MDSAP
Medical Device Single Audit Program

Procedure

MDSAP AU P0038.001

Eligibility of Medical Device Organizations (MDOs) to apply for MDSAP certification

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Preface

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Tracey Duffy, MDSAP Regulatory Authority Council Chair

Contents

1. Purpose

The purpose of this procedure is to establish a voluntary pilot program allowing eligible Medical Device Organizations (MDOs) to voluntarily participate in and apply for MDSAP certification.

2. Scope

This document sets out eligibility criteria for the participation of MDOs in the MDSAP. It provides requirements for AOs performing MDSAP audits and certifications of MDOs. Guidance on which tasks of the MDSAP audit model are applicable to MDOs is included in Appendix 2. This procedure provides for an evaluation of the results of the pilot program.

3. Definitions and acronyms

Term/Acronym	Definition
Medical Device Organization (MDO)	an organization involved in the design or manufacturing of medical devices that does not market devices under its own name or mark or trademark (i.e., not a “legal” manufacturer). Examples of MDOs include contract manufacturers and specification developers.
“Legal” Manufacturer	Any natural or legal person with responsibility for design and/or manufacture of a medical device with the intention of making the medical device available for use, under his name, whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person(s). Notes: 1. This ‘natural or legal person’ has the ultimate legal responsibility for ensuring compliance with all applicable regulatory requirements for the medical device in the countries or jurisdictions where it is intended to be made available or sold, unless this responsibility is specifically imposed on another person by the Regulatory Authority (RA) within that jurisdiction. 2. The manufacturer’s responsibilities include meeting both pre-market requirements and post-market requirements, such as adverse event reporting and notification of corrective actions.

Term/Acronym	Definition
	3. 'Design and/or manufacture', as referred to in the above definition, may include specification development, production, fabrication, assembly, processing, packaging, repackaging, labeling, relabeling, sterilization, installation, or remanufacturing of a medical device; or putting a collection of devices, and possibly other products, together for a medical purpose. 4. Any person who assembles or adapts a medical device that has already been supplied by another person for an individual patient, in accordance with the instructions for use, is not the manufacturer, provided the assembly or adaptation does not change the intended use of the medical device. 5. Any person who changes the intended use of, or modifies, a medical device without acting on behalf of the original manufacturer and who makes it available for use under his own name, should be considered the manufacturer of the modified medical device. 6. An authorized representative, distributor or importer who only adds its own address and contact details to the medical device or the packaging, without covering or changing the existing labeling, is not considered a manufacturer. 7. To the extent that an accessory is subject to the regulatory requirements of a medical device, the person responsible for the design and/or manufacture of that accessory is considered to be a manufacturer.
Contract manufacturer	an organization manufacturing or processing a finished medical device that is placed on the market by another "legal" manufacturer, and operating under its own quality management system.
Internal supplier	an organization's facility (or group of facilities) designing, manufacturing or processing a finished medical device, that operates under the same quality management system as the device's "legal" manufacturer.
Specification developer	an organization that designs medical devices on behalf of another "legal" manufacturer.

Term/Acronym	Definition
Finished medical device	any device or accessory to any device that is suitable for use or capable of functioning, whether or not it is packaged, labeled, or sterilized.

4. Authorities/Responsibilities

	Definition
Auditing Organizations (AOs)	are responsible for the conduct and oversight of audits and subsequent technical reviews and decisions in accordance with the requirements of this pilot program, including ensuring adherence to this procedure and all other relevant MDSAP policies and procedures.
"Regulatory Authorities (RAs)	are responsible for the evaluation of MDSAP audit reports and pilot program surveys and making recommendations on future decisions on the eligibility of medical device organizations to participate in MDSAP upon completion of this pilot program.

5. Procedures

5.1 Eligibility to participate in MDSAP

Prior to this pilot program, the eligibility to participate in the MDSAP was limited to entities that:

- market medical devices under their own name or market in at least one participating jurisdiction (*i.e.*, "legal" manufacturers), AND
- are subject to quality management system (QMS) or good manufacturing practices (GMP) requirements of the participating jurisdiction(s) in which they market their medical devices.

During this pilot program, eligibility is extended to certain types of Medical Device Organizations (MDOs) that are subject to QMS or GMP requirements in participating jurisdictions but do not market medical devices under their own name or mark. As a result of this extension, most of the organizations involved in the design and manufacture of medical devices and subjected to regulatory requirements for quality systems summarized below are eligible to participate in MDSAP. For that, they need to meet at least one of the following criteria:

a) The Australian definition of "manufacturer" (see the Australian Therapeutic Goods (Medical devices) Act – 41BG) of medical devices of class Is, Im, IIa, IIb, III or of IVDs of Class 2, 3 and 4 that are distributed in Australia; OR

b) The Brazilian definition of “manufacturer” (see RDC 665/2022 Art. 3) of medical devices of class III or IV that are distributed in Brazil AND is subject to GMP Certification (see RDC 687/2022 Art. 3); OR

c) The Canadian definition of “manufacturer” (see SOR/98-282 art. 1) of medical devices of class II, III or IV that are distributed in Canada; OR

d) The Japanese definition of “Marketing Authorization Holder” or “Registered Manufacturing Site” (see PMD Act) of medical devices of class II, III or IV that are distributed in Japan; OR

e) The US definition of “manufacturer”* (see 21 CFR 820.3) of medical devices subject to the Quality System or Quality Management System Regulations (QSR/QMSR) [*i.e.*, not “QSR/GMP-exempt] that are distributed in the US.

> * At the present time, participation is limited to those organizations that would register with the FDA per 21 CFR 807 as a “manufacturer” (including kit assemblers), “contract manufacturer” of finished medical devices (including contract packagers), or “specification developer”.

The definitions of “manufacturer” of the participating jurisdictions are reproduced in Appendix 1.

As a result, in the framework of this pilot, the extension of eligibility to participate in MDSAP primarily concerns:

- Brazil: manufacturer according to Brazilian definition subject to GMP certification (see 5.1b) and listed in ANVISA publicly accessible database;
- Japan: Marketing Authorization Holder and “Registered Manufacturing Site” (see 5.1d);
- US: registered with the FDA as manufacturer, contract manufacturer, specification developer (see 5.1d).

5.2. Exclusions and Limitations

Organizations other than “legal” manufacturers that meet the criteria described in item 5.1 are eligible to participate in the pilot program as MDOs. However, prior to accepting an MDO as an MDSAP facility, AOs must observe the following exclusions and limitations:

1. The scope of certification must unambiguously identify the facility as an MDO by using appropriate descriptors (*e.g.*, contract manufacturer of […]). In deviation from MDSAP AU P0026, and to prevent ambiguity regarding the scope applicable to “legal” manufacturers, the certification scope of a Medical Device Organization eligible to participate in this Pilot shall not be stated as “design and manufacture of…”. Instead, the scope of certification should be phrased as follows:
    - Internal supplier: “Internal [specification development and] manufacturing site of…”
    - Contract manufacturer: “Contract [design and] manufacture of…”

2. The scope of certification should provide a clear description of the categories of medical devices, similar to the scope of certification for a “legal” manufacturer.

3. MDO should be audited by a single AO and the audit must cover all medical device activities taking place in the facility.

4. The requirements of Australia and Canada must not be included in the scope of the audit of MDOs nor on the certification documents since the definition of “manufacturer” in these countries is restricted to “legal” manufacturers.

   Note - the TGA will consider audit report content from a MDO site, in combination with the legal manufacturer audit report, to support pre and post market regulatory activities.

   Although evidence of compliance to the Australian Essential Principles and the TG(MD) Regulations are required of the legal manufacturer, the MDO audit report may be reviewed by the TGA if critical activities (for example design, manufacture or final release) have been outsourced by the legal manufacturer.

5. Each AO is limited to a maximum of 20 MDO facilities or no more than 5% of its total MDSAP facilities, whichever is smaller. Any AO that already has MDO as certified clients under MDSAP is to count these clients towards the maximum allowed participation under the Pilot.

6. The candidate participant to the pilot as an MDO must already be registered with at least one of the regulatory authorities for their regulatory role in that jurisdiction.

7. Under MDSAP, if a “legal” manufacturer has an internal supplier design or manufacture its medical devices, regulators usually expect the organization’s scope of certification to cover that internal supplier too. This pilot program especially encourages internal suppliers to participate if they work for multiple “legal” manufacturers.

When an AO decides whether an internal supplier to a “legal” manufacturer can be excluded from the scope of certification, they should consider whether this internal supplier is separately being audited under MDSAP or not, and whether the internal supplier’s activities can effectively be remotely audited.

5.3 Performing audits and certifications of MDOs

The duration of MDSAP audits of MDOs shall be calculated in accordance with MDSAP AU P0008 considering the tasks applicable to MDOs in Appendix 2.

AOs shall perform MDSAP audits and certifications of MDOs in accordance with existing program requirements and in a manner consistent with normal MDSAP audits and certifications. Standard MDSAP audit reports, NGE forms and certificates are to be used.

This pilot program will not affect the timeline for post-audit activities, as required in ISO 17021-1:2015, cl 9.4.5, IMDRF MDSAP WG/N3:2016, and MDSAP AU P0027.

5.4 Duration of Pilot

The duration of this pilot program is twelve (12) months from the date of approval of this procedure with its re-evaluation after 1 year. The pilot program may be terminated early or extended at the discretion of the MDSAP Regulatory Authority Council.

5.5 Evaluation

RA Assessors will verify that the participation limits in section 5.2 are respected during regular MDSAP Assessments.

At the conclusion of this pilot program, a sample of audit reports of MDOs from each participating Auditing Organization will be selected for evaluation by the RAs. The overall evaluation of the pilot may also include other considerations such as the impact on audit package submission timelines, feedback from participating MDOs and AOs as well as other stakeholders (*e.g.*, Observers and Affiliate Members).

6. Forms

MDSAP AU F0008.2: Audit Duration Calculation Form

MDSAP AU F0019.1: Medical Device Regulatory Audit Report

MDSAP AU F0019.2: NC Grading and Exchange Form

7. Reference Documents

GHTF/SG3/N19:2012 - Quality management system – Medical devices - Nonconformity Grading System for Regulatory Purposes and Information Exchange

IMDRF MDSAP WG/N3:2016(ed2): Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition

IMDRF MDSAP WG/N4:2021(ed2): Competence and Training Requirements for Auditing Organizations

ISO/IEC 17021-1:2015: Conformity assessment — Requirements for bodies providing audit and certification of management systems

MDSAP AU P0002: Audit Approach

MDSAP AU P0008: Audit Time Determination Procedure

MDSAP AU P0019: MDSAP Medical Device Regulatory Audit Reports

MDSAP AU P0027: Post-Audit Activities and Timeline Policy

MDSAP AU P0037: Guidelines on the use of Quality management system- Medical devices – Nonconformity Grading System for regulatory Purposes and Information Exchange (GHTF/SG3/N19:2012) for MDSAP purposes

8. Document History

Version No.	Version Date	Description of Change	Author Name/Project Manager
001	2025-07-28	Initial release	Thiago Cunha, ANVISA

Version 001

Approval

Approved: Signature on file Date: 25/07/30

CHAIR, MDSAP RAC

Appendix 1 - Definitions of “Manufacturer”

AUSTRALIA

- **Australian Therapeutic Goods (Medical Devices) Act - 41BG**

The manufacturer of a medical device is the person who is responsible for the design, production, packaging and labelling of the device before it is supplied under the person's name, whether or not it is the person, or another person acting on the person's behalf, who carries out those operations.

BRAZIL

- **RDC 665/2022 - Manufacturer**

any person who designs, manufactures, assembles, or processes a finished product, including those who execute sterilization, labeling, and packaging activities by contract.

- **RDC 687/2022 – Facilities subject to GMP Certification**

I - manufacturing unit that produces a final product on its behalf or for another company.

II - manufacturing unit that performs the final release of the final product, associated with at least one production stage, excluding design, distribution, sterilization, packaging, and labelling.

III - medical software manufacturing unit (Software as a Medical Device – SaMD).

> Paragraph 1. The packaging activity considered as a sterile barrier system for products declared as sterile is considered as a production stage subject to certification of good manufacturing practices for the purposes provided for in item II.
>
> Paragraph 2. The manufacturing units of medical devices for in vitro diagnostics that perform the stages of impregnation, lamination, or cutting of immunochromatography strips are subject to certification of good manufacturing practices under the terms of item II.

CANADA

- **SOR/98-282 art. 1**

Manufacturer means a person who sells a medical device under their own name, or under a trademark, design, trade name or other name or mark owned or controlled by the person, and who is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the device, or for assigning to it a purpose, whether those tasks are performed by that person or on their behalf .

JAPAN

- **PMD Act 23-2.1**

Marketing Authorization Holder: A person who resides in Japan and is granted a license for marketing from a prefectural government.

- **PMD Act 23-2-3.1, 23-2-4.1**

Registered Manufacturing Site: A medical device manufacturing site which conducts one of the designated manufacturing processes listed below and is registered with the Japanese government to do so:

- Main Designing
- Main assembly
- Sterilization
- Domestic storage before final release

USA

- **21 CFR 820.3**

Manufacturer means any person who designs, manufactures, fabricates, assembles, or processes a finished device. Manufacturer includes but is not limited to those who perform the functions of contract sterilization, installation, relabeling, remanufacturing, repacking, or specification development, and initial distributors of foreign entities performing these functions.

Appendix 2 – MDSAP Audit Approach – Tasks applicable to MDOs

		CONTRACT MANUFACTURERS	SPECIFICATION DEVELOPERS	Clause(s)
Task#	**Task**	**Applicable?**	**Applicable?**	
Process: Management				
1	Confirm that quality management system planning is performed to ensure that all required processes are identified, documented, implemented, monitored and maintained in order to conform to the applicable requirements and meet quality objectives. Verify that changes to the quality management system are managed to maintain the conformity of the quality management system and of the devices produced. Verify that a quality manual has been documented.	Y	Y	4.1.1, 4.1.2, 4.1.3, 4.1.4, 4.2.2, 5.4.2
2	Confirm top management has documented the appointment of a management representative. Verify the responsibilities of the management representative include ensuring that quality management system requirements are effectively established and maintained, reporting to top management on the performance of the quality management system, and ensuring the promotion of awareness of regulatory requirements throughout the organization.	Y	Y	5.5.2
3	Verify that a quality policy and objectives have been set at relevant functions and levels within the organization. Ensure the quality objectives are measurable and consistent with the quality policy. Confirm appropriate measures are taken to achieve the quality objectives.	Y	Y	5.3, 5.4.1
4	Review the manufacturer's organizational structure and related documents to verify that they include provisions for responsibilities, authorities (e.g., management representative), personnel, resources for infrastructure, competencies, and training to ensure that personnel have the necessary competence to design and manufacture devices in accordance with the planned arrangements and applicable regulatory requirements.	Y	Y	5.1, 5.5.1, 5.5.2, 6.1, 6.2

		CONTRACT MANUFACTURERS	SPECIFICATION DEVELOPERS	Clause(s)
Task#	**Task**	**Applicable?**	**Applicable?**	
Process: Management				
5	Determine the extent of outsourcing of processes that may affect the conformity of product with specified requirements and verify the proper documentation of controls in the quality management system.	Y	Y	4.1.5, 4.2.1
6	Confirm the organization has determined the necessary competencies for personnel performing work affecting product quality, provided appropriate training, and made personnel aware of the relevance and importance of their activities on product quality and achievement of the quality objectives. Ensure records of training and competencies are maintained.	Y	Y	4.2.1, 6.2
7	Verify that management has committed to and has responsibility for overall risk management planning, including ongoing review of the effectiveness of risk management activities ensuring that policies, procedures and practices are established and documented for analyzing, evaluating and controlling product risk throughout product realization.	Y	Y	7,10
8	Verify that procedures have been defined, documented, and implemented for the control of documents and records required by the quality management system. Confirm the organization retains records and at least one obsolete copy of controlled documents for a period of time at least equivalent to the lifetime of the device, but not less than two years from the date of product release.	Y	Y	4.1.4, 4.2.1, 4.2.4, 4.2.5
9	Verify that management review procedures have been documented, management reviews are being conducted at planned intervals and that they include a review of the suitability and effectiveness of the quality policy, quality objectives, and quality management system to assure that the quality management system meets all applicable regulatory requirements.	Y	Y	5.6, 5.6.1, 5.6.2, 5.6.3

		CONTRACT MANUFACTURERS	SPECIFICATION DEVELOPERS	Clause(s)
Task#	**Task**	**Applicable?**	**Applicable?**	
Process: Management				
10	Confirm that the organization has defined and implemented controls to ensure that only devices that have received the appropriate marketing authorization are distributed or otherwise offered for commercial distribution into the applicable markets.	N	N	4.2.1e
				5,2
				7.2.1
				7.2.3
11	At the conclusion of the audit, a decision should be made as to whether top management has demonstrated the necessary commitment to ensure a suitable and effective quality management system is in place and being maintained and whether the effectiveness of the system has been communicated to personnel.	Y	Y	4.1.1, 4.1.4, 5.1, 5.5.3
Process: Device Marketing Authorization and Facility Registration				
1	Verify the organization has complied with regulatory requirements to register and/or license device facilities and submit device listing information in the appropriate jurisdictions where the organization markets or distributes devices.	Y	Y	4.2.1e
2	Confirm the organization has received appropriate device marketing authorization in the regulatory jurisdictions where the organization markets its devices.	Y/N	Y/N	5,2

		CONTRACT MANUFACTURERS	SPECIFICATION DEVELOPERS	Clause(s)
Task#	**Task**	**Applicable?**	**Applicable?**	
Process: Management				
3	Verify the organization has arranged for assessment of the change (where applicable) and obtained marketing authorization for changes to devices or the quality management system which require amendment to existing marketing authorization.	Y/N	Y/N	7.2.1
				7.2.3
Process: Measurement, Analysis and Improvement				
1	Verify that procedures for measurement, analysis and improvement which address the requirements of the quality management system standard and regulatory authorities have been established and documented. Confirm the organization maintains and implements procedures to monitor and measure product conformity throughout product realization, as well as procedures that provide for mechanisms for feedback to provide early warnings of quality problems and the implementation of corrective action and preventive action.	Y	Y	4.2.1, 8.1, 8.2.1, 8.2.6, 8.5
2	Determine if appropriate sources of quality data have been identified for input into the measurement, analysis and improvement process, including customer complaints, feedback, service records, returned product, internal and external audit findings, nonconformities from regulatory audits and inspections, and data from the monitoring of products, processes, nonconforming products, and suppliers. Confirm that data from these sources are accurate and analyzed according to a documented procedure for the use of valid statistical methods (where appropriate) to identify existing and potential product and quality management system nonconformities that may require corrective or preventive action.	Y	Y	7.5.4, 8.1, 8.2.1, 8.2.6, 8.4

		CONTRACT MANUFACTURERS	SPECIFICATION DEVELOPERS	Clause(s)
Task#	**Task**	**Applicable?**	**Applicable?**	
Process: Management				
3	Determine if investigations are conducted to identify the underlying cause(s) of detected nonconformities, where possible. Confirm investigations are commensurate with the risk of the nonconformity.	Y	Y	8.5.2
4	Determine if investigations are conducted to identify the underlying cause(s) of potential nonconformities, where possible. Confirm investigations are commensurate with the risk of the potential nonconformity.	Y	Y	8.5.3
5	Confirm that corrections, corrective actions, and preventive actions were determined, implemented, documented, effective, and did not adversely affect finished devices. Ensure corrective action and preventive action is appropriate to the risk of the non-conformities or potential nonconformities encountered.	Y	Y	8.2.1, 8.2.5, 8.3.1, 8.5.2, 8.5.3
6	When a corrective or preventive action results in a design change, verify that any new hazard(s) and any new risks are evaluated under the risk management process.	N	Y	7,1
				7.3.9
7	When a corrective or preventive action results in a process change, confirm that the process change is assessed to determine if any new risks to the product are introduced. Verify the manufacturer has performed revalidation of processes where appropriate.	Y	N	4.1.2
				4.1.4
				4.1.6
				4.2.1
				7,1
				7.5.2

		CONTRACT MANUFACTURERS	SPECIFICATION DEVELOPERS	Clause(s)
Task#	**Task**	**Applicable?**	**Applicable?**	
Process: Management				
				7.5.6
				7.5.7
8	Verify that controls are in place to ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. Confirm that an appropriate disposition was made, justified, and documented, that any external party responsible for the nonconformity was notified.	Y	N	8.3.1
				8.3.2
9	Confirm that when nonconforming product is detected after delivery or use, appropriate action is taken commensurate with the risk, or potential risks, of the nonconformity.	Y	Y/N	8.3.3
				8.5.2
10	Verify that internal audits of the quality management system are being conducted according to planned arrangements and documented procedures to ensure the quality management system is in compliance with the established quality management system requirements and applicable regulatory requirements, and to determine the effectiveness of the quality system. Confirm that the internal audits include provisions for auditor training and independence over the areas being audited, corrections, corrective actions, follow-up activities, and the verification of corrective actions.	Y	Y	6.2, 8.2.4
11	Determine if relevant information regarding nonconforming product, quality management system nonconformities, corrections, corrective actions, and preventive actions has been supplied to management for management review.	Y	Y	5.6.2

		CONTRACT MANUFACTURERS	SPECIFICATION DEVELOPERS	Clause(s)
Task#	**Task**	**Applicable?**	**Applicable?**	
Process: Management				
12	Confirm that the manufacturer has made effective arrangements for gaining experience from the post-production phase, handling complaints, and investigating the cause of nonconformities related to advisory notices with provision for feedback into the Measurement, Analysis and Improvement process. Verify that information from the analysis of production and post-production quality data was considered for amending the analysis of product risk, as appropriate.	Y/N	Y/N	4.2.1
				7.2.3
				7.5.4a
				8.2.1
				8.2.2
13	Where investigation determines that activities outside the organization contributed to a customer complaint, verify that records show that relevant information was exchanged between the organizations involved.	Y	N	8.2.2
				4.1.5
				7.4.1
				8.3.1
14	Verify that the organization has defined and documented procedures for the notification of adverse events. Confirm adverse event reporting is performed according to the applicable regulatory requirements.	Y/N	Y/N	4.2.1
				7.2.3
				8.2.3

		CONTRACT MANUFACTURERS	SPECIFICATION DEVELOPERS	Clause(s)
Task#	**Task**	**Applicable?**	**Applicable?**	
Process: Management				
15	Confirm that the manufacturer has made effective arrangements for the timely issuance and implementation of advisory notices. Confirm that reporting of advisory notices is established in a documented procedure and performed according to the applicable regulatory requirements.	Y/N	Y/N	4.2.1
				7.2.3
				8.2.3
16	Determine, based on the assessment of the Measurement, Analysis and Improvement process overall, whether management provides the necessary commitment to detect and address product and quality management system nonconformities, and ensure the continued suitability and effectiveness of the quality management system.	Y	Y	4.1.3, 5.2, 8.1, 8.5.1
Process: Medical Device Adverse Events and Advisory Notices Reporting				
1	Verify that the organization has a process in place for identifying device-related events that may meet reporting criteria as defined by participating regulatory authorities. Verify that the complaint process has a mechanism for reviewing each complaint to determine if a report to a regulatory authority is required. Confirm that the organization's processes meet the timeframes required by each regulatory authority where the product is marketed.	N	N	4.2.1
				7.2.3
				8.2.2

		CONTRACT MANUFACTURERS	SPECIFICATION DEVELOPERS	Clause(s)
Task#	**Task**	**Applicable?**	**Applicable?**	
Process: Management				
2	Verify that advisory notices are reported to regulatory authorities when necessary and comply with the timeframes and recordkeeping requirements established by participating regulatory authorities.	Y/N	Y/N	4.2.1
				7.2.3
				8.2.2
Process: Design and Development				
1	Verify that those devices that are, by regulation, subject to design and development procedures have been identified. (See Annex 1).	N	Y	4.1.1
				4.2.1
				7,1
				7.3.10
2	Select a completed (where applicable) design and development project for review.	N	Y	N/A
3	Verify that the design and development process is planned and controlled. Review the design plan for the selected design and development project to understand the design and development activities; including the design and development stages, the review, verification, validation, and design transfer activities that are appropriate at each stage; and the assignment of responsibilities, authorities, and interfaces between different groups involved in design and development.	N	Y	4.2.1
				7,1
				7.3.2

		CONTRACT MANUFACTURERS	SPECIFICATION DEVELOPERS	Clause(s)
Task#	**Task**	**Applicable?**	**Applicable?**	
Process: Management				
4	For the device design and development record(s) selected, verify that design and development procedures have been established and applied. Confirm the design and development procedures address the design and development stages, review, verification, validation, design transfer, and design changes. United States (FDA): Verify that the design input procedures contain a mechanism for addressing incomplete, ambiguous, or conflicting requirements [21 CFR 820.30(c)].	N	Y	4.2.1
				7.3.1
				7.3.10
5	Verify that design and development inputs were established, reviewed and approved; and that they address customer functional, performance and safety requirements, intended use, applicable regulatory requirements, and other requirements including those arising from human factors issues, essential for design and development. Verify that any risks and risk mitigation measures identified during the risk management process are used as an input in the design and development process.	N	Y	4.2.1
				5.2
				7.2.1
				7.3.3
6	Confirm that the design and development inputs are complete, unambiguous, and not in conflict with each other.	N	Y	7.3.3

		CONTRACT MANUFACTURERS	SPECIFICATION DEVELOPERS	Clause(s)
Task#	**Task**	**Applicable?**	**Applicable?**	
Process: Management				
7	Review medical device specifications to confirm that design and development outputs are traceable to and satisfy design input requirements. Verify that the design and development outputs essential for the proper functioning of the medical device have been identified. Outputs include, but are not limited to, device specifications, specifications for the manufacturing process, specifications for the sterilization process (if applicable), the quality assurance testing, and device labeling and packaging.	N	Y	4.2.1
				4.2.3
				7.3.4
8	Verify that risk management activities are defined and implemented for product and process design and development. Confirm that risk acceptability criteria are established and met throughout the design and development process. Verify that any residual risk is evaluated and, where appropriate, communicated to the customer (e.g., labeling, service documents, advisory notices,etc.).	N	Y	4.2.1
				7,1
				7.3.3
				7.3.4
9	Confirm that design verification and/or design validation includes assurances that risk control measures are effective in controlling or reducing risk.	N	Y	7,1
				7.3.6
				7.3.7

		CONTRACT MANUFACTURERS	SPECIFICATION DEVELOPERS	Clause(s)
Task#	**Task**	**Applicable?**	**Applicable?**	
Process: Management				
10	Verify that design and development validation data show that the approved design meets the requirements for the specified application or intended use(s). Verify that design validation testing is adjusted according to the nature and risk of the product and element being validated.	N	Y	4.2.1
				7.3.7
11	Verify that clinical evaluations and/or evaluation of the medical device safety and performance were performed as part of design validation if required by national or regional regulations.	N	Y	4.2.1
				7.3.7
12	If the medical device contains software, verify that the software was subject to the design and development process. Confirm that the software was included within the risk management process.	N	Y	7.3.2
				7.3.2, 7.3.10
13	Verify that design and development changes were controlled, verified (or where appropriate validated), and approved prior to implementation. Confirm that any new risks associated with the design change have been identified and mitigated to the extent practical.	Y/N	Y/N	
14	Verify that design reviews were conducted at suitable stages as required by the design and development plan. Confirm that the participants in the reviews include representatives of functions concerned with the design and development stage being reviewed, as well as any specialist personnel needed.	N	Y	4.2.1
				7.3.2
				7.3.5

		CONTRACT MANUFACTURERS	SPECIFICATION DEVELOPERS	Clause(s)
Task#	**Task**	**Applicable?**	**Applicable?**	
Process: Management				
15	Verify that design changes have been reviewed for the effect on products previously made and delivered, and that records of review results are maintained.	N	Y	7.3.9
16	Determine if the design was correctly transferred to production.	Y	Y	4.2.1
				4.2.3
				7.3.8
17	Determine, based on the assessment of the design and development process overall, whether management provides the necessary commitment to the design and development process.	N	Y	4.1.3
				5.1
				5.5.1
Process: Production and Service Controls				
1	Verify that the product realization processes are planned, including any necessary controls, controlled conditions, and risk management activities required for the product to meet the specified or intended uses, the statutory and regulatory requirements related to the product, and (when applicable) unique device identifier requirements. Confirm that the planning of product realization is consistent with the requirements of the other processes of the quality management system and performed in consideration of the quality objectives.	Y	N	7,1
				7.2.1
				7.5.1

		CONTRACT MANUFACTURERS	SPECIFICATION DEVELOPERS	Clause(s)
Task#	**Task**	**Applicable?**	**Applicable?**	
Process: Management				
2	Review production processes considering the following criteria. Select one or more production processes to audit.	Y	N	N/A
3	For each selected process, determine if the production and service process is planned and conducted under controlled conditions that include the following: • the availability of information describing product characteristics • the availability of documented procedures, requirements, work instructions, and reference materials, reference measurements, and criteria for workmanship • the use of suitable equipment • the availability and use of monitoring and measuring devices • the implementation of monitoring and measurement of process parameters and product characteristics during production • the implementation of release, delivery and post-delivery activities • the implementation of defined operations for labeling and packaging • the establishment of documented requirements for changes to methods and processes	Y	N	7.5.1
				8.2.5
				8.2.6
4	Determine if the organization has established documented requirements for product cleanliness including any cleaning prior to sterilization, cleanliness requirements if provided non-sterile, and assuring that process agents are removed from the product if required.	Y	N	4.2.1
				4.2.3
				6.4.2
				7.5.2

		CONTRACT MANUFACTURERS	SPECIFICATION DEVELOPERS	Clause(s)
Task#	**Task**	**Applicable?**	**Applicable?**	
Process: Management				
5	Verify that the organization has determined and documented the infrastructure requirements to achieve product conformity, including buildings, workspace, process equipment, and supporting services. Confirm that buildings, workspaces, and supporting services allow product to meet requirements. Verify that there are documented and implemented requirements for maintenance of process equipment where important for product quality, and that records of maintenance are maintained.	Y	N	4.2.1
				6,3
				7.5.1
6	Verify documented requirements have been established, implemented and maintained for: • health, cleanliness, and clothing of personnel that could have an adverse effect on product quality • monitoring and controlling work environment conditions that can have an adverse effect on product quality • training or supervision of personnel who are required to work under special environmental conditions • controlling contaminated or potentially contaminated product (including returned products) in order to prevent contamination of other product, the work environment, or personnel	Y	N	4.2.1
				6,4
7	Determine if the selected process(es) and sub-process(es) have been reviewed, including any outsourced processes, to determine if validation of these processes is required.	Y	N	4.2.1
				4.1.6
				7.5.6

		CONTRACT MANUFACTURERS	SPECIFICATION DEVELOPERS	Clause(s)
Task#	**Task**	**Applicable?**	**Applicable?**	
Process: Management				
8	Verify that the selected process(es) has been validated according to documented procedures if the result of the process cannot be fully verified or can be verified, but is not. Confirm that the validation demonstrates the ability of the process(es) to consistently achieve the planned result. In the event changes have occurred to a previously validated process, confirm that the process was reviewed and evaluated, and re-validation was performed where appropriate.	Y	N	4.2.1
				7.5.6
9	If product is supplied sterile (see Annex 2): • Verify the sterilization process is validated, periodically re-validated, and records of the validation is available • Verify that devices sold in a sterile state are manufactured and sterilized under appropriately controlled conditions • Determine if the sterilization process and results are documented and traceable to each batch of product	Y	N	4.2.1
				7.5.5
				7.5.6
				7.5.7
10	Verify that the system for monitoring and measuring of product characteristics is capable of demonstrating the conformity of products to specified requirements. Confirm that product risk is considered in the type and extent of product monitoring activities.	Y	N	7,1
				7.5.1
				8,1
				8.2.6

		CONTRACT MANUFACTURERS	SPECIFICATION DEVELOPERS	Clause(s)
Task#	**Task**	**Applicable?**	**Applicable?**	
Process: Management				
11	Verify that the processes used in production and service are appropriately controlled, monitored, operated within specified limits and documented in the product realization records. In addition, verify that risk control measures identified by the manufacturer for production processes are implemented, monitored and evaluated.	Y	N	7,1
				7.5.1
				8,1
				8.2.5
12	Verify that personnel are competent to implement and maintain the processes in accordance with the requirements identified by the organization.	Y	N	6,2
13	Confirm that the organization has determined the monitoring and measuring devices needed to provide evidence of conformity to specified requirements. Verify that the monitoring and measuring equipment used in production and service control has been identified, adjusted, calibrated and maintained, and capable of producing valid results.	Y	Y	7.5.1, 7.6
14	Confirm that the organization assesses (and records) the validity of previous measurements when equipment is found not to conform to specified requirements, and takes appropriate action on the equipment and any product affected. Verify that the control of the monitoring and measuring devices is adequate to ensure valid results. Confirm that monitoring and measuring devices are protected from damage or deterioration.	Y	Y	7,60
15	If the selected process is software controlled or if software is used in production equipment or the quality management system, verify that the software is validated for its intended use. Software validation may be part of equipment qualification.	Y	Y	4.1.6, 7.5.6, 7.6

		CONTRACT MANUFACTURERS	SPECIFICATION DEVELOPERS	Clause(s)
Task#	**Task**	**Applicable?**	**Applicable?**	
Process: Management				
16	Determine if the manufacturer has established and maintained a file for each type of device that includes or refers to the location of device specifications, production process specifications, quality assurance procedures, traceability requirements, and packaging, labeling specifications, and when applicable requirements for installation and servicing. Confirm that the manufacturer determined the extent of traceability based on the risk posed by the device in the event the device does not meet specified requirements.	Y	N	4.2.1
				7,1
				7.5.8
				7.5.9.1
17	Determine if the manufacturer has established and maintained a record of the amount manufactured and approved for distribution for each batch of medical devices, the record is verified and approved, the device is manufactured according to the file referenced in task 16, and the requirements for product release were met and documented.	Y	N	4.2.1
				7.5.8
				7.5.9.1
				8.2.6

		CONTRACT MANUFACTURERS	SPECIFICATION DEVELOPERS	Clause(s)
Task#	**Task**	**Applicable?**	**Applicable?**	
Process: Management				
18	If the organization manufactures active or nonactive implantable medical devices, life-supporting or life-sustaining devices, confirm that the manufacturer maintains traceability records of all components, materials, and work environment conditions (if these could cause the medical device to not satisfy its specified requirements) in addition to records of the identity of personnel performing any inspection or testing of these devices. Confirm that the organization requires that agents or distributors of these devices maintain distribution records and makes them available for inspection. Verify that the organization records the name and address of shipping consignees for these devices.	Y	N	4.2.1
				7.5.9.2
				8.2.6
19	Verify that product status identification is adequate to ensure that only product which has passed the required inspections and tests is dispatched, used, or installed.	Y	N	7.5.8
20	Verify that the organization has implemented controls to identify, verify, protect, and safeguard customer property provided for use or incorporation into the product. Verify that the organization treats patient information and confidential health information as customer property.	Y	Y	7.5.10
21	Verify that acceptance activities assure conformity with specifications and are documented. Confirm that the extent of acceptance activities is commensurate with the risk posed by the device. Note: Acceptance activities apply to any incoming component, subassembly, or service, regardless of the manufacturer's financial or business arrangement with the supplier.	Y	N	4.2.1
				7.4.3
				7.5.8

		CONTRACT MANUFACTURERS	SPECIFICATION DEVELOPERS	Clause(s)
Task#	**Task**	**Applicable?**	**Applicable?**	
Process: Management				
				8.2.6
22	Verify that the identification, control, and disposition of nonconforming products is adequate, based on the risk the nonconformity poses to the device meeting its specified requirements.	Y	N	7.5.8
23	If a product needs to be reworked, confirm that the manufacturer has made a determination of any adverse effect of the rework upon the product. Verify that the rework process has been performed according to an approved procedure, that the results of the rework have been documented, and that the reworked product has been re-verified to demonstrate conformity to requirements.	Y	N	8.3.4
24	Verify that procedures are established and maintained for preserving the conformity of product and constituent parts of a product during internal processing, storage, and transport to the intended destination. This preservation encompasses identification, handling, packaging, storage, and protection, including those products with limited shelf-life or requiring special storage conditions.	Y	N	7.5.8
25	Confirm that the organization performs a review of the customer's requirements, including the purchase order requirements, prior to the organization's commitment to supply a product to a customer. Verify that the organization maintains documentation required by regulatory authorities regarding maintenance of distribution records.	Y	Y	
26	If installation activities are required, confirm that records of installation and verification activities are maintained.	N	N	7.5.3
27	Determine if servicing activities are conducted and documented in accordance with defined and implemented instructions and procedures. Confirm that service records are used as a source of quality data in the Measurement, Analysis and Improvement process.	N/Y	N	4.2.1
				7.5.4

		CONTRACT MANUFACTURERS	SPECIFICATION DEVELOPERS	Clause(s)
Task#	**Task**	**Applicable?**	**Applicable?**	
Process: Management				
				8,4
28	When appropriate, verify that risk control and mitigation measures are applied to transport, installation and servicing, in accordance with the organization's risk management practices.	Y	N	7,1
				7.5.1
				7.5.3
				7.5.4
				7.5.11
29	Determine, based on the assessment of the production and service control process overall, whether management provides the necessary commitment to the production and service control process to ensure devices meet specified requirements and quality objectives.	Y	N	5.1, 5.2
Purchasing				
1	Verify that planning activities describe or identify products to purchase and processes to outsource, the specified requirements for purchased products, the requirements for purchasing documentation and records, purchasing resources, the activities for purchased product acceptance, and risk management in supplier selection and purchasing.	Y	N/Y	4.1.2
				4.1.3
				4.1.5
				7,1
				7.4.1
				7.4.2

		CONTRACT MANUFACTURERS	SPECIFICATION DEVELOPERS	Clause(s)
Task#	**Task**	**Applicable?**	**Applicable?**	
Process: Management				
				7.4.3
2	Select one or more supplier evaluation files to audit.	Y	N/Y	NA
3	Verify that procedures for ensuring purchased product conforms to purchasing requirements have been established and documented.	Y	N/Y	7.4.1
4	Verify that the procedures assure the type and extent of control applied to the supplier and the purchased product is dependent upon the effect of the purchased product on subsequent product realization or the final product. Verify that criteria for the selection, evaluation and re-evaluation of suppliers have been established and documented.	Y	N/Y	7.4.1
5	Verify that suppliers are selected based on their ability to supply product or services in accordance with the manufacturer's specified requirements. Confirm that the degree of control applied to the supplier is commensurate with the significance of the supplied product or service on the quality of the finished device, based on risk. Verify that records of supplier evaluations are maintained.	Y	N/Y	4.2.1
				7,1
				7.4.1
6	Verify that the manufacturer maintains effective controls over suppliers and product, so that specified requirements continue to be met.	Y	Y/N	7.4.1
7	Confirm that the re-evaluation of the capability of suppliers to meet specified requirements is performed at intervals consistent with the significance of the product on the finished device.	Y	N	7.4.1

		CONTRACT MANUFACTURERS	SPECIFICATION DEVELOPERS	Clause(s)
Task#	**Task**	**Applicable?**	**Applicable?**	
Process: Management				
8	Verify that the organization assures the adequacy of purchasing requirements for products and services that suppliers are to provide, and defines risk management activities and any necessary risk control measures. Confirm that the manufacturer ensures the adequacy of specified purchase requirements prior to their communication to the supplier and that a written agreement with the supplier is established in which suppliers has to notify the organization about changes in the product.	Y	N	4.2.1
				7.4.2
9	Verify that the organization documents purchasing information, including where appropriate the requirements for approval of product, procedures, processes, equipment, qualification of personnel, sterilization services, and other quality management system requirements. Confirm that documents and records for purchasing are consistent with traceability requirements where applicable.	Y	N	7.4.2
				7.5.9
10	Confirm that the verification (inspection or other activities) of purchased products is adequate to ensure specified requirements are met. Confirm that the manufacturer has implemented an appropriate combination of controls applied to the supplier, the specification of purchase requirements, and acceptance verification activities that are commensurate with the risk of the supplied product upon the finished device. Verify that records of verification activities are maintained.	Y	N	7.1
				7.4.3
11	Verify that data from the evaluation of suppliers, verification activities, and purchasing are considered as a source of quality data for input into the Measurement, Analysis and Improvement process.	Y	N	8,4

		CONTRACT MANUFACTURERS	SPECIFICATION DEVELOPERS	Clause(s)
Task#	**Task**	**Applicable?**	**Applicable?**	
Process: Management				
12	Determine, based on the assessment of the overall purchasing, whether management provides the necessary commitment to the purchase process.	Y	N/Y	4.1.3
				4.1.5
				5.2

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