

## **“MDSAP: Device Marketing Authorization and Facility Registration**

### **Slide 1**

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In this training module, we will be reviewing the Device Marketing Authorization and Facility Registration process for the Medical Device Single Audit Program.

### **Slide 2**

The prerequisites for understanding this Device Marketing Authorization and Facility Registration Process training module are successful completion of the MDSAP training modules: “Introduction to the MDSAP Program”, “Overview of the MDSAP Audit Process, and “MDSAP: Management Process”.

### **Slide 3**

In this Device Marketing Authorization and Facility Registration process training module, we will Explain the Device Marketing Authorization and Facility Registration process, describe the purpose of auditing the Device Marketing Authorization and Facility Registration process, discuss the expected outcomes from the audit of this process, and Explain the audit tasks in terms of the description and related Clauses and Regulations for each audit task, the list of country-specific requirements and assessment of conformity for each audit task, and indicate the links to other MDSAP processes.

### **Slide 4**

Let’s begin with explaining the Device Marketing Authorization and Facility Registration process.

### **Slide 5**

The Device Marketing Authorization and Facility Registration process may be audited as a linkage from the Management process or the Design and Development process.

### **Slide 6**

We will now move to discussion of the purpose of auditing the Device Marketing Authorization and Facility Registration process

So, why do we audit this process?

### **Slide 7**

As you can see from this diagram, the Device Marketing Authorization and Facility Registration can be initially audited as a linkage from the Management process; however, you may find it necessary to revisit the Device Marketing Authorization and Facility Registration process if, during the audit of the Design and Development process, you find that the organization has made changes to their devices that require marketing authorization.

### **Slide 8**

The purpose of auditing the Device Marketing Authorization and Facility Registration process is to verify that the medical device organization has performed the appropriate activities regarding device marketing authorization and facility registration with regulatory authorities participating in the MDSAP.

### **Slide 9**

We will now move to a discussion of the expected outcomes of auditing Device Marketing Authorization and Facility Registration process. The next few slides will discuss these expected outcomes.

### **Slide 10**

As a result of the audit of the Device Marketing Authorization and Facility Registration process, objective evidence will show whether the organization has: complied with requirements to register or license device facilities; submitted device listing information to regulatory authorities when applicable; obtained device marketing authorization in the appropriate jurisdictions; and arranged for assessment of changes, where applicable, and obtained marketing authorization for changes to devices or the quality management system which require amendment to existing marketing authorization.

### **Slide 11**

The next few slides will explain each audit tasks in terms of the Description and related Clauses and Regulations for each audit task, the Country-specific requirements and assessment of conformity, and the Links of the Device Marketing Authorization and Facility Registration process to other MDSAP processes.

Accomplishment of the expected outcomes for the Device Marketing Authorization and Facility Registration process is achieved through the completion of the audit tasks. For this process, the primary means of completing the audit tasks is by verifying that the organization meets the regulatory requirements of the various jurisdictions participating in the Medical Device Single Audit Program.

### **Slide 12**

Task 1: Verify the medical device organization has complied with regulatory requirements to register or license device facilities and submit device listing information in the appropriate jurisdictions where the organization markets or distributes their devices.

The related clauses of ISO 13485:2016 are listed on this slide. There are no related regulations for the participating countries.

### **Slide 13**

There are additional country-specific requirements for Australia, Brazil, Canada, Japan, and United States.

Assessing conformity includes reviewing labeling for product being supplied to a particular jurisdiction. Special attention should be paid to instances where products are being marketed to MDSAP jurisdictions that marketing authorization has not been granted. This may be evident through audit of other processes, such as Design and Development. Detailed information on country-specific requirements and how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 2: Device Marketing Authorization and Facility Registration, under task 1.

### **Slide 14**

This task has a link to Management processes. During audit of the Management process, confirm that management is aware of, and has made arrangements for, device marketing authorization and facility registration.

### **Slide 15**

Task 2: Confirm the medical device organization has received appropriate marketing clearance or approval in the regulatory jurisdictions where the organization markets their devices.

The related clauses of ISO 13485:2016 are listed on this slide. There are no related regulations for the participating countries.

**Slide 16**

There are additional country-specific requirements for Australia, Brazil, Canada, Japan, and the United States.

Detailed information on country-specific requirements and how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 2: Device Marketing Authorization and Facility Registration, under task 2.

**Slide 17**

This task has linkages to Management and Design and Development processes.

During the audit of the Management and Design and Development processes, ensure that management is aware of requirements for device marketing authorization and facility registration, and that these are considered when designing the device. Confirm that management obtains marketing authorization in the appropriate jurisdictions prior to commercial distribution of the device.

**Slide 18**

Task 3: Verify the medical device organization has identified changes to marketed devices or the quality management system which require notification to regulatory authorities. The audit team should pay special attention to situations observed in the audit of the Design and Development process (specifically design changes) that may require notification to the jurisdictions to which the changed devices are marketed.

The related clauses of ISO 13485:2016 are listed on this slide. There are no related regulations for the participating countries.

**Slide 19**

There are additional country-specific requirements for this task for Australia, Brazil, Canada, Japan, and the United States.

Detailed information on country-specific requirements and how to assess conformity for this audit task can be found in the MDSAP Audit Approach, Chapter 2: Device Marketing Authorization and Facility Registration, under task 3.

**Slide 20**

This task has links to the Design and Development process.

During the audit of the Design and Development process, the audit team should confirm the organization has considered regulatory requirements for device marketing authorization and facility registration; and has complied with these requirements prior to marketing the changed device in the applicable regulatory jurisdictions.

**Slide 21**

In summary, the Device Marketing Authorization and Facility Registration process may be audited as a linkage from the Management process or the Design and Development process.

**Slide 22**

This concludes the training module for MDSAP process: Device Marketing Authorization and Facility Registration.