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DEFINITIONS

Term	Description	Source
ANVISA	Agência Nacional de Vigilância Sanitária (National Health Surveillance Agency)	Brazil
AR	Authorized Representative	MDR
CA	Competent Authority	Process Vision
CEP	Clinical Evaluation Plan	MDR
CER	Clinical Evaluation Report	MDR
DoC	Declaration of Conformity	MDR
EUDAMED	European Database on Medical Devices	MDR
FSCA	Field Safety Corrective Action	FDA / MDR
GSPR	General Safety Performance Requirements	MDR
HC	Health Canada	Canada
IFU	Instructions For Use	Process Vision
MHLW	Ministry of Health, Labor and Welfare	Japan
NoBo	Notified Body	Process Vision
PMDA	Pharmaceuticals and Medical Devices Agency	Japan
PMF	Post Market Surveillance	MDR
RMF	Risk Management File	ISO14971

Term	Description	Source
SRN	Single Registration Number.	MDR
TD	Technical Documentation	MDR
TGA	Therapeutic Goods Administration	Australia
TSS	Translation service supplier	Process Vision
UDI	Unique Device Identifier	FDA / MDR
UDI-DI	Device Identifier Fixed code specific to a version or model of a device	MDR
UDI-PI	Production Identifier a variable code related to production data of the device, such as lot/batch number, expiry date, manufacturing date, etc.	MDR
UEF	Usability Engineering File	IEC62366-1
UPC	Universal Product Code	FDA

1. PURPOSE

This document gives for all medical device processes, per process / subject an audit trail with relevant audit questions concerning ISO13485, ISO9001 and specific regulatory requirements (MDR, TGA, ANVISA, MLHW and FDA).
If there are requirements on top of MDR then they are labeled as the example shows below for ANVISA/FDA:

> In-process and final acceptance tests
> The in-process and final acceptance tests [X] [y] contain the following information/mechanisms:
> - Evidence of conformity to acceptance criteria
> - Identification of used test equipment including clear customer property indication
> - Training records of independent person(s): [X]
> - Signed results by independent person(s)
>
> ANVISA /FDA:
> Procedures are defined to ensure that sampling methods are adequate for their intended use and ensure that when changes occur, the sampling plans are reviewed. A review of sampling plans should consider the occurrence of nonconforming product, quality audit reports, complaints and other indicators

The text marked with the orange color concerns ISO9001 requirements.

A filled example is documented in section 2.1.

2. INTERNAL AND SUPPLIER AUDITS

Audit criteria	
ISO clauses:	5.6.2, 8.2.4, 8.4, 8.5.1 9.2, 9.3.2, 10.2
MDR	Articles: 10.9
TGA:	TG(MD)R Sch3 P1 1.4(5)(b)(iii)
ANVISA:	RDC ANVISA 665/2022: Art. 122, Art. 123, Art. 124
MHLW/PMDA:	MO169: 22, 23, 56
FDA:	21 CFR 820.22, 820.100
Reference to documents reviewed	
[A] x	
[B] x	
[C] x	
Audit trail	
Process Procedure [A] defines the process under audit compliant with the standard. Major changes to the procedure with respect to previous audit: - xx A definition of a non-conformity (including major/minor classification) is in place. Audit program An audit program [X] shows that all process areas are covered within a 3-year time span.	

The criteria on which the audit frequency is based is xx
The internal audit before initial certification covered all applicable clauses from the standard

Key processes (x, x) are audited on a yearly basis.
The audit plan contained audit criteria, scope, and audit method.
Out of the xx planned audits, xx audits were executed in time.
Rescheduled audits were justified and recorded: xxx
Results of previous audits were considered in the schedule: xxx

Auditors
The auditor pool consists of auditors which qualification records could be shown:
- Name, function, qualification
- xx

Qualifications are in line with the audit criteria.
None of the auditors has audited his/her own work.
The audit process itself is audited by xxx
Audits are executed by an external party (xxx): see approved supplier list [X]. Qualifications could be shown: [X].

Audit Reports
The following reports were verified: [X], [X]
All non-conformities were followed up by a correction including an appropriate target date assuring on undue delay. Causes were eliminated by corrective actions including due dates. Verification of actions were defined and results of the verification was recorded

QMS effectiveness, device safety& performance
The data analysis on audits is performed via xx
The analysis is input for the management review

Conclusion
This process is in control.

2.1 Example of filled audit trail for internal and supplier audits

Audit criteria	
ISO clauses:	5.6.2, 8.2.4, 8.4, 8.5.1
MDR	Articles: 10.9
TGA:	TG(MD)R Sch3 P1 1.4(5)(b)(iii)
ANVISA:	RDC ANVISA 665/2022: Art. 122, Art. 123, Art. 124
MHLW/PMDA:	MO169: 22, 23, 56
FDA:	21 CFR 820.22, 820.100

Reference to documents reviewed
[A] MFL-00s013 Internal audits, v6.0, 16-Feb-2023
[B] QYP.01 Quality Year Plan & Audit Program 2023, 09-Feb-2023
[C] QAR2302.01 Audit plan Marketing and Sales, 14-Mar-2023
[D] QAR2303.01 Audit plan Installed Base, 14-Jun-2023
[E] WvdBiggelaar - DEKRA - Certificate - ISO13485 CMDCAS lead auditor – 2011, 28-June-2011
[F] WvdBiggelaar - DEKRA - Training Certificate - ISO 13485 - Feb 16 2017
[G] Approved Supplier List, 12-Dec-2022
[H] QAR2302.02 Audit Report Marketing and Sales, 20-Mar-2023
[I] QAR2303.02 Audit Report Installed Base, 25-Jun-2023
[J] KPP v1.0 KPI Plan, 05-Jan-2022
[K] MR2023-01 Management Review, 12-Apr-2023

[L] D Munck - Training Certificate – Internal Auditor ISO9001, Mikrocentrum - Feb 2020

Audit trail

Process

Procedure [A] defines the process under audit compliant with the standard.
Major changes to the procedure with respect to previous audit:

- Redesign complete audit process

A definition of a non-conformity (including major/minor classification) is in place.

Audit program

An audit program [B] shows that all process areas are covered within a 3-year time span.
The criteria on which the audit frequency is based is xx
The internal audit before initial certification covered all applicable clauses from the standard

Key processes (Regulatory Affairs, Marketing & Sales, Manufacturing, Installed Base) are audited on a yearly basis. The audit plan contained audit criteria, scope, and audit method.
Out of the 6 planned audits, all audits were executed in time.
Rescheduled audits were justified and recorded: N/A
Results of previous audits were considered in the schedule: [C]

Auditors

The auditor pool consists of auditors which qualification records could be shown:

- Willem vd Biggelaar, QA Manager [E] [F]
- Dennis de Monck, Development Manager [L]
  NC01 – Qualification records of D. de Munck are not sufficient as the auditor is not trained in the ISO13485 standard.

Qualifications are in line with the audit criteria with exception of **NC01**
None of the auditors has audited his/her own work.
The audit process itself is audited by Dennis de Munck.
Audits are executed by an external party (Process Vision BV) which is considered as a critical supplier: see approved supplier list [G]. Qualifications could be shown: [E] [F].

Audit Reports

The following reports were verified: [H], [I]
All non-conformities were followed up by a correction including an appropriate target date assuring on undue delay. Causes were eliminated by corrective actions including due dates. Verification of actions were defined and results of the verification was recorded.

QMS effectiveness, device safety& performance

The data analysis on audits is performed via [J]
The analysis is input for the management review [K]

Conclusion

This process is in control with the exception of the insufficient qualification of an internal auditor

3. QMS REVIEW (COMPLETE & CONSISTENT) INCLUDING QUALITY MANUAL

Audit criteria	
ISO clauses:	4.1.1, 4.1.2, 4.1.3, 4.1.4, 4.2.1, 4.2.2, 4.2.3, 5.4.2 b)
MDR	Articles: 10.9, Annexes: IX
TGA:	TG(MD)R Sch3 P1 1.4(4);
ANVISA:	RDC ANVISA 665/2022: Art. 4º, Art. 106
MHLW/PMDA:	MHLW MO169: 5-1, 5-2, 5-3, 5-4, 7-1, 14; [Old3: 5, 7, 14]

FDA:	21 CFR 820.20
Reference to documents reviewed	
[A] x [B] x [C] x	
Audit trail	

Quality Manual

The following regulatory requirements and standards are identified in the Quality Manual [A]

- EN-ISO 9001:2015
- EN-ISO13485:2016
- Regulation (EU) 2017/ 745 Medical Device Regulation
- FDA Quality System Regulation, 21CFR 820
- Taiwan's TOC Program
- Australia's TGA
- Japan's PAL program

The following role(s) undertaken by the organization under the above regulatory requirements are identified in the Quality Manual [A]:

- Manufacturer of product xx
- Authorized representative of product xx
- Importer of product xx
- Distributor of product xx

Scope and processes needed for QMS are defined in the Quality Manual [A] considering the roles

- Scope of the QMS including justification for any exclusion and/or non-application is defined
- Outline of structure of the documentation used in the QMS is defined
- Risk based approach to the control of the processes is defined
- Processes are classified as follows:
  - Key processes
  - Supporting processes
  - Resource processes
  - Management processes and
  - Measurement processes.
- Process sequence and interaction are defined
- References to the QMS procedures are documented

The manual is up to date.

Quality System

The Quality System is implemented in xx tool. Validation evidence [X] could be shown

The defined processes are effective, controlled, measured and monitored:

- A risk-based approach (product risk demanded by medical customers, see 4.1b) has been defined to control the processes as follows: xx
- Criteria and methods for effective processes are defined as follows: xx
- Processes are monitored, measured, and analyzed as defined as follows:
- Resources to support operation and process monitoring are in place: xx FTE (process owners), xx FTE (<function>) as defined as follows: xx
- Actions to achieve planned results and maintain the effectiveness of these processes are implemented as follows: xx

Outsourcing

The following / No processes are outsourced: xx
Controls are defined which are proportionate to the risk involved and the ability of the external party to meet the requirements: xx
Quality agreements are in place: [X], [Y]