CHAPTER 6

Production and Service Control

PRODUCTION AND SERVICE CONTROL

- The purpose of the Production and Service Controls process is to manufacture products that meet specifications.
- Developing processes that are adequate to produce devices that meet specifications, validating (or fully verifying the results of) those processes, and monitoring and controlling those processes are all steps that help assure the result will be devices that meet specified requirements.
- After completing the audit of the organization’s Production and Service Controls process, the audit team will return to the Management process to make a final decision of whether top management ensures that an adequate and effective quality management system has been established and maintained at the organization.

PRODUCTION AND SERVICE CONTROLS

- In order to meet the Production and Service Controls requirements of Medical devices – Quality management systems – Requirements for regulatory purposes (ISO 13485:2016), the Quality Management System requirements of the Conformity Assessment Procedures of the Australian Therapeutic Goods (Medical Devices) Regulations (TG(MD)R Sch3), Brazilian Good Manufacturing Practices (RDC ANVISA 16/2013), Japanese QMS Ordinance (MHLW MO 169), the Quality System Regulation (21 CFR Part 820), and specific requirements of medical device regulatory authorities participating in the MDSAP program,
- the organization must understand when deviations from device specifications could occur as a result of the production process or environment.

PRODUCTION AND PROCESS CONTROL

- The **management representative** is responsible for ensuring that the requirements of the quality management system have been effectively defined, documented, implemented, and maintained. Prior to the audit of any MDSAP process, interview the management representative (or designee) to obtain an overview of the process and a feel for management's knowledge and understanding of the process.
- Audit of the Production and Service Controls process will follow audit of the Measurement, Analysis and Improvement process and the Design and Development process per the MDSAP audit sequence. Information the audit team has learned about device and quality management system nonconformities during audit of the Measurement, Analysis and Improvement process, as well as higher risk elements and essential design outputs from the design projects reviewed during audit of the Design and Development process, should be used to make decisions as to the production processes to be reviewed during the audit of the Production and Service Controls process.

AUDITOR REVIEW

- **Purpose:** The purpose of auditing the production and service controls process (including testing, infrastructure, facilities, equipment, and servicing) is to verify that the organization's processes are capable of ensuring that products will meet specifications.
- **Outcomes:** As a result of the audit of the Production and Service Controls process, objective evidence will show whether the organization has:
- A) Defined, documented and implemented procedures to ensure production and service processes
- are planned, developed, conducted, controlled, and monitored to ensure conformity to specified requirements
- B) Developed production and service process controls commensurate with the potential effect of the process on product risk

AUDITOR REVIEW

- C) Ensured that when the results of a process cannot be verified by subsequent monitoring or measurement, the process is validated with a high degree of assurance that the process will consistently achieve the planned result
- D) Implemented procedures for the validation of the application of computer software for production and service processes that affect the ability of the product to conform to specified requirements, including validation of computer software used in the quality management system
- E) Maintained records for each batch of medical devices that provides information for traceability and confirmation that the batch meets specified requirements
- F) Implemented controls to protect customer property, including intellectual property, confidential health information, and other forms of customer property that is used or incorporated into products

LINKS TO OTHER PROCESSES

- ***Links to Other Processes: Management; Design and Development; Measurement, Analysis and Improvement; Purchasing***

AUDIT TASK 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 and the statutory and regulatory requirements related to the product. 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.**
- *Clause and regulation:* [ISO 13485:2003: 7.1, 7.2.1, 7.5.1.1; TG(MD)R Sch 1 P1 2, Sch3 P1 Cl1.4(4), Sch3 P1 Cl1.4(5)(d)&(e); RDC ANVISA 16/2013: 2.2.1, 2.4, 4.1.2, 4.1.7, 5.1; 21 CFR 820.30(b), 820.20(a), 820.30(h), 820.70(a)]
- *Additional country-specific requirements:* None

MANUFACTURER

- In planning product realization, the organization must determine as appropriate the quality objectives and requirements for the product, the processes, documents, and resources specific to the product, the criteria for product acceptance, and the required verification, monitoring, inspection, and test activities specific to the product. Planning of product realization often begins in the design and development of the product, including the translation of the design into production specifications.
- The planning of product realization should be consistent with the risk control and mitigation strategies identified by the organization during risk management activities.

MANUFACTURER

- During the audit, be mindful of requirements for the product that relate to statutory and regulatory requirements, requirements necessary for the product to meet specified or intended uses, and requirements for safe and efficacious use of the product. The organization must ensure their processes, and the monitoring of processes, inspection, and test activities are planned and developed to ensure these requirements are met.
- **Quality objectives**
- Quality objectives are typically expressed as a measurable target or goal. The planning of product realization should include consideration of how the production processes, the criteria for product acceptance, and the required verification, validation, monitoring, inspection, and test activities specific to the product will achieve the quality objectives. Confirm that the organization has defined quality objectives for the device.

LINKS TO OTHER PROCESSES

- ***Link: Management***
- Confirm when necessary that the quality objectives related to the product were considered for inclusion in management review.

TASK 2 PRODUCTION SERVICE PROVISION

- **Review production processes considering the following criteria. Select one or more production processes to audit.**
- **Reminder:** Information the audit team has learned about device and quality management system nonconformities during audit of the Measurement, Analysis and Improvement process, as well as higher risk elements and essential design outputs from the design projects reviewed during audit of the Design and Development process should be used to make decisions as to the production processes to be reviewed.

PRODUCTION SERVICE PROVISION

- **Priority 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

AUDITOR REVIEW

- **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

AUDITOR REVIEW

- 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
- *Clause and regulation:* [ISO 13485:2003: 4.2.1, 7.5.1.1, 8.2.3, 8.2.4; TG(MD)R Sch3 P1 Cl1.4(5)(d)&(e); RDC ANVISA 16/2013: 3.1.3, 4.2, 5.1, 5.2, 5.3, 5.4, 5.6; 5.6.1; 5.6.2; 21 CFR 820.70(a), 820.70(b), 820.75, 820.120, 820.130]

ADDITIONAL COUNTRY REQUIREMENTS

- *Brazil (ANVISA):*

- Determine whether 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. Verify that changes are formally requested, documented and approved before implementation [RDC ANVISA 16/2013: 5.6; 5.6.1; 5.6.2].

AUDITOR REVIEW

- **Establishment of work instructions, procedures, and production processes**
- Production processes that may cause a deviation to a device specification and all validated processes must be controlled and monitored. The planning of production includes the establishment of procedures and work instructions for the control and monitoring of the production processes, including service controls when necessary. Control and monitoring procedures may include in-process and finished device acceptance activities as well as environmental and contamination control measures. The establishment of procedures and work instructions to control the production of the device should provide the controls and tolerances necessary to ensure finished devices conform to product specifications.

TASK 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.**
- *Clause and regulation:* [ISO 13485:2003: 4.2.1, 7.5.1.2.1; TG(MD)R Sch3 P1 Cl1.4(5)(d); RDC ANVISA 16/2013: 5.1.3.1, 5.1.3.4, 5.1.5.3; 21 CFR 820.70(c), 820.70(d), 820.70(e), 820.70(h)

ADDITIONAL COUNTRY REQUIREMENTS

- *Brazil (ANVISA):* 
- Confirm that a pest control program has been established and where chemicals are used as part of the pest control program, the company must ensure that they do not affect product quality [RDC ANVISA 16/2013: 5.1.3.4].
- Verify that the manufacturer has established and maintains housekeeping procedures and schedules for production areas and warehouses, in conformance with production specifications [RDC ANVISA 16/2013: 5.1.3.1].

AUDITOR REVIEW

- **Cleanliness requirements**
- The goal of establishing requirements for product cleanliness is to minimize contamination of the finished device and the manufacturing environment. Sterile devices may require a higher level of control in terms of minimizing the bioburden and particulate contamination in order to assure the desired sterility assurance level is met. Each organization must evaluate the extent of cleanliness required for the proper functioning and intended use of the finished device and implement the 63 necessary control measures. Examples of control measures include, but are not limited to, cleaning procedures, environmental controls (e.g. cleanrooms, or other controlled environments), requirements for attire, and training of personnel. When necessary, confirm the organization has identified the cleanliness requirements for the finished device and the proper controls to achieve the required level of cleanliness.

AUDITOR REVIEW

- **Process agents**
- Process agents, also known as manufacturing materials, are generally defined as materials or substances used to facilitate the manufacturing process, which are present in or on the finished devices as a residue or impurity. Examples of process agents include cleaning agents, mold-release agents, lubricating oils, latex proteins, sterilant residues, etc. The organization must evaluate process agents used during the manufacturing process when the process agent could potentially have an adverse effect on the product. During the design of the product and the development of the manufacturing process, the potential effect of process agents should be considered. If the audit team encounters situations where process agents are being utilized in the manufacturing of the product, and the process agent could potentially have an adverse effect on the product, confirm that the organization has made effective arrangements to control the process agent in a manner commensurate with the risk the agent poses to the finished device

AUDITOR REVIEW

- For example, the organization may need to validate a cleaning process to ensure cutting oil is removed from an orthopedic implant prior to packaging and sterilization.

TASK 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.**
- *Clause and regulation:* [ISO 13485:2003: 4.2.1, 6.3; RDC ANVISA 16/2013: 5.1.2, 5.1.5; CMDR 14; 21 CFR 820.70(g), 820.70(f)]

ADDITIONAL COUNTRY REQUIREMENTS

- *Brazil (ANVISA):*

- Verify that manufacturing facilities are configured in order to provide adequate means for production, avoid 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 16/2013: 5.1.2].

AUDITOR REVIEW

- **Infrastructure requirements**
- The organization is responsible for evaluating the manufacturing facility to ensure that the buildings, utilities, and space allow for the achievement of product conformity. The organization is responsible for ensuring adequate space to prevent mix-ups and ensure orderly handling of products.
- **Equipment maintenance**
- The organization must consider whether maintenance of production equipment may affect product quality. Procedures, including the frequency of maintenance and the records of maintenance must be available for these items of equipment.

AUDIT TASK 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**
- *Additional country-specific requirements*

AUDIT TASK 6

- **• controlling contaminated or potentially contaminated product (including returned**
- **products) in order to prevent contamination of other product, the work environment, or personnel**
- *Clause and regulation:* [ISO 13485:2003: 4.2.1, 6.4; TG(MD)R Sch1 P2 7.2, 8; RDC ANVISA 16/2013: 5.1.3; 21 CFR 820.70(c), 820.70(d), 820.70(e)]

ADDITIONAL COUNTRY REQUIREMENTS

Brazil

- Verify that biosafety standards are used, when applicable [RDC ANVISA 16/2013: 5.1.3.6].

AUDITOR REVIEW

- **Contamination control**
- The organization is responsible for establishing and maintaining procedures to prevent contamination of products, equipment, and personnel by substances that could adversely affect the device. If contamination control measures are necessary to meet specified requirements, cleaning and sanitation procedures and schedules may be required to ensure the contamination control measures are properly functioning. The organization should consider the segregation and decontamination of returned product.
- **Personnel practices**
- Personnel practices must address personnel health, cleanliness, and attire if these could adversely affect product quality or the work environment. In the event that maintenance or other personnel are required to work temporarily under special environmental conditions, these individuals must be appropriately trained or supervised by a trained individual.

AUDIT TASK 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.**
- *Clause and regulation:* [ISO 13485:2003: 4.2.1, 7.5.2.1; TG(MD)R Sch1 P2 8.2, 8.3; Sch3 P1 1.4(5)(d), RDC ANVISA 16/2013: 5.5.2, 5.5.3; 21 CFR 820.75(a)]

ADDITIONAL COUNTRY REQUIREMENTS

- *Brazil (ANVISA):*
- Verify that 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 16/2013: 5.5.2, 5.5.3].

- *Canada (HC):*
- Verify that sterilization methods for devices sold in a sterile state are validated [CMDR 17].

ADDITIONAL COUNTRY REQUIREMENTS

- *United States (FDA):* 
- Process validation is required for sterilization, aseptic processing, injection molding, and welding [21 CFR 820.75; preamble comment 143].

AUDITOR REVIEW

- **Process validation**
- During the planning of product realization, the organization must determine which production processes require validation and which processes can be verified. Process validation may apply to processes that generate components, subassemblies, or finished devices. Process validation is required for processes where the results of the process cannot be fully verified. Processes that cannot be fully verified include processes where clinical or destructive testing is necessary to show that the process produced the desired result, where routine inspection and/or testing does not examine quality attributes essential to the proper functioning of the finished device, or where routine testing has insufficient sensitivity to verify the desired safety and efficacy of the finished product.

AUDITOR REVIEW

- Examples of processes that require validation include, but are not limited to sterilization, aseptic processing, welding, and injection molding. When applicable, confirm that the organization has identified processes which require validation, including validation requirements for any outsourced processes.
- When validating processes, organizations must take into account the current thinking of experts where published information is available (e.g. though the application of ISO standards for sterilization validation).

LINK TO OTHER PROCESSES

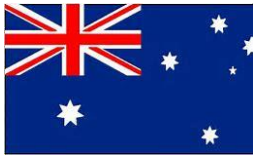
- ***Link: Purchasing***
- The audit team may encounter situations where the organization outsources processes that require validation. During the review of the Purchasing process, review the controls the organization has instituted over suppliers that perform validated processes. This can be particularly important for higher risk validated processes performed by suppliers, since the finished device manufacturer does not have immediate control over those processes.

AUDIT TASK 8

- **Verify that the selected process(es) has been validated if the result of the process cannot be fully verified. 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.**
- *Clause and regulation:* [ISO 13485:2003: 4.2.1, 7.5.2.1; TG(MD)R Sch1 P1 2(1), Sch3 P1 1.4(5)(d); RDC ANVISA 16/2013: 1.2.18, 5.5.1; 21 CFR 820.75(a), 820.75(c)]

COUNTRY SPECIFIC REQUIREMENTS

- *Australia (TGA):*



- 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)].

- *Brazil (ANVISA):*

- Verify that 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 [RDC ANVISA 16/2013: 5.5.1].

COUNTRY SPECIFIC REQUIREMENTS

- *United States (FDA):* 
- 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)].

AUDITOR REVIEW

- **Process validation**
- Process validation means establishing by objective evidence (i.e. data) that a process ***consistently*** produces a ***result*** (e.g., sterility assurance level) or ***product*** meeting predetermined specifications. Remember that the term ***"product"*** applies to components and in-process devices as well as finished devices. Therefore, process validation may apply to processes that generate components, in-process devices, or finished devices.
- **Process validation procedures**
- Some organizations have general process validation procedures. Other organizations establish separate procedures for each individual process validation study. Both methods for establishing process validation procedures are acceptable.

AUDITOR REVIEW

- **Reviewing a validation**
- During review of a validation study, determine when applicable whether:
- 1) The instruments used to generate the data were properly calibrated and maintained;
- 2) Predetermined product and process specifications were established;
- 3) Sampling plans used to collect test samples are based on a statistically valid rationale;
- 4) Data demonstrates predetermined specifications were met consistently;
- 5) Process tolerance limits were challenged;

AUDITOR REVIEW

- 6) Process equipment was properly installed, adjusted, and maintained;
- 7) Process monitoring instruments were properly calibrated and maintained;
- 8) Changes to the validated process were appropriately challenged (if applicable); and
- 9) Process operators were appropriately qualified.

AUDITOR REVIEW

- **Achieving the planned result**
- Process validation activities are predictive, rather than empiric. In order for a process validation study to show the process achieves the planned result, the acceptance criteria must be stated in advance of performing the validation. The data from the process validation study must show the predetermined acceptance criteria have been met.

AUDITOR REVIEW

- **Evidence of nonconformities**
- Process validation studies may also provide valuable insight into process or product nonconformities. For example, the process validation study must demonstrate not only that the process can produce a result or product meeting predetermined specifications but also that the process will consistently produce a result or product meeting predetermined specifications. If process or product nonconformities related to a validated process are encountered at a higher than anticipated rate, it may indicate the process validation study did not confirm that the process could consistently produce a result or product meeting predetermined specifications. Unless the organization recognized this during the process validation study, they may not have investigated the cause of the process inconsistency.

AUDITOR REVIEW

- **If product is supplied sterile:**
- **• Verify the sterilization process is validated, periodically re-validated, and records of**
- **the validation are 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**
- *Clause and regulation:* [ISO 13485:2003: 4.2.1, 7.5.1.3, 7.5.2.2; TG(MD)R Sch1 2(1) & 8.3, Sch3 P1 1.4(5)(d); RDC ANVISA 16/2013: 5.1.6, 5.5; CMDR 17; 21 CFR 820.75, 820.184(d)]

ADDITIONAL COUNTRY REQUIREMENTS

- *Australia (TGA):* 
- 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)].

AUDITOR REVIEW

- **Validation of sterilization processes**
- Sterilization processes include terminal sterilization methods (such as radiation and ethylene oxide) as well as aseptic processing methods. Sterilization processes must be validated, with periodic revalidation as required by established standards or requirements established by the organization.

AUDIT TASK 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.***
- *Clause and regulation:* [ISO 13485:2003: 7.1, 7.5.1.1, 8.1; 8.2.4; TG(MD)R Sch1 P1 2, Sch3 P1 1.4(5)(b)&(e); RDC ANVISA 16/2013: 2.4, 5.1.1, 9.1; 21 CFR 820.70(a), 820.250(a)]

AUDITOR REVIEW

- **Monitoring systems**
- The general goal of monitoring processes and product characteristics during production is to ensure that products conform to the specified requirements defined and approved during the design and development of the device. The organization has the flexibility to determine the controls that are necessary, commensurate with the risk to the finished device if processes or product characteristics do not meet specified requirements. During the audit of production processes, confirm that the control measures are suitable for detecting process or product nonconformities.

AUDIT TASK 11

- **Verify that the processes used in production and service are appropriately controlled, monitored, and operated within specified limits. *In addition, verify that risk control measures identified by the manufacturer for production processes are implemented, monitored and evaluated.***
- *Clause and regulation:* [ISO 13485:2003: 4.2.1, 7.1, 7.5.1.1, 8.1, 8.2.3; TG(MD)R Sch1 P1 2, Sch3 P1 1.4(5)(b)&(e); RDC ANVISA 16/2013: 2.4, 5.1.1, 5.1.6, 8.2, 9.1; 21 CFR 820.70(a), 820.75(b), 820.250]

ADDITIONAL COUNTRY REQUIREMENTS

- *Brazil (ANVISA):* 
- 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 16/2013: 5.1.6].

- *United States (FDA):* 
- 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(a)].

AUDITOR REVIEW

- **Process control and monitoring**
- Processes that may cause a deviation to device specifications and validated processes must be controlled and monitored. Control and monitoring procedures may include in-process and finished device acceptance activities as well as environmental and contamination control measures.
- Compare the process monitoring and acceptance procedures contained or referenced within the records of production specifications with those available to the production personnel. Confirm that the procedures available to the production personnel are the most current approved revisions.

AUDITOR REVIEW

- While in the production area, verify that the building is of suitable design and contains sufficient space to perform necessary operations. Also, verify that the results of control and monitoring activities demonstrate that the process is currently operating in accordance with applicable procedures. This can be done by comparing work instructions with what is actually being done, comparing product acceptance criteria with acceptance activity results, reviewing control charts against specified requirements, etc.

LINKS TO OTHER PROCESSES

- ***Link: Design and Development***
- The design outputs for a device include documents such as diagrams, drawings, specifications, procedures, and the production processes that are essential to the proper manufacturing of the device. Production processes can include not only the manufacturing instructions, but also internal controls, such as the type and extent of acceptance activities, equipment calibration and maintenance intervals, environmental controls, and personnel controls. During the audit of the Production and Service Controls process, consider reviewing production processes that have the highest risk or greatest effect on the essential design outputs.

AUDIT TASK 12

- **Verify that personnel are competent to implement and maintain the processes in accordance with the requirements identified by the organization.**
- *Clause and regulation:* [ISO 13485:2003: 6.2.2; RDC ANVISA 16/2013: 2.3.2; 21 CFR 820.25, 820.70(d), 820.75(b)]

AUDITOR REVIEW

- **Personnel training and qualification**
- Production processes must be performed by adequately trained personnel. The organization must establish procedures for identifying training needs and ensure that all personnel are trained to adequately perform their assigned responsibilities. This training must be documented. In addition, personnel who perform validated processes must be qualified. It is management's responsibility to determine what qualifications are necessary for personnel who perform validated processes.

LINK TO OTHER PROCESSES

- ***Link: Management***
- During the audit of the Production and Service Controls process, ensure that employees who are involved in key operations that affect product realization and product quality have been trained in their specific job tasks, as well as the quality policy and objectives. When appropriate, review the training records for those employees whose activities have contributed to process nonconformities.

TASK 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.**
- *Clause and regulation:* [ISO 13485:2003: 7.5.1.1, 7.6; TG(MD)R Sch3 P1 1.4(5)(e); RDC ANVISA 16/2013: 5.1.5, 5.4; 21 CFR 820.70(g), 820.72]

AUDITOR REVIEW

- **Maintenance and calibration**
- While reviewing the selected production process, make note of significant pieces of process equipment and significant pieces of measuring or test equipment. Consider selecting process and test equipment that, if not properly controlled, could cause devices to not meet specified requirements; or produce inaccurate results that could lead to unrecognized nonconformities. Confirm that the production and test equipment selected for review is suitable for its intended purpose and capable of giving valid results.
- Review the maintenance, control, and calibration procedures (and records) for the equipment selected for review. The initial frequency with which measuring and test equipment is calibrated and maintained is usually based on the equipment manufacturer’s recommendations. As the organization gains experience with the piece of equipment, the frequency of calibration and maintenance may be adjusted, based on a documented rationale.

AUDITOR REVIEW

- **Accuracy and precision**
- When accuracy and precision is a factor in the validity of the result of the measuring equipment, the required accuracy and precision should be defined during the planning of product realization to ensure the equipment is suitable and capable of providing valid results.

AUDITOR REVIEW

- **Reviewing records**
- If production equipment or test equipment is found to be outside of its maintenance or calibration requirements, verify that the organization made an assessment of the effect of the out-of tolerance situation on in-process, finished, or released devices, based on risk. Equipment adjustment, calibration, and maintenance procedures and records may provide insight into nonconformities. Review these procedures and records to determine whether inadequate procedures or the organization's failure to comply with adequate procedures contributed to the nonconformity. For example, determine whether the lack of specified equipment adjustment or maintenance contributed to the production of nonconforming product.

TASK 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.**
- *Clause and regulation:* [ISO 13485:2003: 7.6; TG(MD)R Sch3 P1 1.4(5)(e); RDC ANVISA 16/2013: 5.4; 21 CFR 820.72(a)]

AUDITOR REVIEW

- **Control of monitoring and measuring devices**
- Organizations must maintain proper calibration, storage, and handling controls for measuring, monitoring, and test equipment used in the development, production, installation, and servicing of product. Calibration must be traceable to a national or international measurement standard if one is available. If calibration services are provided by a supplier, the supplier controls are to be applied to ensure calibration is performed competently. Proper controls will help instill confidence in results obtained from the use of the equipment.

AUDITOR REVIEW

- **Procedures**
- Organizations must define, implement, and maintain procedures for the control of monitoring and measuring devices. The organization may choose to develop general policies for the control of monitoring and measuring devices, along with separate, more specific procedures for the actual calibration and control of each piece of equipment. Procedures must account for any environmental controls necessary for the equipment to produce valid results, as well as any specific storage or handling requirements when necessary. For example, a set of calibrated calipers may require storage in a padded case to maintain the required accuracy and precision. Confirm that the organization has the proper procedures and controls in place to preserve the proper functioning of monitoring, measuring, and test equipment.

AUDITOR REVIEW

- **When equipment is found to be out-of-tolerance**
- The organization may discover that monitoring or measuring equipment is no longer within its adjustment or calibration tolerance. In these situations, the organization must assess and record the validity of previous measuring results and take appropriate action on the equipment and any product affected.

TASK 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.**
- *Clause and regulation:* [ISO 13485:2003: 7.5.2.1, 7.6; RDC ANVISA 16/2013: 5.5.2; 21 CFR 820.70(i)]

AUDITOR REVIEW

- **Validation of production and quality system software**
- Production process control software (and any other software used in the organization's quality system) must be validated for its intended use according to an established protocol. If the production process the audit team selected for review is controlled with software, review the software validation documents and records. Software validation documents and records should include:
- a) A software requirements document describing the intended use(s) and user needs associated with the software.
- b) An established validation protocol or similar document describing the activities necessary to demonstrate that the software requirements can be met.

AUDITOR REVIEW

- c) Records of the results of the software validation activities described in the software validation protocol or similar document.
- d) Records that software changes are appropriately controlled (where applicable).

AUDITOR REVIEW

- For off-the-shelf quality management system software and software-controlled production or test equipment, it may not be possible, practical, or necessary for the device manufacturer to review the software code or the various software verification test cases that are typically performed by the software or equipment manufacturer. However, the device manufacturer must still ensure the software is capable of functioning according to the device manufacturer’s needs. The validation to confirm the software meets the device manufacturer’s needs must be performed according to a protocol or similar document with predetermined acceptance criteria.

AUDITOR REVIEW

- If multiple software driven systems are used in the production process, be sure to assess the system(s) most likely to have an impact on the finished device's ability to meet specified requirements. Not all software driven systems used in a production process will need to be audited during each audit.

AUDIT TASK 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 and labeling specifications. *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.*** 72
- *Clause and regulation:* [ISO 13485:2003: 4.2.1; 4.2.4; 7.1; 7.5.3.2.1; TG(MD)R Sch3 P1 1.4(5) (c),(d),(e) & 1.9; RDC ANVISA 16/2013: 1.2.26, 2.4, 4.2, 5.2, 6.4; CMDR 9(2), 21-23, 52-56, 66-68; 21 CFR 820.65, 820.181]

ADDITIONAL COUNTRY REQUIREMENTS

- *Brazil (ANVISA):* 
- Verify that the manufacturer has established and maintains procedures to ensure integrity and to prevent accidental mixing of labels, instructions, and packaging materials [RDC ANVISA 16/2013: 5.2.2.1].
- Confirm that the manufacturer has ensured that labels are designed, printed and, where applicable, applied so that they remain legible and attached to the product during processing, storage, handling and use [RDC ANVISA 16/2013: 5.2.2.2].

ADDITIONAL COUNTRY REQUIREMENTS

- *Canada (HC):* 
- Verify that the manufacturer maintains objective evidence that devices meet the safety and effectiveness requirements of the CMDR [CMDR 9(2)].
- Verify that 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].
- Verify that 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].

ADDITIONAL COUNTRY REQUIREMENTS

- *United States (FDA):* 
- If a control number is required for traceability, confirm that such control number is on or accompanies the device throughout distribution [21 CFR 820.120(e)].

AUDITOR REVIEW

- **Records**
- The required records for each type or model of device include documents such as diagrams, drawings, specifications, and procedures associated with the device, its packaging and labeling; as well as, quality management system and production process requirements; and if applicable, installation and servicing requirements. Documents and records associated with production processes can include not only the manufacturing instructions, but also internal controls, such as the type and extent of acceptance activities, equipment calibration and maintenance intervals, environmental controls, and personnel controls. These documents and records provide the requirements and instructions for the proper manufacturing, labeling, packaging, and testing of the device to assure specified requirements are met during the production of each batch of devices. For the device(s) the audit team has selected to review, confirm that the required records have been established.

AUDITOR REVIEW

- **General traceability**
- It is the responsibility of the organization to establish procedures for traceability. For devices that are not implanted and are not life-supporting or life-sustaining, the organization has the flexibility to determine which raw materials and components are required to be traceable, commensurate with the risk posed by the device in the event the component does not meet specified requirements.
- Traceability systems commonly include elements such as written procedures describing the control numbering system to be used, as well as the documentation of lot numbers, control numbers, or serial numbers identifying the batch of components, subassemblies, finished devices, packaging, and labeling in order to aid their identification in the manufacturing process.

LINKS TO OTHER PROCESSES

- ***Link: Design and Development***
- During the design and development of the device, the essential design outputs for the proper functioning of the device should have been identified. Raw materials, components, and subassemblies should have been considered for traceability if their nonconformity could result in the finished device not meeting its specified requirements and essential functions.

AUDIT TASK 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, and the device is manufactured according to the file referenced in task 16.**
- *Clause and regulation:* [ISO 13485:2003: 4.2.1, 7.5.1.1; 8.2.4.1; RDC ANVISA 16/2013: 3.2, 5.2, 6.4; 21 CFR 820.184]

ADDITIONAL COUNTRY REQUIREMENTS

- *Brazil (ANVISA):* 
- Verify that 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 16/2013: 3.2.1].
- Verify that labeling has not been released for storage or use until a designated individual has examined the labeling for accuracy. The approval, including the date, name, and physical or electronic signature of the person responsible, must be documented in the device history record [RDC ANVISA 16/2013: 5.2.2.3].

ADDITIONAL COUNTRY REQUIREMENTS

- *United States (FDA):* 
- Verify that labeling is not released for storage or use until a designated individual has examined the labeling for accuracy. The release, including the date and signature of the individual performing the examination must be documented in the device history record (i.e. batch record) [21 CFR 820.120(b)].
- Confirm that labeling is stored in a manner that provides proper identification and prevents mix-ups. Verify labeling and packaging operations are controlled to prevent labeling mix-ups [21 CFR 820.120(c) and (d)].
- Verify that 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(e), 820.184(e)].

AUDITOR REVIEW

- **Verify manufacturing of the device**
- Verify that each batch of devices was manufactured in accordance with product and production specifications, being mindful that in some instances, a batch can be a single device. This verification should include a review of the purchasing controls and receiving acceptance activities applied to at least one significant component or raw material, in-process and final finished device acceptance activities and results, environmental and contamination control records (if applicable), and sampling plans for process and environmental controls and monitoring.

AUDITOR REVIEW

- The record for each batch of devices must include, or refer to the location of, the following information:
- (a) The dates of manufacture;
- (b) The quantity manufactured;
- (c) The quantity released for distribution;
- (d) The acceptance records which demonstrate the device has been manufactured in accordance with the planned arrangements and defined product specifications;
- (e) The primary identification label and labeling used for each production unit;
- (f) Any device identification(s) and control number(s) used; and
- (g) A provision to indicate that the record has been verified and approved.

AUDITOR REVIEW

- **Determine if there are problems**
- If, during the accomplishment of this audit task, the audit team observes evidence that the process is outside the organization’s acceptance range for operating parameters or that product nonconformities exist, confirm that the nonconformities were handled appropriately, with input into the Measurement, Analysis and Improvement process when appropriate.

TASK 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.**
- *Clause and regulation:* [ISO 13485:2003: 4.2.1, 7.5.3.2.2, 8.2.4.2; 21 CFR 820.65]

ADDITIONAL COUNTRY REQUIREMENTS

- *Canada (HC):* 
- Verify that 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].
- Verify that 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].

ADDITIONAL COUNTRY REQUIREMENTS

- *United States (FDA):* 
- 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 periodic audits of the tracking system [21 CFR 821].

AUDITOR REVIEW

- **Traceability of implantable, life-supporting or life-sustaining devices**
- Manufacturers of finished devices whose failure could result in serious injury or harm to the user must implement a traceability system. The traceability system must allow for each batch of finished devices to be traced by a control number or similar mechanism throughout the distribution chain. Organizations must also provide for the control and traceability of components and materials used in the manufacture of the device, as well as documentation of the manufacturing conditions when manufacturing conditions could cause the finished device to not meet specified requirements (e.g. cleanroom conditions).
- The determination of which components and raw materials may be required to be traceable may be made by the organization using risk management tools, such as risk analysis, or by identification of the components and processes used to fulfill the essential design outputs.

AUDITOR REVIEW

- **Tracking**
- Some regulatory authorities participating in the MDSAP have requirements for tracking certain types of devices to the end-user. For regulatory authorities that have tracking requirements, these requirements generally apply to a small subset of devices that are life-sustaining or life supporting, intended for implant longer than one year, or are considered by the regulatory authority to be high risk. If the organization manufactures or distributes a device that falls under a tracking requirement, confirm that the organization has the necessary systems in place to provide for tracking each device to the end-user. The organization's tracking system must be periodically reviewed and audited by the organization to confirm that the tracking system is effective.

TASK 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.**
- *Clause and regulation:* [ISO 13485:2003: 7.5.3.3; RDC ANVISA 16/2013: 6.1.2, 6.4; 21 CFR 820.86]

AUDITOR REVIEW

- **Identification**
- Identification is generally defined as the description of the product that distinguishes it from other product. Organizations must define, document, and implement processes for the identification and control of product, including components, process agents, subassemblies, finished devices, packaging, and labeling. This can be accomplished through the use of part numbers, lot numbers, batch numbers, work order numbers, quantities, supplier name, as well as other means. The extent of identification activities should be based on the complexity and risk of the product.

AUDIT TASK 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.**
- *Clause and regulation:* [ISO 13485:2003: 7.5.4]

AUDITOR REVIEW

- **Safeguarding customer property**
- The organization is responsible for safeguarding customer property while it is under the organization’s control. If any customer property is lost, damaged, or otherwise unsuitable for use, this must be reported to the customer and records maintained.

AUDIT ASK 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.
- *Clause and regulation:* [ISO 13485:2003: 4.2.1, 7.4.3, 8.2.4.1, 8.2.4.2; TG(MD)R Sch1 P1 2, Sch3 P1 Cl1.4(5)(d); RDC ANVISA 16/2013: 5.3.1, 5.3.2, 5.3.3, 5.3.4, 9.2; 21 CFR 820.80, 820.250(b)]

ADDITIONAL COUNTRY REQUIREMENTS

- *Brazil (ANVISA):*

- Verify that sampling plans are defined and based on valid statistical rationale. Each manufacturer must establish and maintain procedures to ensure that sampling methods are suitable for their intended use and are reviewed regularly. A review of sampling plans should consider the occurrence of nonconforming product, quality audit reports, complaints and other indicators [RDC ANVISA 16/2013: 9.2].

ADDITIONAL COUNTRY REQUIREMENTS

- *United States (FDA):* 
- Verify that the manufacturer establishes and maintains procedures to ensure that sampling methods are adequate for their intended use and ensure that when changes occur, the sampling plans are reviewed [21 CFR 820.250(b)].

AUDITOR REVIEW

- **Recognized acceptance activities**
- Organizations are expected to define, document, and implement systems and procedures for acceptance activities to verify that products, including finished devices, in-process devices, components, packaging, and labeling conform to specified requirements. Recognized acceptance activities include, but are not limited to, inspections, tests, review of certificates of analysis, and supplier audits. Effective acceptance procedures and systems directly affect the ability of an organization to demonstrate that the process and product meets specifications. During the audit of acceptance activities for the devices selected for audit, confirm that the organization has defined processes for receiving, in-process, and final acceptance activities. Determine if the acceptance activities have been implemented. One way to accomplish this audit task is to review a sample of batch records and confirm that the acceptance activities have been documented and that the acceptance activities show specified requirements have been met. Records should identify who conducted acceptance activities.

AUDITOR REVIEW

- The acceptance status of incoming, in-process, and finished devices must be identified. The identification of acceptance status must be maintained throughout manufacturing, packaging, labeling, and where applicable, installation and servicing to ensure that only product which has passed the required acceptance activities is distributed, used, or installed.

AUDITOR REVIEW

- **Acceptance activities involving related firms**
- The audit team may encounter situations where the organization receives incoming product from a financial or corporate affiliate. It is the receiving organization's responsibility to perform and record the necessary acceptance activities to ensure the received product conforms to specified requirements, as well as applying the necessary purchasing controls to the supplier. Acceptance activities and purchasing controls apply to all product received from outside of the finished manufacturer, whether a payment occurs or not, and regardless of the corporate or financial relationship of the supplier to the finished device manufacturer.

AUDITOR REVIEW

- **Sampling**
- The audit team may encounter the use of sampling during acceptance activities. For example, an organization might choose to use sampling to perform receiving acceptance on a large lot of incoming components. When used, sampling plans must be written and based on a valid statistical rationale and a risk-based methodology.
- **Combination of controls**
- An important concept to remember is that quality cannot be inspected or tested into products. Organizations must establish an appropriate mix of acceptance activities and purchasing controls to ensure products will meet specified requirements. The type and extent of acceptance activities can be based in part on the amount of purchasing controls applied to the supplier, the demonstrated capability of the supplier to provide quality products, and the potential impact of the product on the finished device, including the risk the device poses to the patient or user if specified requirements are not met.

AUDITOR REVIEW

- Organizations that conduct quality control solely in-house must still assess the capability of suppliers to provide acceptable products.
- **Evidence of inadequate acceptance activities**
- The audit team may encounter instances where product has been deemed acceptable by the successful completion of acceptance activities but the product is later shown to not meet specified requirements (i.e. failure of the device leading to product complaint). This can be an indication that the acceptance activities are not sufficient to identify nonconformities. Confirm that the organization has taken the appropriate action to determine the suitability of the acceptance activities.

LINK TO OTHER PROCESSES

- ***Link: Purchasing, Design and Development***
- The audit team should consider reviewing the purchasing controls and requirements for suppliers of higher risk products. The audit team should also consider reviewing the purchasing controls and requirements for suppliers of products that undergo minimal acceptance activities at the device manufacturer, particularly if the supplied product is manufactured using a process that requires validation. During the review of acceptance activities, if the audit team encounters situations where records of acceptance activities for supplied product reveal products that do not meet specified requirements, consider selecting those suppliers for review during the audit of the organization's Purchasing process.

LINK TO OTHER PROCESSES

- The establishment of the necessary purchasing controls and required acceptance activities is a design output. The degree of the purchasing controls necessary and extent of acceptance activities should be based on the risk posed by the product not meeting its specified requirements and essential design outputs.

TASK 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.***
- *Clause and regulation:* [ISO 13485:2003: 7.5.3.1, 8.3; TG(MD)R Sch1 P1 2, Sch3 P1 Cl1.4(5)(b); RDC ANVISA 16/2013: 6.5.1, 6.5.2; 21 CFR 820.60, 820.90(a), 820.86, 820.100(a)]

AUDITOR REVIEW

- **Procedures**
- The purpose of controlling nonconforming product is to prevent the unintended use and distribution of nonconforming product, including components, processing agents, in-process devices, and finished devices. Confirm that the organization has defined and implemented procedures for the identification, control, segregation, evaluation, and disposition of nonconforming product.

AUDITOR REVIEW

- **Handling nonconforming product**
- The organization can address nonconforming product by taking action to eliminate the detected nonconformity (e.g. sorting an incoming lot of components to remove components that do not meet specifications), authorizing its use, release, or acceptance under concession, or by taking action to prevent its original intended use (e.g. allowing the components or devices to be used as demonstration units at marketing conferences).
- Until a disposition can be made, the organization must have a process to properly identify nonconforming product to prevent its accidental or unauthorized use. One example is tagging and moving the nonconforming product to a controlled enclosure away from the production area.

AUDITOR REVIEW

- If nonconforming product is accepted under concession, the records of the identity of the person authorizing the concession must be maintained.
- If nonconforming product has been detected after a product has been released and put into use the organization must consider the risks associated with the device and may need to consider an advisory notice or recall.

AUDITOR REVIEW

- **Evaluation of nonconforming product**
- The evaluation of a nonconformity must include a determination of the need for an investigation and notification of the persons or organizations responsible for the nonconformity, such as a supplier. Ensure that the organization has adequately established an interface / interaction between the processes for the identification of non-conforming product and the processes for corrective action. These interactions should be evident in the quality manual.

LINK TO OTHER PROCESSES

- ***Link: Measurement, Analysis and Improvement***
- The audit team should be mindful of any instances where the acceptance of nonconforming product has led to finished devices not meeting specified requirements. This information can often be found in records of acceptance activities and complaint records. During the review of the organization's corrective and preventive actions, the auditors may have noted instances where nonconforming products were found to be the underlying cause of quality problems and complaints. The audit team should consider reviewing the organization's handling and evaluation of nonconforming products that were determined to be the underlying cause of quality problems. Ensure that the analysis of data regarding nonconforming product is considered as an input to the organization's Measurement, Analysis and Improvement process and that corrective or preventive actions have been implemented when necessary.

TASK 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.**
- *Clause and regulation:* [ISO 13485:2003: 8.3; RDC ANVISA 16/2013: 6.5.3; 21 CFR 820.90(b)]

AUDITOR REVIEW

- **Reworking nonconforming product**
- The audit team may encounter instances where the organization has chosen to address nonconforming product by means of reworking the component, subassembly or finished device. The organization must have suitable approved procedures in place to address nonconforming product destined for rework. Reworked product must be re-evaluated or re-tested to ensure it meets its original specified requirements. Rework must be documented.
- Be mindful of instances where the underlying cause of quality problems, such as complaints that finished devices do not meet specified requirements, are traced to devices that have been reworked. This can be an indication that the rework process was not adequate to ensure the finished device meets specifications.

AUDITOR REVIEW

- Additionally, rework of products manufactured using validated processes can be an indication that the process cannot consistently produce product that meets specified requirements. If the audit team notes a pattern of reworking products that are manufactured using a validated process, consider reviewing the process validation to confirm that the organization has data to show the process is effective, reproducible, and stable; and that the organization is operating the process within the validated parameters.

TASK 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.**
- *Clause and regulation:* [ISO 13485:2003: 4.2.1, 7.5.3.1, 7.5.5; TG(MD)R Sch1 P1 5; RDC ANVISA 16/2013: 5.2.1, 6.1.1, 6.2.1; CMDR 14; 21 CFR 820.130, 820.140, 820.150, 820.160(a)]

ADDITIONAL COUNTRY REQUIREMENTS

- *Brazil (ANVISA):*
- Verify that the manufacturer has established procedures for the packaging of products in order to protect the product from deterioration, damage, or contamination during processing, storage, handling, and distribution [RDC ANVISA 16/2013: 5.2.1].

- *United States (FDA):*
- Confirm that 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)].
- Verify that 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)].

AUDITOR REVIEW

- **Ensuring proper handling**
- The organization must have a documented system that defines product handling requirements at all stages of manufacturing to prevent mix-ups, damage, and deterioration. This can include specified requirements for storage and shipping to ensure the preservation of the product to its destination. For example, an in-vitro diagnostic device may need to be stored and shipped in a frozen state to maintain proper shelf-life of the reagents. These handling requirements should have been considered during the planning of product realization for the device. When necessary, confirm that the needed control measures are implemented to ensure the conformity of product to its specified requirements.

TASK 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.**
- *Clause and regulation:* [ISO 13485:2003: 4.2.1; 5.2, 7.2.2, RDC ANVISA 16/2013: 6.3; 21 CFR 820.160(a)]

ADDITIONAL COUNTRY REQUIRMENTS

- *Brazil (ANVISA):* 
- Verify that the manufacturer maintains distribution records which include or make reference to: the name and address of the consignee, the identification and quantity of products shipped, the date of dispatch, and any numerical control used for traceability [ANVISA RDC 6.3].

- *Canada (HC):* 
- Verify that 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].
- Verify that 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].

ADDITIONAL COUNTRY REQUIREMENTS

- *United States (FDA):* 
- 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)].

AUDITOR REVIEW

- **Distribution records**
- The organization must maintain distribution records which include or refer to the location of the initial consignee, the identification and quantity of devices shipped, the date shipped, and any control numbers used.

TASK 26

- **If installation activities are required, confirm that records of installation and verification activities are maintained.**
- *Clause and regulation:* [ISO 13485:2003: 7.5.1.2.2; RDC ANVISA 16/2013: 8.1; 21 CFR 820.170]

AUDITOR REVIEW

- **Installation activities**
- When a device must be installed for suitable functioning, the organization must establish procedures and instructions to ensure proper installation. These instructions must be made available to personnel performing the installation. Installation activities must be documented.
- **Determining the extent of review**
- In the absence of identified quality problems related to the installation of the selected device, the audit team may choose to limit the review of the installation process to confirming the necessary procedures are in place.

TASK 27

- **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.**
- *Clause and regulation:* [ISO 13485:2003: 4.2.1, 7.5.1.2.3, 8.4; RDC ANVISA 16/2013: 8.2; 21 CFR 820.200]

ADDITIONAL COUNTRY REQUIREMENTS

- *Brazil (ANVISA):* 
- Confirm that the manufacturer has established and maintains procedures to ensure that records of servicing activities are kept with the following information: the product serviced; the control number of the product serviced; the date of completion of service; identification of the service provider; description of service performed; and results of inspections and tests performed [RDC ANVISA 16/2013: 8.2.1].
- Verify that 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 16/2013: 8.2.2].

ADDITIONAL COUNTRY REQUIREMENTS

- *United States (FDA):* 
- Verify that each manufacturer who receives a service report that represents an event that must be reported to FDA as a medical device report automatically considers the report a complaint [21 CFR 820.200(c)].
- Confirm that 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)].

AUDITOR REVIEW

- **Procedures**
- When servicing is a specified requirement, the organization must define and maintain procedures, instructions, and processes for performing and verifying that servicing activities meet specified requirements.
- **Servicing process**
- When organizations implement servicing programs, the organization must ensure components used for repair are acceptable for the intended use, inspection and test procedures are available, and test equipment is properly maintained to ensure serviced devices will perform as intended after servicing. Personnel performing service activities must have the appropriate training.

AUDITOR REVIEW

- The audit team may observe instances where nonconformities occurred and/or complaints were received after the servicing of the device. This can be an indication that the service activity was not properly controlled or that service personnel do not have the proper equipment, instructions, or training to perform the required service.
- **Analysis of service reports**
- Service reports can be an important source of quality data for input into the organization's Measurement, Analysis and Improvement process. When necessary, confirm data regarding service reports is analyzed for possible corrective action or preventive action. Service reports must also be analyzed to determine if the service event represents an adverse event that is reportable to regulatory authorities.

AUDITOR REVIEW

- In some instances, product complaints may be initially recorded by the organization as a service report. For example, a user may report to the device manufacturer that a patient blood parameter monitoring device is not working correctly and requires service. Upon receipt of the device from the user by the organization's service function, the service function notes the reason the monitoring device is not working is that an essential component within the device failed prematurely. This service report should be considered by the organization to be a complaint and analyzed by the manufacturer to determine if an adverse event report needs to be submitted to regulatory authorities.

LINK TO OTHER PROCESSES

- ***Link: Measurement, Analysis and Improvement***
- During the audit of the organization's Measurement, Analysis and Improvement process, the audit team may have already confirmed that quality data from the analysis of servicing activities is analyzed for possible corrective or preventive action. When reviewing the organization's service reports, the audit team should be mindful of service reports that appear to be product complaints. Ensure that service reports that appear to be complaints have been appropriately addressed. In some instances, a similar quality problem for a particular device may be found in the service reports and the complaint records. In these instances, confirm that the organization is taking appropriate corrections and/or corrective actions considering a similar quality problem is observed in multiple data sources.

AUDIT TASK 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.***
- *Clause and regulation:* [ISO 13485:2003: 7.1, 7.5.1.1, 7.5.1.2.2, 7.5.1.2.3; TG(MD)R Sch1 P1 2; RDC ANVISA 16/2013: 2.4; 21 CFR 820.160(a), 820.170(a), 820.200(a)]

AUDITOR REVIEW

- **Risk control**
- The requirements for delivery, installation, and servicing of a particular device should have already been evaluated and addressed by the organization during design and development and planning for product realization. If risk control measures were identified involving the delivery, installation, and servicing for a particular device, confirm that the necessary processes have been implemented to ensure the risk control measures are in place. For example, an organization may have identified that in order for a medical imaging device to give accurate images, servicing must be performed by trained personnel according to specific instructions. Risk control measures might include warnings on the imaging device that only authorized personnel should service the device and the design of a unique tool to access the inside of the device that is only provided to authorized service personnel.

AUDIT TASK 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.**
- Clause and regulation: [ISO 13485:2003: 4.1; RDC ANVISA 16/2013: 2.2.1]