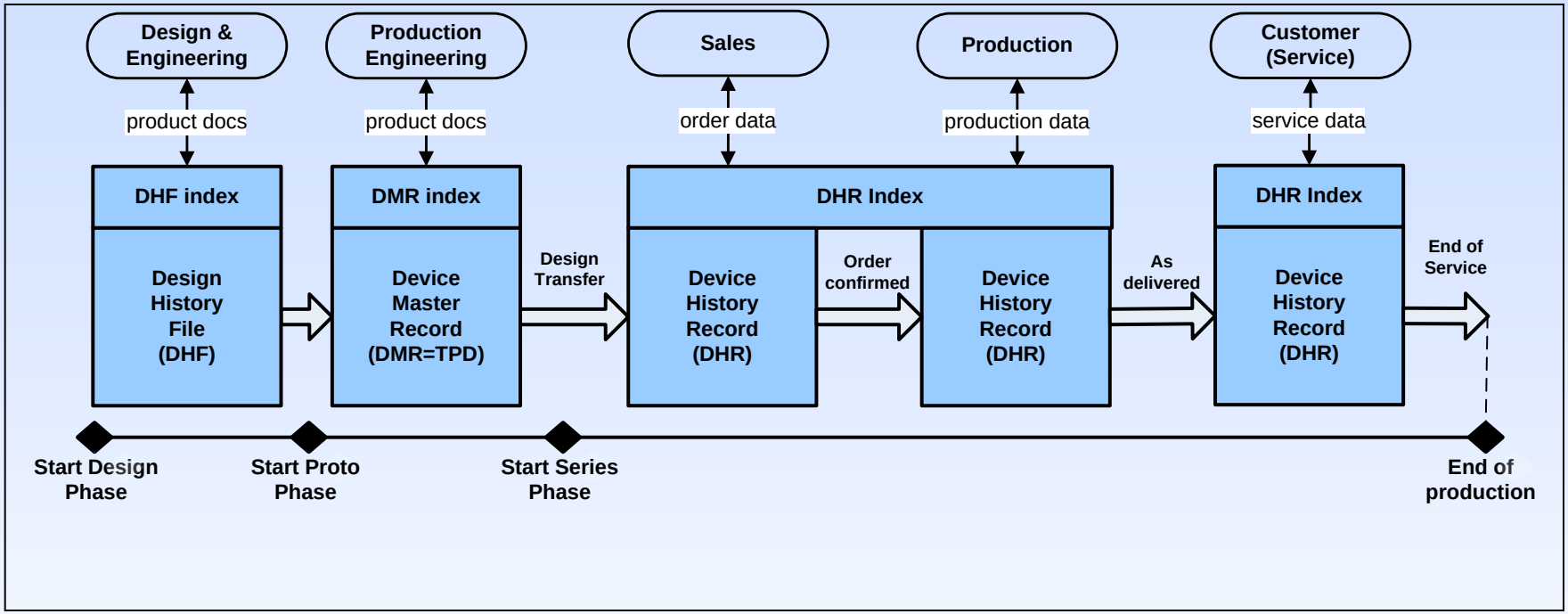
Records are a special type of controlled document
(ISO 13485-4.2.3)



Examples of Controlled documents

- Drawings
- Standard operating procedures (SOPs)
- Plans
- Specifications
- Designs
- Inspection instructions
- Test methods
- Device master records (DMRs)
- Forms
- Labeling including labels for in-process and final devices.
- Inspection and test reports
- Qualification and validation protocols and reports
- Audit reports

DHF → DMR → DHR



Abbr.	Record Type	Description
DHF	820.30 (j) Design History File	Compilation of records which described the design history of a finished device. There is a history file per designed device. It provides proof that product is designed according project plan. E.g. System Requirements, System Design, test specifications, test reports, project plan.
DMR (TPD)	820.81 Device Master Record	Compilation of records containing procedures and specifications for a finished device. There is a master record per designed device. This information needed by manufacturing, end users and service. E.g. assembly instructions, instructions for use, service manual,
DHR	820.184 Device History Record	Compilation of records containing the production history of a finished device. There is a history record per produced device (particular unit or batch of devices). It is the order, production and service history of a device E.g. confirmed sales order, acceptance records (to DMR) and calibration records.

820.184 Content DHR

- Number of produced devices including production date
- Number of distributed devices
- Identification device(s) (SN#)
- BOM including (if applicable) component SN#
- Reference to DMR (e.g. Baseline number)
- Id’s of used (calibrated) measuring devices
- Id’s of used labels
- Id’s of used test software (version)
- Test results
- 820.80 Acceptatance results including conclusion, review and approval evidence
- 820.90 Non conforming records

ISO 13485 requirements design documents

7.3.3 Design and development outputs

- Shall meet the input requirements for design and development
- Outputs examples: specifications, manufacturing procedures, engineering drawings

7.3.5 Design and development verification

- Shall be performed in accordance with planned arrangements to ensure that the design and development outputs have met the design and development input requirements.

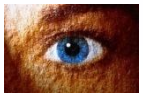
7.3.6 Design and development validation

- Shall be performed in accordance with planned arrangements to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use.

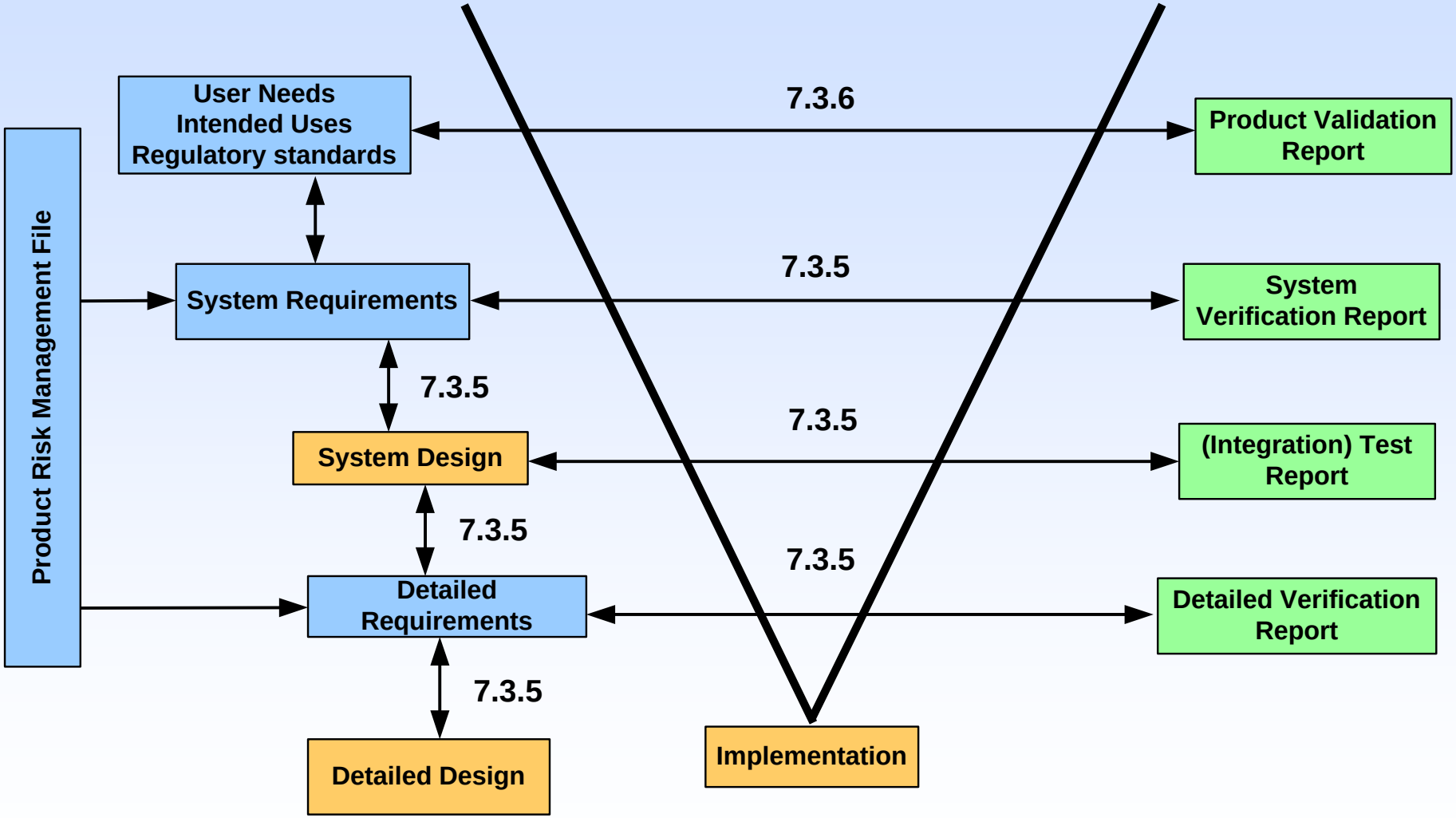
7.3.7 Control of design and development changes

- Shall be identified

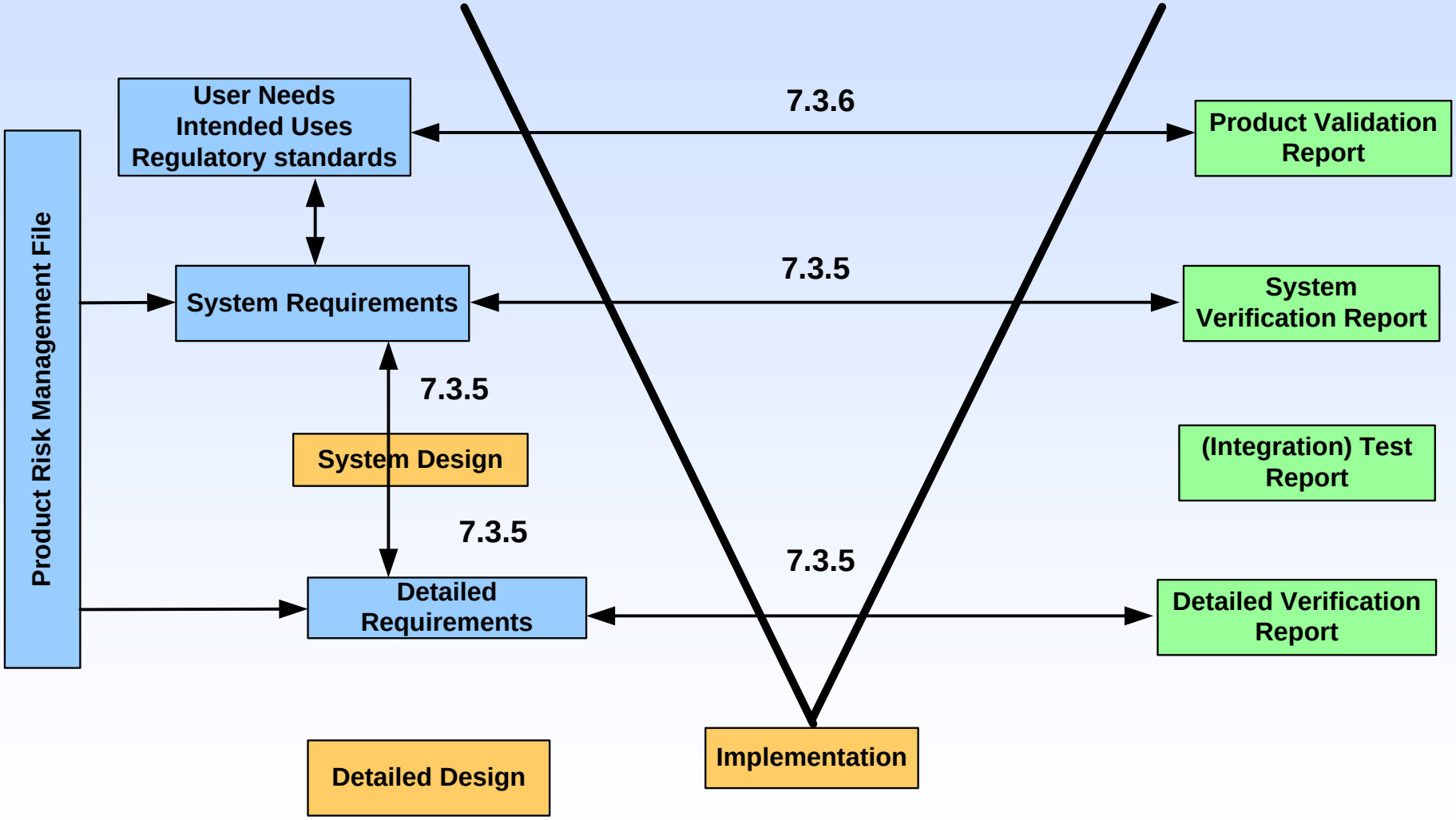
How to achieve above? See next sheet



Requirements and test traceability example maximum



Requirements and test traceability example minimum



Requirements & test traceabiliy

- On requirements level **not on document level**
- You need to have uniquely identifiable requirements

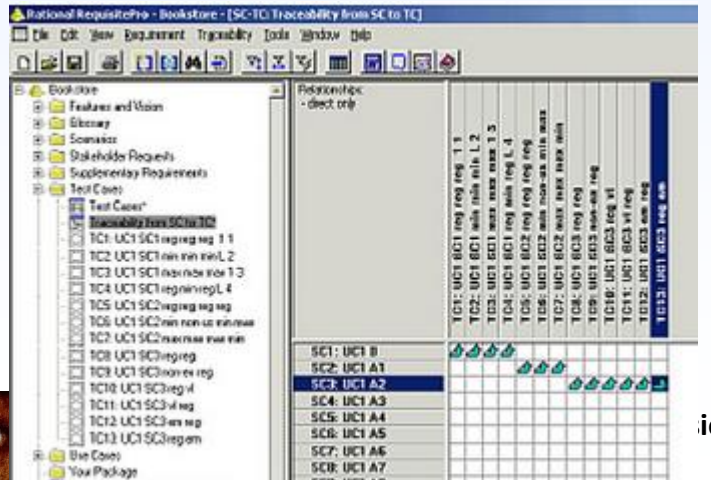
The surgeon performs the actions, seated on a high stool.

SY-0010	The LCD viewing angle must be attuned to this end; dista
SY-0011	Tubing course connection directions must be convenient.
SY-0012	Not used functions can be disabled.
SY-0013	Functions must be supported by a (distinctive) acoustic si
	SWRS

	SWRS	5101	5200	5201	5202	5203	5204	5206	5301	5400	5401	5500	5501	5502	5504	5600	5601	5602
SYRS	Σ	1	2	1	1	1	1	2	1	1	2	1	1	1	1	1	1	1
Hardware	12	1	1	1												1		
SYDS	22										1	1						
SY-0001	0																	
SY-0003	1																	
SY-0005	1																	
SY-0006	1					1												
SY-0007																		
SY-0008																		
SY-0009																		
SY-0010																		

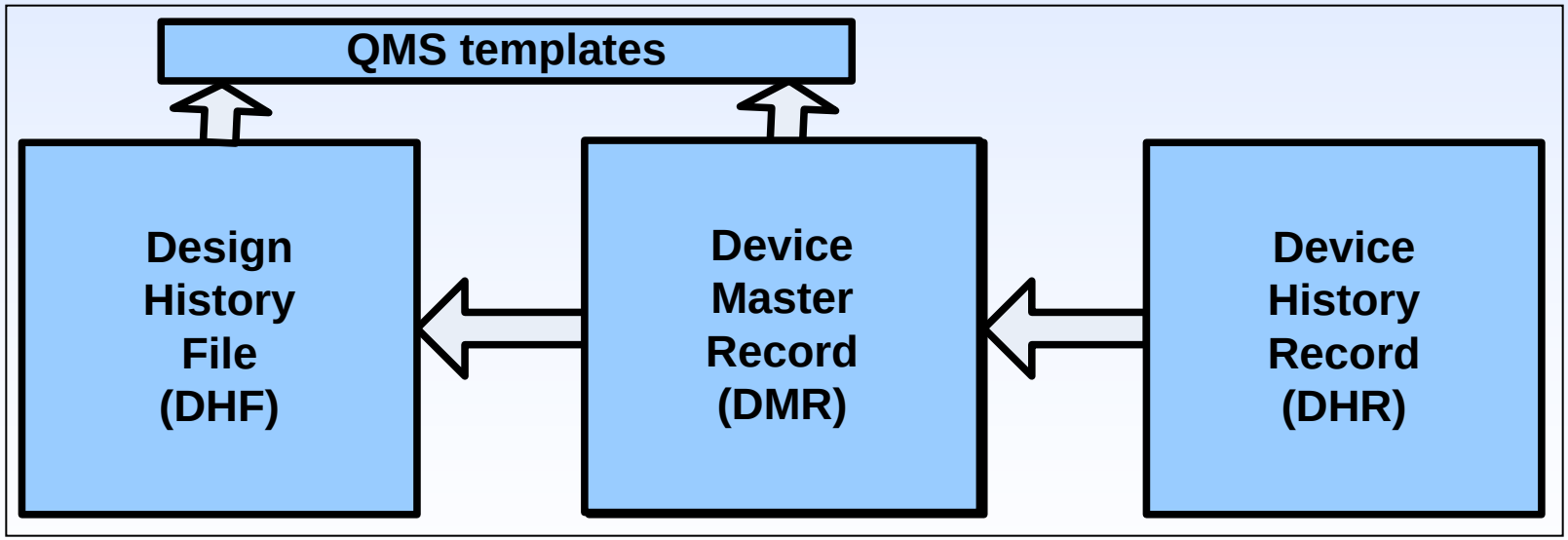
	Comment	SWTS	0001	0002	0003	0004	0005	0006	0007	0008	0009	0010
SWRS		Σ	7	3	3	6	4	6	6	2	1	2
1204		1	1									
1205		1	1									
1206		1		1								
1208		1	1									
1209		1		1								
1210		1		1								
1211		1	1									
1300		2						1			1	
1301		3						1	1	1		
1302		1										
1303		1							1			
1304		1							1			

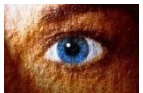
- You need a tool
- Simple tool: excel →
- Complext tool: DOORS



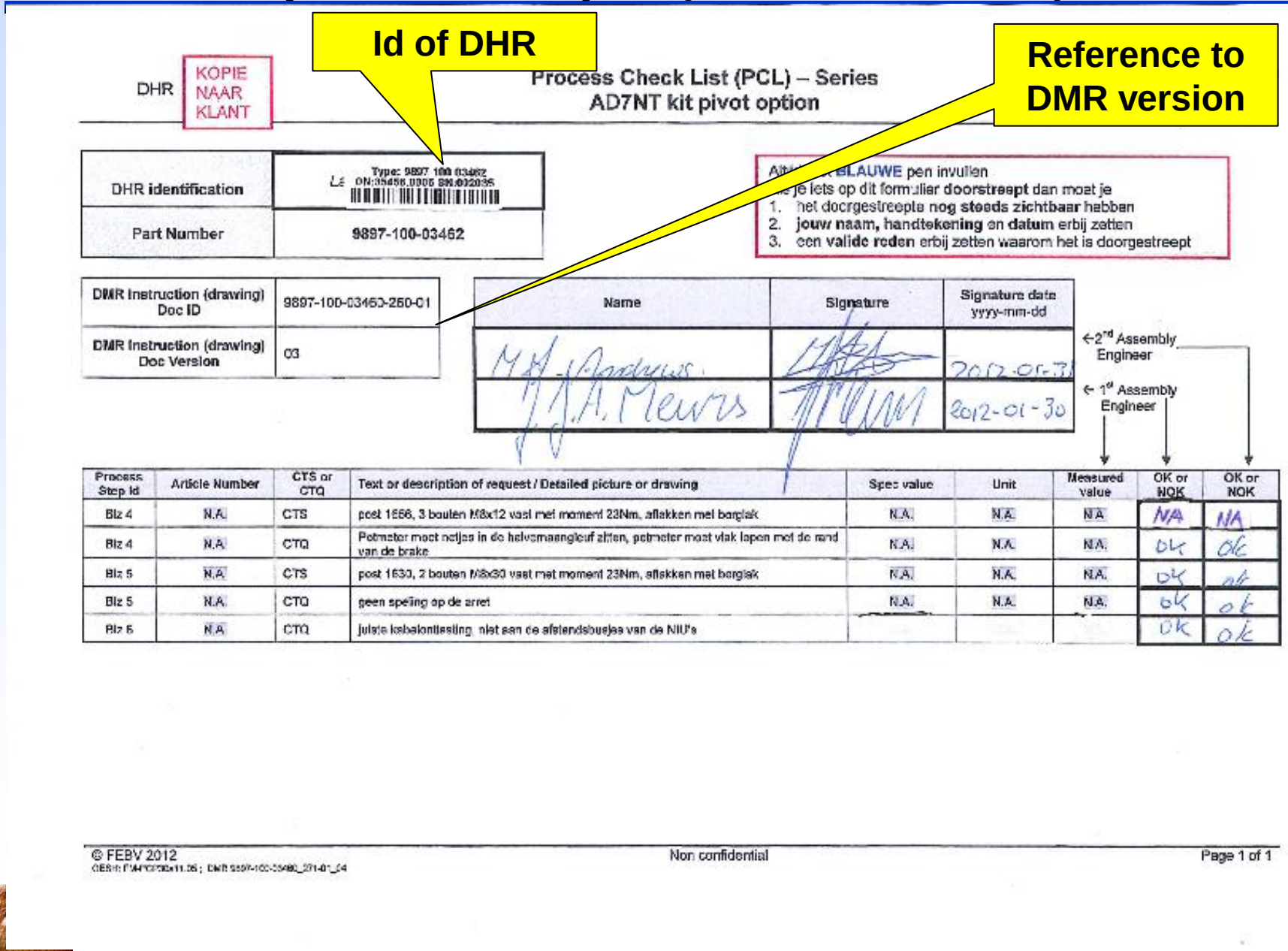
DHF ← DMR ← DHR traceability

- DHR shows version of DMR with which it is build
- DMR must be traceable to DHF of which it is derived
- DMR must be traceable to used QMS templates
- DHF must be traceable to used QMS templates

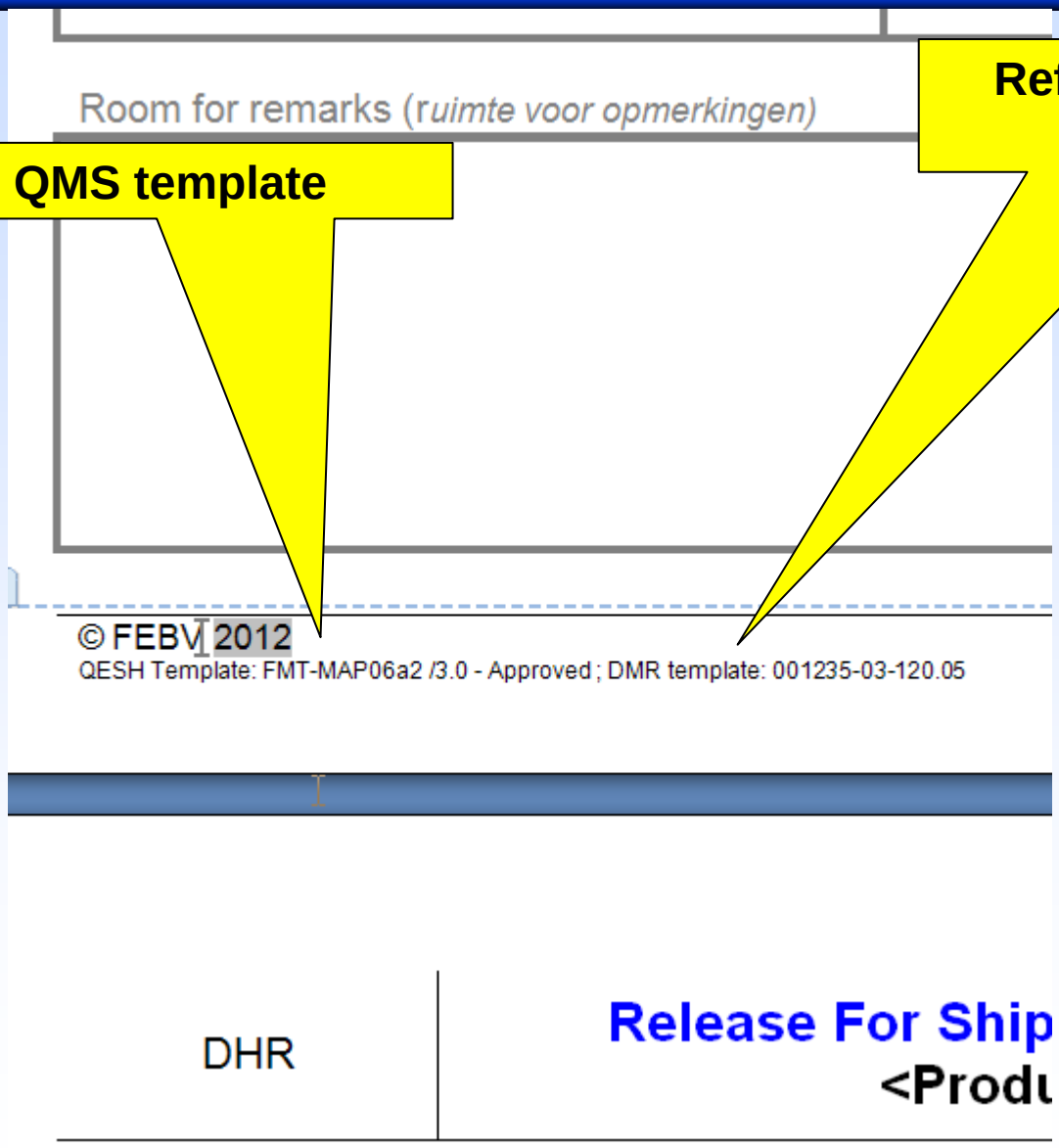




DMR Template example (DMR ← DHR)



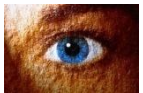
DMR example – QMS ← DMR ← DHR



Ref to QMS template

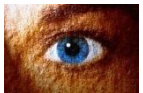
Ref to derived product DMR template

Good Documentation Practices



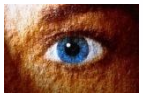
Golden rules for document control

- Consistency throughout DHF, DMR and DHR
  - Same project names
  - Same product names
  - Same definitions and abbreviations
- Mind sequence of approval
  - E.g. test report after test spec, design after requirement
- Always use approved input documents
- Correct doc identification and version control
- Good Documentation Practices (see next sheet)



Good Documentation Practices (GDP)

- Gebruik permanente blauwe inkt
- Eenduidige datum notatie: bv JJJJ-MMM-DD
- Eenduidige naam notaitie: bv initialen + achternaam
- Leesbaar, bv in blokletters
- Geen lege cellen, NA alleen als is toegestaan
- Correcties? Doorhalen met enkele lijn, naam + handtekening + datum + reden
- Gebruik geen “aanhangsels” zonder identificatie
- Afronden getallen alleen bij uitkomst, niet bij bewerking
- Handtekening = verklaring dat je iets hebt gedaan, reden moet helder zijn voor de persoon die tekent
- Handtekening bij afwezigheid alleen door bevoegde personen
- Maak goede templates en train de mensen op GDP



GDP bad example

ORIGINAL

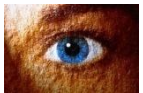
Print date: 06.07.2010 P.O. Trace. List: Yes Page 4 / 4

Material: 9896-030-23261 Description: INSTALLATION PARTS-HFO Plant: NL90 MR
Production order: 300424012 Confirmed release: 06.07.2010 Sched. finish: 07.07.2010
Order type: ZP03 P.O. Scheduler: 005 Marcel van Wetten 760000 Seq. nr.: 0
Quantity: 1 Storage bin:

Job Completion Card

No.	Name	Date	Initials
	Rob	9/7/2010	MA

Nummer en verkeerd format naam (had moeten zijn R. vd Boogaerd)
Geen voorgeschreven datum format en ook verkeerd ingevuld (yyyy-mm-dd)
Initials op template i.p.v. handtekening



GDP good example of a template

GDP Help text

Format help

(Sub)System ID with FMT sales order	*Label product (10 NC incl SN)*
Repair ID (DHR version)	R
Production Order Quantity	1
Start production date =*sales order datum in Glovia*	yyyy-mmm-dd

Altijd met **BLAUWE** pen invullen
Als je iets op dit formulier **doorstreept** dan moet je
1. het doorgestreepte **nog steeds zichtbaar** hebben
2. **jouw naam, handtekening** en **datum** erbij zetten
3. een **valide reden** erbij zetten waarom het is doorgestreept
4. alle **vakken** moeten ingevuld zijn

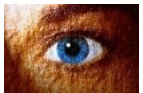
R0=initial production, R1=first repair, R2= second repair, etcetera

Reason for signing off

As 1st **Assembly Engineer**, I hereby declare that
*Als 1ste **assemblage monteur**, verklaar ik dat*

Geef de versie van het bouw boek aan (staat op het index blad) →	**Version** PFI of Assembly DMR
This product is build according to the accompanied assembly instructions of the DMR. *Dit product is gebouwd volgens de bijgeleverde assemblage instructies uit het bouwboek (DMR).*	

Name Assembly Engineer	Signature	Date signature yyyy-mmm-dd



GDP good example of a record

DHR

DHR index
AD7 & AD7NT full option

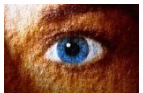
Frencken

(Sub)System ID with FMT sales order	Type: 0722 681 002 SN:000023	(Sub)System ID with PH production order	Type: 0722 681 002 SN:000023
Repair ID (DHR version)	R *1 4	R0=initial production, R1=first repair, R2= second repair, etcetera	
Electronic Archive Path	See FMT Records Location Finder (Doc ID: RLF-FMT)		
Paper archive Location	See FMT Records Location Finder (Doc ID: RLF-FMT)		

☑ = present ☐ = N/A	Description	Archived in Chapter of binder	Number of pages	Archived electronically	Copy?
☑	DHR index (this document)	0	1	N/A	COPY TO CUSTOMER
☑	Deviation Note(s), if applicable	1	1	N/A	
☑	Process Check Lists (PCL) options	2	2	N/A	
☑ ☑	1. Pick List / Trace Report(s) 2. Trace Control Report	3	5	N/A	
☑	Release For Shipment decision (RFS)	4	2	N/A	
☑	Final Test Data: signed off "Meetlijst"	5	8	N/A	
☑ ☑	Final Test Data 1. "Meetlijst" database 2. Raw test data from test tool	N/A	N/A	\testdata	
☑	Traceability list (CSV file)	N/A	N/A	\tracedata	
☑	Work Orders	6	4	N/A	No copy to customer
☑	Process Check Lists (PCL) Assemblies	6	4	N/A	
☑	Licenses	6	1	N/A	
☑	Production Order Package (POP)	N/A	N/A	\pop	

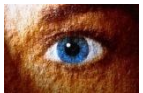
Total number of pages 28

* SCHRIJFFOUT 2012-01-30 WIM VD BIGGELAAR

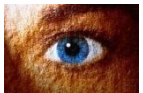


Can I use digital signatures?

- For FDA compliancy with CFR part 11 is mandatory
- Part 11 will not apply when:
  - computers are used to generate paper printouts of electronic records **and**
  - these paper records meet all predicate rule requirements **and**
  - persons rely on the paper records to perform regulated activities.
- Tools that are CFR part 11 compliant are still costly
- Alternative
  - Keep orginal paper documents for audit purpose
  - Scanned pdf for publication purpose



Tooling



Tools are essential in document control

Example landscape

- Analyse current landscape
- Define tool requirements, e.g.
  - Interface possibilities with ERP systems
  - FDA CFR 21 (digital signatures) compliancy
  - Flows for review / approval
  - Interface with change control tooling (or integrated)
  - Generate doc id, automatic versioning
- Choose tool
- Make /Buy tool
- Validate tool (on intended use)
- Use tool
- Re-validate if intended use changes

Document tool examples

PLM system

PLM system

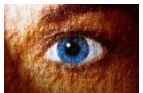
Document Management System

Document Compliance System

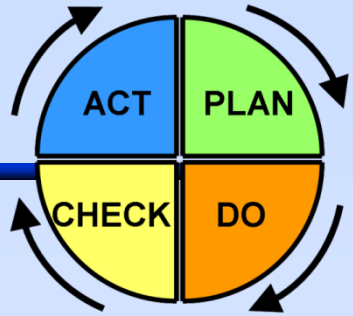
CAPA, NC's , Non conforming, Doc & Change control

Sharepoint user friendly flows plugin

Paperless manufacturing



How to continue?



- Plan Define tooling requirements and choose
- Plan Setup procedures and templates
- Plan Setup tooling environment (inc validation)
- Do Pilot in typical project/product
- Do Train train train people
- Do Transfer of current project/products
- Check Regular Audit on compliance
- Check Train train train people
- Act Adapt if needed based on audits / feedback