The Evolution of MDSAP

Eight Years and counting…

By Royal Charter

BSI Group
An Introduction

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Who is BSI?


The UK National Standards Body
A Certification Body for schemes including ISO 13485, ISO 9001, ISO 14001, ISO 45001 (formerly OHSAS 18001) and ISO 27001
A Notified Body for CE marking under 15 European Directives (Full Scope under MDD, AIMDD, IVDD MDR and IVDR)
A global training provider
A recognized Conformity Assessment and Certification Body for many local market access schemes
An Auditing Organization for MDSAP
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What is MDSAP

MEDICAL DEVICE SINGLE AUDIT PROGRAM

MDSAP
Program Objectives

- Develop, manage, and oversee a single audit program that will allow a single regulatory audit to satisfy the needs of multiple regulatory jurisdictions
- To promote greater alignment of regulatory approaches and technical requirements
- To promote consistency, predictability, and transparency of regulatory programs

MDSAP
Program Benefits

Single Audit by Auditing Organization (AO) would:

- minimize medical device manufacturing disruptions due to multiple regulatory audits
- leverage regulatory resources
- benefit patient health and patient access
- provide global benefit both on short term and longer term goals by IMDRF regulators - harmonization

MDSAP
Manufacturer Benefits

- No additional requirements for manufacturers
  - Compliance to the current requirements for the participating countries?
  - All requirements are 'baked in'
- Single audit optimizes time and resources
- Routine audits are scheduled/planned with AO
  - No surprises
- Expected to improve predictability
- Expected to add additional Regulatory Authorities

MDSAP
Pilot History

- Pilot started in January 2014 (for 3 years, to Dec 2016)
- Certification Bodies from participating member states can apply to become AO's
  - Initially CMDCAS (Canada) recognized registrars
- Office audits and witnessed audits required
  - Conducted by Regulatory Authorities (RAs)
- September 2014 AO's started conducting audits
- Operational program starts January 2017

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Requirements

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MDSAP
Program Requirements

- ISO 13485 plus applicable Country-specific requirements (Australia, Brazil, Canada, Japan and USA)
- A separate report is required per site.
- To recommend certification to MDSAP all applicable processes and jurisdictions must be audited.
- There is no sampling of design and manufacturing sites permitted in the MDSAP program.

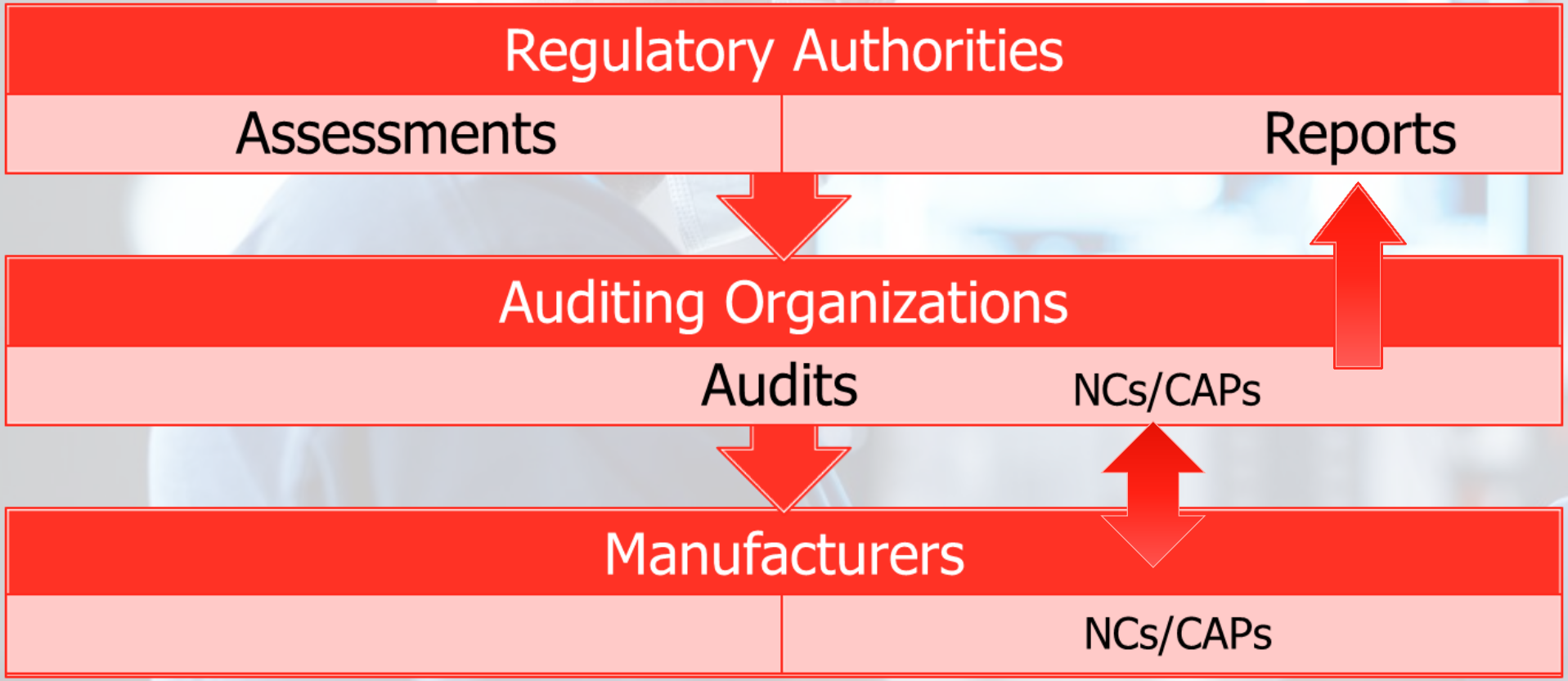
MDSAP Program Status Overview
Use of outputs of MDSAP audits

Australia	Brazil	Canada	Japan	USA
Use as part of evidence to assess compliance with MD market authorization requirements	Input for ANVISA's premarket and post-market assessment procedures	Concurrent with CMDCAS until ends in late Dec 2018	Report might be utilized for a desk review for class 2,3,4 in lieu of a premarket inspection performed by PMDA or registered certification bodies in Japan	Substitute for **Routine** Inspections only. Not for PMA, "For Cause" or "Compliance Follow-up"
	Audits in lieu of ANVISA inspection to grant GMP certs for class 3,4	Use of certificate for obtaining/maintaining a Class 2,3,4 device license	report might also be utilized for periodic post market inspections	Report review with scrutiny on significance of findings
	For renewal of ANVISA's GMP certs bi-annually	From January 2019, Health Canada will only accept MDSAP certificates	Reports will be used in review of on-site inspection for eligible sites so as to obtain a QMS certificate	May use Warning Letters if conclusion of imminent/unreasonable risk to public health

How MDSAP works

MEDICAL DEVICE SINGLE AUDIT PROGRAM

MDSAP
Structure



MDSAP
Information – Official Sources (USA-FDA)

- Pilot Program Announcement (brief description)
- Program Announcement (including benefits)
- MDSAP FAQs
- Eligible Auditing Organizations
- MDSAP Audit Procedures & Forms
- Website
  http://www.fda.gov/MedicalDevices/InternationalPrograms/MDSAPPilot/ucm377578.htm

MDSAP
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
    - changes, nonconformances, suppliers, post-market issue follow-up
  - Audits by Regulatory Authorities
  - Unannounced Audits

MDSAP
Audit Procedures

Audit Procedures & Forms available, e.g., relevant documents

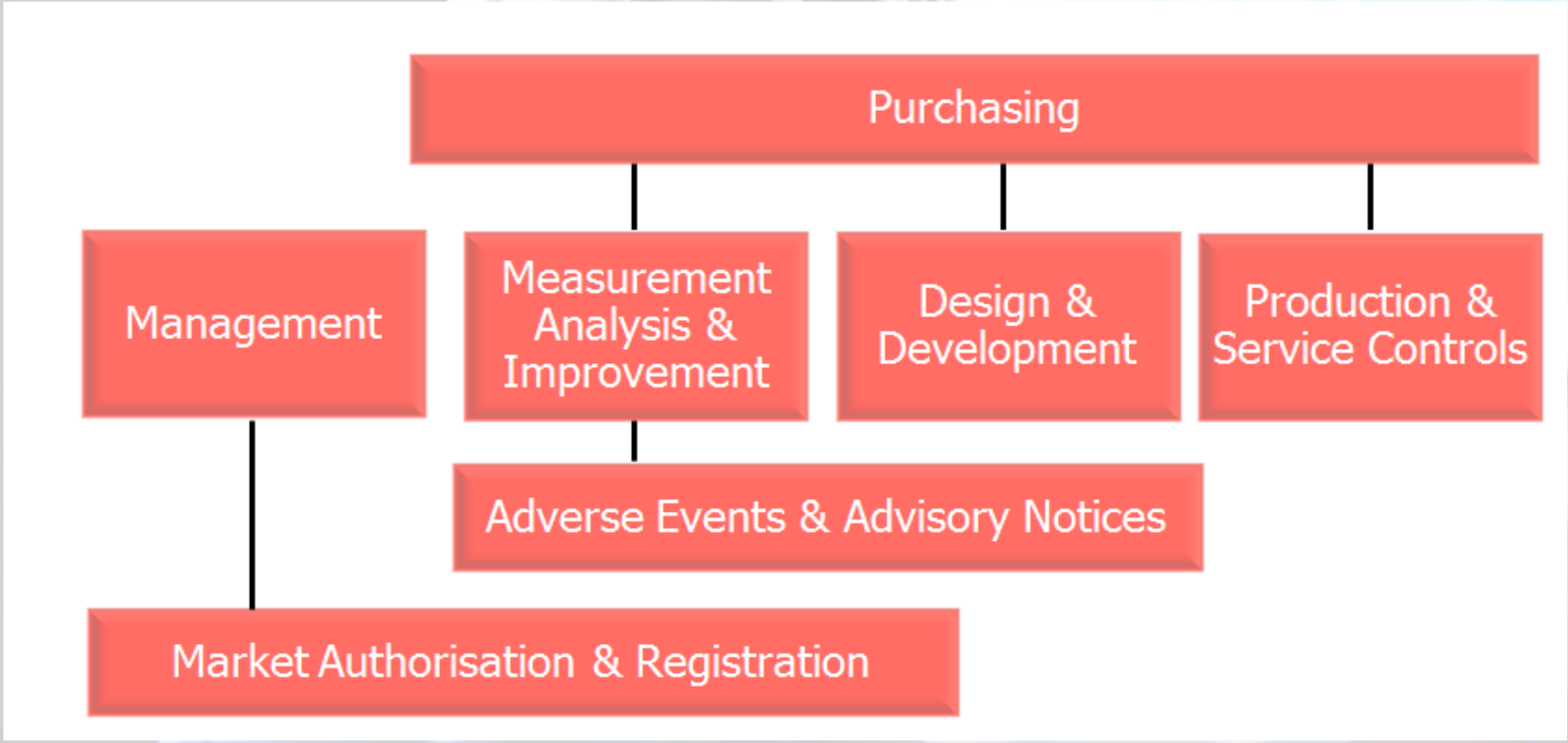
- Audit Model - AU P0002.003 (57 pages)
- Companion Document - AU G0002.1 (95 pages)
- Audit Time Calculation Procedure - P0008.001
- Nonconformity Grading - GHTF/SG3/N19:2012
- Post-Audit Activities and Timeline Policy - MDSAP AU P0027

MDSAP
Audit Model

Follows the process approach, top down

- Four Primary processes
  - Management
  - Measurement, Analysis and Improvement
  - Design and Development
  - Production and Service Controls
- Three Supporting Processes
  - Device Marketing Authorization and Facility Registration
  - Medical Device Adverse Events and Advisory Notices Reporting
  - Purchasing

MDSAP
Audit Sequence



MDSAP
Process selection criteria

During an audit not every production or design product or process can be audited every time. A selection based on risk should consider the following:

- Corrective or preventive action indicators of process problems or potential problems
- Are there new or modified designs and new products
- Are there new/modified processes
- Processes that operate over multiple shifts
- Production processes that directly impact the ability of the device to meet its essential design outputs
- Are there areas not sufficiently covered during previous audits in the cycle

MDSAP
Auditor Approach & Mindset

- **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"

MDSAP
Auditor Approach & Mindset

- Product Listings with classification per jurisdiction
- Records of device registration and product approvals per jurisdiction
- QMS includes jurisdiction specific requirements as well as ISO 13485
- Definition and List of Critical Suppliers per site
- Certificate scope consistent for jurisdiction needs based on included products

MDSAP
Auditor Approach & Mindset

- Site specific responsible activities auditable during on-site audit
- Adverse Event and Advisory Notice reporting per jurisdiction
- Appropriate personnel trained to ISO 13485 and jurisdiction requirements
- Internal audit considered MDSAP requirements
- Management Review considered readiness for MDSAP requirements

MDSAP
Audit Process Timelines

MDSAP Process	MDSAP Tasks per Process	Minutes per Audit Task
Management	11	28.8
Device Marketing Authorization &Facility Registration (DMA&FR)	3	28.0
Measurement Analysis & Improvement (MA&I)	16	30.4
MD Adverse Events & Advisory Notice Reporting (MDAE&ANR)	2	30.4
Design & Development (D&D)	17	16.8
Production & Servicing Controls (P&SC)	29	35.2
Purchasing	12	12.0

MDSAP
Considerations for Audit Time Adjustments

- During Surveillances all tasks per process do not have to be audited but whichever task is chosen all jurisdictions for that task must be reviewed.
- If assessments of corrections and corrective actions are needed during audit each NC is added as an additional task in MA&I.

MDSAP
Considerations for Audit Time Adjustments

- D&D tasks adjustments:
  - No design then only task 1 & 16
  - No active role with new device design or devices prior to regulatory design requirements tasks limited to 1,4 & 13-16
  - Devices containing SW may result in duplicate D&D tasks
- P&SC task adjustments
  - Multiple processes will add time per process
  - Limited processes and no changes since last audit may reduce time
- Purchasing time will be dependent on number of critical suppliers and will include intra-company entities, where applicable

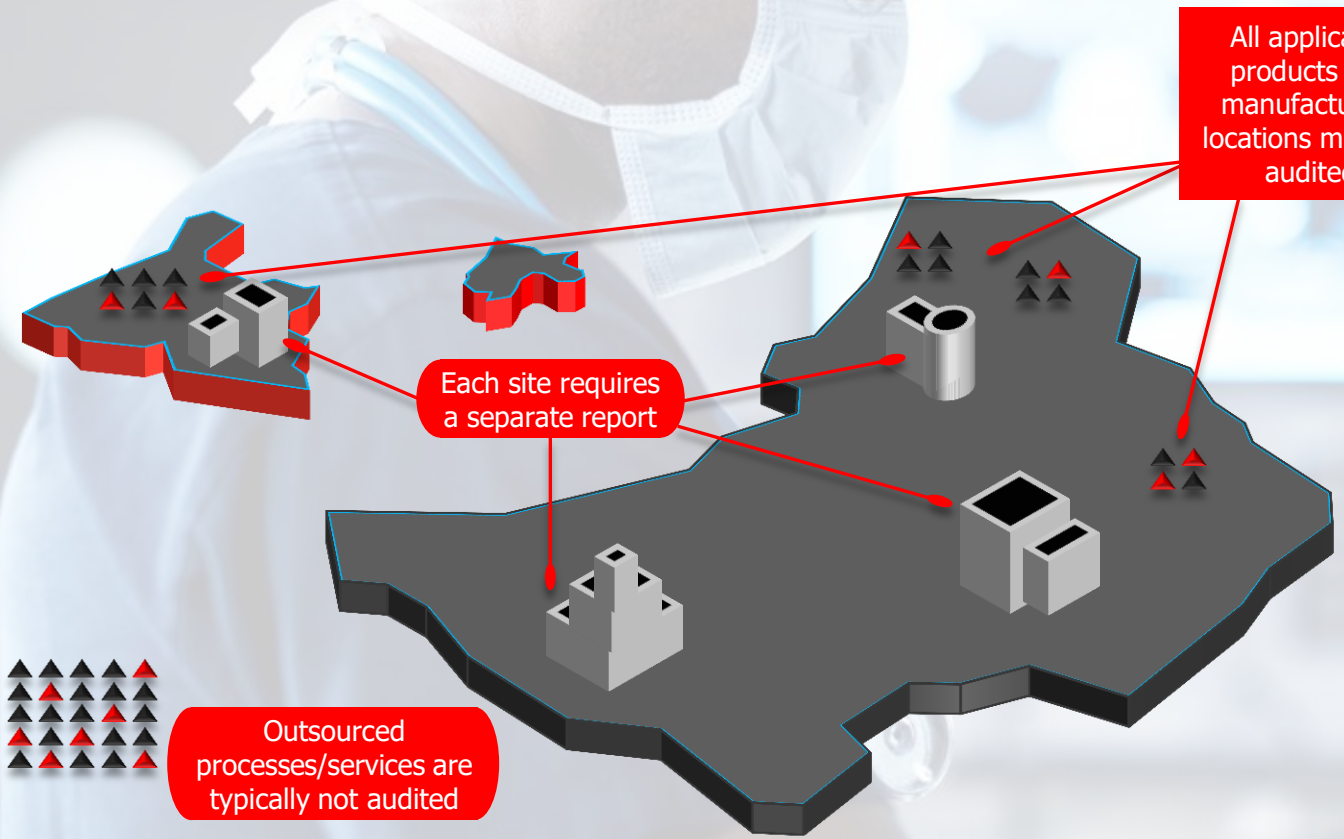
MDSAP
Program Requirements

- ISO 13485
- Country-specific requirements (where applicable)
- If shipping product to a MDSAP jurisdiction, country-specific requirements WILL apply
- For multi-site operations, the sites that conduct activities for another site will be assessed per the requirements for the MDSAP cert.

MDSAP
Program Requirements

- Intra-company support activities are subject to review of contracts, etc., to verify coverage of audit requirements.
- There is no sampling or design and manufacturing sites permitted in the MDSAP program.
- Off-site typically used for preparation and reporting is limited to 20% of the calculated audit time.
- A separate report is required per site.

MDSAP
Program Requirements



MDSAP
What it is NOT

- Product Approvals for marketing in specific jurisdictions
  - Each jurisdiction still has own pathways to approval for product entry
- Review of Technical Files/Design Dossiers for compliance to EU conformity assessment
  - Review of clinical trial evidence to support claims
  - Content review of product safety and performance claims
- Un-ended duration. Some regulatory assessments can last as long as the regulator wants- this is not the case with MDSAP.
- NOT based on number of personnel at a site
- Mechanism to close Regulator imposed audit findings cited to site

Audits for ISO 13485 vs MDSAP

Criteria	ISO 13485	MDSAP
Program Customer	Manufacturer	Regulator
Output of success	Certificate	Report & Certificate
Auditing Organization Qualification	Competent Body	Regulators
Audit Duration	Employee count	Fixed time
Nonconformance Grading	Major/Minor	1, 2, 3, 4, 5

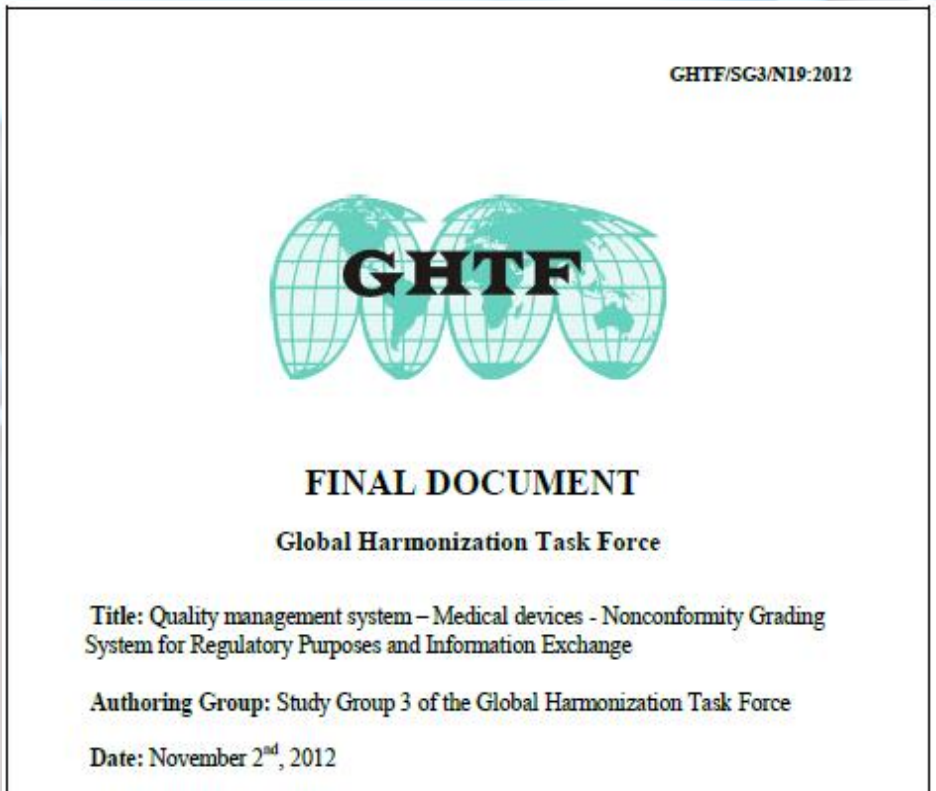
Regulations in addition to ISO 13485

	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 - Nonconformities

MDSAP
Nonconformity Grading

- Uses GHTF Document SG3/N19:2012 - Nonconformity Grading System for Regulatory Purposes and Information Exchange
- Definition of nonconformity unchanged – non-fulfillment of requirement
- Creates a quantitative grading system



GHTF/SG3/N19:2012

GHTF

FINAL DOCUMENT

Global Harmonization Task Force

Title: Quality management system – Medical devices - Nonconformity Grading System for Regulatory Purposes and Information Exchange

Authoring Group: Study Group 3 of the Global Harmonization Task Force

Date: November 2nd, 2012

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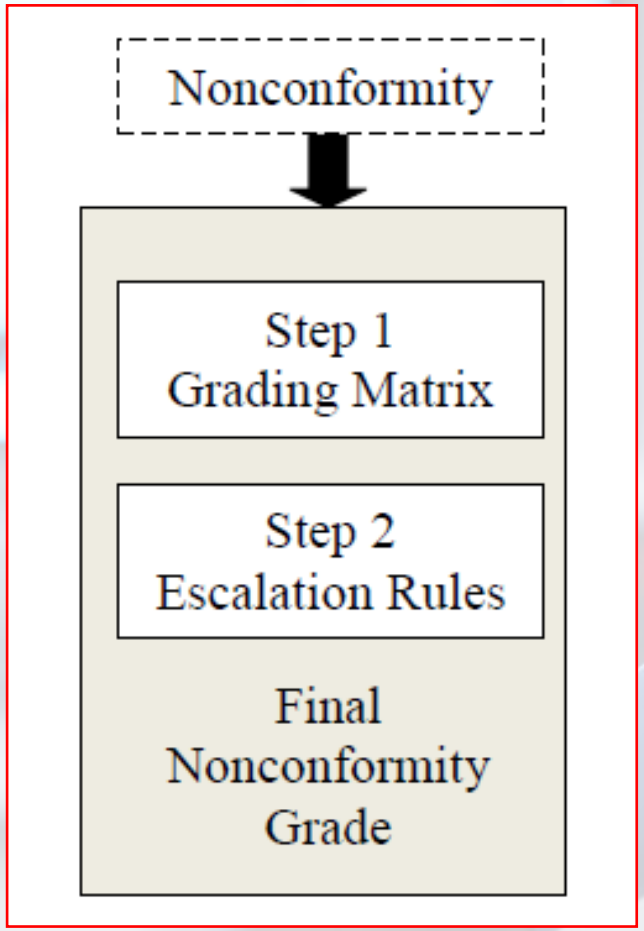
MDSAP
Nonconformity Identification

- Step 1 – Initial Grading
  - Impact
  - Occurrence
- Step 2 – Escalation rules

- Final nonconformity grade



MDSAP
Nonconformity Initial Grading - Impact

Influence of safety & performance

Indirect

- ISO 13485:2003 clauses 4.1 through 6.3
- Considered "enablers" for QMS processes to operate

Direct

- ISO 13485:2003 clauses 6.4 through 8.5
- Considered to have direct influence on design, and manufacturing controls

Matrix

QMS Impact		
	Direct	3
	Indirect	1

MDSAP
Nonconformity Initial Grading - Occurrence

In the same sub-clause (X.X.X)

First

- First time not observed in two previous QMS audits

Repeat

- Identified within either of two previous QMS audits

Matrix

Occurrence	**Repeat**	**+1**
	First	**0**

MDSAP
Nonconformity Escalation Rules

Escalation

- Absence of documented process or procedure
- Release of a nonconforming medical device

Matrix

Absence of Process or Procedure	+1
Led to Nonconforming devices on market	+1
Escalation Criteria	

MDSAP
Nonconformity Grading Final

QMS Impact	Direct	3	4	Absence of Process or Procedure	+1
	Indirect	1	2	Led to Nonconforming devices on market	+1
		First	Repeat		
		Occurrence		Escalation Criteria	

Maximum grade is a 5!

MDSAP Program

Post audit activities per program requirements	
D_0	Audit end date (closing meeting)
D_0 + 5 W-days	**AO** informs RA if 1or 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
Access to Reports

- MDSAP Database REPS has been operational since Fall 2018 is portal for submission of audit reports
- All Regulatory Authorities for the jurisdictions where the devices are marketed

How does MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM fit with other certifications

For Manufacturers Currently Holding ISO 13485 (accredited), CE MDD/IVD/AIMD Certificates and MDR certificates

- Check with current Certification / Notified Body whether capable
- Investigate best plan for the type of MDSAP audit to conduct:
  - Full initial certification audit or during a Surveillance audit?
  - Consider current ISO certification cycle
  - 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/will include CE requirements

MDSAP Status

MEDICAL DEVICE SINGLE AUDIT PROGRAM

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MDSAP
Regulator Engagement

- Regulators rotate leadership in the program every 3 years. USA started now being led by Brazil (Jan. 1, 2016 thru Dec 31, 2018).
- Five jurisdictions currently engaged in program
    - All participate in Witness audit activities (AO's and Manufacturers)
- Observer status is held by World Health Organization and European Union
- Regulators meet formally at least twice a year
- Engage with Auditing Organizations at least annually

MDSAP
Auditing Organizations Status as of August 30, 2019

- CMDCAS recognized registrars were eligible to participate when program launched
- All AO's that have reached authorization status will achieve recognition status upon closure of all open nonconformances from regulator witness audit events.
- Remaining AO's will have up to 2 years to complete the program and become recognized.
- MDSAP will be the only program for Canadian market access by Jan 1, 2019.

Authorized to Conduct	Recognized
2	11
LRQA, SAI Global	BSI, Dekra, DQS, Intertek, GMED, NSAI, SGS, TUV Rheinland, TUV SUD America, TUV USA, UL

MDSAP
Enrollment continues to grow

MDSAP Participating Manufacturing Sites
(does not necessarily include all buildings within a campus)

2014, Dec	-	6
2015, Dec	-	61
2016, May	-	105
2017, Sep	-	417
2018, Dec	-	2900
2019, Dec	-	3700

MDSAP
Program Challenges since Launch

- Understanding the nuisances of the different jurisdiction regulations
  - Does device classification affect the scope of the QMS to be audited?
  - If different classifications in the marketed jurisdictions how is that approached?
  - What and who has responsibility for registration
  - What type of reporting is required and when and by whom?
  - Regulatory roles played by manufacturer
  - Contract service providers

MDSAP
Program Challenges since Launch

- How the jurisdictions determine compliance
  - Full QMS or site-specific focus
  - Certificate Holder (Legal manufacturer)
  - Who can get a MDSAP certificate
- Use of MDSAP reports for non-MDSAP jurisdictions
  - Name of the manufacturer and "doing business as" allowances
  - Types of signatures accepted
  - Starting a MDSAP Affiliate program
- Regulators learning more about each others programs and making adjustments

Challenges within the greater Medical Device community
Are we really moving toward Harmonization?

- Difference between MDSAP and other schemes accreditation requirements (MDSAP, ISO 13485, CE)
  - Regulatory roles within Manufacturer and within the auditing organizations
  - Timing and grading of NC issuance and follow-up

The Evolution of MDSAP

QUESTIONS ???

THANK YOU for attending this presentation.

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