Medical Device Single Audit Program (MDSAP)

October 2017 Roadshow
How MDSAP works
Timelines and Status
Auditing Organization Perspective
Key Points for Manufacturers
How MDSAP Works
Medical Device Single Audit Program (MDSAP)

The International Medical Device Regulators Forum (IMDRF) recognizes that a global approach to auditing and monitoring the manufacturing of medical devices could improve their safety and oversight on an international scale. At its inaugural meeting in Singapore in 2012, the IMDRF identified a work group to develop specific documents for advancing a Medical Device Single Audit Program (MDSAP).

The Medical Device Single Audit Program allows an MDSAP recognized Auditing Organization to conduct a single regulatory audit of a medical device manufacturer that satisfies the relevant requirements of the regulatory authorities participating in the program.

International partners that are participating in the MDSAP include:

- Therapeutic Goods Administration of Australia
- Brazil’s Agência Nacional de Vigilância Sanitária
- Health Canada
- Japan’s Ministry of Health, Labour and Welfare, and the Japanese Pharmaceuticals and Medical Devices Agency
- The World Health Organization (WHO) Prequalification of In Vitro Diagnostics (IVDs) Programme and the European Union (EU)
Available Documents

- MDSAP Policies, Procedures, Templates and Forms
  (Policies, procedures and other related documents supporting MDSAP)

- MDSAP Audit Procedures and Forms
  (Procedures and forms supporting Auditing Organization Audits)

- MDSAP Assessment Procedures and Forms
  (Procedures and forms supporting Regulatory Authority assessments)

- MDSAP Training Material
  (Auditing Organization and Regulatory Authority training material)

- MDSAP QMS Procedures and Forms
  (Procedures and forms supporting the MDSAP Quality Management System)

- MDSAP QMS Concern Resolution Report Form (PDF - 702KB)

- IMDRF/MDSAP WG and GHTF Documents
  (IMDRF MDSAP WG and GHTF documents supporting the program)

- MDSAP International Regulations [English] (Australia, Brazil, Canada, Japan, and USA)
MDSAP Audit Procedures and Forms

MDSAP AU P0002

- MDSAP AU P0002.003 Audit Model (PDF - 984KB) (ISO 13485:2003)
- MDSAP AU P0002.004 Audit Model (PDF - 680KB) (ISO 13485:2016)
- MDSAP AU G0002.1.003 revised 2017-04-17 (PDF - 1.1MB) (ISO 13485:2003)
- MDSAP AU G0002.1.004 revised 2017-04-17 (PDF - 1.1MB) (ISO 13485:2016)
MDSAP Audit Information

• Audit Procedures & Forms available, e.g., relevant documents
  • Audit Model   AU P0002.003 & .004 (81 pages)
  • Companion Document   AU G0002.1.003 & .004 (122 pages)
  • Audit Duration Calculation Form   F0008.1.003 & .2.002 Tab#2
  • Nonconformity Grading   GHTF/SG3/N19:2012
  • Post-Audit Activities and Timeline Policy   MDSAP AU P0027.004
  • Others on “MDSAP Documents” page
Audit Cycle

• Three Year Audit Cycle
  • Initial Audit (Stage One & Stage Two)
  • Surveillance Audits (Years 1 and 2)
  • Re-audit (Recertification Audit)
    • Note that not all Regulatory Authorities require “certificate”

• Other Possible Audits
  • Special Audits – extensions to scopes, moves, etc.
  • Audits by Regulatory Authorities
  • Unannounced Audits
How Does MDSAP Work?

- Regulatory Authorities
  - Assessments
  - Reports

- Auditing Organizations
  - Audits
  - NCs/CAPs

- Manufacturers
  - NCs/CAPs
Requirements

• ISO 13485 :2003 or :2016
• Country-specific requirements (where applicable)
  • TGR Sch 3, RDC 16, MO 169, CFR 21 Part 820
  • Clearly *identified* in the Audit Model & Companion Document
  • dIf shipping product to an MDSAP jurisdiction, country-specific requirements WILL apply (cannot opt out)
MDSAP Nonconformity Grading

• Definition of nonconformity unchanged (non fulfillment of requirement)
## MDSAP Nonconformity Grading

<table>
<thead>
<tr>
<th>QMS Impact</th>
<th>Direct</th>
<th>Indirect</th>
<th>Occurrence</th>
<th>Escalation Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct: 6.4 – 8.5</td>
<td>3</td>
<td>1</td>
<td>First</td>
<td>Absence of Process or Procedure or Led to Nonconforming devices on market</td>
</tr>
<tr>
<td>Indirect: 4.1-6.3</td>
<td>4</td>
<td>2</td>
<td>Repeat</td>
<td>+1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Occurrence</th>
<th>Escalation Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>First</td>
<td>Repeat</td>
</tr>
</tbody>
</table>

Maximum grade is a 5.
Unannounced Audits

• Upon request of Regulatory Authority
• Triggered by 1 or more Grade 5 NCs or 3 or more Grade 4 NCs
• Typically 6 to 9 months post-audit
• By two auditors, not less that one day
• Could take place at critical supplier
Access to Reports

• All Regulatory Authorities that are part of MDSAP get the reports (as applicable)

• MDSAP Database expected to be implemented 2018 – controlled access
Timelines and Status
## Timelines - QMS

<table>
<thead>
<tr>
<th></th>
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<th></th>
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<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CMDCAS</strong></td>
<td>Will continue to accept</td>
<td></td>
<td></td>
<td></td>
<td>ISO 13485: 2003 &amp; 2016</td>
<td>Only MDSAP</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Accept both ISO 13485 and MDSAP</td>
<td></td>
</tr>
<tr>
<td><strong>MDSAP</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>MDSAP Pilot Program</td>
<td></td>
<td>MDSAP Formal Program --&gt;</td>
<td></td>
</tr>
</tbody>
</table>

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For Manufacturers Currently Holding ISO 13485, ISO 13485 CMDCAS, CE MDD/IVD/AIMD Certificates

• Check with current Certification / Notified Body whether authorized AO
• Investigate best plan for timing of MDSAP audit considering:
  • Current ISO audit cycle/expiry and CMDCAS termination date
  • Transition plans to ISO 13485:2016, considering deadlines
  • Consider business plans (new markets?)
• MDSAP audit includes ISO 13485 requirements
• Investigate with CB/NB how they implement - whether the audit can include CE and/or ISO 9001:2015 requirements
• Are they fully scoped for future needs, such as MDR, IVDR
BSI Status

• BSI assessed early 2014 (first)
• Commenced audits fall 2014 (first)
• Completed assessments and witness audits by RAs (first)
• Continuing audits through present time (200+)
• Continued & increasing interest from manufacturers
• Increasing resources
## Update – AO’s (as of 4 October 2017)

<table>
<thead>
<tr>
<th>Auditing Organization</th>
<th>Application Received</th>
<th>Authorized to Conduct Audits</th>
<th>Recognition</th>
</tr>
</thead>
<tbody>
<tr>
<td>BSI</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>TUV-SUD</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Intertek</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>LNE G-MED</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>TUV-USA</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>SAI Global</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>DQS-MED</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Auditing Organization</th>
<th>Application Received</th>
<th>Authorized to Conduct Audits</th>
<th>Recognition</th>
</tr>
</thead>
<tbody>
<tr>
<td>DEKRA</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>TUV-Rheinland</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>LRQA</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>SGS</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>UL</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>NSF</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>NSAI</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

Source document:
Enrollment continues to grow

Data as of end August 2017

MDSAP Participating Manufacturer Sites - Calendar Year

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Key Points – for Manufacturers

• Manufacturers’ Feedback
  • Audits followed a set sequence of activities which allowed for planning
  • An increased focus on risk helped to drive risk-based thinking deeper into their organization
  • Strong focus on product and process quality and risks associated with change implementation
  • Cost benefit for a single audit for multiple jurisdictions
  • Need to get other jurisdictions to embrace the program to enhance benefit
  • Less business disruption
  • Consistent audit process
MDSAP - AO Perspective

MDSAP Program Truths

• New program and it will evolve and settle-down over time
• All Manufacturers are not alike in their approach and readiness for MDSAP audits
• All Auditing Organizations are also not alike in how they conduct MDSAP audits
• All auditors within an AO are not alike in how they assess to the MDSAP requirements
• However the requirements are known and the same for all
• Best practices will evolve, leading to improved implementation
# MDSAP - AO Perspective

## Program Distinctions

<table>
<thead>
<tr>
<th>Criteria</th>
<th>ISO 13485</th>
<th>MDSAP</th>
<th>CE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Program Customer</td>
<td>Manufacturer</td>
<td>Regulator</td>
<td>Mfr/Regulator</td>
</tr>
<tr>
<td>Auditing Organization Qualification</td>
<td>Competent Authority Accreditation Bodies</td>
<td>Regulators</td>
<td>Competent Authority</td>
</tr>
<tr>
<td>Audit Duration</td>
<td>Employee Count</td>
<td>Fixed Timing</td>
<td>Variable</td>
</tr>
<tr>
<td>Scheduled Assessments</td>
<td>Yes</td>
<td>Yes + unannounced follow-ups</td>
<td>Yes + unannounced</td>
</tr>
<tr>
<td>Nonconformance Grading</td>
<td>Major / Minor</td>
<td>1, 2, 3, 4, 5</td>
<td>Major / Minor</td>
</tr>
<tr>
<td>Product Approvals</td>
<td>N/A</td>
<td>Regulators</td>
<td>Notified Body</td>
</tr>
</tbody>
</table>
MDSAP - AO Perspective

MDSAP Challenges

1. Jurisdictional requirements
   • Interaction with ISO 13485
   • Complexity of differences
   • Inclusion of CE

2. Multiple Locations
   • How they interact
   • Where they are located

3. Adoption by manufacturers

4. Length of audit
   • Sufficient resources
   • Organization of audit plan

5. Reporting
   • Active voice
   • All jurisdictions
   • Specific timelines
   • NCR grading
### MDSAP - AO Perspective

**Audit Model Challenges**

<table>
<thead>
<tr>
<th>Auditors</th>
<th>Manufacturers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Task-based</td>
<td>Confused by delivery</td>
</tr>
<tr>
<td>Not ISO 13485 Plus</td>
<td>Single audit</td>
</tr>
<tr>
<td>Deep Dive into processes</td>
<td>Consistent flow</td>
</tr>
<tr>
<td>Regulatory Audit</td>
<td>Product - focused</td>
</tr>
<tr>
<td>Risk key part of audit</td>
<td>Risk focus support</td>
</tr>
</tbody>
</table>
MDSAP requirements

All applicable products and manufacturing locations must be audited.

Each site requires a separate report.

Outsourced processes/services may not be audited.
MDSAP - AO Perspective - Observations thus far

- Clarifying who and where control is managed over processes
- Focus on risk management throughout QMS
  - Appropriate amount defined and demonstrated
- Determining correct regulatory roles per jurisdiction
- Tracking implementation from quality planning activities in D&D thru to implementation in Production & Servicing
- Tracking decisions and control regarding selected suppliers and their ability to meet requirements from the initial on-boarding through to ongoing delivery and component/device performance.
- Statistical support for analysis of data gathered regarding effectiveness of QMS
Single Site Manufacturer

• Stage 1 easier to understand and plan for Stage 2
• Simpler QMS to review
• Responsibilities more clearly defined
• All activity auditable primarily at one location
• Regulatory roles usually managed simply
• Changes more easily managed by site and supplier versus multiple sites and divergent steps in processes
• Licensing more easily tracked
MDSAP - AO Perspective - Observations thus far

Multi-site Manufacturer

- Stage 1 is complex
  - How many certificates are to be issued?
  - How is it to be organized?
  - What sites and activities per site?
- Complex relationships between processes and types of sites, e.g. component mfg, finished device mfg, final packaging and distribution
- Central control over key QMS processes; e.g. Supplier approval and management, Internal Audits, Mgmt Review, Adverse Event reporting, Document Control, CAPA
- Coverage of requirements at each site to satisfy RAs needs for decisions related to certificates
MDSAP - AO Perspective

Additional changes on the horizon

• Website navigation instructions for each jurisdiction
• Audit task timeline changes
• Rationales for reduction in audit durations for unique mfr types; SW only, Virtual Mfr, small organizations (45 employees or less, rather than previous capped at 15)
• Campus location definition (1km)
• Site versus QMS focus for regulator review conclusions
• Adoption of on-line portal (REPS)
MDSAP - AO Perspective

Future Outlook

• Manufacturers embracing MDSAP program – large influx in new sites since start of 2017
• New jurisdictions engage as MDSAP Regulators
• Current jurisdictions expand use of MDSAP audit for other approvals / inspections
• Other jurisdictions accept MDSAP reports / certificate without engaging as Regulator in the program
MDSAP - AO Perspective

Improvement Opportunities

• Improved Regulatory training on jurisdictional requirements
• Guidance for conducting remote or all electronic audit records review versus current paper-based.
Focus – Key Points for Manufacturers
Key Points – for Manufacturers

- **Canada** – Health Canada QMS section:
Key Points – for Manufacturers

**MDSAP Transition Reminder**

In accordance with Health Canada’s announced MDSAP transition plan, CMDCAS certificates will no longer be accepted after December 31st 2018. Manufacturers will be required to submit valid MDSAP certificates by no later than January 1st, 2019 in order to maintain their medical device licences. To facilitate a smooth transition, Health Canada is encouraging manufacturers to begin the transition process in a timely matter to ensure compliance with the regulatory requirements at the end of the transition period. More information on the MDSAP transition plan and the regulatory requirements can be found in a Health Canada notice.

- Other MDSAP related information in “Activities – International”
Key Points – for Manufacturers

• Q4 from FAQ document excerpt:

Q4: I sell devices only in Canada. Do I still need the MDSAP certificate?
A: Yes. All manufacturers must transition from CMDCAS to MDSAP certificates to meet the quality management system requirements of the **Medical Devices Regulations**. For manufacturers who only sell in Canada, the regulatory requirements of the other MDSAP participants (United States, Brazil, Australia, and Japan) will not be audited. Distributors and retailers are not subject to the quality management system requirements.

• Cannot opt out IF supplying to any of 5 jurisdictions
  • refer to excerpt from Description/Announcement document:

  Can the manufacturer exclude a jurisdiction from the scope of an MDSAP pilot audit?

  A manufacturer may exclude the requirements of a jurisdiction where the organization does not intend to supply medical devices. In other words, audit criteria under the MDSAP Pilot include at a minimum ISO 13485:2003 and the medical device regulations that are applicable in any of the participating regulatory authority’s jurisdiction where the organization supplies medical devices.
Key Points – for Manufacturers

• Repeat: Cannot opt out IF supplying to any of 5 jurisdictions
  • refer to excerpt from FAQ document Question 95:

95. Can the manufacturer exclude a jurisdiction from the scope of an MDSAP audit?

A manufacturer may exclude the requirements of a jurisdiction where the organization does not intend to supply medical devices. In other words, audit criteria under the MDSAP include at a minimum ISO 13485 and the medical device regulations that are applicable in any of the participating regulatory authority’s jurisdiction where the organization supplies medical devices.
Key Points – for Manufacturers’ Preparation

• Companion Document !!
• Lists/records of products registered by jurisdiction
• Technical documents, 510(k)s
• Risk management throughout product life cycle
• For multi-site manufacturers: clear documentation of roles/responsibilities
• Internal audits covering all applicable regulations, along with records of auditor training
• Work very early with selected AO to plan/schedule
For additional follow-up:
Tony Rizzo, AVP Medical Devices - Development
anthony.rizzo@bsigroup.com
(m) +1 (571) 344-3783