Critical update on Medical Device Single Audit Program (MDSAP)

Countdown for Canada

Critical Update on MDSAP

Topics

- MDSAP program overview
- Regulators use of Program Deliverables
- What manufacturers can expect
- Status thus far
- Timelines

MDSAP Program Overview

Q4 2017

MDSAP origin and objectives

Develop, manage and oversee a single audit program

Allowing a single regulatory audit to satisfy the needs of multiple regulatory jurisdictions

Promote greater alignment of regulatory approaches and technical requirements

Promote consistency, predictability and transparency of regulatory programs

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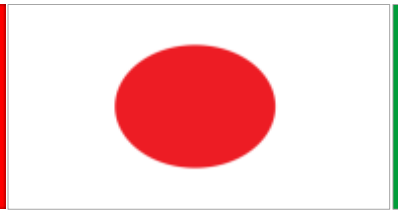
MDSAP Regulatory requirements

ISO 13485:2016


Australia


Canada


Japan


Brazil


USA

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Regulations in addition to ISO 13485

	Requirements
	Therapeutic Goods Act 1989 Therapeutic Goods (Medical Devices) Regulations 2002
	ANVISA Pre-Market Approval RDC 185/2001 ANVISA Good Manufacturing Practices RDC 16/2013 ANVISA GMP Certification – Requirement for Product Registration RDC 25/2009 ANVISA PMS RDC 67/2009 and RDC 23/2011
	Food and Drugs Act R.S.C., 1985, c. F-27 CMDR SOR-98-282
	Quality System Regulation 21 CFR 820, Medical Device Reporting 21 CFR 803, Reports of Corrections & Removals 21 CF 806, Registration & Listing 21 CFR 807 subparts A to D, Device Tracking 21 CFR 821
	MHLW Ministerial Ordinance No. 169

MDSAP Participants and Observers

Participants


Therapeutics Goods Administration (TGA)


Agência Nacional de Vigilância Sanitária (ANVISA)


Health Canada


MHLW* and PMDA**


Food and Drug Administration (FDA)

Observers


World Health Organization (WHO)


European Union

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** Ministry of Health, Labor and Welfare*
*** Pharmaceuticals and Medical Device Agency*

MDSAP

Information – Official Sources (USA-FDA)

- Program Announcement (including benefits)
- MDSAP FAQs
- List of Eligible Auditing Organizations
- MDSAP Audit Procedures & Forms (AO requirements)
- Website for all MDSAP Documents
  http://www.fda.gov/MedicalDevices/InternationalPrograms/MDSAPPilot/ucm377578.htm

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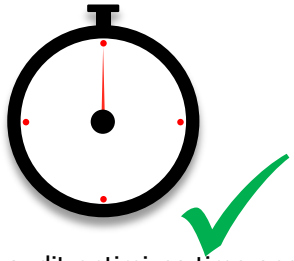
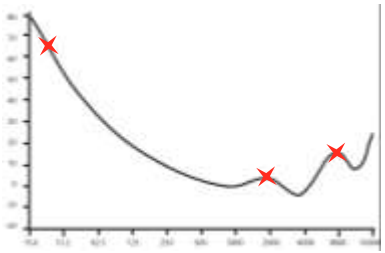
Manufacturer benefits in the MDSAP

No additional requirements for manufacturers

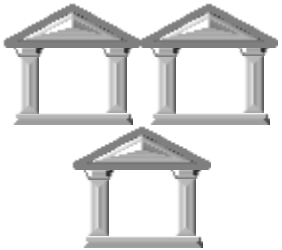


Single audit optimizes time and resources

Routine audits are scheduled/planned



Expected to improve predictability



Expected to add additional jurisdictions that will accept MDSAP certificate or reports for their markets.

MDSAP

Audit Cycle

Three Year Audit Cycle

- Initial Audit (Stage One & Stage Two)
- Surveillance Audits (Years 1 and 2)
- Re-audit (Recertification Audit)

Other Possible Audits

- Special Audits
  - changes, nonconformances, suppliers, post-market issue follow-up
- Audits by Regulatory Authorities
- Unannounced Audits (to close multiple Gr 4 and Gr 5 nonconformances)

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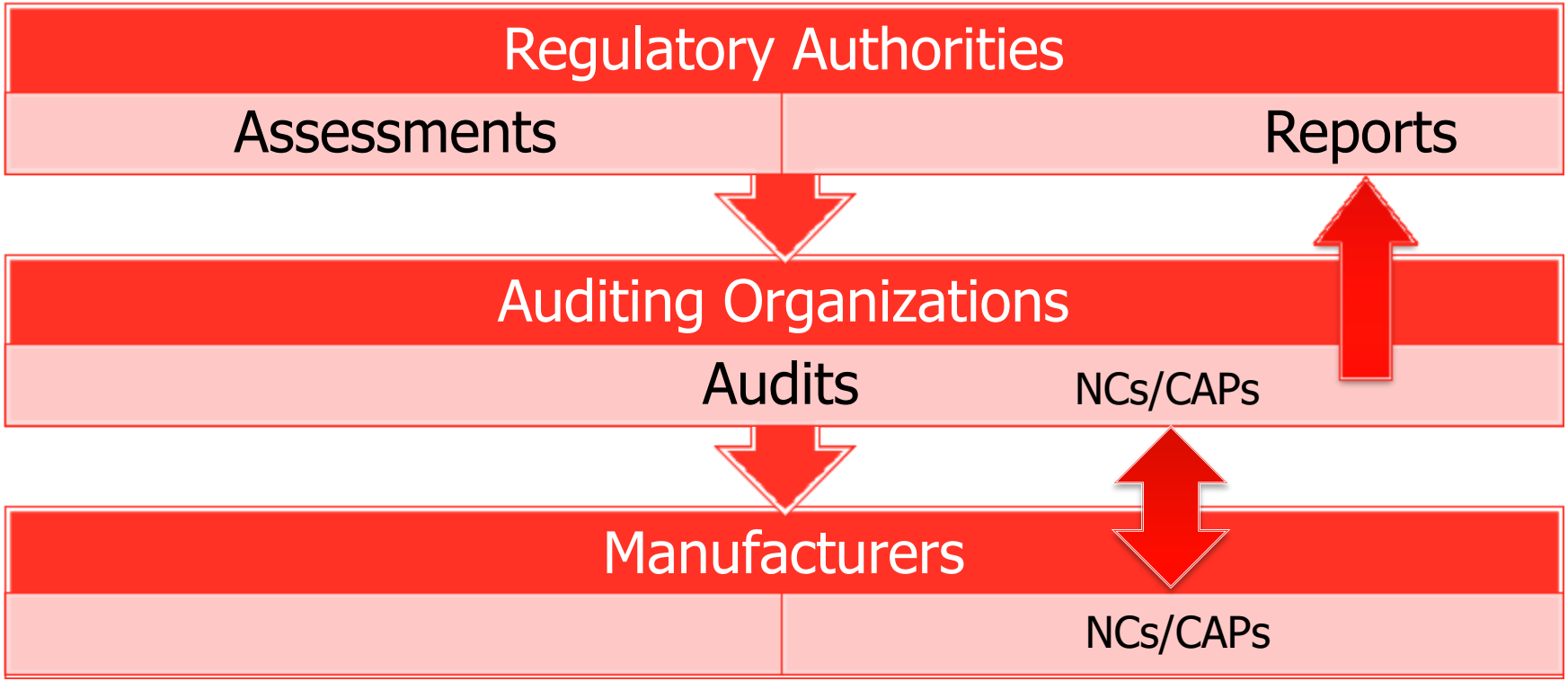
MDSAP Program



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MDSAP Overview

Auditor Approach & Mind-set

- **Regulators are the customers, this is a Regulatory audit**
- Audit reports need to give regulators information regarding whether the manufacturers QMS continues to produce devices that are safe and do not pose a threat to public health.
- Record selection should be based on risk
- Strive to review all products/processes in 3-year cycle
- Stage 1 is for "Discovery" while Stage 2 is for "Substantiation"

No need to re-review procedures and work instructions done in Stage 1, only focus on significant changes

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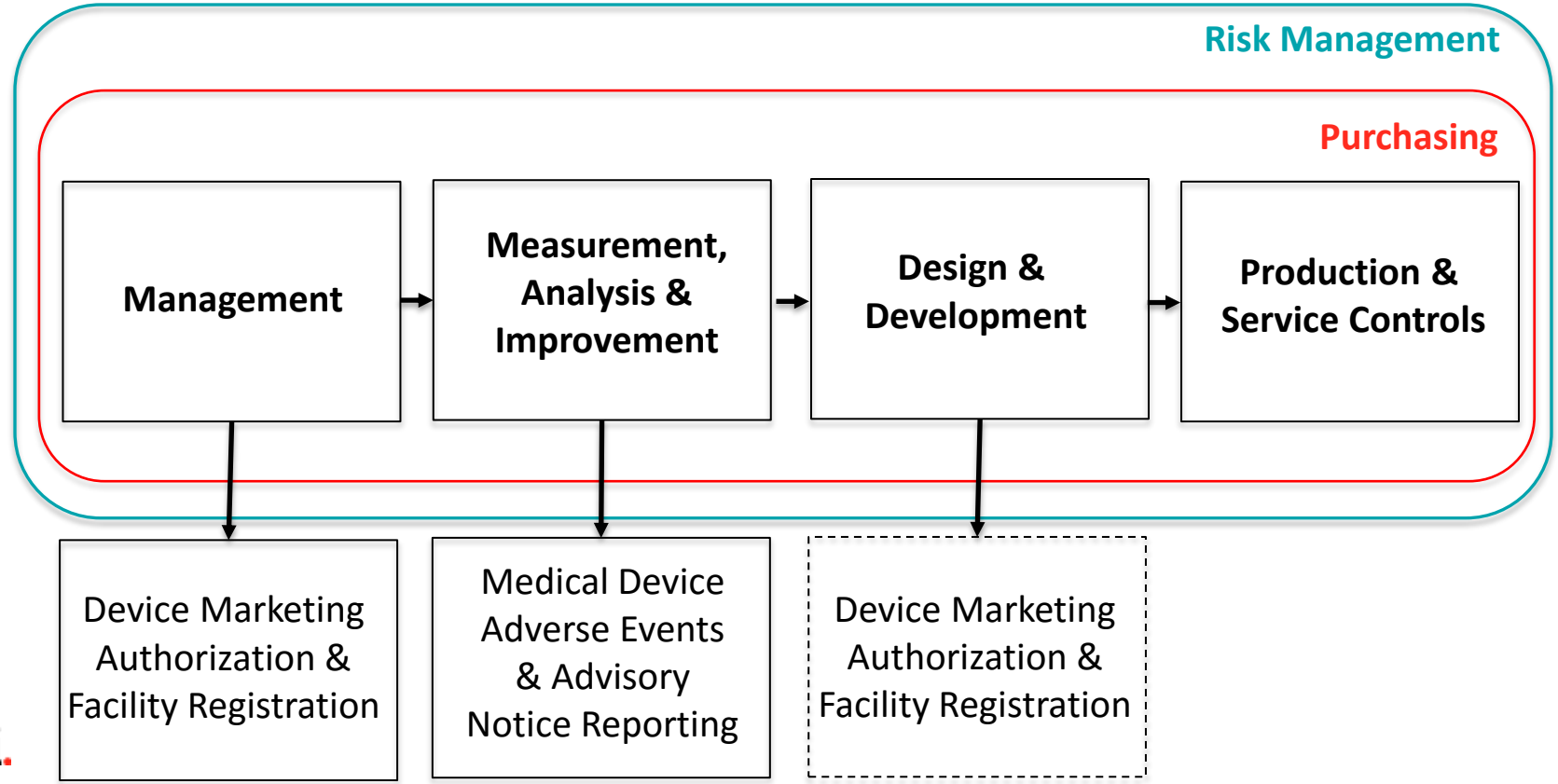
Audit Method

MDSAP AU P0002 Audit Model



Audit Duration

MDSAP AU P0008 Audit Time Determination Procedure

(ex.)

MDSAP Process	Number of Tasks per Process	Initial Audit (Stage 1 + Stage 2)	
		Number of Applicable Tasks to be Audited	Time per Process (hh:mm)
Management	11	11	6:36
DMA&FR	3	3	1:45
MA&I	16	16	10:08
MDAE&ANR	2	2	1:16
D&D	17	17	5:57
P&SC	29	29	21:16
Purchasing	12	12	3:00
Sub-Total	90	90	49:58
Additional time, as deemed necessary by the Auditing Organization, including for Stage 1 if applicable (hh:mm)			
Adjustment (%)			0:00
Total (hh:mm)			49:58
Duration of Audit (man-days)			**6 days and 2 hours**

Possible adjustment considerations*

* Risk of product/processes

Employee count*

- 10% reduction <45 employees
- 20% reduction <15 employees

No design or not needed

- reduce number of tasks in D&D

No on-site manufacturing

- reduce number of tasks in P&SC

All/some processes out-sourced

- verify via Purchasing controls

Multiple jurisdictions - add time to DMA&FR and MDAE&ANR

Multiple product lines/unique processes

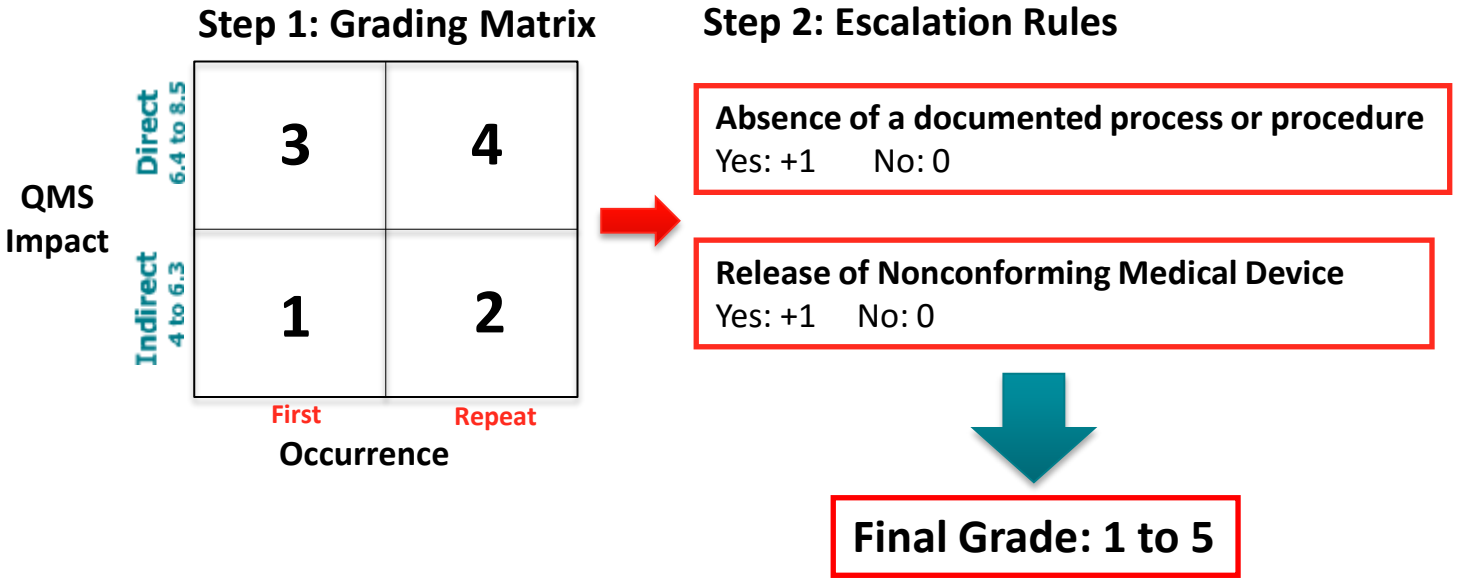
- add time to D&D and P&SC

Surveillance & Recertification time

- 20% reduction

Audit Nonconformity (NC) Grading

GHTF/SG3/N19:2012, Quality management system – Medical devices - Nonconformity Grading System for Regulatory Purposes and Information Exchange

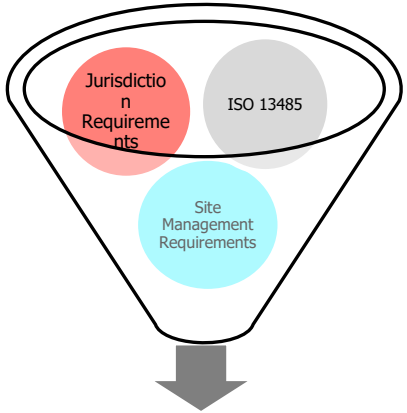


MDSAP Program

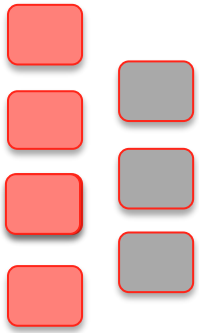
Post audit activities per program requirements

D_0	Audit end date (closing meeting)
D_0 + 5 W-days	**AO** informs RA if 1 or more Gr 5 NC or more than 2 Gr 4, or public health threat, or fraudulent activity or counterfeit product (**MDSAP 5-day Notice**)
D_0 + 15 C-days	**Mfr.** provide for each NC a remediation plan (Investigation result of NC and its cause, planned correction and planned corrective action).
D_0 + 30 C-days	**Mfr.** provide for each NC evidence of implementation of the remediation actions taken for any Gr 4 or Gr 5 NC
D_0 + 45 C-days	**AO** to provide complete audit report package if audit meets criteria for a **MDSAP 5-day Notice**.
D_0 + 90 C-days	**AO** to provide complete audit report package for all other audits.

MDSAP - AO Considerations for MDSAP Planning

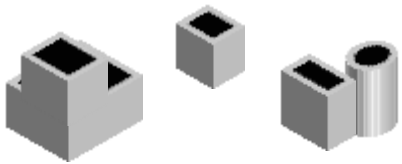


Auditable QMS



Audit Sequence

Assessment Team



Manufacturers

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Regulators use of the Program Deliverables

MDSAP Program

Output

- Regulatory Audit Report demonstrating compliance to MDSAP program requirements for the site visited
- Certificate for MDSAP – unaccredited certificate to ISO 13485 and MDSAP jurisdiction requirements of the QMS (only a requirement for HC submission, but recognized by Australia as well)
- Market access to Australia, Brazil, Canada, Japan and USA once assessed to confirm jurisdiction requirements are incorporated into QMS

- Additional outputs possible as linked to other BSI programs for ISO 13485 certification
  - UKAS
  - SCC

Utilization of MDSAP Audit Outcomes

Australia - whether the QMS requirements of the conformity are satisfied by the "legal" manufacturer.

Brazil - whether to issue or maintain GMP certificates to the audited site.

Canada - whether to issue device license, using MDSAP certification of the "legal" manufacturer.

Japan - to confirm the registered manufacturing site's conformance to part of Japanese requirements.

USA - whether regulatory action towards the site is potentially indicated.

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What manufacturers can expect

MDSAP - AO Perspective

Program Distinctions

Criteria	ISO 13485	MDSAP	CE (directives)
Program Customer	Manufacturer	Regulator	Mfr/Regulator
Output of success	Report & Certificate Manufacturer	Report & Certificate Manufacturer & RA	Report & Certificate Manufacturer
Auditing Organization Qualification	Competent Body	Regulators	Competent Body
Audit Duration	Employee Count	Fixed Timing	Variable
Scheduled Assessments	Yes	Yes + unannounced follow-ups as necessary	Yes + unannounced
Nonconformance Grading	Major / Minor	1, 2, 3, 4, 5	Major / Minor
Product Approvals	N/A	Regulators	Notified Body

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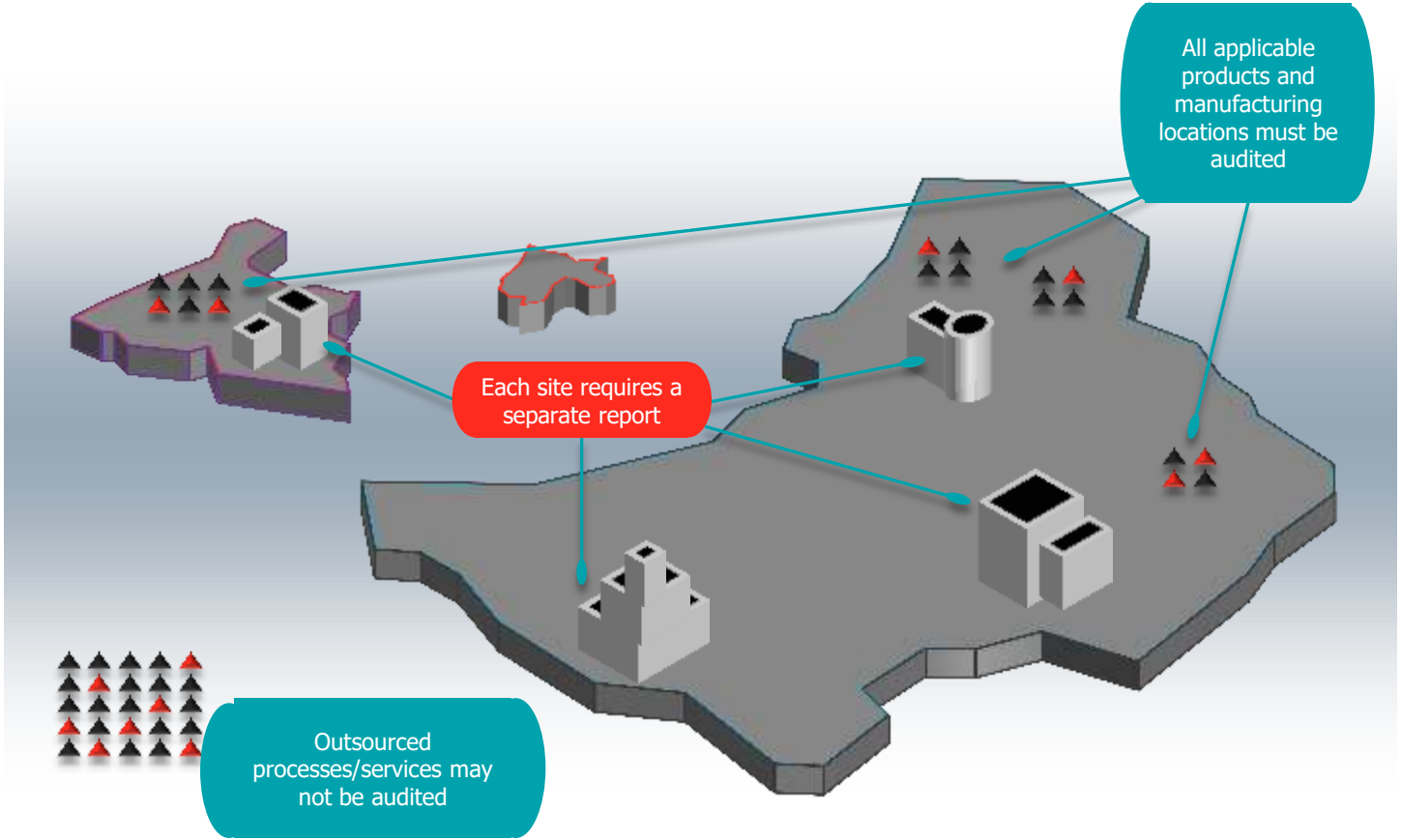
MDSAP requirements



MDSAP Audit Expectations

* **Management's knowledge and understanding of the processes of QMS**

MDSAP Process Audit Outcomes

- Companion document (CD)
- Each process has specific outcomes detailed in the CD
- How have you verified that you have met the expectations during your internal audits?
- What will you prepare to demonstrate meeting the outcomes to the auditor?

Auditors approach

- Could issues lead to a threat to public health
- Process audit to ISO 13485 including jurisdiction additions
- If already in the MDSAP regions there should be nothing additional for the manufacturer
- Specific order of processes
- Diversity of records reviewed
- Risk focus on samples taken

Audit report

- Not a re-hash of what you already know about your QMS
- First person perspective
- Use records as support for conclusions drawn
- All jurisdictions represented, specifically calling out differences from ISO 13485
- Makes conclusions to support meeting objectives and tied to *

MDSAP - AO Perspective

Assessment Observations thus far:

- Clarifying who and where control is managed over processes
- Appropriate amount of control defined and demonstrated
  - E.g., Outsourcing, competence assessments, external documents, record retention, changes, design reviews, distribution, sample retention
- Focus on risk management throughout QMS
- Determining correct regulatory roles per jurisdiction
- Tracking implementation from quality planning activities in D&D thru to implementation in Production & Servicing and Post Market
- 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

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MDSAP - AO Perspective

Single Site Manufacturer

1. Stage 1 easier to understand and plan for Stage 2
2. Simpler QMS to review
3. Responsibilities more clearly defined
4. All activity auditable primarily at one location
5. Regulatory roles usually managed simply
6. Changes more easily managed by site and supplier versus multiple sites and divergent steps in processes.
7. Licensing more easily tracked.

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MDSAP - AO Perspective

Multi-site Manufacturer

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

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MDSAP - AO Perspective

MDSAP Program Truths

1. This is a new program and it will evolve and settle-down over time.
    a. All Manufacturers are not alike in their approach and readiness for MDSAP audits.
    b. All Auditing organizations are also not alike in how they conduct MDSAP audits.
    c. All auditors within an AO are not alike in how they assess to the MDSAP requirements.
2. However the requirements are known and the same for all.
3. Best practices will evolve.
4. Leading to improved implementation.

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Status thus far

Q3 2017

AO Journey To Recognition

Assessment Activity	Program Status	Auditing Organizations
Application reviewed favorably	Application Received	NSF
Stage 1 + Stage 2 (+ Critical Locations) + Response to any nonconformity deemed acceptable	Authorized to conduct MDSAP audits (the first 3 to be witnessed)	Dekra, DQS, LNE/G-Med, LRQA, NSAI, SAI Global, SGS, TUV-Rh, TUV-USA
3 Witnessed Audits + Response to any nonconformity deemed acceptable Recognition Decision	Recognized	BSI, Intertek, TUV-Sud, UL

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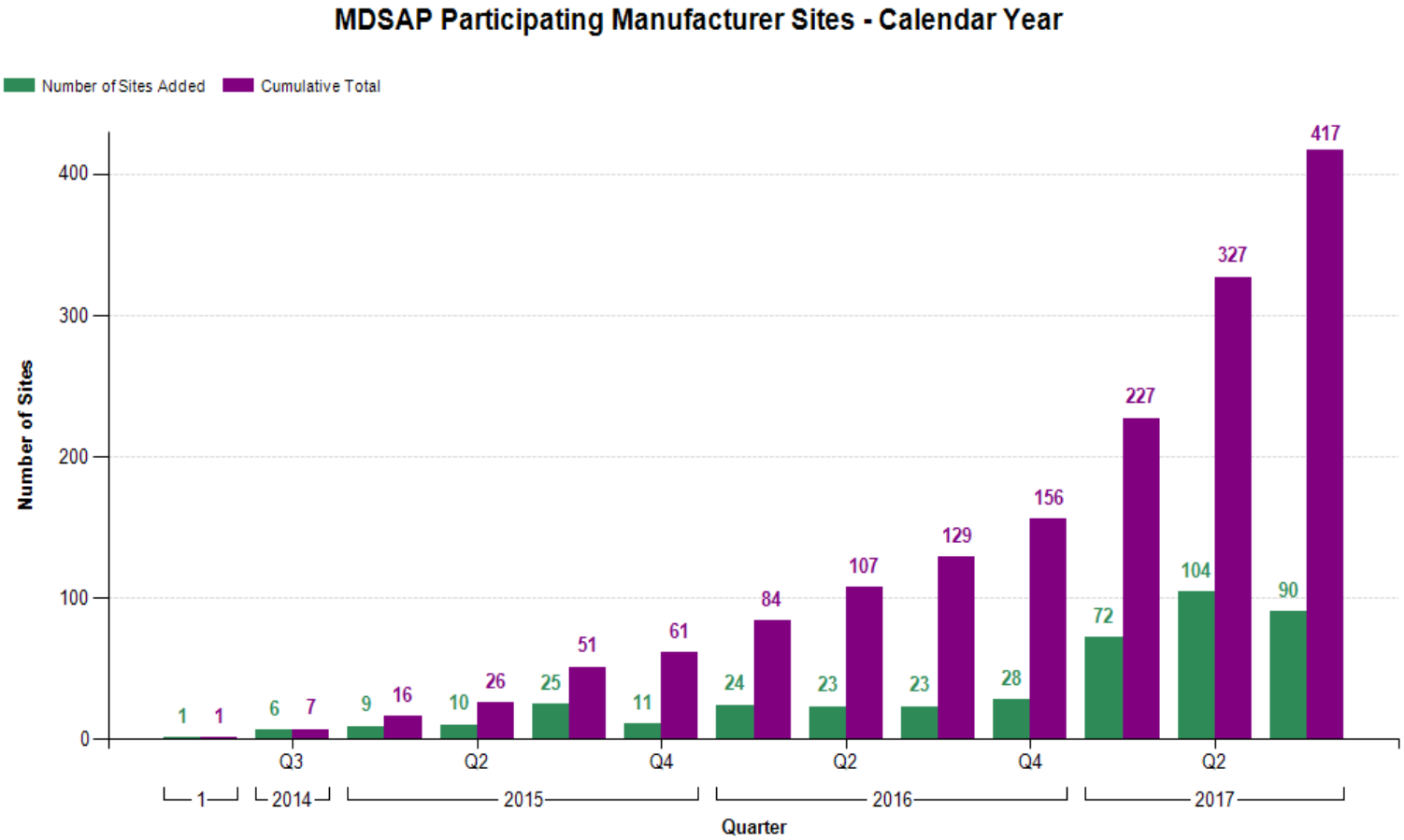
Manufacturer Participating Sites



Program settling in

Changes evolved through the Pilot and into Operational Phase

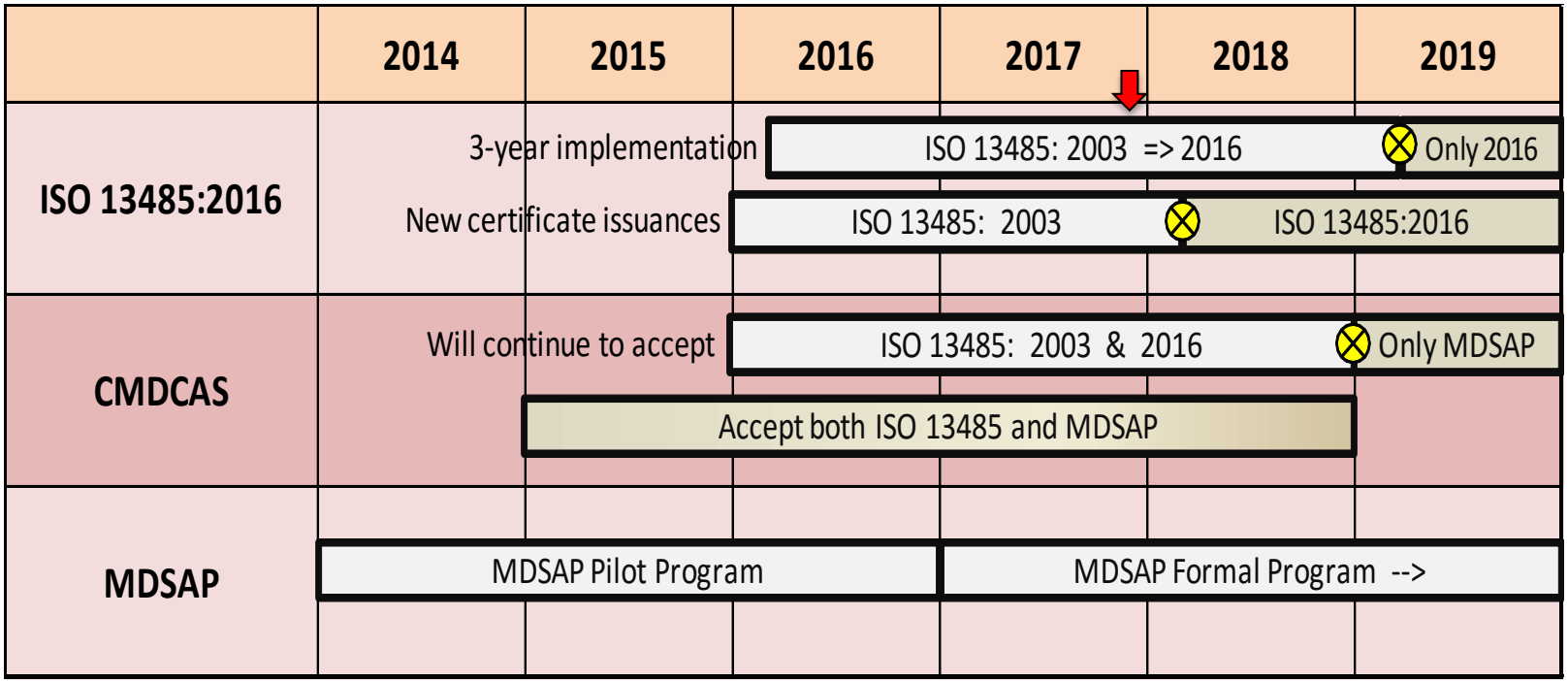
1. Changed definition of small company to allow greater % reduction
2. Audit task timeline changes, reduced approximately 20% for CAV and Recert
3. Clarification on expectations for assessment of controls related to sterile product and regarding technical documentation review
4. Campus location definition (1 km radius?)
5. New report templates
6. Manufacturers engagement growing dramatically in 2017 (3x), despite low numbers in Pilot phase
7. Having sufficient auditor resources for the last year push since many manufacturers have delayed engagement

Timelines

Countdown to HC deadline

MDSAP

Consider ISO 13485:2016 transition *and* Health Canada deadline



MDSAP Transition

Health Canada:

- Starting January 1st, 2019, all manufactures of class II, III and IV medical devices will require a valid MDSAP certificate in order to obtain, maintain, or amend medical device licences.
- The implication of this deadline is that manufacturers that fail to transition from CMDCAS to MDSAP will see their medical device licences suspended some time after January 1st, 2019

**As presented at RAPS, September 2017, by HC representative.*

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MDSAP Transition

- Voluntary and encouraged to -
  - Register devices in Australia – especially combination products.
  - Obtain ANVISA GMP certificate – devices class III and IV.
  - Substitute to PMDA audits.
  - Substitute routine FDA inspections – any devices.

**As presented at RAPS, September 2017, by HC representative.*

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MDSAP

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

- Check with current Certification / Notified Body whether capable
- In final year only option to meet deadline is a full audit (Stage 1 and Stage 2) in 2018
- Consider business plans (new markets?)
- Note that new marketing authorizations from a Regulatory Authority will require a full audit (rather than a surveillance audit)
- Investigate with CB/NB whether the audit can include CE requirements

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BSI MDSAP Webinar Nov 2017

Questions

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