MDSAP
Medical Device Single Audit Program

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International Medical Device Regulators Forum (IMDRF)

- The IMDRF replaced the GHTF.
- Only regulators will make decisions.
- The mission of the IMDRF is to strategically accelerate international medical device regulatory convergence to promote an efficient and effective regulatory model for medical devices that is responsive to emerging challenges in the sector while protecting and maximizing public health and safety.
Regulatory Convergence

- Voluntary process whereby the regulatory requirements and approaches across countries and regions become more similar or aligned over time as a result of the adoption of the same technical documents, standards and scientific principles (harmonization) and similar regulatory practices and procedures.
Management Committee Members

- US Food and Drug Administration (FDA)
- Health Canada Medical Devices Bureau
- Brazilian Health Surveillance Agency (ANVISA)
- Australia Therapeutic Goods Administration (TGA)
- Europe: Medicines and Healthcare products Regulatory Agency (MHRA)
- Japan Pharmaceuticals and Medical Devices Agency (PMDA)
**Official Observers**

- World Health Organization (WHO)

**Affiliate Organizations**

- Asian Harmonization Working Party
- APEC Regulatory Harmonization Steering Committee, Life Sciences Innovation Forum
IMDRF Work Items

- A Review of the NCAR system
- Roadmap for implementation of UDI system
- Recognized standards
- Regulated Product Submission
- Medical Device Single Audit Program (MDSAP)
- Standalone Software
MDSAP Work Group Members

- US Food and Drug Administration (FDA)
- Health Canada Medical Devices Bureau
- Brazilian Health Surveillance Agency (ANVISA)
- Australia Therapeutic Goods Administration (TGA)
- Japan Pharmaceutical and Food Safety Bureau
- Europe (MHRA)
- Asian Harmonization Working Party (Saudi Food & Drug Authority)
Medical Device Single Audit Program (MDSAP)

• The Work Group is developing a standard set of requirements for auditing organizations (certification bodies) performing regulatory audits of medical device manufacturers’ quality management systems.

• The documents will be applicable to competent authority auditing groups/inspectorates, as well as third party organizations that conduct such audits. This is an initial critical step in establishing a single audit program.

• MDSAP will not require changes to country specific regulations
The FDA will not accept MDSAP for initial visits but will accept in lieu of routine inspections. (not acceptable “for cause”)

ANVISA will accept MDSAP for initial audits except for some higher risk devices. (1200 companies are waiting to be inspected)

Health Canada will use MDSAP in the same manner as CMDCAS.

TGA will use MDSAP as part of the evidence for compliance with medical device market authorization requirements.
• MDSAP source documents considered as input for the program:
  – HC Draft Auditing Organization Recognition Criteria and HC GD 210
  – Japan MHLW Registration Criteria for Medical Device Conformity Assessment Bodies
  – US FDA -AP Inspection Program Rating Criteria
  – IAF MD9:2011
MDSAP

- MDSAP Additional Requirements
  - Impartiality, Appearance of Conflict of Interest,
  - Outsourcing Auditing Activities
  - Arrangements with Medical Device Manufacturers for the Sharing of Audit Information
- It still not clear what the role of the Accreditation Bodies will be. The regulators will likely audit and approve the Certification Bodies directly.
Key MDSAP Documents

- **WG (PD2)/N3R5**: Recognition and Monitoring of Organizations undertaking Audits of Medical Device Manufacturers (21 pages)
- **WG (PD1)/N4R2**: Auditor Competency and Training Requirements for Organizations undertaking Audits of Medical Device Manufacturers (23 pages)
- **WG (PD1)/N5R2**: Regulatory Assessment Program and Assessment Strategy Utilizing for the Recognition and Monitoring of Medical Device Auditing Organizations (112 pages)
- Quality Management System Audit Reports (19 pages)
- Audit Model (56 pages)
- Companion Document (details of audit tasks for each process) (96 pages)
- Audit Time Calculation Procedure (5 pages)
MDSAP Processes and Audit Sequence

Process approach with four primary processes:
1. Management;
2. Measurement, Analysis and Improvement;
3. Design and Development;
4. Production and Service Controls;

And a supporting process
- Purchasing

The MDSAP audit process has two additional supporting processes:
- Device Marketing Authorization and Facility Registration
- Medical Device Adverse Events and Advisory Notices Reporting.
By following the MDSAP audit sequence:

• Audits performed for MDSAP will be conducted in a consistent manner across auditing organizations.

• Audits will be conducted logically and efficiently, with attention to the interactions between processes.

• Auditors will be able to determine whether systemic quality management system nonconformities are present.
All surveillance audits must cover at least the following:

- A review of changes to the manufacturer, QMS, or products since the last audit
- All of the MDSAP Management process
- All of the MDSAP Measurement, Analysis, and Improvement Process
- All of the MDSAP Medical Device Adverse Events and Advisory Notices Reporting Process
- All of the MDSAP Device Marketing and Facility Registration Process
- Task 1 of the MDSAP Design and Development Process, with sampling focused on products introduced since the last audit
Audit Model

• Each process is made up of a number of audit tasks
• The Audit Model will direct the auditor to confirm specific evidence for each task.
• Each task will reference the applicable clause of ISO 13485 and specific regulatory requirements from the four participating countries.
• There are also noted linkages to other processes.
• There is a focus on Risk Management throughout the audit. The interrelationships of risk management are noted in “blue” italic font.
• The Companion Document provides more details and explanations
• Verify that a quality policy and objectives have been set at relevant functions and levels within the organization. Ensure the quality objectives are measurable and consistent with the quality policy. Confirm appropriate measures are taken to achieve the quality objectives.

• Clause and Regulation: [ISO 13485:2003: 5.3, 5.4.1; TG(MD)R Sch3 P1 1.4(5)(a); RDC ANVISA 16/2013: 2.2.1; 21 CFR 820.20(a)]

• Additional country-specific requirements: None
• It is the responsibility of the Auditing Organization to collect and maintain evidence that demonstrates that personnel involved in audits and decision making functions meet the minimum specified competency requirements.
Auditor Competency

Documented processes to:

1. initially qualify personnel involved in audits and decision making functions to the specified requirements based on demonstrated competence;
2. ensure that the competence of personnel involved in audits and decision making functions is maintained on a continuing basis;
3. provide personnel with appropriate support and resources where needed and,
4. maintain records of these activities including a signed Code of Conduct for each person involved in the Regulatory Audit process.
Prerequisite Education

- Lead Auditors, Auditors, Final Reviewers, and Technical Experts should hold a diploma from a university or technical college in medicine, science, or engineering. Disciplines of interest include, for example:
  - Biology
  - Microbiology
  - Chemistry
  - Biochemistry
  - Computer hardware and software technology
  - Material sciences
  - Engineering - electrical, mechanical, biomedical, clinical, bioengineering,
  - Human physiology
  - Medicine
  - Pharmacy
  - Physics and biophysics
On-line Computer Training

- The MDSAP training on the audit model is intended to be performed in the following order:
  1. Introduction to MDSAP
  2. MDSAP Management
  3. MDSAP Device Marketing Authorization and Facility Registration
  4. MDSAP Measurement, Analysis and Improvement
  5. MDSAP Medical Device Adverse Events and Advisory Notices Reporting
  6. MDSAP Design and Development
  7. MDSAP Production and Service Controls, part 1
  8. MDSAP Production and Service Controls, part 2
  9. MDSAP Production and Service Controls, part 3
  10. MDSAP Purchasing

- Learners must score 70% or better on each of the Final Quizzes for successful completion of the training.
## Auditor Competency Rating Criteria

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<tr>
<th>Importance</th>
<th>Requirement</th>
<th>Level</th>
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</thead>
<tbody>
<tr>
<td>Critical Skill or Knowledge</td>
<td>Must have</td>
<td>4</td>
</tr>
<tr>
<td>Important Skill or Knowledge</td>
<td>Should have</td>
<td>3</td>
</tr>
<tr>
<td>Helpful Skill or Knowledge</td>
<td>Preferable to have</td>
<td>2</td>
</tr>
<tr>
<td>Supplemental Skill Set</td>
<td>Optional</td>
<td>1</td>
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## Fundamental Competencies

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<tr>
<th></th>
<th>Program Administrator</th>
<th>Lead Auditor</th>
<th>Auditor</th>
<th>Technical Expert</th>
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<tr>
<td>Ethics</td>
<td>4</td>
<td>4</td>
<td>4</td>
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<td>Objectivity</td>
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<td>Reasoning</td>
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<td>3</td>
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<td>Interpersonal Skills</td>
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<td>4</td>
<td>4</td>
<td>3</td>
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<tr>
<td>Analysis</td>
<td>4</td>
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<td>Communication</td>
<td>4</td>
<td>4</td>
<td>3</td>
<td>3</td>
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<tr>
<td>Diligence</td>
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<td>4</td>
<td>4</td>
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<td>Adaptability</td>
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<td>4</td>
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<tr>
<td>Tenacity</td>
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<td>Intuition</td>
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<td>4</td>
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<tr>
<td>Observation</td>
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<td>4</td>
<td>4</td>
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MDSAP Transition

• There will be a pilot program starting in January 2014.
• Several CB’s will be in the Pilot Program.
• Pilot Program countries will be USA, Canada, Brazil and Australia.
• Pilot will finish at the end of 2016.
• Once fully implemented MDSAP will replace CMDCAS in Canada.
• It is unclear if Europe will join MDSAP in the future.
• Japan is involved in the Pilot Program as an observer.
Unannounced Audits

- Regulatory Authorities themselves can perform special audits, including unannounced audits, anytime it deems necessary and within the purview of its jurisdiction.
- Auditing Organizations shall carry out unannounced audits if previous audits indicate serious and/or frequent nonconformities.
- The timing of the unannounced audits should be unpredictable and in addition to the normally scheduled audits.
MDSAP Nonconformities

MDSAP use of GHTF document SG3/N19

- Nonconformity grading system for regulatory purposes and information exchange
- Intended for regulatory authorities and auditing organizations.
- Introduces a standardized nonconformity grading system for regulatory purposes that will enable exchange of information among regulatory authorities.
- Currently, the significance of a nonconformity may vary between regulatory authorities and auditing organizations.
- Current grading of nonconformities as major or minor does not provide enough detail for global information exchange. N19 does not use these terms.
Grading a nonconformity

Step 1 Grading Matrix

Absence of documented process or procedure (add 1)

Release of Nonconforming Medical Device (add 1)

Step 2 Escalation Rules

Nonconformity Grade

Final Nonconformity Grade

Audit Report + Regulatory Exchange form
Nonconformity Grading

Indirect QMS Impact:
• ISO 13485:2003 clauses 4.1 through 6.3, are seen as “enablers” (making it possible or feasible) for the QMS processes to operate. These clauses are therefore considered to have indirect influence on medical device safety and performance.

Direct QMS Impact:
• ISO 13485:2003 clauses 6.4 through 8.5, are seen as having direct influence on design, and manufacturing controls. These clauses are therefore considered to have direct influence on medical device safety and performance.
<table>
<thead>
<tr>
<th>NC#</th>
<th>Nonconformity Description</th>
<th>ISO 13485:2003 Clause</th>
<th>Step 1 Grade</th>
<th>Absence</th>
<th>Medical Device</th>
<th>Grade</th>
<th>EU</th>
<th>CAN</th>
<th>USA</th>
<th>AUS</th>
<th>JPN</th>
<th>OTHER</th>
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<tr>
<td>1</td>
<td>There is an absence of a Quality Policy in the organization.</td>
<td>5.3</td>
<td>1</td>
<td>+1</td>
<td>2</td>
<td>2</td>
<td></td>
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<tr>
<td>2</td>
<td>Documented procedures for identifying training needs are not established.</td>
<td>3</td>
<td>4</td>
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**QMS Impact**

Absence of documented process or procedure (add 1)

Release of Nonconforming Medical Device (add 1)
Audit Man-Days

- Audit time is based on “tasks” and **not** employee count
- There will be additive and subtractive adjustments
  - Adjustments specific to Design and Development (when applicable)
  - Adjustments specific to Production & Service Control (when applicable)
  - Adjustments specific to assessment of previously cited nonconformities
  - Multiple Site Audits
  - Other adjustments based on ISO/IEC 17021
- Justification for audit time must be documented.
- Data will be collected during the pilot program. There could be a new man-day system in place at the end of the pilot program.
MDSAP IT Portal

Auditing Organizations (AO’s)

MDSAP IT PORTAL

Regulatory Authorities
Questions ?