# Measurement Analysis and Improvement

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# CHAPTER 3 MDSAP COMPANION DOCUMENT

- One of the most important activities in the quality management system is the identification of existing and potential causes of product and quality problems. Such causes must be identified so that appropriate and effective corrective or preventive actions can take place. These activities are carried out under the Measurement, Analysis and Improvement process.
- The purpose of an organization's Measurement, Analysis and Improvement process is to collect and analyze information, identify and investigate existing and potential causes of product and quality problems, and take appropriate and effective corrective or preventive action to prevent recurrence

# MEASUREMENT ANALYSIS AND IMPROVEMENT

- or occurrence. It is essential that an organization verify or validate these actions, communicate corrective and preventive action activities to responsible people, provide relevant information for management review, and document these activities. These activities will help the organization deal effectively with existing or potential product and quality problems, prevent their recurrence and/or occurrence, and prevent or minimize device failures or other quality problems.

# MEASUREMENT ANALYSIS AND IMPROVEMENT

- 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 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.

# MEASUREMENT ANALYSIS AND IMPROVEMENT

- The Measurement, Analysis and Improvement process is the second primary process to be audited per the MDSAP audit sequence. When applicable, information regarding device or identified quality management system nonconformities observed during the audit of the Measurement, Analysis and Improvement process should be used to make decisions as to design projects or design changes to assess during audit of the Design and Development process, suppliers to evaluate during audit of the Purchasing process, and processes to review during audit of the Production and Service Controls process.

# AUDITOR REVIEW

- **Purpose:** The purpose of auditing the Measurement, Analysis and Improvement process is to verify that the manufacturer's processes ensure that information related to products, processes, or the quality management system is collected and analyzed to identify actual and potential product, process, or quality system nonconformities, that problems and potential problems are investigated, and that appropriate and effective corrective actions and preventive actions are taken.

# AUDIT REVIEW

- **Outcomes:** As a result of the audit of the Measurement, Analysis and Improvement process, objective evidence will show whether the organization has:
- A) Defined, documented, and implemented procedures for measurement, analysis and improvement that address the requirements of the quality management systemstandard and participating MDSAP regulatory authorities
- B) Identified, analyzed, and monitored appropriate sources of quality data to identify nonconformities or potential nonconformities and determined the need for corrective or preventive action

# AUDITOR REVIEW

- Ensured investigations are conducted to identify the underlying cause(s) of nonconformities and potential nonconformities, where possible
- D) Implemented appropriate corrective action to eliminate the recurrence or preventive action to prevent the occurrence of product or quality system nonconformities, commensurate with the risks associated with the nonconformities or potential nonconformities encountered
- E) Reviewed the effectiveness of corrective action and preventive action

# AUDITOR REVIEW

- F) Utilized information from the analysis of production and post-production quality data to amend the analysis of product risk, as appropriate

# LINKS TO OTHER PROCESSES

- **Links to Other Processes:** Design and Development; Production and Service Controls; Purchasing; Medical Device Adverse Events and Advisory Notices Reporting; Management

# TASK 1 MA&I

- **Verify that procedures for measurement, analysis and improvement which address the requirements of the quality management system standard and regulatory authorities have been established and documented. Confirm the organization maintains and implements procedures to monitor and measure product conformity throughout product realization, as well as procedures that provide for mechanisms for feedback to provide early warnings of quality problems and the implementation of corrective action and preventive action.**
- *Clause and regulation:* [ISO 13485:2016: 4.2.1, 8.1, 8.2.1, 8.2.6, 8.5; TG(MD)R Sch3 P1 1.4(3)(a),(b), (5)(b)(iii), (f); ; RDC ANVISA 16/2013: 5.3.1, 7.1, 7.2; MHLW MO169: 6, 54, 55, 58, 62, 63, 64; 21 CFR 820.100(a)]

# ADDITIONAL COUNTRY REQUIREMENTS

- *Brazil (ANVISA):* 
- 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 16/2013: 7.1.1.6].
- *United States (FDA):* 
- Verify 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)].

# ADDITIONAL COUNTRY REQUIREMENTS

- Confirm 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)].

# AUDITOR REVIEW

- Each organization must establish and maintain procedures for analyzing data and implementing corrective action and preventive action. The procedures must include requirements for:
- (a)Analyzing feedback, conformity to product requirements, characteristics and trends of processes and products (including opportunities for preventive action), and conformity of suppliers
- (b)Reviewing nonconformities, including customer complaints
- (c)Evaluating the need for action to prevent recurrence or occurrence of nonconformities

# AUDITOR REVIEW

- (d)Recording the results of any investigations and of actions taken
- (e)Identifying the action(s) needed to correct and prevent recurrence or occurrence of nonconforming product and other quality problems
- (f) Ensure that action is effective and does not adversely affect the finished device
- (g)Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems

# AUDITOR REVIEW

- (h)Ensuring 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

# TASK 2 MA&I

- **Determine if appropriate sources of quality data have been identified for input into the measurement, analysis and improvement process, including customer complaints, feedback, service records, returned product, internal and external audit findings, nonconformities from regulatory audits and inspections, and data from the monitoring of products, processes, nonconforming products, and suppliers. Confirm that data from these sources are accurate and analyzed according to a documented procedure for the use of valid statistical methods (where appropriate) to identify existing and potential product and quality management system nonconformities that may require corrective or preventive action.**

# TASK 2 MA&I

- Clause and regulation: [ISO 13485:2016: 7.5.4, 8.1, 8.2.1, 8.2.6, 8.4; TG(MD)R Sch3 P1 1.4(3)(a),(b), (5)(b)(iii), (f); RDC ANVISA 16/2013: 7.1.1.1, 9.1; MHLW MO169: 43, 54, 55, 58, 61; 21 CFR 820.100(a)]

# AUDITOR REVIEW

- **Quality data sources**
- Complaints, records of acceptance activities and concessions, nonconformities identified in internal audits, service records, acceptability of supplied product and supplier performance, and data presented in management review are common quality data sources that are useful in identifying quality problems,among others.
- Some sources of quality data that may be useful in identifying potential problems are acceptance activities, such as component, in-process, or finished device testing; environmental monitoring, and statistical process control (SPC). Results of acceptance activities may indicate an unfavorable trend that left unattended may result in product nonconformity.

# AUDITOR REVIEW

- During the audit of the Measurement, Analysis and Improvement process, it is recommended that the auditor(s) review the previous audit report if there is one for the organization. If this information is available, the audit team should use the information in the report when selecting some quality data sources to review during the audit. For example, if service records were reviewed during the previous audit and the organization was handling the data appropriately, the audit team may wish to select a different data source for review during the audit. However, if the previous audit documented that the data from service records were not being entered into the Measurement, Analysis and Improvement process appropriately, the audit team should consider reviewing service records again to determine whether the previous

# AUDITOR REVIEW

- deficiency was effectively addressed.
- Select some sources of quality data. Determine if the data from these sources were entered into the organization's Measurement, Analysis and Improvement process for analysis and whether
- the information was complete, accurate, and entered in a timely fashion. Be mindful of quality problems that appear in more than one data source. For example, device nonconformities noted in complaints should be compared with similar nonconformities noted during the organization's analysis of data from other data sources such as product reject reports, or nonconforming product or process reports.

# AUDITOR REVIEW

- This comparison will help the organization and the audit team understand the full extent of the quality problem

# MANUFACTURER

- **Analysis of data**
- An organization should use data from a variety of quality data sources to identify the causes of existing product and quality problems. Not all organizations will have the same sources of quality data. For example, service records and installation reports are quality data sources that may not be found at every device manufacturer. As the audit team is conducting the audit, determine what sources of quality data the organization has identified. The audit team will also determine whether the sources identified by the organization are appropriate and if the organization is analyzing quality data from these sources to identify existing product problems as well as existing problems within its quality system. Later in the evaluation of the

# MANUFACTURER

- Measurement, Analysis and Improvement process, the audit team will be sampling raw quality data to determine how the organization analyzed the quality data and responded to the results of its analysis.
- An organization should also use data froma variety of quality data sources to identify the causes of potential product and quality problems. The organization should be looking for trends or other indications of potential problems before the problems actually occur. The organization may choose to perform analysis of competing devices, including reviewing advisory notices related to competing devices, to determine whether similar nonconformities could occur in the organization’s devices. Determine whether the organization can identify potential product and quality problems that may require preventive action.

# MANUFACTURER

- An organization has the flexibility to use whatever methods of analysis are appropriate to identify existing and potential causes of nonconforming product or other quality problems. However, an organization must use appropriate statistical methodology where necessary to detect recurring quality problems.
- An organization must also use appropriate statistical tools when it is necessary to use statistical methodology. It should not misuse statistics in an effort to minimize the problem or avoid addressing the problem.

# LINKS TO OTHER PROCESSES

- ***Link: Purchasing***
- During the audit of the Measurement, Analysis and Improvement process, the audit team may encounter data involving product nonconformities, including complaints involving finished devices, where the underlying cause of the quality problem has been traced to a supplied product. During the audit of the Purchasing process, the audit team should consider selecting suppliers to audit that have corrective action indicators of nonconformities with supplied components or processes.

# TASK 3 MA & I

- **Determine if investigations are conducted to identify the underlying cause(s) of detected nonconformities, where possible. *Confirm investigations are commensurate with the risk of the nonconformity.***
- *Clause and regulation:* [ISO 13485:2016: 8.5.2; TG(MD)R Sch3 P1 1.4(3)(a),(b), (5)(b)(iii),(f), TG(MD)R Sch1 P1 2; RDC ANVISA 16/2013: 2.4, 6.5.1, 7.1.1.2; MHLW MO169: 63; 21 CFR 820.100 (a)(2)]
- *Additional country-specific requirements:* None

# AUDITOR REVIEW

- Organizations must define and implement a process for investigations. The process should consist of a structured, risk-based approach (in a mature QS) intended to determine the root or underlying cause(s) of a quality problem. Criteria should be defined to determine when an investigation is necessary and the extent of the investigation. The investigation should be based on a pre-approved plan or other defined approach, timelines should be defined, roles and responsibilities should be assigned, and the course of action should be assessed when the underlying cause cannot be determined. The results of the investigation must be recorded. The depth of the organization’s investigation of a process, product, or other quality system nonconformity should be commensurate with the significance and risk of the nonconformity.

# AUDITOR REVIEW

- The process for determining the extent of an investigation may be linked to the organization's risk management system and the design outputs essential to the proper functioning of the device.
- A correction is not the same as a corrective action. In order for an organization to take a corrective action (i.e., action taken to prevent recurrence of an existing nonconformity), an investigation
- must be conducted to determine the cause of the nonconformity. Often an organization will only make a correction to handle the immediate problem (e.g. relabeling a lot of mislabeled finished devices). Determining the cause of the lot of mislabeled finished devices is more difficult and may be overlooked.

# AUDITOR REVIEW

- Where possible, the organization should identify the underlying cause or causes of the nonconformity so that appropriate corrective action can be taken.
- **Selecting records**
- When selecting records of investigations to review, be mindful of the risk of the nonconformity to the product or process. Select records of investigations 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 4 MA&I

- **Determine if investigations are conducted to identify the underlying cause(s) of potential nonconformities, where possible. *Confirm investigations are commensurate with the risk of the potential nonconformity.***
- *Clause and regulation:* [ISO 13485:2016: 8.5.3; TG(MD)R Sch3 P1 1.4(3)(a),(b), (5)(b)(iii),(f),TG(MD)R Sch1 P1 2; RDC ANVISA 16/2013: 2.4, 7.1.1.1; MHLW MO169: 64; 21 CFR
- 820.100(a)(2)]
- *Additional country-specific requirements:* None

# AUDITOR REVIEW

- **Investigations of potential nonconformities**
- The depth of the organization’s investigation into potential process, product, or other quality systemnonconformities should be commensurate with the risk of the nonconformity if it were to occur. The process for determining the extent of an investigation may be linked to the organization’s risk management systemand outputs essential to the proper functioning of the device.
- **Selecting records**
- When selecting records of investigations to review, be mindful of the risk of the potential nonconformity to the product or process. Select records of investigations where the potential

# AUDITOR REVIEW

- nonconformity has a higher risk of adversely affecting the ability of the finished device to meet its essential design outputs or the potential nonconformity could affect the safety and efficacy of the product.

# AUDIT TASK 5 MA&I

- **Confirm that corrections, corrective actions, and preventive actions were determined, implemented, documented, effective, and did not adversely affect finished devices. Ensure corrective action and preventive action is appropriate to the risk of the non-conformities or potential nonconformities encountered.**
- *Clause and regulation:* [ISO 13485:2016: 8.2.1, 8.2.5, 8.3.1,8.5.2, 8.5.3; TG(MD)R Sch1 P1 2, TG(MD)R Sch3 P1 1.4(3)(a),(b), (5)(b)(iii), (f);; RDC ANVISA 16/2013: 2.4, 6.5, 7.1.1.3, 7.1.1.4, 7.1.1.5; MHLW MO169: 55, 57, 60, 63, 64; 21 CFR 820.100(a)(3), 820.100 (a)(4),820.100(a)(6), 820.100(b)]
- *Additional country-specific requirements:* None

# AUDITOR REVIEW

- **Determining the extent of actions**
- Corrective actions taken by an organization can vary depending on the situation. Corrective actions are intended to correct and also prevent recurrence of not only nonconforming product but also poor practices, such as inadequate training.
- In developing corrective action addressing nonconforming product, the organization should consider corrections to be taken regarding the affected products, whether distributed or not. Corrections and corrective actions must be commensurate with the risk associated with the nonconformity.

# AUDITOR REVIEW

- The audit team may encounter situations where a quality problem has been identified, but the organization's management has decided not to undertake corrective actions. Confirm that the organization's decision not to take corrective action has been made using appropriate risk-based decision making, including a determination that the finished device meets risk acceptability criteria.
- **Determining the effectiveness of actions**
- During the audit of the Measurement, Analysis and Improvement process, review the mechanisms by which the organization assessed effectiveness of the corrective and preventive actions. Compare the records of significant and/or higher risk corrective actions and preventive actions to the organization's product and quality data analyses,

# AUDITOR REVIEW

- such as trend results. Look for product or quality problems or trends that continued or began after the actions were implemented. This may indicate that the corrective actions or preventive actions were not effective.
- Review how the organization has determined that the actions do not adversely affect the finished device(s).

# LINK TO OTHER PROCESSES

- ***Link: Medical Device Adverse Events and Advisory Notices Reporting***
- Determine whether any of the organization's corrective actions require reporting to participating
- MDSAP authorities.

# TASK 6 MA&I

- ***When a corrective or preventive action results in a design change, verify that any new hazard(s) and any new risks are evaluated under the risk management process.***
- *Clause and regulation:* [ISO 13485:2016: 7.1, 7.3.9; TG(MD)R Sch1 P1 2; RDC ANVISA 16/2013: 2.4, 4.1.10; MHLW MO169: 26, 36; 21 CFR 820.30(i), 820.30(g)]
- *Additional country-specific requirements:* None

# AUDITOR REVIEW

## Design Changes

- Completing this audit task may involve linkages to other subsystems. Verification and validation are important elements in assuring that corrective actions and preventive actions that result in design changes are effective and do not introduce new hazards.

# LINK TO OTHER PROCESSES

***Design and Development***

- If the corrective action or preventive action involves changing the design, design controls should be applied to the change where applicable. When necessary, confirm that design controls were applied to the change according to the organization's procedures. In addition, design changes should be evaluated under the organization's risk management process to ensure that changes do not introduce new hazards.

# TASK 7 MA&I

- ***When a corrective or preventive action results in a process change, confirm that the process change is assessed to determine if any new risks to the product are introduced.*** **Verify the manufacturer has performed revalidation of processes where appropriate.**
- *Clause and regulation:* [ISO 13485:2016: 4.1.2, 4.1.4, 4.1.6, 4.2.1, 7.1, 7.5.2, 7.5.6, 7.5.7; TG(MD)R Sch1 P1 2; Sch3 P1 1.5(4); RDC ANVISA 16/2013: 2.4, 5.6, 7.1.1.4; MHLW MO169: 5, 6, 26, 45, 46; 21 CFR 820.100(a)(4), 820.100(a)(5), 820.70(b), 820.75(c)]

# ADDITIONAL COUNTRY REQUIREMENTS

- *Additional country-specific requirements:*
- *Australia (TGA):*

- 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)].

# ADDITIONAL COUNTRY REQUIREMENTS

- *Canada (HC):*
- Verify that the manufacturer has a process or procedure for identifying a “significant change” to a class III or IV device. Verify that information about “significant changes” is submitted in a medical device license amendment application [CMDR 1, 34].

# ADDITIONAL COUNTRY REQUIREMENTS

- *Japan (MHLW):*

- 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].

# LINKS TO OTHER PROCESSES

- Completing this audit task may involve linkages to other quality management system processes. Production processes require at least some degree of qualification, verification, or validation. If the change involves a validated process, review the organization’s evaluation of the process change to determine if revalidation is needed.
- For changes to production processes that are performed by suppliers, the audit team should consider selecting those suppliers for evaluation during audit of the Purchasing process. In cases where the organization makes a change to a validated process performed by a supplier, the audit team should evaluate whether re-validation is required. If re-validation of production processes is required, confirm the results show the process meets the planned result.

# LINKS TO OTHER PROCESSES

- ***Production and Service Controls, Purchasing***
- If the corrective action or preventive action involves changing a production process, the audit team should consider selecting this change for evaluation during audit of Production and Service Controls.
- If the corrective or preventive action involves a change to a product outsourced during review of purchasing the vendor evaluation and control of changes should be considered to be reviewed.

# TASK 8 MA&I

- **Verify that controls are in place to ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. Confirm that an appropriate disposition was made, justified, and documented and that any external party responsible for the nonconformity was notified.**
- *Clause and regulation:* [ISO 13485:2016: 8.3.1, 8.3.2; TG(MD)R Sch3 P1 1.4(5)(b)(iii); RDC ANVISA 16/2013: 6.5, 7.1.1.6; MHLW MO169: 60; 21CFR 820.90(a)]
- *Additional country-specific requirements:* None

# AUDITOR REVIEW

- The audit team should review procedures and controls for preventing the unintended distribution of nonconforming product. The auditor(s) may choose to select a sample of records involving nonconforming product that was in stock or returned to review how the procedures and controls were applied to control the nonconforming product.
- Confirm the organization has established and maintained procedures that define the responsibility
- for review and the authority for the disposition of nonconforming product, as well as the execution of the review and disposition process. Disposition of nonconforming product must be documented.

# AUDITOR REVIEW

- The audit team may encounter situations where the organization’s management has decided to authorize the use of nonconforming product under concession. Documentation must include the justification for use of nonconforming product and the signature of the individual(s) authorizing the use. Confirm that the organization’s decision to use nonconforming product under concession
- has been made using appropriate risk-based decision making, including a determination that
- the finished device meets specified requirements. Be mindful of instances where the use of nonconforming product under concession has led to devices not meeting specifications.

# AUDITOR REVIEW

- When selecting records of nonconforming products to review, be mindful of the risk of the nonconformity to the finished device and the patient or user. 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 9 MA& I

- **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.**
- *Clause and regulation:* [ISO 13485:2016: 8.3.3, 8.5.2; TG(MD)R Sch1 P1 2, TG(MD)R Sch3 P1 1.4(3)(a),(b), (5)(b)(iii), (f); RDC ANVISA 16/2013: 2.4, 7.1.1.8; MHLW MO169: 60, 63; 21 CFR 820.100(a)]
- *Additional country-specific requirements:* None

# AUDITOR REVIEW

- During this audit task, confirm that the organization has determined the control and actions to
- be taken on nonconforming products detected after delivery or use, commensurate with the risk associated with a product failure.
- While it may not be necessary for the organization to recall nonconforming product from distribution as part of its identified actions needed to correct and prevent recurrence of the problem, confirm that the decision is made using an adequate risk justification.

# LINK TO OTHER PROCESSES

- ***Link: Medical Device Adverse Events and Advisory Notices Reporting***
- If the organization has taken field action on products already distributed, confirm that the appropriate MDSAP regulatory authorities have been notified, as necessary.

# TASK 10 MA&I

- **Verify that internal audits of the quality management system are being conducted according to planned arrangements and documented procedures to ensure the quality management system is in compliance with the established quality management system requirements and applicable regulatory requirements, and to determine the effectiveness of the quality system. Confirm that the internal audits include provisions for auditor training and independence over the areas being audited, corrections, corrective actions, follow-up activities, and the verification of corrective actions.**
- *Clause and Regulation:* [ISO 13485:2016: 6.2, 8.2.4; TG(MD)R Sch3 P1 1.4(5)(b)(iii); RDC ANVISA 16/2013: 7.3; MHLW MO169: 22, 23, 56; 21 CFR 820.22, 820.100]

# AUDITOR REVIEW

- Internal audits are systematic, independent examinations of an organization's quality management system that are performed at defined intervals and at sufficient frequency to determine whether both quality management system activities and the results of such activities comply with quality management system procedures. Internal audits should also determine whether these procedures are implemented effectively and whether they are suitable to achieve quality management system objectives.
- Internal audits are to be conducted according to established procedures by appropriately trained individuals not having direct responsibility for the matters being audited. If possible, interview auditors and ask how audits are conducted, how long audits typically last, what documents are typically reviewed, etc.

# AUDITOR REVIEW

- Internal audit procedures typically include requirements for auditor qualifications, requirements for the frequency of audits, specified functional areas to be audited, and audit plans (or the requirement to establish audit plans prior to the audit). Procedures should also include requirements for how audit activities and results are to be communicated, addressed, and followed up (including re-audit, if necessary) and for how audit activities are to be documented.
- Management having responsibility for the matters audited must review the report of the quality audit. The dates and results of all quality audits (and subsequent re-audits, if necessary) must be documented, as well as any corrective or preventive actions resulting from the internal audits.

# LINK TO OTHER PROCESSES

- ***Link: Management, training, CAPA***
- During the audit of the Management process, the audit team should confirm that the output of internal audits is an input to management review.
- Auditor training records should be reviewed
- Corrective and or Preventive Actions should be reviewed to ensure that requirements are met.

# TASK 11 MA&I

- **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.**
- *Clause and regulation:* [ISO 13485:2016: 5.6.2; TG(MD)R Sch3 P1 1.4(5)(b)(iii); RDC ANVISA 16/2013: 2.2.6,
- 7.1.1.7; MHLW MO169: 19; 21 CFR 820.100 (a)(7)]
- *Additional country-specific requirements:* None

# AUDITOR REVIEW

- **Management review**
- During the performance of this audit task, the auditor(s) may choose to select a recent, significant corrective or preventive action and determine which records or information regarding the event was submitted for management review.

# LINK TO OTHER PROCESSES

- ***Link: Management***
- During the audit of the Management process, the audit team should have confirmed that the status of corrective and preventive actions is an input to the management review. During the audit of the Measurement, Analysis and Improvement process, determine that top management is aware of higher-risk quality problems, as well as significant corrective and preventive actions, when necessary.

# TASK 12 MA&I

- **Confirm that the manufacturer has made effective arrangements for gaining experience from the post-production phase, handling complaints, and investigating the cause of nonconformities related to advisory notices with provision for feedback into the**
- **Measurement, Analysis and Improvement process.** ***Verify that information from the analysis of production and post-production quality data was considered for amending the analysis of product risk, as appropriate.***
- *Clause and regulation:* [ISO 13485:2016: 4.2.1, 7.2.3, 7.5.4 (a), 8.2.1, 8.2.2; TG(MD)R Sch1 P1 2, Sch3 P1 1.4(3), 1.4(5)(b)(iii) &1.4(5)(f); RDC ANVISA 16/2013: 7.2; CMDR 57-58; MHLW MO169: 6, 29, 43, 55, 62.6; 21 CFR 820.198]

# COUNTRY SPECIFIC REQUIREMENTS

- *Australia (TGA):*

- Verify that the organization has procedures for a post-marketing system that includes a systematic review of post-production experience (e.g. from; expert user groups, customer surveys, customer complaints and warranty claims, service and repair information, literature reviews, post-production clinical trials, user feedback other than complaints, device tracking and registration schemes, user reactions during training, adverse event reports). Investigation should take place in a timely manner to ensure that reporting timeframes for adverse events or the implementation of advisory notices (recalls)may be met by the Australian Sponsor [TG(MD)R Sch3 P1 1.4(3)(a)].

# COUNTRY SPECIFIC REQUIREMENTS

- Note: In Australia the conduct of a recall is the responsibility of the Australian Sponsor in accordance with the Australian Uniform Recall Procedure for Therapeutic Goods.

# COUNTRY SPECIFIC REQUIREMENT

- *Brazil (ANVISA):*


- 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, complaintsmust be reported to the competent health authority;

# COUNTRY SPECIFIC REQUIREMENTS

- (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;

# ADDITIONAL COUNTRY REQUIREMENTS

- *Canada (HC)*

- Verify that 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].
- Verify that 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

# ADDITIONAL COUNTRY REQUIREMENTS

- carry out an effective and timely recall of the device [CMDR Section 58].

- *Japan (MHLW/PMDA)*

- Confirm that the person operating the Registered Manufacturing Site has determined and implemented effective arrangement for communicating with the Japanese Marketing Authorization Holder in relation to customer feedback, including customer complaints, and advisory notices [No.169: 29].

# ADDITIONAL COUNTY REQUIREMENTS

- *United States (FDA):*

- Verify procedures have been defined, documented, and implemented for receiving, reviewing, and evaluating complaints by a formally designated unit. Procedures must ensure that:
- (1) All complaints are processed in a uniform and timely manner
- (2) Oral complaints are documented upon receipt
- (3) Complaints are evaluated to determine whether the complaint represents an event which is required to be reported to FDA

# ADDITIONAL COUNTRY REQUIREMENTS

- 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.
- 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 beenmade for a similar complaint and another investigation is not necessary.

# ADDITIONAL COUNTRY REQUIREMENTS

- 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:
- (1) Whether the device failed to meet specifications
- (2) Whether the device was being used for treatment or diagnosis
- (3) The relationship, if any, of the device to the reported incident or adverse event

# ADDITIONAL COUNTRY REQUIREMENTS

- When an investigation is made, a record of the investigation must be maintained by the formally designated unit. The record of investigation must include:
- (1) The name of the device
- (2) The date the complaint was received
- (3) Any unique identifier (UDI), or Universal Product Code(UPC) or any other device identification(s) and control number(s) used
- (4) The name, address, and telephone number of the complainant
- (5) The nature and details of the complaint

# ADDITIONAL COUNTRY REQUIREMENTS

- (6) The dates and results of investigation
- (7) Any corrective action taken
- 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].

# AUDITOR REVIEW

- During the review of quality data sources that serve as inputs to the Measurement, Analysis and Improvement process, the audit team may choose to review complaints and customer feedback. Confirm that complaints are handled as required by the MDSAP participating regulatory authorities. Complaints can be an important source of information regarding quality problems and are often indicative that distributed devices (or their packaging or labeling) did not meet specified requirements.

# AUDITOR REVIEW

- **Selecting records**
- One method to analyze complaints and customer feedback is to review the analysis of complaint data and select one or more complaint failure modes, **preferably failure modes associated with higher risk to the patient or user**. Once the audit team has selected complaint failure modes, the auditor(s) can select a sample of complaints from those failure modes and confirm
- the complaints are handled appropriately, including investigation and implementation of corrective action when necessary.

# AUDITOR REVIEW

- **Risk management**
- Information from post-production sources, including complaints and customer feedback, can provide important information for the risk management activities for the device. In particular, previously unidentified risks discovered during the post-production monitoring may indicate a need for improving the risk management process or may indicate a need for design changes. Additionally, on the basis of post-production quality data, the organization may choose to enact new or more stringent controls to maintain an acceptable level of product risk.

# LINK TO OTHER PROCESSES

- ***Link: Medical Device Adverse Events and Advisory Notices Reporting***
- During the review of complaints and feedback, confirmthat individual medical device reports were made to the appropriate regulatory authorities when necessary.

# TASK 13 MA&I

- **Where investigation determines that activities outside the organization contributed to a customer complaint, verify that records show that relevant information was exchanged between the organizations involved.**
- *Clause and regulation:* [ISO 13485:2016: 4.1.5, 7.4.1, 8.3.1; RDC ANVISA 16/2013: 7.1.1.6; MHLW MO169: 5, 37, 60; 21 CFR 820.100(a)(6)]
- *Additional country-specific requirements:* None

# AUDITOR REVIEW

- **Complaints and nonconformities attributed to supplied product**
- Confirm that information related to quality problems or nonconforming product, including complaints, is disseminated to those directly responsible for assuring the quality of product. This includes instances where investigation reveals the underlying cause of the complaint or nonconforming product to be related to supplied product. The organization should notify the
- supplier of the quality problem and appropriate corrective actionmust be taken when necessary. Failure of an outside organization to provide products that meet specified requirements may disqualify them as an acceptable or approved supplier.

# LINKS TO OTHER PROCESSES

- **Link: Purchasing**
- During the audit of the Measurement, Analysis and Improvement process, if significant nonconformities are related to supplied product, the audit team should consider selecting those suppliers for evaluation during the audit of the organization’s Purchasing process.

# TASK 14 MA&I

- **Verify that the organization has defined and documented procedures for the notification of adverse events. Confirm adverse event reporting is performed according to the applicable regulatory requirements.**
- *Clause and regulation:* [ISO 13485:2016: 4.2.1,7.2.3, 8.2.3; TG(MD)R Sch3 P1 1.4(3)(c); RDC ANVISA 16/2013: 7.1.1.8, RDC ANVISA 67/2009; CMDR 59-61.1; MHLW MO169: 6, 29, 62; 21 CFR 803]
- *Additional country-specific requirements:* Refer to MDSAP process Medical Device Adverse Events and Advisory
- Notices Reporting

# AUDITOR REVIEW

- **Individual adverse event reports**
- An output of the activities associated with the Measurement, Analysis and Improvement process, such as complaint handling, may be the reporting of individual adverse events to regulatory authorities in which the device is marketed. When applicable, select complaint records that meet criteria for reporting and confirm the appropriate reports and information was provided to the regulatory authority. Ensure the individual adverse event reports contain accurate information by comparing the submitted reports to the associated complaint and complaint investigation.

# AUDITOR REVIEW

- Reportable events are often an important Measurement, Analysis and Improvement process quality data source since these events are indicative that the finished device has caused death, serious injury, or has malfunctioned in a manner such that if the malfunction were to recur, the result could be death or serious injury. Any death, even if the organization attributes it to user error, is considered to have potentially high risk associated with it. Confirm that reportable events were evaluated for corrective action when necessary.

# TASK 15 MA&I

- **Confirm that the manufacturer has made effective arrangements for the timely issuance and implementation of advisory notices. Confirm that reporting of advisory notices is established in a documented procedure and performed according to the applicable regulatory requirements.** 39
- *Clause and regulation:* [ISO 13485:2016: 4.2.1, 7.2.3, 8.3.3; TG(MD)R Sch3 P1 1.4(3)(c); RDC ANVISA 16/2013: 7.1.1.8, RDC ANVISA 23/2012; CMDR 63-65.1; MHLW MO169: 6, 29, 60; 21 CFR 806]
- *Additional country-specific requirements:* Refer to MDSAP process Medical Device Adverse Events and Advisory
- Notices Reporting

# AUDITOR REVIEW

- **Advisory notices**
- An output of the activities associated with the Measurement, Analysis and Improvement process,
- including complaint handling and the discovery of nonconforming product that has been distributed, may be the reporting of advisory notices to regulatory authorities in which the device is marketed. When applicable, select advisory notices that meet criteria for reporting and confirm that the appropriate reports and information were provided to the regulatory authority.

# AUDITOR REVIEW

- The quality problems that led to an advisory notice is often an important quality data source for the corrective actions process since these events are indicative that the finished device does not meet specified requirements and has the potential for unreasonable risk to the user. Confirm that quality problems that resulted in advisory notices were evaluated for corrective action. If corrective action was taken, evaluate the mechanism by which the organization assured the action is effective and does not adversely affect the ability of the device to meet specified requirements. If corrective action was not taken for quality problems associated with a correction, removal, or advisory notice, review the organization's rationale for not undertaking corrective action and confirm that the decision is appropriate using a risk-based decision making process.

# AUDITOR REVIEW

- **Decisions to not report a correction, removal, or advisory notice**
- The audit team may encounter instances where the organization has performed activities involving issuance of advisory notices without notifying regulatory authorities in the markets in which the device is marketed. In these situations, review the organization's rationale for not reporting these actions and ensure that the rationale is appropriate. Verify that records of the action are maintained.

# TASK 16 MA&I

- **Determine, based on the assessment of the Measurement, Analysis and Improvement process overall, whether management provides the necessary commitment to detect and address product and quality management system nonconformities, and ensure the continued suitability and effectiveness of the quality management system.**
- Clause and regulation: [ISO 13485:2016: 4.1.3, 5.2, 8.1, 8.5.1; RDC ANVISA 16/2013: 2.2.1; MHLW MO169: 5, 11, 54, 62]

# CHAPTER 4 ADVERSE EVENT AND ADVISORY NOTICE

- The Medical Device Adverse Events and Advisory Notices Reporting process may be audited as a linkage from the Measurement, Analysis and Improvement process.
- **Purpose:** The purpose of auditing the Medical Device Adverse Events and Advisory Notices Reporting is to 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.

# CHAPTER 4 ADVERSE EVENT AND ADVISORY NOTICE

- **Outcomes:** As a result of the audit of the Medical Device Adverse Events and Advisory Notices
- Reporting process, objective evidence will show whether the organization has:
- A) Defined processes to ensure individual device-related adverse events are reported to regulatory authorities as required
- B) Ensured that advisory notices are reported to regulatory authorities and authorized representatives when necessary
- C) Maintained appropriate records of individual device-related adverse events and advisory notices

# LINKS TO OTHER PROCESSES

- ***Links to Other Processes:***
- ***Measurement, Analysis and Improvement***

# AUDIT TASK 1 AE&AN

- **Verify that the organization has a process in place for identifying device-related events that may meet reporting criteria as defined by participating regulatory authorities. Verify that the complaint process has a mechanism for reviewing each complaint to determine**
- **if a report to a regulatory authority is required. Confirm that the organization's processes meet the timeframes required by each regulatory authority where the product is marketed.**
- *Clause and regulation:* [ISO 13485:2016: 4.2.1, 7.2.3, 8.2.2, 8.2.3; see the country-specific requirements below]

# ADDITIONAL COUNTRY REQUIREMENTS

- *Australia (TGA):*

- Manufacturers are required to implement a post-marketing system that includes provisions for adverse event reporting – e.g. Therapeutic Goods (Medical Devices) Regulations 2002 Schedule 3 Part1 Clause 1.4(3)(c)(i). In view of the written agreement between Manufacturers and the Australian Sponsor [TG Act 41FD], events must be reported by the manufacturer to the TGA, or to the Sponsor in a timely manner to ensure that a Sponsor can meet their reporting obligations under the Therapeutic Goods (Medical Devices) Regulation 5.7:
- Verify that the manufacturer or other person becoming aware of an event that represents a serious threat to public health provides information as soon as practicable.

# ADDITIONAL COUNTRY REQUIREMENTS

- The Sponsor is to report the event within 48 hours.
- Verify that the manufacturer or other person becoming aware of an event that led to the death or serious deterioration in the state of health of a patient, a user, or other person provides information as soon as practicable. The Sponsor is to report the event within 10 days.
- Verify that the manufacturer or other person becoming aware of an event that the recurrence of which might lead to the death or serious deterioration in the state of health of a patient, a user, or other person provides information as soon as practicable. The Sponsor is to report the event within 30 days.

# ADDITIONAL COUNTRY REQUIREMENTS

- Note: An event that leads to a serious threat to human health is a hazard arising from a systematic failure of the devices or an event or other occurrence that may lead to death or serious injury.
- Note: Adverse events may be reported on-line to the TGA, by the Manufacturer or Sponsor, at https://www.tga.gov.au/reporting-problems.
- Note: It is a condition on Australian Sponsors of Class AIMD, Class III and Implantable Class IIb devices
- that they provide three consecutive annual reports to the TGA following inclusion of the device in the ARTG. Annual reports are due 1 October each year. Reports should be for the period 1 July to 30 June. The report is to include:

# ADDITIONAL COUNTRY REQUIREMENTS

- ARTG no.
- Product name
- Model no(s)
- Number supplied in Australia
- Number supplied worldwide (Numbers should include devices that are the same but supplied under a
- different name in another jurisdiction)
- Number of complaints in Australia
- Number of complaints worldwide
- Number of adverse events and incident rates in Australia (Rate= No. of events/ No. Supplied x 100 =

# ADDITIONAL COUNTRY REQUIREMENTS

- Rate%)
- Number of adverse events and incident rates world wide
- A list of the more common complaints and all of the adverse events
- Device Incident Report (DIR) number of those adverse events reported to the TGA
- Regulatory/corrective action/notification by manufacturer
- Note: Australian Sponsors are required to provide manufacturers with any information that will assist the manufacturer to comply with the obligations of a conformity assessment procedure (e.g. information in relation to adverse events) [TG(MD)R Reg 5.8].

# ADDITIONAL COUNTRY REQUIREMENTS

- *Brazil (ANVISA):*

- Verify that a post-market surveillance system is established and implemented in the organization and integrated into the Quality System, with procedures and work flows established to ensure the correct and the prompt identification of adverse events, the performance of investigations and use of the results to improve the safety and effectiveness of the device when necessary [RDC ANVISA 67/2009 – Art. 6º].
- For domestic manufacturers (also applies to legal representatives in Brazil) - verify that top management has designated a professional to be responsible for the post-market surveillance system. This designation shall be documented [RDC ANVISA 67/2009 – Art. 5º].

# ADDITIONAL COUNTRY REQUIREMENTS

- Verify that the organization has mechanisms for processing and recording complaints, conducting investigations, and providing feedback directly to the complainant, or in the case of an international manufacturer, to their legal representative in Brazil, as necessary [RDC ANVISA 67/2009 – Art. 6º, Art. 7º, Art. 9º].
- Verify that the organization has notified the regulatory authority about problems associated with their devices, including adverse events (critical or non-critical), any technical defect that was identified regarding products already marketed, anything that can cause a serious hazard to public health, or cases of counterfeit [RDC ANVISA 67/2009 – Art. 8º].

# ADDITIONAL COUNTRY REQUIREMENTS

- For international manufacturer, verify that the legal representative in Brazil is aware about the occurrence of possibility of death, serious hazard to public health or cases of counterfeit, associated with their products exported to Brazil [RDC ANVISA 67/2009 – Art. 8º].

# ADDITIONAL COUNTRY REQUIREMENTS

- *Canada (HC):* 
- Medical Device Regulations SOR/98-282, Section 59-61.1:
- Verify that the manufacturer and the importer of a medical device make a preliminary and final report to the minister concerning any incident occurring inside or outside Canada involving a device sold in Canada.
- a. Related to the failure of the device or deterioration in its effectiveness or any inadequacy in its labeling or in its directions for use.
- b. Has led to death or serious deterioration in the state of health of a patient, user, or other person, or could do so if it were to occur [CMDR 59].

# ADDITIONAL COUNTRY REQUIREMENTS

- Verify that the manufacturer or other person becoming aware of an event that led to the death or serious deterioration in the state of health of a patient, a user, or other person provides information in a preliminary report within 10 days after the person becomes aware of the event or occurrence [CMDR 60 (1) (a) (i)].
- Verify that the manufacturer or other person becoming aware of an event that the recurrence of which might lead to the death or serious deterioration in the state of health of a patient, a user, or other person provides information in a preliminary report within 30 days after the person becomes aware of the event or occurrence [CMDR 60 (1) (a) (ii)].

# ADDITIONAL COUNTRY REQUIREMENTS

- Verify that manufacturer has made effective arrangements to submit preliminary reports to the
- Minister and that the reports contain [CMDR 60 (2)]:
- (a) the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or medical device group family;
- (b) if the report is made by
- (i) the manufacturer: the name and address of that manufacturer and of any known importer, and the name, title and telephone and facsimile numbers of a representative of the manufacturer to contact for any information concerning the incident, or

# ADDITIONAL COUNTRY REQUIREMENTS

- (ii) the importer of the device: the name and address of the importer and of the manufacturer, and the name, title and telephone and facsimile numbers of a representative of the importer to contact for any information concerning the incident;
- (c) the date on which the incident came to the attention of the manufacturer or importer;
- (d) the details known in respect of the incident, including the date on which the incident occurred and the consequences for the patient, user or other person;
- (e) the name, address and telephone number, if known, of the person who reported the incident to the manufacturer or importer;

# ADDITIONAL COUNTRY REQUIREMENTS

- (f) the identity of any other medical devices or accessories involved in the incident, if known; (g) the manufacturer's or importer's preliminary comments with respect to the incident;
- (h) the course of action, including an investigation, that the manufacturer or importer proposes to follow in respect of the incident and a timetable for carrying out any proposed action and for submitting a final report; and
- (i) a statement indicating whether a previous report has beenmade to the Minister with respect to the device and, if so, the date of the report.

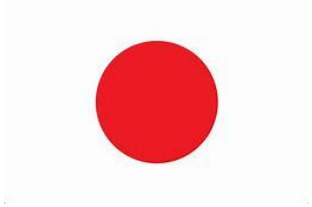
# ADDITIONAL COUNTRY REQUIREMENTS

- If a preliminary report required by section 60 is submitted to the Minister and/or Importer, verify that the manufacturer has submitted a final report to the Minister in writing in accordance with the timetable established under CMDR 60(2)(h) and the final report contains [CMDR 61(1)]:
- (a) a description of the incident, including the number of persons who have experienced a serious deterioration in the state of their health or who have died;
- (b) a detailed explanation of the cause of the incident and a justification for the actions taken in respect of the incident; and

# ADDITIONAL COUNTRY REQUIREMENTS

- (c) any actions taken as a result of the investigation, which may include:
- (i) increased post-market surveillance of the device,
- (ii) corrective and preventive action respecting the design and manufacture of the device, and
- (iii) recall of the device.
- If the reports required by section 60 and 61 are submitted to the Minister just by the Importer, verify that the manufacturer has advised the Minister in writing that the reports the manufacturer and importerwould have submitted were identical and that the manufacturer has permitted the importer to prepare and submit reports to the Minister on the manufacturer’s behalf [CMDR 61.1].

# ADDITIONAL COUNTRY REQUIREMENTS



- *Japan (MHLW):*
- Marketing Authorization Holders are required to implement post market safety activities in accordance with domestic (Japanese) regulatory requirements in addition to the QMS requirements.
- The persons operating the Registered Manufacturing Sites are not required to report any adverse event directly to a Regulatory Authority, but shall report any adverse event which meets the criteria specified by the Ordinance for Enforcement of PMD Act Article 228-20.2 to the Marketing Authorization Holder [MHLW MO169: 62.6] .
- • 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 (see below), to the Marketing Authorization Holder in a timely manner.

# ADDITIONAL COUNTRY REQUIREMENTS

- (a) The following malfunction events which may cause or may have caused health damage:
- (i) Serious event (domestic and foreign)
- (ii) Unlabeled non-Serious event (domestic)
- (b) The following Adverse Reaction events which was caused or might have been caused by the malfunction of a medical device.
- (i) Serious event (domestic and foreign)
- (ii) Unlabeled non-Serious event (domestic)

# ADDITIONAL COUNTRY REQUIREMENTS

- (c) Any action taken for preventing the occurrence or expansion of public health hazard in relation to a medical device which is marketed in foreign countries and is equivalent to the one marketed in Japan. The action includes but not limited to:
- (i) Suspension of manufacturing, importing or selling,
- (ii) Recall and
- (iii) Abolishment.

# ADDITIONAL COUNTRY REQUIREMENTS

- (d) Study report that indicates:
- (i) Possibility of event of cancer and other serious illness, injury or death caused by malfunction of a medical device (domestic and foreign), or by infectious disease arising from usage of a device (domestic and foreign),
- (ii) Significant occurrence rate change of event etc. caused by malfunction of a medical device (domestic and foreign),
- (iii) Significant occurrence rate change of infectious disease caused by usage of a medical device (domestic and foreign) and
- (iv) The fact that a medical device is less effective than claimed when approved.

# ADDITIONAL COUNTRY REQUIREMENTS

- *United States (FDA):* 
- 21 CFR 803: Medical Device Reporting
- Determine whether the manufacturer has developed a process for reporting to FDA incidents involving device-related deaths, serious injuries, and reportable malfunctions that occur within and outside the United States if the same or similar device is marketed to the United States.
- Confirm that the manufacturer has developed, maintained, and implemented written medical device reporting (MDR) procedures for the following:

# ADDITIONAL COUNTRY REQUIREMENTS

- (a) Internal processes that provide for:
- (1) Timely and effective identification, communication, and evaluation of events that may be subject to MDR requirements;
- (2) A standardized review process or procedure for determining when an event meets the criteria for reporting; and
- (3) Timely transmission of complete medical device reports to FDA

# ADDITIONAL COUNTRY REQUIREMENTS

- (b) Documentation and recordkeeping requirements for:
- (1) Information that was evaluated to determine if an event was reportable;
- (2) All medical device reports and information submitted to FDA
- (3) Processes that ensure access to information that facilitates timely follow-up and audit.

# ADDITIONAL COUNTRY REQUIREMENTS

- Verify that any reports are made within 30 calendar days after the day that the manufacturer receives or otherwise becomes aware of information, from any source, that reasonably suggests that a device that is marketed:
- (1) May have caused or contributed to a death or serious injury; or
- (2) Has malfunctioned and this device or a similar device that is marketed would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur. Confirm the manufacturer's MDR files contain the following:
- (1) Information (or references to information) related to the adverse event, including all documentation of deliberations and decision-making processes used to determine if a device-

# ADDITIONAL COUNTRY REQUIREMENTS

- related death, serious injury, or malfunction was or was not reportable to FDA.
- (2) Copies of all MDR forms and other information related to the event submitted to FDA.
- (3) If the manufacturer maintains MDR event files as part of the complaint file, ensure that the manufacturer has prominently identified these records as MDR reportable events. FDA will not consider a submitted MDR report to comply with 21 CFR 803 unless the manufacturer evaluates an event in accordance with the quality management system requirements. Confirm that the manufacturer has documented and maintained in the MDR event files an explanation of why the manufacturer did not submit or could not obtain any information required by 21 CFR 803, as well as the results of the evaluation of each event.

# ADDITIONAL COUNTRY REQUIREMENTS

- Compare the information submitted on the individual medical device report to the information contained in the associated complaint and confirm the medical device report contains all information related to the event that is reasonably known to the manufacturer.

# ADDITIONAL COUNTRY REQUIREMENTS

- Verify the manufacturer has submitted reports to FDA no later than 5 work days after the day that the manufacturer becomes aware that:
- (a) An MDR reportable event necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health. The manufacturer may become aware of the need for remedial action from any information, including any trend analysis; or
- (b) FDA has made a written request for the submission of a 5-day report. If the manufacturer receives such a written request from FDA, the manufacturer must submit, without further requests, a 5-day report for all subsequent events of the same nature that involve substantially similar devices for the time period specified in the written request. FDA may extend the time period stated in the original written request if FDA determines it is in the interest of the public health.

# ADDITIONAL COUNTRY REQUIREMENTS

- Verify the manufacturer submitted supplemental reports within one month of obtaining information that was not submitted in an initial report.
- Confirm that medical device reports include the unique device identifier (UDI) that appears on the device label or on the device package.
- Medical device reports submitted to FDA must be submitted electronically via the Electronic Submissions Gateway (ESG) using eSubmitter or the AS2 Gateway-to-Gateway using HL7 ICSR XML software.

# LINKS TO OTHER PROCESSES

- ***Link: Measurement, Analysis and Improvement***
- Reports of individual adverse events are a form of feedback and must be analyzed as appropriate for trends requiring improvement or corrective action. During the audit of the Measurement, Analysis and Improvement process, confirm that the organization has considered individual adverse events and trends of adverse events in the analysis of data.

# TASK 2 MDAE

- **Verify that advisory notices are reported to regulatory authorities when necessary and comply with the timeframes and recordkeeping requirements established by participating regulatory authorities.**
- Clause and regulation: [ISO 13485:2016: 4.2.1, 7.2.3, 8.2.3, 8.3.3; see the country-specific requirements below]

# ADDITIONAL COUNTRY REQUIREMENTS

- *Australia (TGA):*

- Manufacturers are required to implement a post-marketing system that includes provisions for the recovery of devices – e.g. Therapeutic Goods (Medical Devices) Regulations 2002 Schedule 3 Part1 Clause 1.4(3)(c)(ii). In view of the written agreement between Manufacturers and the Australian Sponsor [TG Act 41FD] proposed recalls must be reported by the manufacturer to the TGA, or to the Sponsor in a timely manner to ensure that a Sponsor can meet their reporting obligations [Therapeutic Goods (Medical Devices) Regulation 5.7, *Therapeutic Goods Act Part 4-9* and the Uniform Recall Procedure for Therapeutic Goods (URPTG)].

# ADDITIONAL COUNTRY REQUIREMENTS

- Note: Further information concerning the Australian requirements for advisory notices and the recovery of devices is available at https://www.tga.gov.au/recalls.
- Note: Australian Sponsors are required to provide manufacturers with any information that will assist the manufacturer to comply with the obligations of a conformity assessment procedure (e.g. information in relation to the recovery of devices) [TG(MD)R Reg 5.8].

# ADDITIONAL COUNTRY REQUIREMENTS

- *Brazil (ANVISA):*
- Verify that procedures and work flows were established in order to identify when field actions (recalls and corrections) are necessary, in accordance with the organization's post-market surveillance system and quality system [RDC ANVISA 67/2009 - Art. 6º; RDC ANVISA 23/2012 – Art. 1º, Art. 5º].
- Verify that the organization keeps records regarding field actions performed, including those that do not need to be reported to regulatory authorities [RDC ANVISA 23/2012 – Art. 4º; Art. 6º, Art. 10, Art. 11, Art. 16].
- For domestic manufacturers (also applies to legal representatives in Brazil) - verify that the organization has sent to the regulatory authority the reports requested, according Brazilian regulation [RDC ANVISA 23/2012– Art. 10, Art. 11].

# ADDITIONAL COUNTRY REQUIRMEMENTS

- Verify that the organization has performed field actions based on potential or concrete evidence that their product does not comply with essential requirements of safety and effectiveness [RDC ANVISA 23/2012 – Art. 4º, Art. 6º, Art. 7º, Art. 13, Art. 14, Art. 15].
- For domestic manufacturers (also applies to legal representatives in Brazil) - verify that the organization has performed field actions when required by the regulatory authority [RDC ANVISA 23/2012 – Art. 6º].
- For domestic manufacturers (also applies to legal representatives in Brazil) - verify that the organization notified the regulatory authority regarding field actions, in accordance with requirements and deadlines established per Brazilian regulation [RDC ANVISA 23/2012 – Art. 7º, Art. 8º].
- For international manufacturers, verify that the legal representative in Brazil was aware about the occurrence of field actions performed on products exported to Brazil [RDC ANVISA 67/2009 – Art. 8

# ADDITIONAL COUNTRY REQUIREMENTS

- *Canada (HC):* 
- Medical Device Regulations SOR/98-282, Section 63 – 65.1:
- Verify that the manufacturer and the importer of a medical device, on or before undertaking a recall of a device provide the minister with the following information [CMDR 64]:
- (a) the name of the device and its identifier, including the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or medical device group family;
- (b) the name and address of the manufacturer and importer, and the name and address of the establishment where the device was manufactured, if different from that of the manufacturer;

# ADDITIONAL COUNTRY REQUIRMENETS

- (c) the reason for the recall, the nature of the defectiveness or possible defectiveness and the date on and circumstances under which the defectiveness or possible defectiveness was discovered;
- (d) an evaluation of the risk associated with the defectiveness or possible defectiveness;
- (e) the number of affected units of the device that the manufacturer or importer
- (i) manufactured in Canada,
- (ii) imported into Canada, and
- (iii) sold in Canada;
- (f) the period during which the affected units of the device were distributed in Canada by the manufacturer or importer;

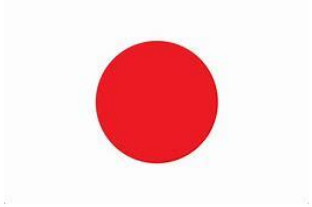
# ADDITIONAL COUNTRY REQUIREMENTS

- (g) the name of each person to whom the affected device was sold by the manufacturer or importer and the number of units of the device sold to each person;
- (h) a copy of any communication issued with respect to the recall;
- (i) the proposed strategy for conducting the recall, including the date for beginning the recall, information as to how and when the Minister will be informed of the progress of the recall and the proposed date for its completion;
- (j) the proposed action to prevent a recurrence of the problem; and
- (k) the name, title and telephone number of the representative of the manufacturer or importer to contact for any information concerning the recall.

# ADDITIONAL COUNTRY REQUIREMENTS

- Verify that as soon as possible after the completion of the recall the manufacturer and the importer reports to the minister the results of the recall and the action taken to prevent a recurrence of the problem [CMDR 65].
- If the reports required by section 64 and 65 are submitted to the Minister just by the Importer, verify that the manufacturer has advised the Minister in writing that the reports the manufacturer and importerwould have submitted were identical and that the manufacturer has permitted the importer to prepare and submit reports to the Minister on the manufacturer's behalf [CMDR 65.1].

# ADDITIONAL COUNTRY REQUIREMENTS

- *Japan (MHLW):* 
- Marketing Authorization Holders are required to report advisory notices to Regulatory Authorities [PMD Act 68-11].
- Confirm that the person operating the Registered Manufacturing Site has determined and implemented effective arrangement for communicating with the Marketing Authorization Holder in relation to advisory notices [MHLW MO169: 29].
- Note: Persons operating Registered Manufacturing Sites are not required to report any advisory notice directly to regulatory authority, but shall communicate with the Marketing Authorization Holder, so they can take necessary regulatory actions.

# ADDITIONAL COUNTRY REQUIREMENTS

- *United States (FDA):* 
- 21 CFR 806: Medical Devices; Reports of Corrections and Removals
- Verify that the manufacturer has a process in place to notify FDA in the event of actions concerning device corrections and removals and to maintain records of those corrections and removals.
- Verify that the written report to FDA of any correction or removal initiated to reduce a risk to health or remedy a violation of the U.S. Food, Drug and Cosmetic Act is reported within 10 working days of initiating the correction or removal. Confirm that the report contains the unique device identifier (UDI) that appears on the device label or on the device package, or the device identifier, universal product code (UPC), model, catalog, or code number of the device and the manufacturing lot or serial number of the device or other identification number.

# ADDITIONAL COUNTRY REQUIRMENTS

- Confirm that the manufacturer maintains records of any correction and removal not required to be reported to FDA (e.g. corrections and removals conducted to correct a minor violation of the U.S. Food, Drug and Cosmetic Act or no risk to health). Confirm that records of corrections and removals not required to be reported contain the unique device identifier (UDI) that appears on the device label or on the device 48 package, or the device identifier, universal product code (UPC), model, catalog, or code number of the device and the manufacturing lot or serial number of the device or other identification number.

# LINKS TO OTHER PROCESSES

- ***Link: Measurement, Analysis and Improvement***
- Corrections and removals are indicative that the product or process does not meet specified requirements or planned results and the nonconformity was not detected prior to distribution. When specified requirements or planned results are not achieved, correction and corrective action must be taken as necessary. During the audit of the Measurement, Analysis and Improvement process, confirm the organization has taken appropriate correction regarding devices already distributed, and taken appropriate corrective action to prevent recurrence of the condition(s) that caused the nonconformity.

# Questions