Did the audit team team satisfactorily complete all applicable critical elements and 70% of non-critical elements?	Critical Elements	Non-Critical Elements
All criteria?	incomplete	incomplete
Management Process?	incomplete	incomplete
Measurement, Analysis & Improvement Process?	incomplete	incomplete
Design & Development Process?	incomplete	incomplete
Production and Service Controls	incomplete	incomplete
Purchasing process?	incomplete	incomplete

	Yes	No	N/A
Knowledge of Standards, Regulations, and the MDSAP Audit Process	x		x
****Did the audit team have access to current applicable resource information: ISO 13485:2003; MDSAP Audit Tasks and Companion Document; specific regulations from participating MDSAP regulatory authorities?**			
****Did the audit team successfully complete all required MDSAP training?**			
Was anything observed to indicate the audit team did not know relevant standards or regulations?			
Did the audit team adequately prepare for the audit? (e.g. review previous audit reports)			
****Did the audit team demonstrate an understanding of the MDSAP audit sequence and approach?**			
Did the audit team verify correction of nonconformities from prior audits?			
****Did the audit team recognize and make adjustments to the audit plan when serious health risks were identified?**			
Did the audit scope appropriately account for any justified exclusions and non-applicability?			
Is there ample time allotted for the audit to ensure that all tasks can be sufficiently addressed?			
Audit Process	x		x
Did the audit team clearly explain the purpose and scope of an MDSAP audit and response adequately to questions from the organization?			
****Did the audit team follow the MDSAP audit sequence?**			
****Did the audit team demonstrate understanding of the linkages and follow leads appropriately?**			
Did the audit team stay focused on the audit tasks and outcomes?			
(placeholder for additional elements)			
Management Process	x		x
****Did the audit team use the MDSAP audit tasks and outcomes to determine whether top management ensures that an adequate and effective quality management system has been effectively established and maintained?**			
Task 1: Did the audit team verify that a quality manual, management review, and quality management system procedures and instructions have been defined and documented?			

	Yes	No	N/A
Task 1: United States (FDA): Did the audit team confirm the organization has established a quality plan which defines the quality practices, resources, and activities relevant to devices that are designed and manufactured [21 CFR 820.20(d)]?			
Task 2: Did the audit team confirm that: (1) top management has documented the appointment of a management representative; and (2) 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?			
Task 3: Did the audit team 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, and confirm appropriate measures are taken to achieve the quality objectives?			
Task 4: Did the audit team 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?			
*****Task 5: Did the audit team 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?**			
Task 5(a): Australia (TGA): Did the audit team verify that the roles and responsibilities of the Australian Sponsor are documented in the manufacturer's quality management system and that the Sponsor is qualified and controlled as a supplier?			
Task 5(b): Canada: Did the audit team verify that the roles and responsibilities of any regulatory correspondents, importers, distributors, or providers of a service are clearly documented in the organization's quality management system and are qualified as suppliers and controlled?			
Task 6: Did the audit team 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, and ensure records of training and competencies are maintained?			
Task 6(a): Brazil (ANVISA): Did the audit team confirm that: (1) the manufacturer ensures that any consultant who gives advice regarding design, purchasing, manufacturing, packaging, labeling, storing, installation, or servicing of medical devices has proper qualification to perform such tasks; and (2) those consultants are contracted as a formal service supplier, according purchasing controls defined by the manufacturer [RDC ANVISA 2.3.3]?			

	Yes	No	N/A
Task 6(b): United States (FDA) Did the audit team verify that resources include the assignment of trained personnel to meet the requirements of 21 CFR Part 820, including management, performance of work, assessment activities, and internal quality audits [21 CFR 820.20(b)(2)]?			
Task 7: Did the audit team 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?			
Task 8: Did the audit team verify that procedures have been defined, documented, and implemented for the control of documents and records required by the quality management system, and 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?			
Task 8(a): Australia (TGA): Did the audit team confirm that Quality Management System documentation and records in relation to a device are retained by the manufacturer for at least 5 years [TG(MD)R Sch3 P1 1.9]?			
Task 8(b): Brazil (ANVISA): Did the audit team verify: (1) that change records include a description of the change, identification of the affected documents, the signature of the approving individual(s), the approval date, and when the change becomes effective [RDC ANVISA 3.1.5] (2) that the manufacturer maintains a master list of the approved and effective documents [RDC ANVISA 3.1.5]; and (3) that electronic records and documents have backups [RDC ANVISA 3.1.6]?			
Task 8(c): Japan(MHLW): Did the audit team confirm that Quality Management System documentation and records in relation to a device are retained for the following periods (5 years for training records and documentation). [MHLW MO169: 8.4, 9.3, 67, 68]. (1) 15 years for 'specially designated maintenance control required medical devices' [or one year plus the shelf life for products when the shelf life or the expiry date (hereinafter simply referred to as the "shelf life") plus one year exceeds 15 years] (2) 5 years for the products other than the 'specially designated maintenance control required medical devices' (or one year plus the shelf life for the products of which the shelf life plus one year exceeds 5 years)?			
Task 8(d): United States (FDA) Did the audit team confirm that approved changes to documents are communicated to the appropriate personnel in a timely manner [21 CFR 820.40(b)]?			
****Task 9: Did the audit team verify that 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?**			

	Yes	No	N/A
Task 9(a): Did the audit team confirm that the output of internal audits is an input to management review? (Linkage from Measurement, Analysis and Improvement, task 10)			
Task 10: Did the audit team confirm that management has identified and ensured the applicable device market authorization and facility registration processes have been followed and that appropriate documents have been submitted to the applicable regulatory authorities in the markets in which the devices are offered for commercial distribution?			
Task 10(a): Australia (TGA): Did the audit team confirm that: (1) the manufacturer is aware of the Australian Sponsor's entries in the Australian Register of Therapeutic Goods (ARTG)? (2) the manufacturer has a written agreement with the Australian Sponsor to ensure that information about the compliance of a device included in the ARTG, with the Essential Principles through the application of a relevant conformity assessment procedure, and information concerning adverse events, advisory notices and recalls is readily available to the Sponsor or the TGA?			
Task 10(b): Brazil (ANVISA): For domestic manufacturers, did the audit team confirm that the establishment has ANVISA's authorization to manufacture medical devices (AFE - Autorização de Funcionamento da Empresa)? For domestic and international manufacturers, did the audit team verify that the products already distributed in the Brazilian market, are registered/notified with ANVISA [Brazilian Federal Law 6360/76]?			
Task 10(c): Canada (HC): Did the audit team verify that: (1) the manufacturer has defined, documented, and implemented processes to ensure that devices are licensed prior to sale [CMDR Sections 26, 32, 34, 43]; and (2) the manufacturer has defined, documented and implemented processes to ensure that any new or modified quality management system certificate issued to the manufacturer for regulatory purposes is submitted to the Minister within 30 days after it is issued [CMDR Section 43.1]?			
Task 10(d): Japan(MHLW): (1) Did the audit team confirm that the products already distributed in the Japanese market, are approved/ certified/ notified with PMDA/ Registered Certification Bodies [PMD Act: 23-2-5.1, 23-2-23.1, 23-2-12]? (2) for the manufacturing site which conducts main designing, main assembly, sterilization, domestic storage until final release of products, did the audit team confirm that the site is registered by MHLW. [PMD Act: 23-2-3.1, 23-2-4]?			

	Yes	No	N/A
Task 10(e): United States (FDA): Did the audit team confirm that: (1) the establishment is registered with FDA and devices marketed to the United States are listed; and (2) the manufacturer has submitted a pre-market notification or approval (as applicable) to FDA prior to marketing the device in the United States [21 CFR 807]?			
Device Marketing Authorization and Facility Registration	x		x
****Did the audit team use the audit tasks and outcomes to determine whether the organization has performed the appropriate activities regarding device marketing authorization and facility registration with regulatory authorities participating in the MDSAP?**			
Task 1: Did the audit team 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?			
Task 2: Did the audit team confirm the organization has received appropriate device marketing authorization in the regulatory jurisdictions where the organization markets its devices?			
Task 3: Did the audit team 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? Note: this task may be addressed as a linkage from the Design and Development process			
Measurement, Analysis and Improvement	x		x
****Did the audit team use the MDSAP audit tasks and outcomes to determine whether the organization has established a system for finding existing or potential product and quality problems and implementing corrective and preventive actions?**			
Task 1: Did the audit team verify that: (1) procedures for measurement, analysis and improvement which address the requirements of the quality management system standard and regulatory authorities have been established and documented; and (2) 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?			
Task 1(a): United States (FDA): Did the audit team verify that: (1) procedures are in place for verifying or validating the corrective and preventive action to ensure the action is effective and does not adversely affect the finished device [21 CFR 820.100(a)(4)] (2) procedures ensure that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of problems [21 CFR 820.100(a)(6)]; and (3) procedures provide for the submission of relevant information on identified quality problems, as well as corrective and preventive actions, for management review [21 CFR 820.100(a)(7)]?			

	Yes	No	N/A
****Task 2: Did the audit team determine:** **(1) 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, and data from the monitoring of products, processes, nonconforming products, and suppliers; and** **(2) confirm that data from these sources are accurate and analyzed using valid statistical methods (where appropriate) to identify existing and potential product and quality management system nonconformities that may require corrective or preventive action?**			
Task 2(a): Brazil (ANVISA): Did the audit team verify that the organization has established and maintained procedures for identifying valid statistical techniques required for verifying the quality system performance and process capability for achieving established specifications [RDC ANVISA 9.1]?			
Task 2(b): United States (FDA): Did the audit team verify the organization has established and maintained procedures for identifying valid statistical techniques required for establishing, controlling, and verifying the acceptability of process capability and product characteristics [21 CFR 820.250(a)]?			
****Task 3: Did the audit team determine if investigations are conducted to identify the underlying cause(s) of detected nonconformities, where possible; and confirm investigations are commensurate with the risk of the nonconformity?**			
Task 3(a): Did the audit team select records of investigations to review where the nonconformity has a higher risk of adversely affecting the ability of the finished device to meet its essential design outputs or the nonconformity affects the safety and efficacy of the product? (Excerpt from Companion Document)			
Task 4: Did the audit team determine if investigations are conducted to identify the underlying cause(s) of potential nonconformities, where possible; and confirm investigations are commensurate with the risk of the potential nonconformity?			
Task 4(a): Did the audit team select records of investigations to review where the potential nonconformity has a higher risk of adversely affecting the ability of the finished device to meet its essential design outputs or the nonconformity affects the safety and efficacy of the product? (Excerpt from Companion Document)			
****Task 5: Did the audit team confirm that corrections, corrective actions, and preventive actions were determined, implemented, documented, effective, and did not adversely affect finished devices; and ensure corrective action and preventive action is appropriate to the risk of the non-conformities or potential nonconformities encountered?**			
Task 6: When a corrective or preventive action results in a design change, did the audit team verify that any new hazard(s) and any new risks are evaluated under the risk management process?			
Task 7: When a corrective or preventive action results in a process change, did the audit team confirm that the process change is assessed to determine if any new risks to the product are introduced; and verify the manufacturer has performed revalidation of processes where appropriate?			

	Yes	No	N/A
Task 7(a): Australia (TGA): Did the audit team confirm that when a manufacturer plans to make a substantial change to a critical process (e.g. sterilization, processing materials of animal origin, processing materials of microbial or recombinant origin, or processes that incorporate a medicinal substance in a medical device), the manufacturer notifies the auditing organization who will determine if an assessment of the change is required before implementation. [TG(MD)R Sch3 P1 1.5(2)]?			
Task 7(b): Canada (HC): Did the audit team verify that the manufacturer has a process or procedure for identifying a “significant change” to a class III or IV device; and verify that information about “significant changes” is submitted in a medical device license amendment application [CMDR 1. 34]?			
Task 7(c): Japan(MHLW): Did the audit team confirm that when the Registered Manufacturing Site plans to make a significant change to a manufacturing processes (e.g. sterilization site change, manufacturing site change), the Registered Manufacturing Site notifies the Marketing Authorization Holder so as the Marketing Authorization Holder can take appropriate regulatory actions [MHLW MO169: 29]?			
Task 8: Did the audit team 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; and confirm that an appropriate disposition was made, justified, and documented?			
Task 8(a): Did the audit team select records of nonconforming products to review where the nonconformity has a higher risk of adversely affecting the ability of the finished device to meet its essential design outputs or the nonconformity affects the safety and efficacy of the product?			
Task 8(b): Did the audit team confirm that the evaluation of non-conforming product includes a determination of the need for an investigation and notification of the persons or organizations responsible for the nonconformance; and that the evaluation and any investigation is documented [RDC ANVISA 6.5.1]? Brazil (ANVISA)			
Task 8(c): United States (FDA): Did the audit team confirm that the evaluation of non-conforming product includes a determination of the need for an investigation and notification of the persons or organizations responsible for the nonconformance; and that the evaluation and any investigation is documented [21 CFR 820.90(a)]?			
Task 9: Did the audit team 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?			
Task 9: Brazil (ANVISA) Did the audit team verify that the manufacturer has procedures to determine the product recall and other field actions that are relevant in the case of products already distributed [RDC ANVISA 7.1.1.8]?			

	Yes	No	N/A
****Task 10: Did the audit team verify that:** **(1) 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; and** **(2) confirm the internal audits include provisions for audit team independence over the areas being audited, corrections, corrective actions, follow-up activities, and the verification of corrective actions?**			
Task 10(a): Brazil (ANVISA): Did the audit team verify that quality audits are conducted by trained people in accordance with established audit procedures [RDC ANVISA 7.3.2]?			
Task 10(b): United States (FDA): Did the audit team verify that resources include the assignment of trained personnel to meet the requirements of 21 CFR Part 820, including management, performance of work, assessment activities, and internal quality audits [21 CFR 820.20(b)(2)]?			
Task 11: Did the audit team 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?			
Task 11(a): Brazil (ANVISA): Did the audit team confirm that relevant information about quality problems is identified and corrective and preventive actions are submitted to executive management for information and monitoring, as well as the competent health authority, if applicable [RDC ANVISA 7.1.1.7]?			
****Task 12: Did the audit team 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; and verify information from the analysis of production and post-production quality data was considered for amending the analysis of product risk, as appropriate?**			
Task 12(a): Australia (TGA): Did the audit team verify that the organization has procedures for a post-marketing system that includes a systematic review of post-production experience; and confirm that investigation takes place in a timely manner to ensure that reporting timeframes for adverse events or advisory notices may be met [TG(MD)R Sch3 P1 1.4(3)(a)]?			

	Yes	No	N/A
Task 12(b): Brazil (ANVISA): Did the audit team verify that each manufacturer has established and maintains procedures to receive, examine, evaluate, investigate and document complaints? Such procedures must ensure that: (1) Complaints are received, documented, analyzed, evaluated, investigated and documented by a formally designated unit; (2) Where applicable, complaints must be notified to the competent health authority; (3) Complaints must be examined to determine whether an investigation is necessary. When an investigation is not done, the unit must maintain a record that includes the reason that the investigation was not performed and the name of the responsible for that decision; (4) Each manufacturer must examine, evaluate and investigate all complaints involving possible nonconformities of the product. Any claim for death, injury or threat to public health must be immediately reviewed, evaluated and investigated. (5) The records of the investigation must include: product name; date of receipt of the complaint; any number of control used; name, address and telephone number of the complainant; nature of complaint; and data and research results including actions taken? [RDC ANVISA 7.2]			
Task 12(c): Canada (HC): Did the audit team verify that: (1) the manufacturer maintains records of reported problems related to the performance characteristics or safety of a device, including any consumer complaints received by the manufacturer after the device was first sold in Canada, and all actions taken by the manufacturer in response to the problems referred to in the complaints [CMDR Section 57]; and (2) the manufacturer has established and implemented documented procedures that will enable it to carry out an effective and timely investigation of the problems reports through the customer complaints, and to carry out an effective and timely recall of the device [CMDR Section 58]?			
Task 12(d): United States (FDA): Did the audit team verify that: (1) procedures have been defined, documented, and implemented for receiving, reviewing, and evaluating complaints by a formally designated unit. Procedures must ensure that: all complaints are processed in a uniform and timely manner; oral complaints are documented upon receipt; and complaints are evaluated to determine whether the complaint represents an event which is required to be reported to FDA (2) each manufacturer must review and evaluate all complaints to determine whether an investigation is necessary. When no investigation is made, the manufacturer must maintain a record that includes the reason no investigation was made and the name of the individual responsible for the decision not to investigate. (3) any complaint of the failure of the device, labeling, or packaging to meet any of its specifications must be reviewed, evaluated, and investigated, unless such investigation has already been made for a similar complaint and another investigation is not necessary.			

	Yes	No	N/A
Task 12(d): (continued) United States (FDA): Did the audit team verify that: (4) any complaint that represents an event which must be reported to FDA must be promptly reviewed, evaluated, and investigated by a designated individual(s) and must be maintained in a separate portion of the complaint files or otherwise clearly identified. Records of investigation must include a determination of: whether the device failed to meet specifications; whether the device was being used for treatment or diagnosis; and the relationship, if any, of the device to the reported incident or adverse event (5) when an investigation is made, a record of the investigation must be maintained by the formally designated unit. The record of investigation must include: the name of the device; date the complaint was received; any device identification(s) and control number(s) used;the name, address, and telephone number of the complainant; the nature and details of the complaint;the dates and results of investigation; and any corrective action taken (6) when the manufacturer's formally designated unit is located at a site separate from the manufacturing establishment, the investigated complaint(s) and the record(s) of investigation must be reasonably accessible to the manufacturing establishment [21 CFR 820.198]?			
Task 13: Where investigation determines that activities outside the organization contributed to a customer complaint, did the audit team verify that records show that relevant information was exchanged between the organizations involved?			
Task 13(a): Brazil (ANVISA): Did the audit team verify that the manufacturer has ensured that information about quality problems or nonconforming products are properly disseminated to those directly involved in the maintenance of product quality and to prevent occurrence of such problems [RDC ANVISA 7.1.1.6]?			
Task 13(b): United States (FDA): Did the audit team verify that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems [21 CFR 820.100(a)(6)]?			
Task 14: Did the audit team verify that the organization has defined and documented procedures for the notification of adverse events; and confirm adverse event reporting is performed according to the applicable regulatory requirements?			
Task 15: Did the audit team confirm that the manufacturer has made effective arrangements for the timely issuance and implementation of advisory notices; and confirm that reporting of advisory notices is performed according to the applicable regulatory requirements?			
Medical Device Adverse Events and Advisory Notice Reporting	x		x
****Did the audit team use the audit tasks and outcomes to determine whether the organization's processes ensure that individual device-related adverse events and advisory notices involving medical devices are reported to regulatory authorities within required timeframes?**			
Task 1: Did the audit team verify that the organization's processes ensure that individual device-related adverse events and advisory notices involving medical devices are reported to regulatory authorities within required timeframes?			
Task 2: Did the audit team verify that advisory notices are reported to regulatory authorities when necessary and comply with the timeframes and recordkeeping requirements established by participating regulatory authorities?			
Design and Development	x		x

	Yes	No	N/A
****Did the audit team use the audit tasks and outcomes to determine whether the organization has established a system for controlling the design process to assure that devices meet user needs, intended uses, and specified requirements?**			
Task 1: Did the audit team verify that those devices that are, by regulation, subject to design and development procedures have been identified?			
Task 1(a): Australia (TGA): Did the audit team verify that: (1) the manufacturer prepares and maintains complete and current objective evidence that demonstrates compliance with the Essential Principles of Safety and Performance [TG(MD)R Sch3 P1 1.4(5)(c) & 1.9] (2) devices to be sold in Australia have labeling and instructions for use that comply with the Essential Principles for information that is to be provided with a device. [TG(MD)R Sch1 P2 13]; and (3) when the Therapeutic Goods (Medical Devices) Regulations 2002 does not require a manufacturer to apply design and development controls for the Class of the medical device (Class IIa, Class I Measuring, Class I Sterile), the manufacturer shall prepare and maintain, complete and current objective evidence that demonstrates compliance with the Essential Principles of Safety and Performance [See TG(MD)R Sch3 P6 6.4 - Required Technical Documentation]?			
Task 1(b): Brazil (ANVISA): If design activities are outsourced, did the audit team verify that the manufacturer has a complete device master record for the device and records of the design transfer to the production [RDC ANVISA 4.1.7, 4.2]?			
Task 1(c): Canada (HC): With respect to Class II devices that are not subject to Design and Development controls, did the audit team verify that the manufacturer has objective evidence to establish that Class II devices meet the safety and effectiveness requirements of section 10 to 20 [CMDR 9, 10 to 20]?			
Task 1(d): Japan(MHLW): Did the audit team verify that the person operating the Registered Manufacturing Site provides events which meets the following criteria defined by the Ordinance for Enforcement of PMD Act Article 228-20.2, to the Marketing Authorization Holder in a timely manner[MHLW MO169: 62.6] ?			
****Task 2: Did the audit team select a completed (where applicable) design and development project for review, using the following priority criteria for selection?** **• complaints or known problems with a particular device** **• product risk** **• recent design changes, particularly design changes made to correct quality problems associated with the device design** **• age of design (prefer most recent)** **• designs that have not been recently audited**			

	Yes	No	N/A
Task 3: Did the audit team verify the design and development process is planned and controlled, and 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?			
Task 3(a): Australia (TGA): Did the audit team verify that effective planning for design and development is documented, typically as part of a Quality Plan [TG(MD)R Sch3 P1 Cl 1.4(4)]?			
Task 3(b): Canada (HC): Did the audit team verify that manufacturers of Class IV devices maintain a quality plan that sets out the specific quality practices, resources, and sequence of activities relevant to the device [CMDR 32]?			
Task 4: For the device design and development record(s) selected, did the audit team verify that design and development procedures have been established and applied; and confirm the design and development procedures address the design and development stages, review, verification, validation, design transfer, and design changes?			
Task 4(a): United States (FDA): Did the audit team verify the design input procedures contain a mechanism for addressing incomplete, ambiguous, or conflicting requirements [21 CFR 820.30(c)]?			
Task 5: Did the audit team verify that: (1) 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; and (2) any risks and risk mitigation measures identified during the risk management process are used as an input in the design and development process?			
Task 5(a): Australia (TGA): Did the audit team verify that the manufacturer has identified the relevant Essential Principles that apply to the medical device [TG(MD)R Sch1 Essential Principles]?			
Task 5(b): United States (FDA): For the selected device(s), did the audit team verify the firm has the appropriate marketing clearance [510(k)] or pre-market approval (PMA) if distributing the devices in the United States [21 CFR 807]?			
Task 6: Did the audit team confirm the design and development inputs are complete, unambiguous, and not in conflict with each other?			

	Yes	No	N/A
Task 7: Did the audit team review medical device specifications to confirm that design and development outputs are traceable to and satisfy design input requirements; and 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, the quality assurance testing, and device labeling and packaging.			
Task 7(a): Did the audit team confirm that the organization has considered the effect of purchased product on the essential design outputs? For suppliers that provide product and services related to the essential design outputs, the degree of purchasing controls necessary is commensurate with the effect of the supplied product on the proper functioning of the finished device. This task is a linkage from the Purchasing process.			
Task 7(b): Australia (TGA): Did the audit team confirm that documentation identifies whether relevant state of the art standards have been applied in full or in part? Did the audit team confirm that documentation identifies whether relevant state of the art standards have been applied in full or in part? If standards have not been applied, did the audit team ensure that the manufacturer has documented a rationale to explain why alternative methods have been applied to demonstrate compliance with the Essential Principles [TG(MD)R Sch3 Part 1.4(5)(c)(iii)(C)]? For devices incorporating a medicinal substance, did the audit team verify that documentation also identifies the data to be derived from tests conducted in relation to the substance, and its interaction with the device [TG(MD)R Sch 3 Part 1.4(5)(c)(v)]?			
****Task 8: Did the audit team verify that: (1) risk management activities are defined and implemented for product and process design and development, (2) risk acceptability criteria are established and met throughout the design and development process, and (3) any residual risk is evaluated and, where appropriate, communicated to the customer (e.g., labeling, service documents, advisory notices, etc)?**			
Task 8(a): Brazil (ANVISA): Did the audit team verify that the manufacture has established and maintains a continuous process of risk management which covers the entire life cycle of the product? Possible hazards must be identified in both, normal and fault conditions, including those arising from human factors issues. The risk associated with those hazards, shall be calculated. Risks must be analyzed, evaluated and controlled, as necessary. Effectiveness of risk controls implemented shall be evaluated [RDC ANVISA 56/2001, RDC ANVISA 2.4]			

	Yes	No	N/A
Task 8(b): United States (FDA): Did the audit team confirm that the manufacturer has identified the possible hazards associated with the device in both normal and fault conditions? The risks associated with the hazards, including those resulting from user error, should be calculated in both normal and fault conditions. If any risk is judged to be unacceptable, it should be reduced to acceptable levels by the appropriate means. Did the audit team ensure changes to the device to eliminate or minimize hazards do not introduce new hazards [21 CFR 820.30(g); preamble comment 83]?			
Task 9: Did the audit team confirm that design verification and/or design validation includes assurances that risk control measures are effective in controlling or reducing risk?			
****Task 10: Did the audit team verify that design and development validation data show that the approved design meets the requirements for the specified application or intended use(s); and verify that design validation testing is adjusted according to the risk of the product and element being validated?**			
Task 10(a): Brazil (ANVISA): Did the audit team verify that design validation has been performed under defined operating conditions on initial production units, lots, or batches? Validation shall include device testing under real or simulated conditions of use. Design validation shall include software validation, as necessary. Stability studies shall be performed as necessary. [RDC ANVISA 4.1.8].			
Task 10(b): United States (FDA): Did the audit team verify that design validation has been performed on initial production units, lots, or batches, or their equivalents? When equivalent devices are used in the final validation, did the audit team confirm that the manufacturer documented in detail how the device was manufactured and how the device is similar to and possibly different from initial production? When there are differences, the manufacturer must justify why design validation results are valid for the production units, lots, or batches. Did the audit team verify design validation includes testing of production units under actual or simulated use conditions [21 CFR 820.30(g)]?			
Task 11: Did the audit team 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?			

	Yes	No	N/A
Task 11(a): Australia (TGA): Did the audit team verify that records of the validation include clinical evidence as required by the clinical evidence procedures [TG(MD) Sch3 P1 Cl 1.4(5)(c)(vii) and TG(MD) Sch3 P8]?			
Task 12: If the medical device contains software, did the audit team verify that the software was subject to the design and development process, and confirm the software was included within the risk management process?			
Task 13: Did the audit team verify that: (1) design and development changes were controlled, verified (or where appropriate validated), and approved prior to implementation; and (2) any new risks associated with the design change have been identified and mitigated to the extent practical?			
Task 13(a): Australia (TGA): Did the audit team verify that: (1) the manufacturer has a process or procedure for notifying the auditing organization of a substantial change to the design process or the range of products to be manufactured [TG(MD)R Sch3 Cl1.5] (2) the manufacturer has a process or procedure for identifying a proposed substantial change to the design, or the intended performance, of a Class AIMD or Class III device, and to notify the assessment body prior to implementing the change [TG(MD)R Sch3 P1 Cl 1.6(4)]?			
Task 13(b) Brazil (ANVISA): If the medical device evaluated is already registered/notified with ANVISA, did the audit team verify that the design change was correctly and promptly submitted to ANVISA for approval, when applicable [Brazilian Law 6360/76 - Art. 13]?			
Task 13(c): Canada (HC): Did the audit team verify that: (1) the manufacturer has a process or procedure for identifying a “significant change” to a Class III or IV medical device (2) information about “significant changes” is submitted in a medical device license amendment application [CMDR 1, 34]?			
Task 13(d): Japan(MHLW): (1)For the Marketing Authorization Holder, did the audit team confirm if the Marketing Authorization Holder has submitted a new application, a change application, or a change notification to PMDA/ a Registered Certification Body[PMD Act 23-2-5.1, 23-2-5.11, 23-2-5.17, 23-2-23.1, 23-2-23.6, 23-2-23.7]? (2)For the Registered Manufacturing Site, did the audit team confirm if the site has a mechanism to communicate with the Marketing Authorization Holder about device modifications, so the Marketing Authorization Holder can take appropriate actions; and (3)If a critical medical device modification has happened in the Registered Manufacturing Site, did the audit team confirm if the Registered Manufacturing Site has communicated with Marketing Authorization Holder about the change [MHLW MO169: 29]?			

	Yes	No	N/A
Task 13(e): United States (FDA): Did the audit team verify that design changes to the device do not require the firm to obtain a new 510(k) or supplement to the pre-market approval [21 CFR 807]?			
Task 14: Did the audit team verify that design reviews were conducted at suitable stages as required by the design and development plan; and confirm 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?			
Task 14(b): United States (FDA): Did the audit team verify that procedures ensure that participants include representatives of all functions concerned with the design stage being reviewed and an individual(s) who does not have direct responsibility for the design stage being reviewed, as well as any specialists needed [21 CFR 820.30(e)]?			
Task 15: Did the audit team verify that design changes have been reviewed for the effect on products previously made and delivered, and that records of review results are maintained?			
Task 16: Did the audit team determine if the design was correctly transferred to production?			
Task 16(a): Brazil (ANVISA): Did the audit team verify that: (1) procedures ensure that the device design is correctly translated into production specification [RDC ANVISA 4.1.7] (2) the manufacturer ensures that the design release occurs only after approval(s) of designated person. Before the final release, design and development records must be reviewed to confirm that it is complete and that the final design meets the approved design. Final release, including signature(s) (manual or electronic) and dates, shall be documented [RDC ANVISA 4.1.9, 4.1.11] (3) production specifications are documented (e.g. Device Master Record – DMR). The record shall include or make reference to: a) device specification, including software source code (if applicable), drawings, composition (BOM – Bill of materials), etc.; b) production specification (ex. work instructions, environmental controls, measurement equipment, etc.); c) labeling and packaging specification; c) measurement and inspection tests, with acceptance criteria; and d) methods and procedures for installation and servicing (if applicable) [RDC ANVISA 4.2]?			
Production and Service Controls	x		x
****Did the audit team use the audit tasks and outcomes to determine whether the organization has established a system for developing, conducting, controlling, and monitoring production processes to ensure devices conform to their specifications?**			
Task 1: Did the audit team verify that: (1) 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 and the statutory and regulatory requirements related to the product; (2) 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?			

	Yes	No	N/A
****Task 2: Did the audit team review production processes using the following criteria for selection?** **• Corrective and preventive action indicators of process problems or potential problems** **• Use of the production process for higher risk products** **• Use of production processes that directly impact the ability of the device to meet its essential design outputs** **• New production processes or new technologies** **• Use of the process in manufacturing multiple products** **• Processes that operate over multiple shifts** **• Processes not covered during previous audits**			
Task 3: For each selected process, did the audit team 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			
Task 3(a): Brazil (ANVISA): Did the audit team determine if the manufacturer has established and maintained a procedure for change control in order to track changes in auxiliary systems, software, equipment, processes, methods or other changes that may affect the quality of products, including risk assessment within the risk management process? The procedure must describe the actions to be taken, including, when appropriate, the need for re-qualification or re-validation. Did the audit team verify if changes are formally requested, documented and approved before implementation [RDC ANVISA 5.6; 5.6.1; 5.6.2]?			
Task 4: Did the audit team 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?			
Task 4(a): Brazil (ANVISA): Did the audit team confirm that: (1) a pest control program has been established and where chemicals are used, the company must ensure that they do not affect product quality. [RDC ANVISA 5.1.3.4]; and (2) the manufacturer has established and maintains housekeeping procedures and schedules for production areas and warehouse, in conformance with production specifications [RDC ANVISA 5.1.3.1]?			

	Yes	No	N/A
Task 5: Did the audit team verify that: (1) the organization has determined and documented the infrastructure requirements to achieve product conformity, including buildings, workspace, process equipment, and supporting services; (2) buildings, workspaces, and supporting services allow product to meet requirements; and (3) there are documented and implemented requirements for maintenance of process equipment, where important for product quality, and that records of maintenance are maintained?			
Task 5(a): Brazil (ANVISA): Did the audit team verify that manufacturing facilities are configured in order to provide adequate means for production, avoiding mix-ups or contamination of components, raw materials, in process products and finished devices; and to ensure the correct handling of the devices and production flow [RDC ANVISA 5.1.2]?			
Task 6: Did the audit team 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?			
Task 6(a): Brazil (ANVISA): Did the audit team verify that biosafety standards are used, when applicable [RDC ANVISA 5.1.3.6]?			
Task 7: Did the audit team 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?			
Task 7(a): Did the audit team review the controls the organization has instituted over suppliers that perform validated processes? This typically includes confirming that the finished device manufacturer has reviewed the process validation data generated by the supplier to ensure the process is effective, reproducible, and stable. This can be particularly important for higher risk validated processes performed by suppliers, since the finished device manufacturer does not have immediate control over those processes. This task is a linkage from the Purchasing process.			
Task 7(b): Brazil (ANVISA): Did the audit team verify that the analytical methods, utilities, computer systems and automated software that can adversely affect product quality or the quality system are validated, periodically reviewed and, when necessary, revalidated. [RDC ANVISA 5.5.2, 5.5.3]?			
Task 7(c): Canada (HC): Did the audit team verify that sterilization methods for devices sold in a sterile state are validated [CMDR 17]?			

	Yes	No	N/A
Task 7(d): United States (FDA): Did the audit team confirm that process validation was performed for sterilization, aseptic processing, injection molding, and welding processes [21 CFR 820.75; preamble comment 143]?			
****Task 8: Did the audit team verify that:** **(1) the selected process(es) has been validated if the result of the process cannot be fully verified.** **(2) the validation demonstrates the ability of the process(es) to consistently achieve the planned result.** **(3) in the event changes have occurred to a previously validated process, were the processes reviewed and evaluated, and re-validation performed where appropriate?**			
Task 8(a): Australia (TGA): Did the audit team confirm that methods of validation have regard to the generally acknowledged state of the art (e.g. current Medical Device Standard Orders – MDSO, ISO/IEC Standards, BP, EP, USP etc) [TG Act s41CB, TG(MD)R Sch 1 P1 2(1)]?			
Task 8(b): Brazil (ANVISA): Did the audit team verify that the processes requiring validation are validated according to previously established protocols? The results of validations, including date and identification of the person responsible for its approval, must be recorded [ANVISA RDC 5.5.1]			
Task 8(c): United States (FDA) Did the audit team confirm that the validation activities and results, including the date and signature of the individual approving the validation and where appropriate the major equipment validated, have been documented [21 CFR 820.75(a)]?			
****Task 9: If product is supplied sterile, did the audit team verify that:** **• the sterilization process is validated, periodically re-validated, and records of the validation are available** **• devices sold in a sterile state are manufactured and sterilized under appropriately controlled conditions** **• if the sterilization process and results are documented and traceable to each batch of product**			
Task 9(a): Australia (TGA): Did the audit team verify that methods of sterilization validation have regard to the generally acknowledged state of the art (e.g. current Australian Medical Device Standard Orders – MDSO, ISO 11135, ISO 11137) [TG(MD)R Sch1 P1 2(1)]?			
Task 10: Did the audit team verify that the system for monitoring and measuring of product characteristics is capable of demonstrating the conformity of products to specified requirements; and confirm that product risk is considered in the type and extent of product monitoring activities?			
Task 11: Did the audit team verify that the processes used in production and service are appropriately controlled, monitored, and operated within specified limits; and verify that risk control measures identified by the manufacturer for production processes are implemented, monitored and evaluated?			

	Yes	No	N/A
Task 11(a): Brazil (ANVISA): Did the audit team verify that processes which cannot be fully verified are conducted in accordance with established procedures and parameters to ensure conformance to specifications? Critical parameters should be monitored and recorded in the batch record [RDC ANVISA 5.1.6].			
Task 11(b): United States (FDA): Did the audit team verify that the manufacturer has established and maintains procedures for identifying valid statistical techniques required for establishing, controlling and verifying the acceptability of process capability and product characteristics, where appropriate [21 CFR 820.250]?			
Task 12: Did the audit team verify that personnel are competent to implement and maintain the processes in accordance with the requirements identified by the organization?			
Task 13: Did the audit team confirm that the organization has determined the monitoring and measuring devices needed to provide evidence of conformity to specified requirements; and 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?			
Task 14: Did the audit team confirm that: (1) 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; (2) the control of the monitoring and measuring devices is adequate to ensure valid results; and (3) confirm that monitoring and measuring devices are protected from damage or deterioration?			
Task 15: If the selected process is software controlled or if software is used in production equipment or the quality management system, did the audit team verify that the software is validated for its intended use? Software validation may be part of equipment qualification.			
Task 16: Did the audit team 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, packaging and labeling specifications; and 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?			
Task 16(a): Brazil (ANVISA): Did the audit team verify that: (1) the manufacturer has established and maintained procedures to ensure integrity and to prevent accidental mixing of labels, instructions, packaging materials or identifying labels [RDC ANVISA 5.2.2.1]; and (2) the manufacturer has ensured that labels are designed, printed and, where applicable, applied so that they remain legible and attached to the product during the processing, storage, handling and use [RDC ANVISA 5.2.2.2]?			

	Yes	No	N/A
Task 16(b): Canada (HC): Did the audit team verify that: (1) the manufacturer maintains objective evidence that devices meet the safety and effectiveness requirements of the CMDR [CMDR 9(2)] (2) devices sold in Canada have labeling that conforms to Canadian English and French language requirements and contains the manufacturer's name and address, device identifier, control number (for Class III and IV devices), contents of packaging, sterility, expiry, intended use, directions for use and any special storage conditions [CMDR 21-23]; and (3) the manufacturer maintains distribution records in respect of a device that will permit a complete and rapid withdrawal of the device from the market [CMDR 52-56]?			
Task 16(c): United States (FDA): If a control number is required for traceability, did the audit team confirm that such control number is on or accompanies the device throughout distribution [21 CFR 820.120(c)]?			
Task 17: Did the audit team 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, and the device is manufactured according to the file referenced in task 16?			
Task 17(a): Brazil (ANVISA): Did the audit team verify that: (1) the device history record of the product includes or refers to the following information: date of manufacture; components used; quantity manufactured; results of inspections and tests; parameters of special processes; quantity released for distribution; labeling; identification of the serial number or batch of production; and final release of the product [RDC ANVISA 3.2.1]; and (2) labeling has not been released for storage or use until a designated individual has examined the labeling for accuracy; and that the approval, including date, name and physical or electronic signature of the person responsible, is documented in the device history record [RDC ANVISA 5.2.2.3]?			
Task 17(b): United States (FDA): Did the audit team verify that: (1) labeling is not released for storage or use until a designated individual has examined the labeling for accuracy; and that the release, including the date and signature of the individual performing the examination is documented in the device history record (batch record) [21 CFR 820.120(b)] (2) labeling is stored in a manner that provides proper identification and prevents mix-ups[21 CFR 820.120© and (d)]; and (3) the label and labeling used for each production unit, lot, or batch are documented in the batch record, as well as any control numbers used [21 CFR 820.120(c), 820.184(c)]?			

	Yes	No	N/A
Task 18: If the organization manufactures active or nonactive implantable medical devices, life-supporting or life-sustaining devices, did the audit team confirm that: (1) 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; (2) the organization requires that agents or distributors of these devices maintain distribution records and makes them available for inspection; and (3) the organization records the name and address of shipping consignees for these devices?			
Task 18(a): Canada (HC): Did the audit team verify that: (1) the manufacturer has identified Schedule 2 implants and provides implant registration cards with devices or employs another suitable system approved by Health Canada [CMDR 66-68]; and (2) the manufacturer of devices that are listed on Schedule 2 of the Medical Devices Regulations maintains distribution records of these devices as well as any information received on implant registration cards related to these Schedule 2 devices [CMDR 54]?			
Task 18(b): United States (FDA): Did the audit team verify that the manufacturer has implemented a tracking system for devices for which the manufacturer has received a tracking order from FDA? The tracking system must ensure the manufacturer is able to track the device to the end-user. The manufacturer must conduct period audits of the tracking system [21 CFR 821].			
Task 19: Did the audit team 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?			
Task 20: Did the audit team verify that the organization has implemented controls to identify, verify, protect, and safeguard customer property provided for use or incorporation into the product; and verify the organization treats patient information and confidential health information as customer property?			
Task 21: Did the audit team verify that acceptance activities assure conformity with specifications and are documented. Confirm the extent of acceptance activities are 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.			
Task 21(a): Did the audit team review the purchasing controls and requirements for suppliers of products that undergo minimal acceptance activities at the device manufacturer? This task is a linkage from the Purchasing process.			

	Yes	No	N/A
Task 21(b): Brazil (ANVISA): Did the audit team verify that: (1) sampling plans are defined and based on valid statistical rationale (2) the manufacturer must establish and maintain procedures to ensure that sampling methods are suitable for the intended use and are reviewed regularly; and (3) a review of sampling plans should consider the occurrence of nonconforming product, quality audit reports, complaints and other indicators. [RDC ANVISA 9.2]?			
Task 21(c): United States (FDA): Did the audit team verify that the manufacturer establishes and maintain procedures to ensure sampling methods are adequate for their intended use and ensure that when changes occur, the sampling plans are reviewed [21 CFR 820.250(b)]?			
Task 22: Did the audit team 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?			
****Task 23: If a product needs to be reworked, did the audit team confirm the manufacturer has made a determination of any adverse effect of the rework upon the product, verify 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?**			
Task 24: Did the audit team 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.			
Task 24(a) Brazil (ANVISA): Did the audit team verify that the manufacturer has established procedures for packaging of products in order to protect the product from deterioration, damage or contamination during the processing, storage, handling and distribution [RDC ANVISA 5.2.1]?			
Task 24(b): United States (FDA): Did the audit team confirm that: (1) the manufacturer established and maintains procedures that describe the methods for authorizing receipt from and dispatch to storage areas and stock rooms [21 CFR 150(b)]; and (2) the manufacturer established and maintains procedures for control and distribution of finished devices to ensure that only those devices approved for release are distributed and that purchase orders are reviewed to ensure ambiguities and errors are resolved before devices are released for distribution [21 CFR 820.160(a)]?			
Task 25: Did the audit team confirm the organization performs a review of customer's requirements, including the purchase order requirements, prior to the organization's commitment to supply a product to a customer; and verify that the organization maintains documentation required by regulatory authorities regarding maintenance of distribution records?			

	Yes	No	N/A
Task 25(a): Brazil (ANVISA): Did the audit team verify that the manufacturer maintains distribution records which include or make reference to: name and address of consignee; identification and quantity of products shipped, with date of dispatch; and any numerical control used for traceability [ANVISA RDC 6.3]?			
Task 25(b): Canada (HC): Did the audit team verify that: (1) the manufacturer maintains distribution records that contain sufficient information to permit complete and rapid withdrawal of the medical device from the market [CMDR 52-53]; and (2) distribution records of a device are retained by the manufacturer in a manner that will allow for timely retrieval, for the longer of (a) the projected useful life of the device; and (b) two years after the date the device was shipped [CMDR 55-56]?			
Task 25(c): United States (FDA): Did the audit team verify that the manufacturer maintains distribution records which include or refer to the location of the name and address of the initial consignee, the identification and quantity of devices shipped; and any control numbers used [21 CFR 820.160(b)]?			
Task 26: If installation activities are required, did the audit team confirm records of installation and verification activities are maintained?			
Task 27: Did the audit team determine if servicing activities are conducted and documented in accordance with defined and implemented instructions and procedures; and confirm service records are used as a source of quality data in the Measurement, Analysis and Improvement process?			
Task 27(a): Brazil (ANVISA): Did the audit team confirm that: (1) the manufacturer has established and maintains procedures to ensure that records of servicing activities are kept with the following information: the product serviced; control number of product serviced; date of completion of service; identification of the service provider; description of service performed; and results of inspection and tests performed [RDC ANVISA 8.2.1]; and (2) the manufacturer periodically reviews the records of servicing activities? In cases where the analysis identifies trends that pose danger or records involving death or serious injury, a corrective or preventive action must be initiated [RDC ANVISA 8.2.2]			
Task 27(b): United States (FDA): Did the audit team verify that: (1) each manufacturer who receives a service report that represents an event that must be reported to FDA as a medical device report must automatically consider the report a complaint [21 CFR 820.200(c)]; and (2) service reports are documented and include the name of the device serviced, any device identification(s) and control number(s) used, and the date of service [21 CFR 820.200(d)]?			

	Yes	No	N/A
Task 28: When appropriate, did the audit team verify that risk control and mitigation measures are applied to transport, installation and servicing, in accordance with the organization's risk management practices?			
Purchasing	x		x
****Did the audit team use the audit tasks and outcomes to determine whether the organization's processes ensure that products, (e.g. components, materials and services provided by suppliers, including contractors and consultants) are in conformance with specified purchase requirements, including quality management system requirements?**			
Task 1: Did the audit team 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?			
****Task 2: Did the audit team select one or more supplier evaluation files to audit using the following priority criteria for selection?** **•Indications of problems with supplied products or processes from audit of the Measurement, Analysis and Improvement process** **•Suppliers of higher risk products or processes** **•Suppliers who provide products or services that directly impact the design outputs required for proper functioning of the device** **•Suppliers of processes that require validation or revalidation** **•Newly approved suppliers of products or services** **•Suppliers of products or services used in the manufacturing of multiple products** **•Suppliers of components or services not covered during previous audits**			
Task 3: Did the audit team verify that procedures for ensuring purchased product conforms to purchasing requirements have been established and documented?			
Task 4: Did the audit team 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?			
Task 5: Did the audit team verify that criteria for the selection, evaluation and re-evaluation of suppliers have been established?			
****Task 6: Did the audit team verify that:** **(1) suppliers are selected based on their ability to supply product or services in accordance with the manufacturer's specified requirements; and** **(2) 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?**			
Task 6(a): Australia (TGA): If the manufacturer outsources to the Australian Sponsor a quality management system requirement or an obligation on the manufacturer from the Australian regulations, did the audit team verify that the manufacturer treats the Sponsor as a supplier and has adequate supplier controls for those activities?			
Task 6(b): Canada (HC): Did the audit team verify that any regulatory correspondent used by the manufacturer is treated as a supplier and is adequately qualified?			

	Yes	No	N/A
Task 6(c): Japan (MHLW): (1)If the Marketing Authorization Holder (MAH) has outsourced any process that affects product conformity with requirements, to a Registered Manufacturing Site(RMS), did the audit team verify the MAH has performed the necessary verification that the RMS has an appropriate quality management system; (2)If the site of a supplier is a Registered Manufacturing Site, did the audit team verify the MAH has performed the necessary verification that the supplier has an appropriate quality management system; and (3)If the RMS has outsourced any process that affects product conformity with requirements, to another RMS, did the audit team verify the outsourcing RMS has performed the necessary verification that the outsourced RMS has an appropriate quality management system. If the site of a supplier is a RMS, then verify the purchase controlling RMS has performed the necessary verification that the supplier has an appropriate quality management system [MHLW MO169: 65]?			
Task 7: Did the audit team verify that records of supplier evaluations are maintained?			
Task 7(a): Brazil (ANVISA): Did the audit team confirm the manufacturer establishes and maintains records of approved suppliers, contractors, and consultants [RDC ANVISA 2.3.3, 2.5.3]?			
Task 7(b): United States (FDA): Did the audit team confirm the manufacturer establishes and maintains records of acceptable suppliers, contractors, and consultants [21 CFR 820.50(a)(3)]?			
Task 8: Did the audit team verify that the manufacturer maintains effective controls over suppliers and product, so that specified requirements continue to be met?			
Task 9: Did the audit team confirm 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?			
Task 10: Did the audit team 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; and confirm the manufacturer ensures the adequacy of specified purchase requirements prior to their communication to the supplier?			
Task 10(a): Brazil (ANVISA): Did the audit team confirm that purchasing orders are approved by a designated person, and that the approval, including date and signature, is documented [RDC ANVISA 2.5.4]?			
Task 11: Did the audit team verify that the organization documents purchasing information, including where appropriate the requirements for approval of product, procedures, processes, equipment, qualification of personnel, and other quality management system requirements?			

	Yes	No	N/A
Task 11(a): Brazil (ANVISA): Did the audit team confirm that an agreement is established and documented in which suppliers agree to notify the manufacturer of any change in the product or service, so that the manufacturer can determine whether the change affects the quality of the finished product [RDC ANVISA 2.5.5]?			
Task 11(b): United States (FDA): Did the audit team verify that purchasing documents contain, where possible, an agreement that the supplier agrees to notify the manufacturer of changes in products or services that may affect the quality of a finished device [21 CFR 820.50(b)]?			
Task 12: Did the audit team verify that documents and records for purchasing are consistent with traceability requirements where applicable?			
Task 13: Did the audit team confirm that: (1) the verification (inspection or other activities) of purchased products is adequate to ensure specified requirements are met; and (2) 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?			
Task 13(a): Brazil (ANVISA): Did the audit team verify that the manufacturer has established and maintains procedures to ensure the retention of components, raw materials, in process products and returned products until inspections, tests or other specified verifications have been performed and documented [RDC ANVISA 5.3.3]?			
Task 14: Did the audit team verify that records of verification activities are maintained?			
****Task 15: Did the audit team 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?**			
Nonconformities and the Final Report	x		x
****Did the audit team appropriately identify nonconformities to ISO 13485:2003 and country-specific requirements?**			
****Did the audit team report nonconformities related to specific requirements of participating regulatory authorities appropriately?**			
Did the audit team demonstrate the ability to clearly word nonconformities?			
Did the audit team have appropriate evidence to support nonconformities?			
****Did the audit team appropriately inform top management of nonconformities related to requirements of ISO 13485:2003 and specific requirements of participat**			
Did the audit team prepare the final r			