MDSAP Overview
Marseille, 20.10.2017

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EMEA Client Manager – MDSAP Support Specialist

Who is this woman?!?

- Sigrid Krimmer-Quendler PhD, MSc
- Biotechnologist, Nutrition Physiologist
- 13 years in Healthcare
  - Orthopaedics
  - Passive Medical Devices
  - Passive Implantable Medical Devices
  - In-vitro Diagnostic Devices
  - Pharmaceuticals
- 2.5 years with BSI
- EMEA Client Manager – Lead Assessor
- MDSAP Support Specialist

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MDSAP Overview

Agenda

- What is MDSAP
- How MDSAP Works
- How does MDSAP fit with other certifications
- MDSAP Status
- Preparation and Assessment Considerations
- Questions?

International Medical Device Regulatory Forum (IMDRF)

History of IMDRF

- IMDRF Management Committee (MC) regulators:
  - Australia, Brazil, Canada, China, the European Union, Japan, Russia, and the United States of America
- Observers:
  - WHO - World Health Organization
  - APEC LSIF (Asia Pacific Economic Cooperation Life Science Innovation Forum)
- Affiliate Organizations:
  - Asian Harmonization Working Party
  - Pan American Health Organization
- Working Groups:
  - Standards; MDSAP; Submissions; UDI; NCAR; Software

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

MSDAP

Program Distinctions

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

THAT'S HOW WE ALWAYS DID IT
WILL NOT WORK IN THE MDSAP PROGRAM!

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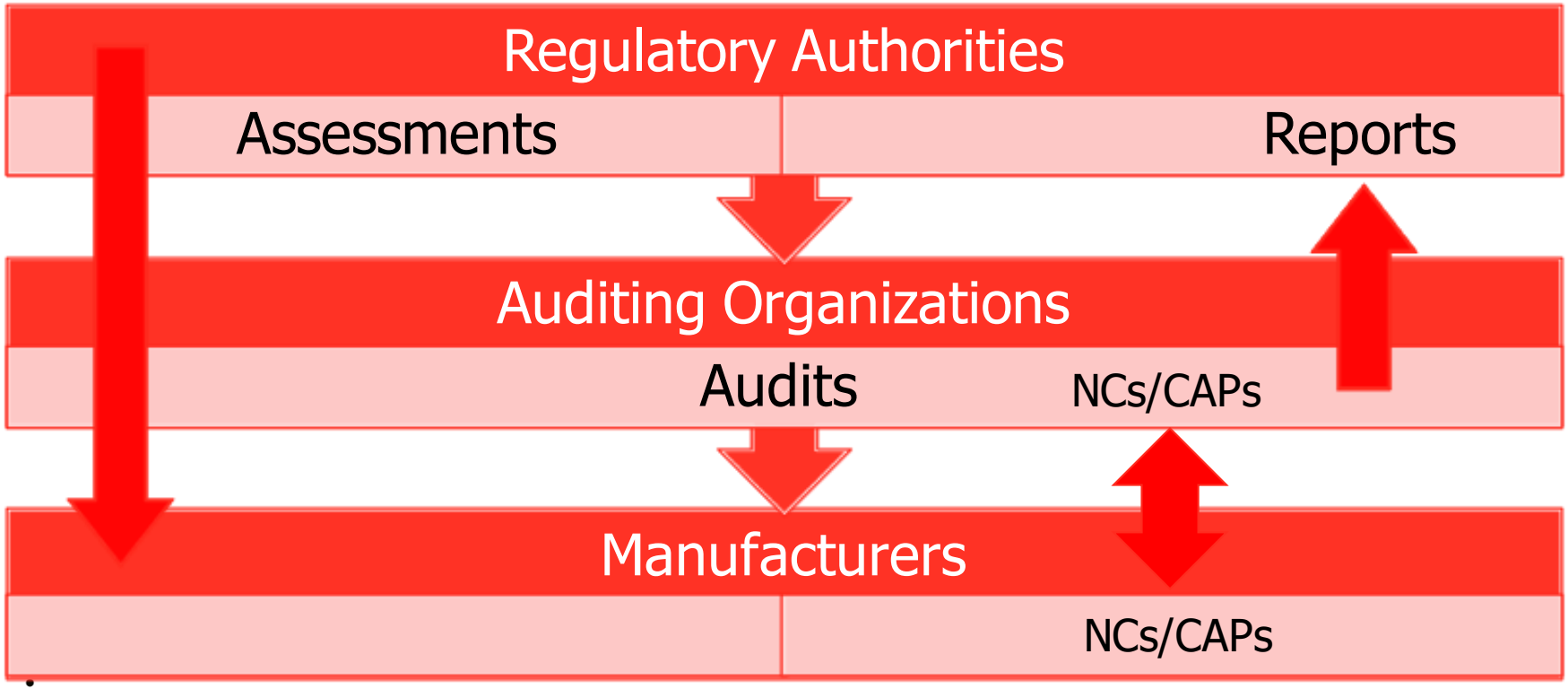
MDSAP

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

MDSAP Structure



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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 (to close major nonconformances)

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Program Requirements

- ISO 13485 plus applicable Country-specific requirements
- 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.
- All RA's in the program get copies of submitted reports

MDSAP Overview

Program Output

- Regulatory Audit Report demonstrating compliance to MDSAP program requirements
- Certificate for MDSAP – unaccredited (only a requirement for Canada)
- Certificate for ISO 13485:2016 now (may be used for other jurisdictions as well as for CE)
- Market access to Australia, Brazil, Canada, Japan and USA

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

Some ‘Alternative Facts…’

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 conforming 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

MDSAP Assessment – Initial: Stage 1 & Stage 2

Stage 1

Process	Task Number
Management	1, 3*, 4*, 5*, 8, 9
MA&I	1 & 10
D&D	4, 13, 16
Production & Service Controls	1, 4*, 5, 7*, 8, 11, 13, 15-18, 21, 23-27
Purchasing	3-9, 11*

* Lists/Documents to be available for review throughout audit.

Stage 2

Process	Task Number
Management	2, 3, 6, 7, 10, 11
MA&I	2-9, 11-16
D&D	1-3, 5-16
Production & Service Controls	2-12, 13-15, 17-23, 25-29
Purchasing	1-2, 6-10, 12-16
DMA&FR	1, 2
MDAE&ANR	1-3

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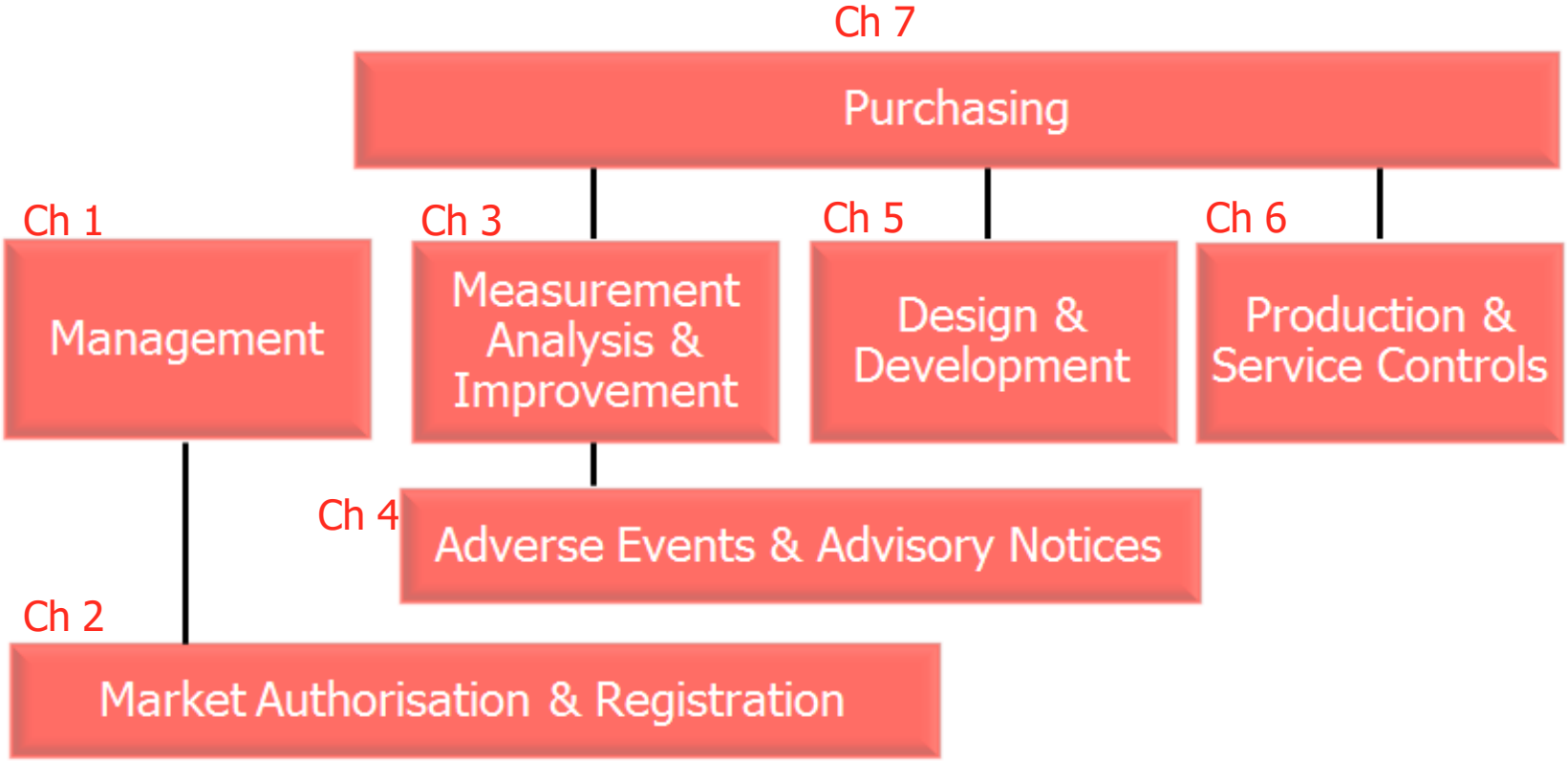
MDSAP Audit Sequence



MDSAP Audit Process Sequence and Estimated Durations *ISO 13485:2016

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 Audit Time Calculations *SAMPLE (hh:mm)*

	Initial Cert.	Surv 1*	Surv 2*	Recert.#
Management	6:36	5:16	5:16	5:16
DMA&FR	1:10	0:56	0:56	0:56
MA&I	10:08	8:06	8:06	8:06
MDAE&ANR	1:16	1:00	1:00	1:00
D&D	5:57	4:45	4:45	4:45
P&SC	21:16	17:00	17:00	17:00
Purchasing	3:00	2:24	2:24	2:24
On-site Total	49:23 (6.2d)	~60% of cert.	~60% of cert.	~60% of cert.

*D&D and P&SC can be split between Surv 1&2, Purchasing to follow based on device trail

No stage 1 activities

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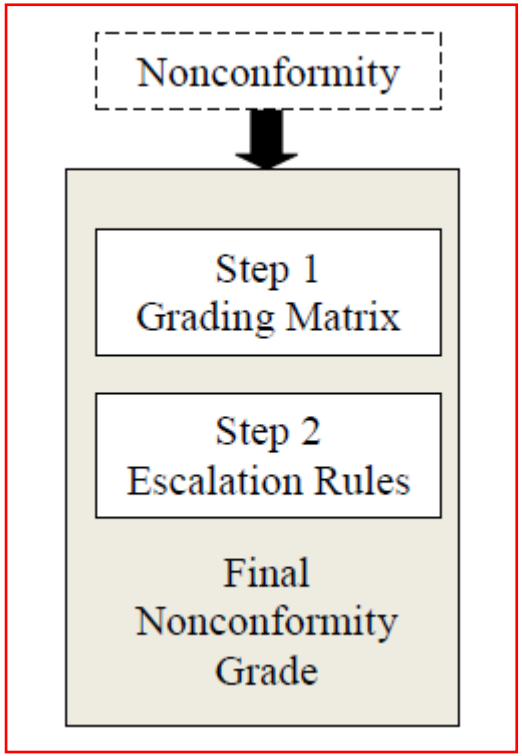
Nonconformity Grading

- 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



MDSAP Nonconformity Grading - Final

QMS Impact on safety & performance	**Direct**	**3**	**4**	**Absence of Process or Procedure**	**+1**
	Indirect	**1**	**2**	**Led to Nonconforming devices on market**	**+1**
		First	**Repeat**		
		Occurrence in same sub-clause (X.X.X)		**Escalation Criteria**	

Maximum grade is a 5.

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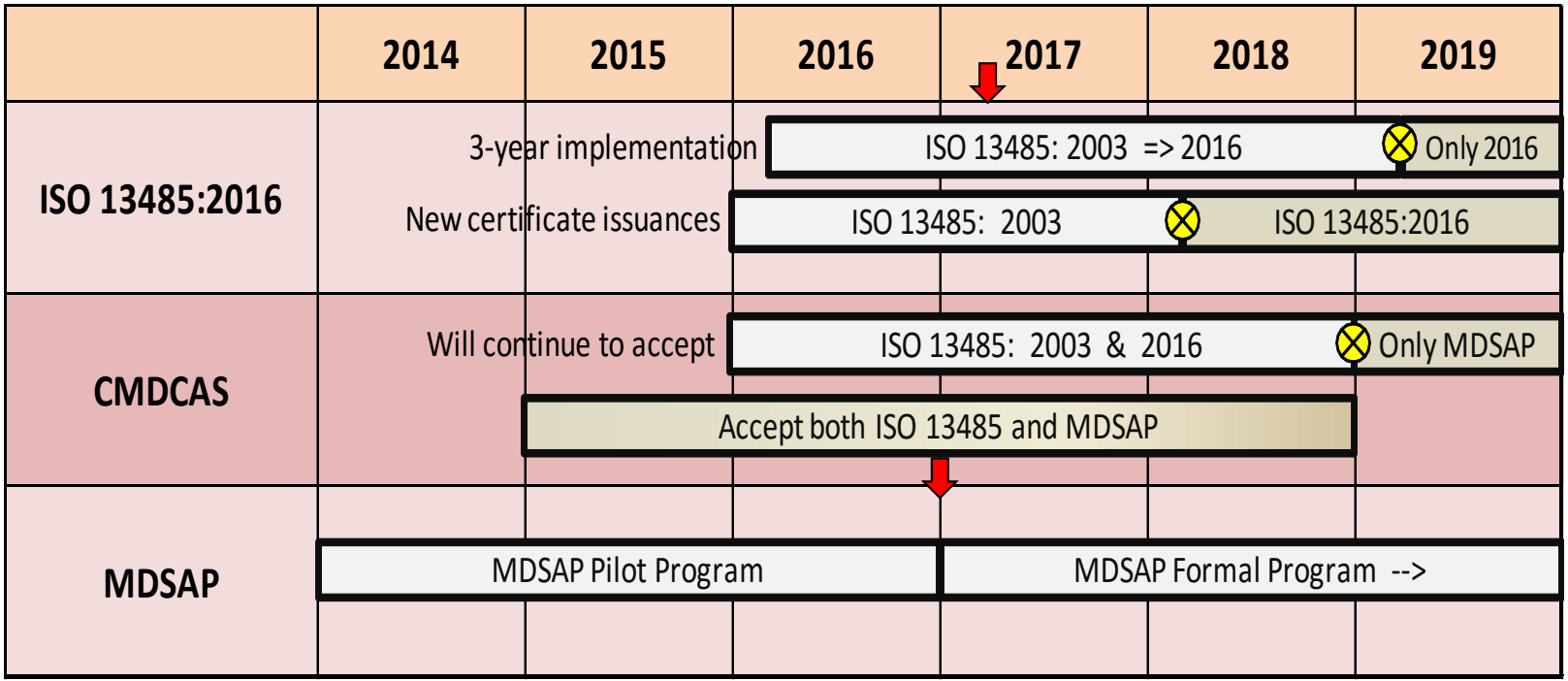
Transitions: 13485 & MDSAP

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



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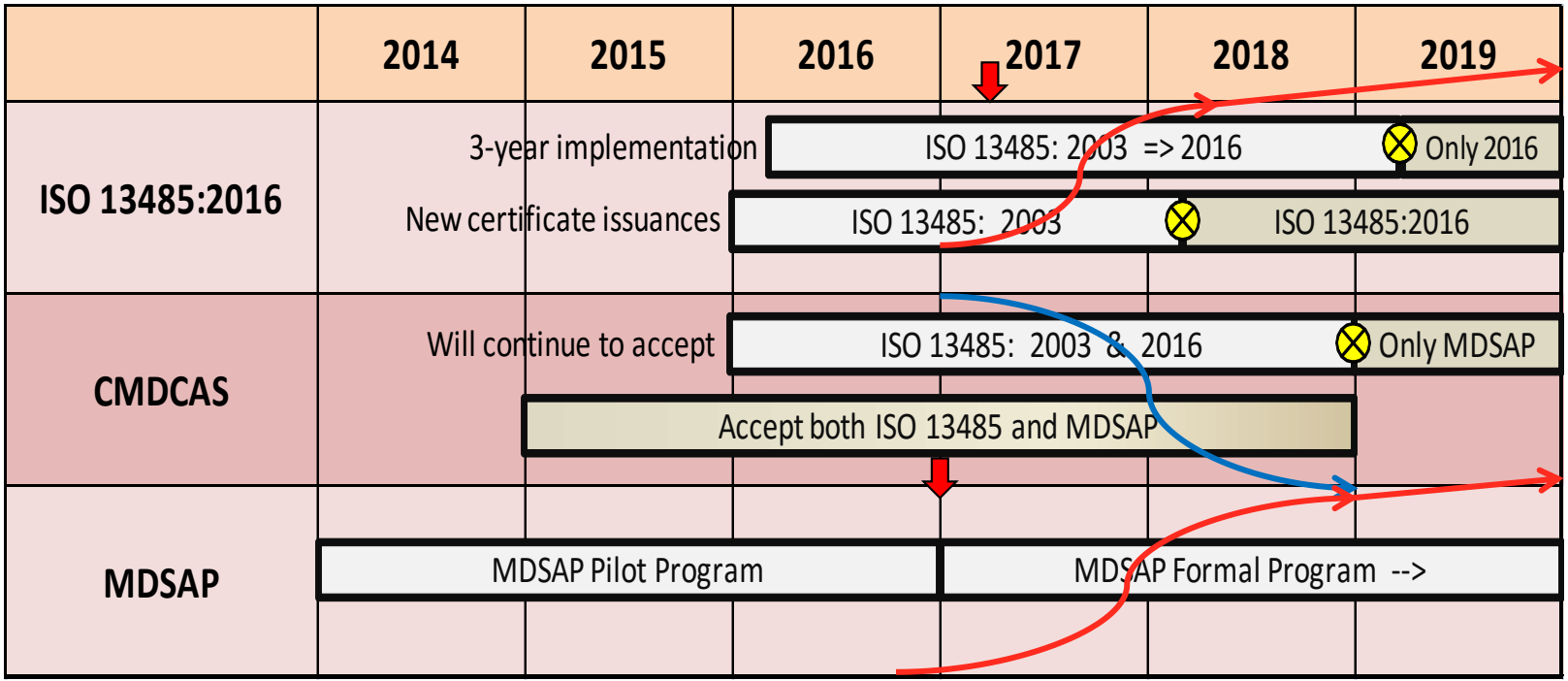

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For Manufacturers Currently Holding ISO 13485, ISO 13485 CMDCAS, CE MDD/IVD/AIMD Certificates

- Check with current Certification / Notified Body whether capable
- Investigate best plan for the type of MDSAP audit to conduct:
  - Full initial audit or Surveillance audit? – *recommend certification*
  - 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 include CE requirements

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MDSAP Program Status

Manufacturers Perspective

- June 2016 MDSAP Forum meeting included 13 manufacturers who have had a MDSAP audit
  - 3M Healthcare, Berlin Heart, Boston Scientific, Capillus, Cook, Ethicon, GE Healthcare, Medtronic, Mentor, Siemens, St Jude, Stryker and Wright Medical
- Comments included an overall positive image of the program
  - Audits followed a set sequence of activities which allowed for planning for employee participation
  - An increased focus on risk helped to drive risk-based thinking deeper into their organization
  - Strong focus on product and process quality and risks associated with change implementation
  - Cost benefit for a single audit for multiple jurisdictions
  - Need to get other jurisdictions to embrace the program to enhance benefit
  - Less business disruption
  - Consistent audit process

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MDSAP Program Status

- CMDCAS recognized registrars were eligible to participate and several have engaged in the program.
- Three stages of engagement during **Pilot Phase (2014 – 2016)**

Application Stage	Begin Audit Stage	Completed Audit Stage
5	5	3
LRQA, NSAI, SGS, UL, TUV Rheinland	Dekra, DQS, LNE (G-MED), SAI Global, TUV USA	BSI, Intertek, TUV SUD

- **Operational Phase (began Jan 1, 2017)**

Application Stage	Can Conduct Audits	Recognized
3	7	4
LRQA, NSAI, NSF	Dekra, DQS, LNE (G-Med), SAI Global, SGS, TUV USA, TUV Rheinland	UL, BSI, Intertek, TUV SUD

MDSAP Program Update

Manufacturer's next steps

- Ask what markets are for their product now and in the future
- If they are due for recertification to CMDCAS and intend to market in Canada then they must consider transition to MDSAP asap.
    - Those who had already recertified in 2016 you will need to become certified to MDSAP before their next recertification comes up.
- Coordination of MDSAP and ISO 13485:2016 is crucial in their planning process.
- *Contract for MDSAP audit - ASAP time is of the essence!!!*

- Use On-Line survey to provide feedback to the regulators about your experience with the MDSAP program.
  http://www.fda.gov/MedicalDevices/InternationalPrograms/MDSAPPilot/default.htm

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Future MDSAP Auditors - Extensive training requirements

P37/21T

MDSAP Trainee

- Annual Code of Conduct signed
- Complete MDSAP Mandatory and Regulatory Training Modules
- MDD Training P37/00
- Risk Management training
- Annual Auditor Training courses
- Must hold P13485, Assessor code
- Must work with 2x Mentor with code P37/21Q (Observe + QR)
- MDSAP Scheme Manual review
- MDSAP Program document s Review

P37/21

MDSAP Team Member

- Annual Code of Conduct signed
- Must be verified by a Mentor with code P37/21Q
- All requirements for P37/21T apply

P37/21Q

MDSAP Mentor/ Qualifying Reviewer

- Annual Code of Conduct signed
- Must Hold P37/21
- Must be designated by MDSAP Program Manager

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Assessment Preparation

Review PF473

Excel doc with client information.

Prepared at quotation stage.

- Contains client background info
- Certificate info
- Relevant tasks
- Additional time on some tasks
- Additional time beyond MDSAP requirements (e.g. EU requirements)

Review Regulatory Info

Regulatory websites –
AUS/ BRA/ CAN/ JAP/ USA

Review information held by regulators

- Product listings

(what, where, classification etc.)

- Recalls
- Warnings

Review previous reports

ALL reports over the last two years

Identify NCs and possible trends.

- Understand history
- Identify and be aware of all NCs
- Identify possible trends

Assessment

Audit Process

- Assessment in Chapter order
- Audit by process, not task by task
- Some tasks highlight specific regulator requirements.

Links

- Some tasks identify links to Risk Management (Blue in Companion)
- Some tasks identify links to tasks in other chapters (Orange boxes in Companion)
- Some links are forward, some backward.

Report

- Write in First Person, Past Tense
- Write report in terms of outcomes per chapter.
- Describe the overall sample size and justify why you chose the samples.

Regulators

- Want to see evidence of a regulatory audit, not just QMS
- Consideration of regulatory requirements

Audit by Chapter and Process: Ch1 - Management

Process Audit Outcomes	Report Content Expectations	Closest QMS Process	Task # (description)	Links task, chapter (tasks) <reason>	Tasks with specific Country Regulatory Requirements # Jurisdiction(s)
A, D	the extent of outsourcing of processes that may affect the conformity of product with specified requirements and verification of the proper documentation of controls in the quality management system	Identification of the extent of outsourcing in the QMS	5 (outsourcing)	5 Purchasing (1, 4)	5 AUS/CAN
A, B, C, F, H, I	verification that management reviews are being conducted at planned intervals and that they include a review of the suitability and effectiveness of the quality policy, quality objectives, and quality management system to assure that the quality management system meets all applicable regulatory requirements;	Core QMS: Manual, exclusions and non applicables, policy, objectives, management review	1 (Quality Manual) 3 (Policy and Obj) 9 (Mgmt Review)	3 P&SC (1) 3 Purchasing (1) 9 MA&I (3, 4) outputs->CAPA 9 MA&I (10, 11) are these review inputs?	1 USA
A, D, E, F, H	description of the organization's organizational structure and verification as to whether or not the responsibilities and authorities (e.g., management representative) were established	Org Structure / Resp&Authority	4 (Org Struct) 2 (Mgmt Rep)	None	None
B	description of the organization's documents and records control	Control of Docs & Records	8 (docs & records)	None	8 AUS/BRA/JAP USA
E	verification that the organization has determined the competencies for personnel performing work affecting product quality, including a description of the training procedures and records verified.	Training (process)	6 (training)	6 P&SC (12) – check training of shop floor & MA&I internal auditors	6 BRA/USA
G	None Defined	Risk: Top Management involvement…	7 (Risk – Top Mgmt)	7 D&D (8, 9) Risk implementation (also risks from other processes)	None
I	None Defined	Segway into DMA&FR	10 (DMA&FR process)	10 (all of Chapter 2 DMA&FR)	10 AUS/BRA/ CAN/JAP/USA

MDSAP Overview

- Questions?

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MEDICAL DEVICE SINGLE AUDIT PROGRAM

MDSAP Overview

The End