



# Measurement, Analysis and Improvement Process

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# Course Prerequisites

- Successful completion of the following MDSAP training modules is a prerequisite to this course:
  - Introduction to the MDSAP Program
  - Overview of the MDSAP Audit Process
  - MDSAP: Management Process
  - MDSAP: Device Marketing Authorization and Facility Registration Process

# Learning Objectives

- Explain the Measurement, Analysis and Improvement process
- Describe the purpose of auditing the Measurement, Analysis and Improvement process
- Discuss the expected outcomes from audit of the Measurement, Analysis and Improvement process
- Explain the audit tasks to include:
  - Description and related Clauses and Regulations
  - Country-specific requirements and assessment of conformity
  - Links to other MDSAP processes

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# Measurement, Analysis and Improvement Process

- Process activities that are one of the most important activity in the quality management system
- Identifies existing and potential causes of product and quality problems
- Identifies causes so that appropriate and effective corrective or preventive actions can take place

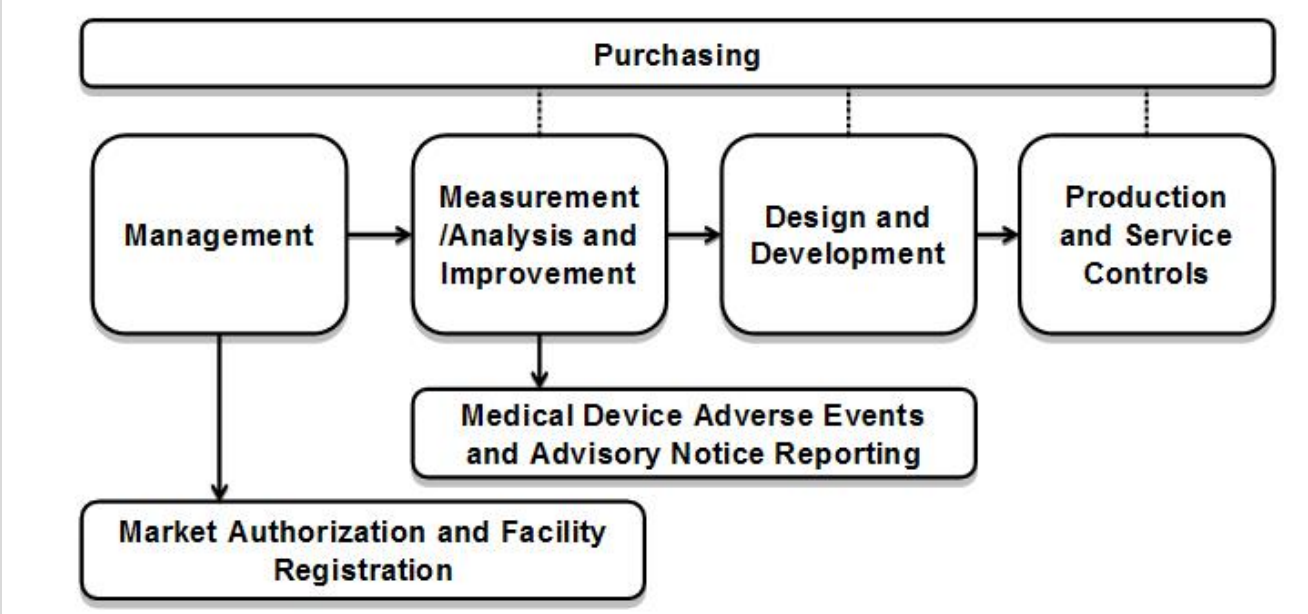
# Measurement, Analysis and Improvement Process

- Collects and analyzes information
- Identifies and investigates existing and potential causes of product and quality problems
- Takes appropriate and effective corrective or preventive action to prevent recurrence or occurrence
- Verifies or validates the corrective and preventive actions
- Communicates corrective and preventive action activities to responsible people
- Provides relevant information for management review
- Documents the activities performed

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# MDSAP Audit Sequence





# Purpose of Auditing

- Purpose of auditing the Measurement, Analysis and Improvement process is to:
  - Verify that information related to products, processes, or the quality management system is collected and analyzed to identify nonconformities
  - Verify that problems and potential problems are investigated
  - Take appropriate and effective corrective and preventive actions

# Learning Objectives

- Explain the Measurement, Analysis and Improvement process
- Describe the purpose of auditing the Measurement, Analysis and Improvement process
- **Discuss the expected outcomes from audit of the Measurement, Analysis and Improvement process**
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  - Description and related Clauses and Regulations
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# Expected 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 system standard 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

# Expected Outcomes

As a result of the audit of the Measurement, Analysis and Improvement process, objective evidence will show whether the organization has:

- C. 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

# Expected Outcomes

As a result of the audit of the Measurement, Analysis and Improvement process, objective evidence will show whether the organization has:

- E. Reviewed the effectiveness of corrective action and preventive action
- F. Utilized information from the analysis of production and post-production quality data to amend the analysis of product risk, as appropriate

# Learning Objectives

- Explain the Measurement, Analysis and Improvement process
- Describe the purpose of auditing the Measurement, Analysis and Improvement process
- Discuss the expected outcomes from audit of the Measurement, Analysis and Improvement process
- **Explain the audit tasks to include:**
  - Description and related Clauses and Regulations
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# Task 1

1. **Verify that procedures for measurement, analysis and improvement which address the requirements of the quality management system standard and regulatory authorities have been established and documented. Confirm the organization maintains and implements procedures to monitor and measure product conformity throughout product realization, as well as procedures that provide for mechanisms for feedback to provide early warnings of quality problems and the implementation of corrective action and preventive action.**

*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, 55-1, 58, 59, 62, 63, 64 (Old: 6, 54, 55, 58, 59, 62, 63, 64); 21 CFR 820.100(a)]

# Task 1

- Additional country-specific requirements: Brazil (ANVISA); and United States (FDA)
- Assessing conformity:  

Detailed information on how to assess conformity for this audit task can be found in the [MDSAP Audit Approach](#), Chapter 3: Measurement, Analysis and Improvement, under task 1



# Task 2

2. **Determine if appropriate sources of quality data have been identified for input into the measurement, analysis and improvement process, including customer complaints, feedback, service records, returned product, internal and external audit findings, and data from the monitoring of products, processes, nonconforming products, and suppliers. Confirm that data from these sources are accurate and analyzed using valid statistical methods (where appropriate) to identify existing and potential product and quality management system nonconformities that may require corrective or preventive action. Information from the organization's analysis of quality data should be used to inform the audit team's decision as to specific complaint records to review in Task 12, and products and processes to audit during the Design and Development, Production and Service Controls, and Purchasing processes.**

*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, 55-1, 58, 59, 61 (Old: 43, 54, 55, 58, 59, 61); 21 CFR 820.100(a)]*

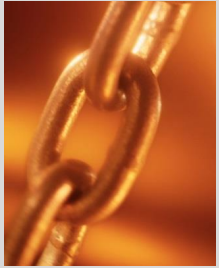
# Task 2

- Additional country-specific requirements: None
- Assessing conformity:
  - Review the previous audit report if there is one
  - Consider reviewing service records again
  - Sample raw quality data

Detailed information on how to assess conformity for this audit task can be found in the [MDSAP Audit Approach](#), Chapter 3: Measurement, Analysis and Improvement, under task 2

# Task 2

- *Links:*



- *Purchasing*

- During the audit of the Purchasing process

- Consider selecting suppliers to audit that have corrective action indicators of nonconformities with supplied components or processes

# Task 3

- 3. Determine if investigations are conducted to identify the underlying cause(s) of detected nonconformities, where possible. Confirm investigations are commensurate with the risk of the nonconformity.**

*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)]*

# Task 3

- Additional country-specific requirements: None
- Assessing conformity:
  - Select records of investigation where nonconformity has a higher risk of adversely affecting:
    - The finished device's ability to meet its essential design outputs
    - The safety and efficacy of the product

Detailed information on how to assess conformity for this audit task can be found in the [MDSAP Audit Approach](#), Chapter 3: Measurement, Analysis and Improvement, under task 3

# Task 4

4. **Determine if investigations are conducted to identify the underlying cause(s) of potential nonconformities, where possible. Confirm investigations are commensurate with the risk of the potential nonconformity.**

*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)]*

# Task 4

- Additional country-specific requirements: None
- Assessing conformity:
  - Select records of investigation where the potential nonconformity has a higher risk of adversely affecting:
    - The finished device's ability to meet its essential design outputs
    - The safety and efficacy of the product

Detailed information on how to assess conformity for this audit task can be found in the [MDSAP Audit Approach](#), Chapter 3: Measurement, Analysis and Improvement, under task 4

# Task 5

5. **Confirm that corrections, corrective actions, and preventive actions were determined, implemented, documented, effective, and did not adversely affect finished devices. Ensure corrective action and preventive action is appropriate to the risk of the nonconformities 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: 55-1, 57, 60-1, 63, 64 (Old: 55, 57, 60, 63, 64): 21 CFR 820.100(a)(3), 820.100 (a)(4), 820.100(a)(6), 820.100(b)]*



# Task 5

- Additional country-specific requirements: None
- Assessing conformity:
  - Confirm that the decision not to take corrective action was made using risk based decision
  - Look for problems or trends that continued or began after the actions were implemented

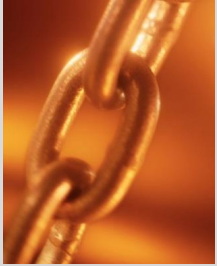
Detailed information on country-specific requirements and how to assess conformity for this audit task can be found in the [MDSAP Audit Approach](#), Chapter 3: Measurement, Analysis and Improvement, under task 5

# Task 5

- *Links:*

- 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

- 6. When a corrective or preventive action results in a design change, verify that any new hazard(s) and any new risks are evaluated under the risk management process.**

*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, 36-1 (Old: 26, 36); 21 CFR 820.30(i), 820.30(g)]*

# Task 6

- Additional country-specific requirements: None
- Assessing conformity:

Detailed information on how to assess conformity for this audit task can be found in the [MDSAP Audit Approach](#), Chapter 3: Measurement, Analysis and Improvement, under task 6

# Task 6

- *Links:*

- *Design and Development*

- When necessary, confirm that design controls were applied to the change
    - Evaluate design changes as part of its risk management activities



# Task 7

7. ***When a corrective or preventive action results in a process change, confirm that the process change is assessed to determine if any new risks to the product are introduced. Verify the manufacturer has performed revalidation of processes where appropriate.***

*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: 5-2, 5-4, 5-6, 6, 26, 41, 45, 46 (Old: 5, 6, 26, 41, 45, 46); 21 CFR 820.100(a)(4), 820.100(a)(5), 820.70(b), 820.75(c)]*

# Task 7

- Additional country-specific requirements: Australia (TGA); Canada (HC); and Japan (MHLW)
- Assessing conformity:
  - Review evaluation of the process change to determine if revalidation is needed
  - Consider selecting suppliers for evaluation during audit of the Purchasing process that performed production and process changes

Detailed information on how to assess conformity for this audit task can be found in the [MDSAP Audit Approach](#), Chapter 3: Measurement, Analysis and Improvement, under task 7

# Task 7

- *Links:*

- *Production and Service Controls*

- During audit of Production and Service Controls:

- If the corrective action or preventive action involves changing a production process, consider selecting this process for evaluation

- *Purchasing*

- During audit of Purchasing:

- Consider selecting suppliers for evaluation that performed production and process changes





# Task 8

- 8. Verify that controls are in place to ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. Confirm that an appropriate disposition was made, justified, and documented 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: 60-1, 60-2 (Old: 60); 21 CFR 820.90(a)]*

# Task 8

- Additional country-specific requirements: None
- Assessing conformity:
  - Select a sample of records involving nonconforming product that was in stock or returned
  - Confirm that the decision to use nonconforming product was made using risk based decision making
  - Select records of nonconforming products where the nonconformity has a higher risk of adversely affecting:
    - The ability of the finished device to meet its essential design outputs
    - The safety and efficacy of the product.

Detailed information on how to assess conformity for this audit task can be found in the [MDSAP Audit Approach](#), Chapter 3: Measurement, Analysis and Improvement, under task 8

# Task 9

9. **Confirm that when nonconforming product is detected after delivery or use, appropriate action is taken commensurate with the risk, or potential risks, of the nonconformity.**

*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: 60-3, 63 (Old: 60, 63); 21 CFR 820.100(a)]*

[MDSAP Audit Approach](#)

# Task 9

- Additional country-specific requirements: None
- Assessing conformity:
  - Confirm that the control and actions to be taken on nonconforming products detected after delivery or use was determined
  - Confirm decisions are made using adequate risk justification

Detailed information on how to assess conformity for this audit task can be found in the [MDSAP Audit Approach](#), Chapter 3: Measurement, Analysis and Improvement, under task 9

# Task 9

- *Link:*
  - *Medical Device Adverse Events and Advisory Notices Reporting*
    - Confirm that the appropriate MDSAP regulatory authorities have been notified, as necessary



# Task 10

- 10. Verify that internal audits of the quality management system are being conducted according to planned arrangements and documented procedures to ensure the quality management system is in compliance with the established quality management system requirements and applicable regulatory requirements, and to determine the effectiveness of the quality system. Confirm the internal audits include provisions for auditor 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]*

# Task 10

- Additional country-specific requirements: None
- Assessing conformity:
  - Interview auditors and ask
    - How are audits conducted
    - How long audits typically last
    - What documents are typically reviewed

Detailed information on country-specific requirements and how to assess conformity for this audit task can be found in the [MDSAP Audit Approach](#), Chapter 3: Measurement, Analysis and Improvement, under task 10

# Task 10

- *Links:*
  - *Management*
    - During the audit of the Management process, the audit team should confirm that the output of internal audits is an input to management review.





# Task 11

- 11. Determine if relevant information regarding nonconforming product, quality management system nonconformities, corrections, corrective actions, and preventive actions has been supplied to management for management review.**

*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)]*

# Task 11

- Additional country-specific requirements: None
- Assessing conformity:
  - Select a recent, significant corrective or preventive action
  - Determine which records or information regarding the event was submitted for management review

Detailed information on how to assess conformity for this audit task can be found in the [MDSAP Audit Approach](#), Chapter 3: Measurement, Analysis and Improvement, under task 11

# Task 11

- *Links:*
  - *Management*
    - During the audit of the Management process:
      - Confirm that the status of corrective and preventive actions is an input to management review



# Task 12

- 12. Confirm that the manufacturer has made effective arrangements for gaining experience from the post-production phase, handling complaint, and investigating the cause of nonconformities related to advisory notices with provision for feedback into Measurement, Analysis and Improvement process.**

**Select records of complaints for review that represent the highest risk to the user or have the largest impact on the ability of the device to meet its essential design outputs.**

**Verify 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, 55-1, 55-2, 62 (Old: 6, 29, 43, 55, 62); 21 CFR 820.198]*

# Task 12

- Additional country-specific requirements: Australia (TGA); Brazil (ANVISA); Canada (HC); Japan (MHLW); and United States (FDA)
- Assessing conformity:
  - Review complaints and customer feedback
  - Review the analysis of complaint data and postmarket surveillance activities
  - Select one or more complaint failure modes

Detailed information on country-specific requirements and how to assess conformity for this audit task can be found in the [MDSAP Audit Approach](#), Chapter 3: Measurement, Analysis and Improvement, under task 12

# Task 12

- *Links:*
  - *Medical Device Adverse Events and Advisory Notices Reporting*
    - During the review of complaints and feedback:
      - Confirm that individual medical device reports were made to the appropriate regulatory authorities when necessary.
  - *Design and Development*
  - *Production and Service Controls*



# Task 13

- 13. Where investigation determines that activities outside the organization contributed to a customer complaint, verify that records show that relevant information was exchanged between the organizations involved.**

*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: 5-5, 37, 60-1 (Old: 5, 37, 60); 21 CFR 820.100(a)(6)]*

# Task 13

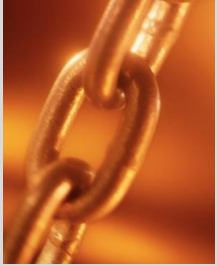
- Additional country-specific requirements: None
- Assessing conformity:
  - Confirm that information related to quality problems or nonconforming product is disseminated

Detailed information on how to assess conformity for this audit task can be found in the [MDSAP Audit Approach](#), Chapter 3: Measurement, Analysis and Improvement, under task 13



# Task 13

- *Links:*
  - *Purchasing*
    - During the audit of the organization's Purchasing process:
      - If significant nonconformities are related to supplied product, the audit team should consider selecting those suppliers for evaluation



# Task 14

- 14. Verify that the medical device organization has defined and documented procedures for evaluation of complaints for adverse event reporting.**

**Confirm that decisions to not report complaints were made according to established procedures and a documented rationale.**

*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, 55-3 (Old; 6, 29, 62); 21 CFR 803]*

# Task 14

- Additional country-specific requirements: Refer to MDSAP process Medical Device Adverse Events and Advisory Notices Reporting
- Assessing conformity:
  - Asses whether the complaint was evaluated
  - Confirm the appropriate reports and information was provided to the regulatory authority when appropriate
  - Compare the submitted reports to the associated complaint and complaint investigation
  - Confirm that reportable events were evaluated for corrective action when necessary

Detailed information on country-specific requirements and how to assess conformity for this audit task can be found in the [MDSAP Audit Approach](#), Chapter 3: Measurement, Analysis and Improvement, under task 14

# Task 15

- 15. Confirm that the manufacturer has made effective arrangements for the timely evaluation of quality problems involving distributed product for potential issuance and implementation of advisory notices.**

**Select records for review of quality problems that were evaluated for potential issuance of advisory notices (include records where a decision was made not to issue an advisory notice as well as records of decision to issue advisory notices) and assess whether the organization has taken actions appropriately based on risk and documented the rationale.**

*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, 60-3 (Old: 6, 29, 60); 21 CFR 806.820.100(a)]*

# Task 15

- Additional country-specific requirements: Refer to MDSAP process Medical Device Adverse Events and Advisory Notices Reporting
- Assessing conformity:
  - Select quality issues evaluated for potential advisory actions
  - Assess whether appropriate actions were taken and decisions were justified based on risk
  - Assess whether the scope of the quality issue was determined appropriately

Detailed information on how to assess conformity for this audit task can be found in the [MDSAP Audit Approach](#), Chapter 3: Measurement, Analysis and Improvement, under task 15

# Task 16

- 16. Determine, based on the assessment of the Measurement, Analysis and Improvement process overall, whether management provides the necessary commitment to detect and address product and quality management system nonconformities, and ensure the continued suitability and effectiveness of the quality management system.**

*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: 5-3, 11, 54, 62; (Old: 5, 11, 54, 62)]

# Task 16

- Additional country-specific requirements: None
- Assessing conformity:

Information on and how to assess conformity for this audit task can be found in the [MDSAP Audit Approach](#), Chapter 3: Measurement, Analysis and Improvement, under task 16.

# Summary

- The Measurement, Analysis and Improvement process is the second primary process to be audited per the MDSAP audit sequence.
- The identification of existing and potential causes of product and quality problems is:
  - One of the most important activities in the quality management system
  - Carried out under the Measurement, Analysis and Improvement process



# Conclusion

This concludes the training module for the MDSAP process: Measurement, Analysis and Improvement

