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MDSAP
Medical Device Single Audit Program

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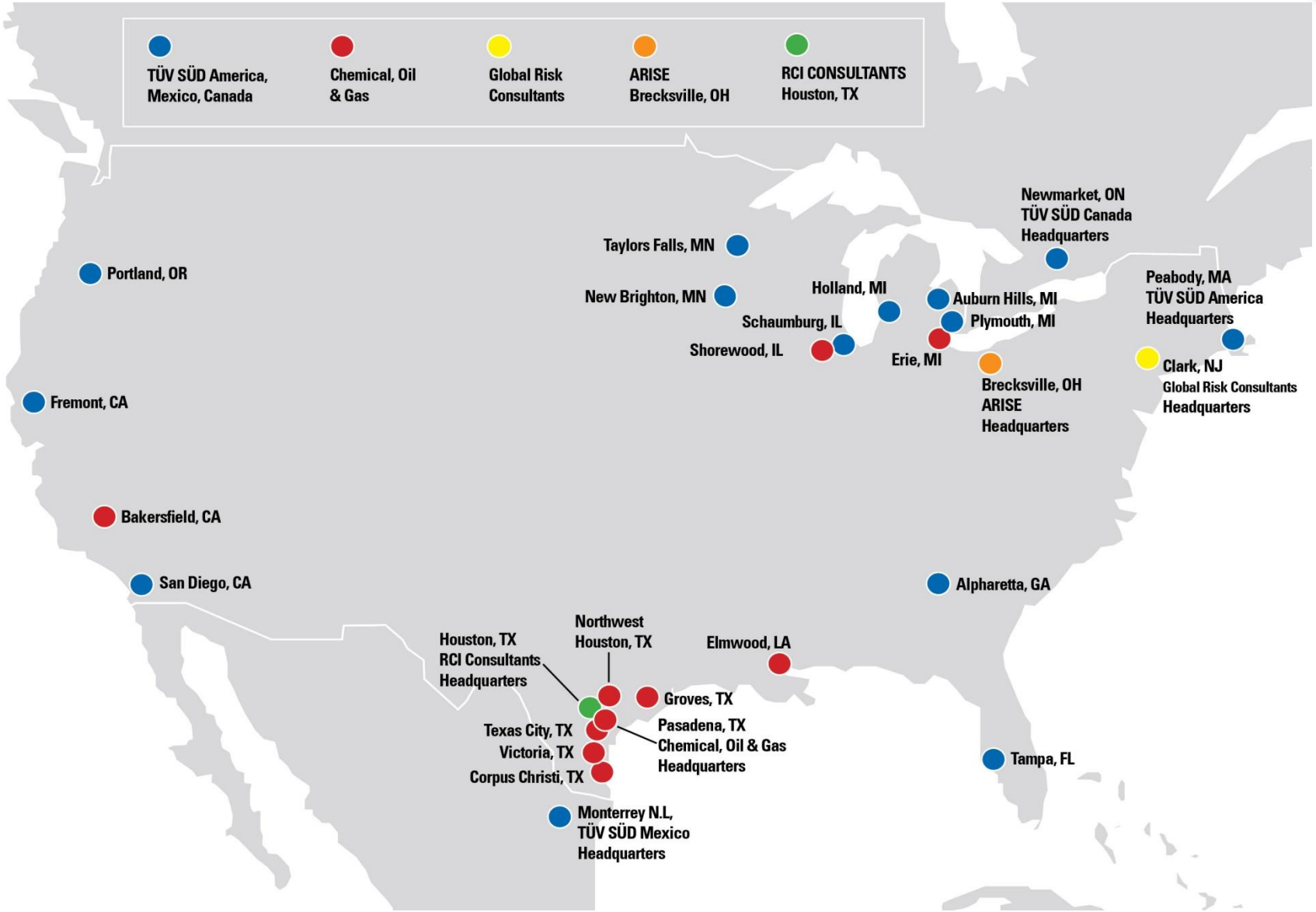


Overview of Topics

- Background and Overall objectives of the Medical Device Single Audit Program
- MDSAP pilot program and transition
- Regulator Acceptance of MDSAP
- Key MDSAP Procedures and Forms: MDSAP Process and Audit Sequence (Audit Model)
- Differences between current audits and audits conducted under MDSAP
- MDSAP Nonconformity Grading
- MDSAP Unannounced Audits
- Benefits of participating in the MDSAP pilot program

International Medical Device Regulators Forum (IMDRF)

- The IMDRF replaced the GHTF.
- Only regulators will make decisions.

Management Committee Members

- US Food and Drug Administration (FDA)
- Health Canada Medical Devices Bureau
- Brazilian Health Surveillance Agency (ANVISA)
- Australia Therapeutic Goods Administration (TGA)
- European Commission Directorate General Health and Consumers
- Japan Pharmaceuticals and Medical Devices Agency (PMDA)
- China Food and Drug Administration
- Russian Ministry of Health

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 Participating Regulatory Authorities

Participants

- US Food and Drug Administration (FDA)
- Health Canada Medical Devices Bureau
- Brazilian Health Surveillance Agency (ANVISA)
- Australia Therapeutic Goods Administration (TGA)

Observers

- Japan Pharmaceuticals and Medical Devices Agency (PMDA)
- European Commission

MDSAP Objective

- *"The overall objective of the Medical Device Single Audit Program is to develop, manage, and oversee a single audit program that will allow a single regulatory audit of a medical device manufacturer conducted by an MDSAP recognized auditing organization* (certification body) *to satisfy the needs of multiple regulatory jurisdictions."*
- MDSAP will not require changes to country specific regulations
- The audit is based on ISO 13485 plus regulatory specific requirements.

MDSAP Goals and Key Strategies:

- A single audit to satisfy the regulatory requirements of multiple participants
- More effective, efficient, and less burdensome regulatory oversight of the quality management systems of medical device manufacturers

- A single audit program
- Appropriate regulatory oversight/reduced regulatory burdens
- More efficient and flexible use of regulatory resources
- Greater global alignment of regulatory approaches and technical requirements
- Promote consistency, predictability, and transparency of regulatory programs
- Leverage existing conformity assessment structures

MDSAP Pilot Program and Transition

- Pilot program started in January 2014 and is now underway
- Several CB's are in the Pilot Program, Office audits and witnessed audits are required (conducted by regulators)
- Pilot Program countries are USA, Canada, Brazil and Australia.
- Pilot will finish at the end of 2016.
- Once fully implemented MDSAP will replace CMDCAS in Canada (expectation is 2018)
- It is unclear if Europe will join MDSAP in the future.
- Japan is involved in the Pilot Program as an observer

Regulator Acceptance of MDSAP

USA

- The FDA will accept the MDSAP Pilot audit reports as a substitute for FDA routine inspections (biannual by policy). The FDA will not accept MDSAP for initial visits or “for cause” inspections.
- An organization must sign a contract for MDSAP before a FDA routine inspection is announced, otherwise the inspection will still occur.

Canada

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

Regulator Acceptance of MDSAP

Brazil

- ANVISA plans to use MDSAP Pilot audits in lieu of a premarket inspection by ANVISA to grant ANVISA's GMP Certificate to manufacturers intending to put class III or IV medical devices on the Brazilian market.
- Undergoing an MDSAP Pilot audit may accelerate ANVISA´s GMP certification process. There is a 3 year backlog for ANVISA to conduct their own audits.

Regulator Acceptance of MDSAP

Australia

- The TGA will take into account MDSAP Pilot audit reports when considering
  - whether a manufacturer has demonstrated compliance with an Australian Conformity Assessment procedure.
  - whether to issue or maintain a TGA Conformity Assessment Certificate in relation to manufacturers of kinds of products prescribed in regulation1.
- Under some circumstances a manufacturer may avoid routine TGA inspections
- The TGA will accept MDSAP certificates as evidence of compliance with ISO13485:2003 where the Standard has been used to demonstrate partial compliance with the requirements of an Australian Conformity Assessment Procedure.

Japan and MDSAP

- Japan has been an official observer and active participant in the Pilot Program. They have contributed to the development of MDSAP documents since 2012.
- The new amendment on medical devices became effective November 2014. Regulations are becoming more aligned (not 100%). with MDSAP documents and GHTF documents for Nonconformities and Audit Reports.
- Japan will not have full access to reports as they are not yet a full participating regulatory authority.
- Japan has not clearly indicated when they will participate in the MDSAP program

Japan and MDSAP

- Japan is evaluating the following possibilities:
  - For manufacturers intending to put medical devices of class II, III or IV on the Japanese market, an MDSAP Pilot audit report might be utilized for a desk review instead of a premarket inspection performed by PMDA or registered certification bodies in Japan.
  - An MDSAP Pilot audit report might also be utilized in this manner for periodical post market inspections.
  - Undergoing an MDSAP Pilot audit may accelerate the Marketing Authorization with fewer burdens as well as reduce some burden for a post market phase.

Europe and MDSAP

- The hope is that Europe will adopt IMDRF documents for use in their regulatory system.
- It is unlikely that Europe will ever be a full participant in MDSAP because of the difficulty in getting confidentially agreements with an additional 28 countries.

MDSAP Documents

- Available at: http://www.fda.gov/medicaldevices/internationalprograms/mdsappilot/default.htm

MDSAP 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

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 is a focus on Risk Management throughout the audit.

Audit Task Example

- ***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*

MDSAP Audit Criteria

- ISO 13485:20013
- GMP requirements of the regulatory bodies
- Certification audit required to add MDSAP (considered as initial certification)
- One audit to address all requirements
- 3 years audit cycle

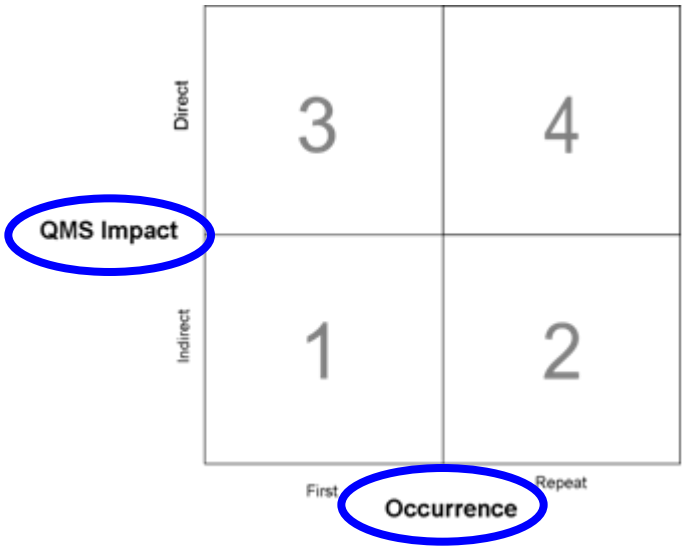
Audit Man-Days

- 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
- 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 use of GHTF document SG3/N19

- Nonconformity grading system for regulatory purposes and information exchange
- 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.

Grading a Nonconformity



Absence of documented process or procedure (add 1)

Release of Nonconforming Medical Device (add 1)

Nonconformity

Step 1
Grading Matrix

Step 2
Escalation Rules

Final
Nonconformity
Grade

Audit Report +
Regulatory Exchange form

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.

NC Response Timing

- D_0 = last day of audit
- Initial response due dates with correction plans, root cause and corrective action plans
  - D_0 + 15 calendar days for all nonconformity grades
- Final response due dates with evidence of effective implementation of correction and corrective action
  - D_0 + 30 calendar days for grades 4 or 5

MDSAP 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.

Summary of differences

- Grading of nonconformities considering the impact to the QMS
- MDSAP report includes regulations from Heath Canada, FDA, Anvisa and TGA, as applicable to the organization
- Audit sequence
- Reports are submitted to all regulators

Participating in the MDSAP Pilot Program / Benefits

- Any manufacturer may participate if a product falls under the scope of at least one participating Regulatory Authority and subject to their quality management system requirements.
- A manufacturer may be located anywhere in the world.
- Only the MDSAP participating countries will have direct access to the audit reports.
- Regulators will witness some audits to evaluate the Auditing Organizations, not the manufacturer.
- One benefit is your ability to provide feedback to the regulators and influence the future of the program at the end of the pilot phase.
- In case you are due or a routine inspection, you potentially can reduce the inspection expenses and resource assignments $\Rightarrow$ reduction of audits, cost savings

Participating in the MDSAP Pilot Program

- For upgrades audits during surveillance AO's will need to conduct recertification audits.
- Manufacturer's cannot select which of the 4 regulatory schemes to include within the audit scope.
- The country specific requirements are to be included if the manufacturer's products are sold into that country. (e.g., current 4 participating countries)

Questions?