
Johnson & Johnson

Sharing MDSAP Best Practices
Medical Device Manufacturer Perspectives

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MDSAP Best Practices

Tip #1: Review the MDSAP Audit Approach document

- The MDSAP Audit Approach (MDSAP AU P0002) is the Auditing Organization's guide and tool:
  - Combines the formerly separate "MDSAP Audit Model" and "Companion Document" into a single document (Effective September 1, 2020)
  - ***Everything*** needed is clearly described in the MDSAP Audit Approach document and other MDSAP documents – including all of the questions that will be asked
- Each question is cross-referenced with the applicable section of ISO 13485:2016 or the country-specific regulation

Tip #2: Conduct a Thorough Gap Assessment

- Use the MDSAP Audit Approach document to **perform a gap analysis**
- **Perform internal audit**(s) that reviews the specific information that the Auditing Organization will be focusing on

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Tip #3: Organize your Documents

- The MDSAP audit is very comprehensive **and it is timed**.
- All documents will need to be **organized** and quickly accessible
- The Auditing Organization **will not** be able to re-visit areas where documents and records were not readily available.
- Have as much information and records **pre-loaded** into electronic files (and organized) or **pre-printed**

Tip #4: Be prepared to describe supplier controls

- Organizations need to **demonstrate** (and justify) how control over suppliers is maintained.
- Controls need to be **incorporated into procedures** and continually monitored to ensure that the supplier is compliant.
    - Can NOT just say the supplier is ISO or MDSAP certified

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Tip #5: Be Clear on Scope of Activities

- Be able to **clearly desc**ribe the scope of activities at a particular location
- **Clearly list** the scope of activities at various sites and the relationships
- Very important to define this early with the Auditing Organization (Stage 1 audit) so that the proper amount of time can be calculated for Stage 2.

Tip #6: Employees must be proven competent

- Ensure there is objective evidence that employees are **competent** (and not just trained) in regulatory requirements of all pertinent jurisdictions
- Objective evidence may include testing after training, job function checks to assure competency, etc.

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Tip #7: Keep the Auditor's Perspective in Mind

- Keep the goals of the Auditing Organization in mind. They are trying to assess compliance on behalf of the Regulatory Authorities – this is a large responsibility
- Explain things carefully and completely, don't assume they understand all of the related processes within an organization

Other Tips, Tricks, and Reminders

☑ **Set recurring meetings** (as frequently as needed) with site leadership, audit team and subject matter experts. For example:

- Align on approach for onsite and/or remote audit that works for your location
- Discuss agenda and requests etc.
- Ensure availability of SME's; assure each key audit role has a back up available
- Define process for scanning of records located on site
- Ensure audit team has access and is trained to the technology that will be used

☑ **Connect in advance** with Lead Auditor to align on pre-requests, agenda, execution logistics and technology that will utilized during the audit.

Other Tips, Tricks, and Reminders

- ☑ Perform **trial run** of platform & technology
- ☑ **Create electronic or physical paper record flows** and train your front room, back room, and subject matter experts on the process
- ☑ Get agreement on the **internal communication channels** that will be used during the audit and set these up
- ☑ Pre-empt and prepare as many requests up front – and **map and organize** according to the agenda
- ☑ **Clarify requests** with auditor; ensure understanding of the “size” of the request, especially if records require scanning

Other Tips, Tricks, and Reminders

- ☑ Maintain **strong verbal communication** with the auditor to help build the relationship
  - Difficult to predict/visualise how they are feeling, especially remotely
  - Are you all looking at the same page of the document & moving at the same pace. Note: Due to the style of the auditor this could vary
- ☑ Records are generally selected based on **risk**. Review analysis reports (e.g., NCs, CAPA, Complaints, etc.) and be prepared to present high-risk areas
- ☑ Be prepared to present **Quality Agreements** with different areas of the company (if needed) and suppliers and demonstrate how execution of responsibilities outlined is ensured. Ensure Quality Agreements reflect all applicable regulations and standards.

The key to success in the MDSAP Program…

Prepare, prepare, prepare

Thank you.


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