International Track 2: Beyond MDSAP and ISO 13485: Beyond MDSAP and ISO 13485: Multi-Purpose Global Regulatory Audits

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Outline

- MDSAP State of Play & Outlook with MDR on the Horizon
- Gap Analysis Tool
- Audit Management:
  - Experience with Notified Body Auditors
  - Experience Using MDSAP Audit Module and Companion Document
- Challenges with the initial MDSAP Certification Audit
- Challenges with the Surveillance MDSAP Audits
- After Audit Management
- Certificates and Reports Delayed
- MDSAP Surveys and Feedback Communications
- Q&A
MDSAP

International consortium of countries dedicated to pooling technology, resources, and services to improve the safety and oversight of medical devices on an international scale in an Audit and Assessment Program
The international consortium of countries for MDSAP as of June 2015:

- Therapeutic Goods Administration (TGA)
- Agência Nacional de Vigilância Sanitária (ANVISA)
- Health Canada (HC)
- Pharmaceuticals and Medical Devices Agency (PMDA)
- U.S. Food and Drug Administration (FDA)
International Consortium

- Since Spring 2014:
  - World Health Organization (WHO) Diagnostic Prequalification Program
  - European Union as Observers
**Concept**

**RA**: Regulatory Authorities; **AO**: Auditing Organizations; **Mfr**: Manufacturers

- Assess and recognize
- Share audit report and certificate
- Make regulatory decisions
- Audit and certify
The MDSAP audit process was designed and developed to ensure a single audit will provide efficient yet thorough coverage of the quality management system requirements:

- ISO 13485:2003
- Brazilian Good Manufacturing Practices (ANVISA RDC 16)
- Japanese requirements (MHLW MO 169)
- FDA’s Quality System Regulation (21 CFR Part 820)
MDSAP Audit Process

AND other specific requirements of medical device regulatory authorities participating in the Pilot MDSAP program such as:

- registration
- licensing
- adverse event reporting and more
Australia:

Where regulations do not require a TGA CAC, TGA will accept MDSAP certificates as evidence of compliance with ISO 13485 where the standard has been used to demonstrate partial compliance with the requirements of an Australian Conformity Assessment Procedure.

Where regulations require a TGA CAC, TGA will take into account MDSAP certificates when deciding to issue or maintain a TGA CAC. Under some circumstances, a manufacturer may avoid routine TGA inspections.
Outputs of an MDSAP Audit

**Brazil:**

ANVISA may use MDSAP audit reports in lieu of premarket inspections by ANVISA to grant ANVISA’s GMP Certificates.

ANVISA can also use MDSAP audit reports to renew ANVISA GMP Certificates bi-annually as an alternative to an ANVISA comprehensive inspection.

**Canada:**

Health Canada will accept MDSAP certificates as evidence of conformity in accordance with section 32(2)(f), (3)(j), 4(p), 34, and 43.1.
Outputs of an MDSAP Audit

**Japan:**

MHLW and PMDA can use MDSAP audit reports to:

- Exempt a manufacturing site from on-site inspection (restrictions apply)
- Substitute considerable part of the documentation to be supplied by the Marketing Authorization Holder for inspection with the MDSAP audit report.

**US FDA:**

CDRH will accept MDSAP audit reports as a substitute for FDA routine inspections.
Status of the Program

MDSAP Participating Manufacturer (Facilities)

- 11 AO recognized
- 2 AO authorized to audit
- 1 new applicant

*FDA Data presented publically April 2019
Audit and FDA Inspection Progression

MDSAP Audits and FDA Inspections during fiscal years 2017 and 2018

*FDA Data presented publically April 2019
MDSAP Timeline

2012 - 2013
Pre-Pilot

2014 - 2016
MDSAP Pilot

2017 - 2018
Transition

2019 - 2020
Full MDSAP


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ISO 13485:2016 and MDSAP Timeline

ISO 13485:2003 or 2016 Certifications
- Mar. 1, 2016

13485:2003 New Certifications Discouraged
- Mar. 1, 2017

No 13485:2003 Certifications or Re-Certifications Allowed
- Mar. 1, 2018

ISO 13485:2016
- Mar. 1, 2019

MDSAP
- Jan. 1, 2016
- Jan. 1, 2017
- Jan. 1, 2018

MDSAP Certificate to ISO 13485:2016
- Jan. 1, 2019

Mandatory in HC

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Medical Device Regulatory Global Timeline

ISO 13485:2016
- Mar. 1, 2016
- Mar. 1, 2017
- Mar. 1, 2018
- Mar. 1, 2019

MDSAP
- Jan. 1, 2016
- Jan. 1, 2017
- Jan. 1, 2018
- Jan. 1, 2019

ISO 13485:2003 or 2016 Certifications
- 13485:2003 New Certifications Discouraged
- No 13485:2003 Certifications or Re-Certifications Allowed

Brexit
- Oct. 31, 2019

EU MDR and EU IVDR
- May 25, 2020

ASEAN Medical Device Directive (AMDD)
- 2020

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GAP ANALYSIS

EU MDR/ISO 13485:2016/
MDSAP Linkages
Specific to Article 10
Description:

Article 10 of the European Medical Device Regulation (EU) 2017/745 describes a robust set of general obligations that a manufacturer must assume. The following tabulations have been developed to provide the user with a guide to the general obligations and to correlate those obligations to both EN ISO 13485:2016 requirements and MDSAP chapters and tasks.
<table>
<thead>
<tr>
<th>Article 10 Ob.</th>
<th>Requirement</th>
<th>MDR Article / Annex</th>
<th>Typical QMS Process / Procedure</th>
<th>EN ISO13485:2016 Clause(s)</th>
<th>MDSAP Chapter and Task</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>When placing their devices on the market or putting them into service, manufacturers shall ensure that they have been designed and manufactured in accordance with the requirements of this Regulation.</td>
<td>-</td>
<td>Design control Product realisation</td>
<td>7.3 7.1, 7.5.1</td>
<td>Chapter 5  Chapter 6</td>
</tr>
<tr>
<td>2.</td>
<td>Manufacturers shall establish, document, implement and maintain a system for risk management as described in Section 3 of Annex I.</td>
<td>Annex I S3</td>
<td>Risk Management</td>
<td>7.1</td>
<td>Ch1, T7  Ch3, T3 - T7, T9, T12  Ch5, T8-T10, T12 – T13  Ch6, T10 – 11, T16, T21, T22, T28</td>
</tr>
<tr>
<td>3.</td>
<td>Manufacturers shall conduct a clinical evaluation in accordance with the requirements set out in Article 61 and Annex XIV, including a PMCF.</td>
<td>Article 61 Annex XIV</td>
<td>Clinical Evaluation</td>
<td>7.3.7</td>
<td>Ch5, T11</td>
</tr>
<tr>
<td>4.</td>
<td>Manufacturers of devices other than custom-made devices shall draw up and keep up to date technical documentation for those devices. The technical documentation shall be such as to allow the conformity of the device with the requirements of this Regulation to be assessed. The technical documentation shall include the elements set out in Annexes II and III.</td>
<td>Annex II Annex III</td>
<td>Technical documentation</td>
<td>4.2.3</td>
<td>Annex 1 (Audit of technical documentation)</td>
</tr>
</tbody>
</table>
Audit Management

Strategic Rational for a Manufacture to be In or Out of Scope for MDSAP:

• Health Canada Required Certification Transition
• What You Don’t Distribute within Canadian?
  ◦ Benefit of Reduced Routine FDA inspections
  ◦ Notified Body Recommended
  ◦ Inspection Cost Management
  ◦ MDSAP Additional Audit Cost (15-35% Increase)
Mixed Results in the Reduction in the number of Health Authority Audits

- Variable Reduced Rate of FDA inspections at US Locations
- Decrease Rate of FDA Inspections at Non-US Locations
- Increase Number of Directed FDA Audits
Audit Management

- No Significant Reduction in Non-FDA audits
- Market Access for Participating Jurisdiction
  - MDSAP Audit Reports support country registration, renewals etc.
  - Some Health Authorities Accepted MDSAP Certs In Lieu of Onsite Audits
- Have not seen MDSAP Program Transparency and Sharing Triggering Multiple HA Audits
Optimizing Audit process for centralized services

- Last Year - Same system being reviewed at multiple sites as we share same processes / procedures
- Recent Audit Tactic – In opening deck, describe overall QMS and shared elements
  - Highlight the site that is the process owner / SME’s
  - Define “in scope / out of scope” for the site being audited
Experience with Notified Body Auditors

- Imbalance: MDSAP Certified Auditors vs. Workload

- Audit Schedule Conflicts and Availability

- Introduced Partnering between Notified Bodies to execute MDSAP and ISO Audit
Improved Audit Management

• Guide Audit Team Preparation
• Front Room/Back Room Audit Execution Alignment
• Audit Request Delivery Accuracy
• Subject Mater Expert Readiness/Planning
Experience Using MDSAP Audit Module and Companion Document

In addition:

• Used as an Audit Management Training Tool
• Internal Auditor Train Tool
Experience Using MDSAP Audit Module and Companion Document

• In general, following the process

• Good diligence sticking to Surveillance Areas
Challenges with the Initial MDSAP Certification Audit

- Fulfilling Audit Request
  - New Requests not originally Part of ISO 13485

- Longer Wait Time for Document and Record
  - Request by Global Partners
  - Prestaging is Now More Important

- Variability in Audit Depth, Record Sampling, Quality System Topics

- Industry and Auditors are on a Learning Journey
MDSAP Audit Depth, Sampling, Topics

- At my smaller sites, auditors are getting into the details (reviewing a lot of records) vs larger sites it’s been more hi-level
Challenges with the Surveillance MDSAP Audits

- Scheduling Delays
- Auditor Team Assignment
- Audit Plans the week before the Audit
- Audit plan not clearly delineating the reduced quality systems as defined in MDSAP
- Small Time Reduction in MDSAP Surveillance Audit Duration
Challenges with the Surveillance MDSAP Audits

- Auditors didn’t plan enough time to get thru last years NC’s to close
  - Coming back for 1 day…..

- Was not clear that last years NC review had to be captured specifically on the NB NC Form with all evidence ready for review
  - We had planned to demonstrate closure / share evidence via our QIS Audit Module
Challenges with the Surveillance MDSAP Audits

- Some of last years NC’s went past initial commitment dates, a couple failed VOE

  - NB Expectation was that all actions would be implemented (and verified) within 6 months of being issued at the audit close
  - NB expected us to notify them immediately with any misses, and provide formal updates on the NC forms
Challenges with the Surveillance MDSAP Audits

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After Audit Management: Multiple Sites with observations

• 4 Sites – 4 audits over 4 consecutive months
• Given response time constraints, we had to address each sites NC’s separately
• After ALL audits were complete and responded to:
  - We stepped back for a more holistic review of root cause and systemic corrective actions
  - Chose to capture these additional, belt and suspender actions, in an Internal Audit
Certificates and Reports Delayed

- 1st company/sites going thru MDSAP for our NB
- A lot of back and forth with the NB before correction action plans were accepted
  - i.e. – 1st audit in April, NB Acceptance of corrective action responses in September

- Acceptance and certification recommended in August
  - Told Approximately 6 weeks to receive certs
Certificates and Reports Delayed

- Late Nov – Certs coming but taking time internally; may want to consider a Stop Gap Cert
- Dec – STILL NO Certs
- January 3rd – Stop-Gap Interim Cert provided after many requests
- January - more requests for follow-up / evidence at NB Approval Board
- Late February - Certs Issued
- Mid March – Last years Audit Reports issued
Participant Survey

Medical Device Firms and Auditing Organizations participating in the Medical Device Single Audit Program are invited to provide feedback through targeted surveys:

- Following each AUDIT, for the Medical Device Firm
- Following each AUDIT, for the Lead Auditor
- Following each ASSESSMENT, for the Auditing Organization
MDSAP Surveys and Feedback Communications

- MDSAP QMS P0011.005: Complaints and/or Customer Feedback Procedure (PDF - 238KB)

MDSAP QMS F0013.1 Concern Resolution Report Form
Questions?