

## **MDSAP: Production and Service Controls: Part 3**

### **Slide 1**

I am CAPT Kimberly Lewandowski-Walker, Senior Regulatory Officer at the Center for Devices and Radiological Health at the U.S. Food and Drug Administration. I will be your presenter for this module. In this training module, we will be reviewing the third of three trainings for the Medical Device Single Audit Program (or MDSAP): Production and Service Controls and how to audit this process.

### **Slide 2**

The prerequisites for understanding this Production and Service Controls training module are the MDSAP training modules: "Introduction to the MDSAP Program", "Overview of the MDSAP Audit Process", "Management Process", "Measurement, Analysis and Improvement Process", "Design and Development Process", and Production and Service Controls Process: Parts 1 and 2 are prerequisites to this course.

### **Slide 3**

In this training module, we will review the purpose of auditing the Production and Service Controls process and continue with explaining the audit tasks for Production and Service Controls process: **Part 3** in terms of description and related Clauses and Regulations; country-specific requirements and assessment of conformity; and links to other MDSAP processes.

### **Slide 4**

We will begin again with reviewing the purpose of auditing the Production and Service Controls process.

### **Slide 5**

The purpose of auditing the production and service controls process (including testing, infrastructure, facilities, equipment, and servicing) is to verify that the manufacturer's processes are capable of ensuring that products will meet specifications.

Accomplishment of the outcomes for the Production and Service Controls process is accomplished through the completion of the audit tasks. We will now continue our discussion of the audit tasks and links to the interrelated MDSAP processes.

### **Slide 6**

We will now continue our discussion of the audit of the Production and Service Controls process by explaining the remaining audit tasks for the Production and Service Controls process, Part 3 in terms of the description and related Clauses and Regulations; the country-specific requirements and assessment of conformity; and links to other MDSAP processes.

### **Slide 7**

Audit tasks 1-10 were discussed in MDSAP training module Production and Service Controls, Part 1. Audit tasks 11-20 were discussed in MDSAP training module Production and Service Controls, Part 2. Part 3 will commence with audit Task 21.

### **Slide 8**

Task 21: Verify that acceptance activities assure conformity with specifications and are documented. Confirm the extent of acceptance activities are commensurate with the risk posed by the device.

The related clauses of ISO 13485:2016 are listed on this slide along with related regulations for the participating countries.

#### **Slide 9**

There are additional country-specific requirements for Brazil and the United States. Assessing conformity includes confirming that the medical device organization has defined processes for receiving, in-process, and final acceptance activities, reviewing a sample of batch records and confirm that acceptance activities have been documents and show specified requirements have been met, and confirming that the organization has taken the appropriate action to determine suitability of the acceptance activities.

Detailed information on country-specific requirements and how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 6: Production and Service Controls, under Task 21.

#### **Slide 10**

The audit team may choose to review the purchasing controls and requirements for suppliers of higher risk products. The audit team should also consider reviewing the purchasing controls and requirements for suppliers of products that undergo minimal acceptance activities at the device manufacturer, particularly if the supplied product is manufactured using a process that requires validation.

During the review of acceptance activities, if the audit team encounters situations where records of acceptance activities for supplied product reveal products that do not meet specified requirements, consider selecting those suppliers for review during the audit of the organization's Purchasing process. The establishment of the necessary purchasing controls and required acceptance activities is a design output.

The degree of the purchasing controls necessary and extent of acceptance activities should be based on the risk posed by the product not meeting its specified requirements and essential function.

#### **Slide 11**

Task 22: Verify that the identification, control, and disposition of nonconforming products is adequate, based on the risk the nonconformity poses to the device meeting its specified requirements.

The related clauses of ISO 13485:2016 are listed on this slide along with related regulations for the participating countries.

#### **Slide 12**

There are no additional country-specific requirements for this task. Assessing conformity includes confirming that the medical device organization has defined and implemented procedures for identification, control, segregation, evaluation, and disposition of nonconforming product and ensuring that the medical device organization has established an interface/interaction between processes for identification of nonconforming product and corrective action.

Detailed information on how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 6: Production and Service Controls, under Task 22.

#### **Slide 13**

The audit team should be mindful of any instances where the acceptance of nonconforming product has led to finished devices not meeting specified requirements. This information can often be found in records of acceptance activities and complaint records.

During the review of the organization's corrective and preventive actions, the auditors may have noted instances where nonconforming products were found to be the underlying cause of quality problems and complaints.

The audit team should consider reviewing the organization's handling and evaluation of nonconforming products that were determined to be the underlying cause of quality problems.

#### **Slide 14**

Ensure the analysis of data regarding nonconforming product is considered as an input to the organization's Measurement, Analysis and Improvement process and that corrective or preventive actions have been implemented when necessary.

#### **Slide 15**

Task 23: If a product needs to be reworked, confirm the manufacturer has made a determination of any adverse effect of the rework upon the product. Verify the rework process has been performed according to an approved procedure, that the results of the rework have been documented, and that the reworked product has been re-verified to demonstrate conformity to requirements.

The related clauses of ISO 13485:2016 are listed on this slide along with related regulations for the participating countries.

#### **Slide 16**

There are no additional country-specific requirements for this task. Assessing conformity includes being mindful of instances where the underlying cause of quality problems such as complaints that finished devices do not meet specified requirements, are traced to devices that have been reworked and considering reviewing process validation to confirm that the medical device organization has data to show the process is effective, reproducible, and stable, and that the medical device organization is operating the process within the validated parameters.

Detailed information on how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 6: Production and Service Controls, under Task 23.

There are no links to other MDSAP processes for Task 23.

#### **Slide 17**

Task 24: Verify that procedures are established and maintained for preserving the conformity of product and constituent parts of a product during internal processing, storage, and transport to the intended destination. This preservation encompasses identification, handling, packaging, storage, and protection, including those products with limited shelf-life or requiring special storage conditions.

The related clauses of ISO 13485:2016 are listed on this slide along with related regulations for the participating countries.

#### **Slide 18**

There are no additional country-specific requirements for this task. Assessing conformity includes confirming that the needed control measures are implemented to ensure the conformity of product to its specified requirements.

Detailed information on how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 6: Production and Service Controls, under Task 24.

There are no links to other MDSAP processes for Task 24.

### **Slide 19**

Task 25: Confirm that the medical device organization performs a review of customer requirements, including the purchase order requirements, prior to the organization's commitment to supply a product to a customer. Verify that the medical device organization maintains documentation required by regulatory authorities regarding maintenance of distribution records.

The related clauses of ISO 13485:2016 are listed on this slide along with related regulations for the participating countries.

### **Slide 20**

There are additional country-specific requirements for Brazil, Canada, and United States for this task. Detailed information on country-specific requirements and how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 6: Production and Service Controls, under Task 25.

There are no links to other MDSAP processes for Task 25.

### **Slide 21**

Task 26: If installation activities are required, confirm records of installation and verification activities are maintained.

The related clauses of ISO 13485:2016 are listed on this slide along with related regulations for the participating countries.

### **Slide 22**

There are no additional country-specific requirements for this task. Assessing conformity includes limiting the review of the installation procedures to confirming the necessary procedures are in place.

Detailed information on how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 6: Production and Service Controls, under Task 26.

There are no links to other MDSAP processes to Task 26.

### **Slide 23**

Task 27: Determine if servicing activities are conducted and documented in accordance with defined and implemented instructions and procedures. Confirm service records are used as a source of quality data in the Measurement, Analysis and Improvement process.

The related clauses of ISO 13485:2016 are listed on this slide along with related regulations for the participating countries.

#### **Slide 24**

There are additional country-specific requirements for Brazil and United States for this task. Assessing conformity includes observing instances of where nonconformities occurred and/or complaints were received after the servicing of the device, and confirming, when necessary, that data regarding service reports is analyzed for possible corrective action or preventive action.

Detailed information on additional country-specific requirements and how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 6: Production and Service Controls, under Task 27.

#### **Slide 25**

This task has a link to Measurement, Analysis and Improvement process. During the audit of the organization's Measurement, Analysis and Improvement process, the audit team may have already confirmed that quality data from the analysis of servicing activities is analyzed for possible corrective or preventive action.

When reviewing the organization's service reports, the audit team should be mindful of service reports that appear to be product complaints. Ensure that service reports that appear to be complaints have been appropriately addressed. In some instances, a similar quality problem for a particular device may be found in the service reports and the complaint records. In these instances, confirm the organization is taking appropriate corrections and/or corrective actions considering a similar quality problem is observed in multiple data sources.

#### **Slide 26**

Task 28: When appropriate, verify that risk control and mitigation measures are applied to transport, installation and servicing, in accordance with the organization's risk management practices.

The related clauses of ISO 13485:2016 are listed on this slide along with related regulations for the participating countries.

#### **Slide 27**

There are no additional country-specific requirements for this task. Assessing conformity includes confirming that the necessary processes have been implemented to ensure the risk control measures are in place if risk control measures were identified involving the delivery, installation, and servicing for a particular device.

Detailed information on how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 6: Production and Service Controls, under Task 28.

There are no links to other MDSAP processes for Task 28.

#### **Slide 28**

Task 29: Determine, based on the assessment of the production and service process overall, whether management provides the necessary commitment to the production and service process to ensure devices meet specified requirements and quality objectives.

The related clauses of ISO 13485:2016 are listed on this slide along with related regulations for the participating countries.

**Slide 29**

There are no additional country-specific requirements for this task. Detailed information on how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 6: Production and Service Controls, under Task 29.

**Slide 30**

In summary, accomplishment of the expected outcomes of auditing the Production and Service Controls process is accomplished through the completion of all 29 audit tasks.

**Slide 31**

This concludes the training for MDSAP process: Production and Service Controls: Part 3 and is the final training module for the Production and Service Control process.

