ISO 13485:2016 and MDSAP

Mapi™
Insight for solutions

Practical tips to prepare for the changes

Presenters

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Agenda

- ***Introduction***
- Why are changes being made?
- Who is affected?
- What are the changes?
- How to plan?
- When are the deadlines?
- Where to get help?

Introduction

- Big changes coming!
- Impact: Regulation of medical devices (Class II-IV) sold in Canada
  - ISO 13485:2016
  - MDSAP (Medical Device Single Audit Program)
- Health Canada Notice July 2016

TO ALL CANADIAN AND FOREIGN MANUFACTURERS

Attention to persons responsible for regulatory affairs and quality management systems

NOTICE

TRANSITION TO THE REVISED VERSION OF ISO 13485 AND ITS IMPACT ON THE COMPLIANCE TO THE QUALITY MANAGEMENT SYSTEM REQUIREMENTS OF THE CANADIAN MEDICAL DEVICES REGULATIONS

APPLICATION

The transition to ISO 13485:2016 applies to:

- all CANADIAN and FOREIGN manufacturers holding class II, III, and IV medical device licences
- all CANADIAN and FOREIGN manufacturers applying for class II, III and IV medical device licences

MDSAP TRANSITION REMINDER

In accordance with Health Canada's announced MDSAP transition plan, CMDCAS certificates will no longer be accepted after December 31st 2018. Manufacturers will be required to submit valid MDSAP certificates by no later than January 1st, 2019 in order to maintain their medical device licences.

To facilitate a smooth transition, Health Canada is encouraging manufacturers to begin the transition process in a timely matter to ensure compliance with the regulatory requirements at the end of the transition period. More information on the MDSAP transition plan and the regulatory requirements can be found on the following website.

July/juillet 2016

n Santé
da Canada

Health Canada
www.hc-sc.gc.ca

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Drugs and Health Products

Notice: Transition Plan for the Medical Device Single Audit (MDSAP)

December 4, 2015
Our reference number: 15-112791-35

Background

Agenda

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ISO 13485:2016

- ISO standards are reviewed every five years to establish if a revision is required in order to keep it current and relevant for the marketplace
- Revision commenced in 2012
- Many changes in technology, regulatory requirements, expectations since 2003 version released
- Keep up!

MDSAP – Medical Device Single Audit Program

- Global Harmonization Task Force (GHTF), subsequently International Medical Device Regulators Forum (IMDRF)
- Multiple countries participating
- Two decades of effort, many working groups, topics
- Promote a uniform approach to regulation
- Time, resources, market authorization
- Quality systems, regulatory audits – separate audits for each jurisdiction = duplication of effort, increasing costs
- Goal = one audit to meet requirements for many jurisdictions
- Manufacturers control audit timing, costs
- Canada, US, Brazil, Australia, Japan
- Industry - divided support

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Canadian Perspective: Affects Manufacturers, Registrars

Manufacturers who sell in Canada: Class II, III, IV devices

- Hold current licences
- New licence applications

CMDCAS Registrars

- Third party auditing organizations recognized by Health Canada, SCC (Standards Council of Canada)

http://www.hc-sc.gc.ca/dhp-mps/md-im/qualsys/list_liste_regist-eng.php

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  - ***MDSAP***
  - ***ISO 13485***
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    - ***Manufacturers***
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MDSAP - participants

International partners that are participating:

Australia -Therapeutic Goods Administration (TGA)

Brazil - Agência Nacional de Vigilância Sanitária (ANVISA)

Canada -Health Canada

Japan - Ministry of Health, Labour and Welfare (MHLW), and the Japanese Pharmaceuticals and Medical Devices Agency

United States - Food and Drug Administration (FDA)

The World Health Organization (WHO) Prequalification of In Vitro Diagnostics (IVDs) Programme and the European Union (EU) are Official Observers

MDSAP – Medical Device Single Audit Program

Goals, objectives:

- One audit program, multiple jurisdictions, with confidence in outcomes ie audit results
- Enable regulatory oversight of medical device manufacturers' quality management systems
- Efficient use of resources
- Minimize regulatory burden on industry
- Promote alignment of regulatory approaches, technical requirements based on international standards, best practices, improve safety and oversight
- Allows a medical device manufacturer to contract with an MDSAP recognized Auditing Organization (AO), have one quality management system audit to meet requirements of all participating regulatory authorities
- Each country defines how MDSAP outcomes (audit results, certificates) are used based on their legislation, regulations

MDSAP program/use of certificates:

Canada: Health Canada will use MDSAP to replace CMDCAS effective January 2019. Therefore, medical device manufacturers currently selling in Canada will have to obtain MDSAP certification.

United States: FDA will accept MDSAP in lieu of routine inspection, but **not** for initial visits or "for cause inspections."

Brazil: ANVISA will accept MDSAP for initial audits. This will help with the country's current backlog of inspections, but the agency will still require its auditors to conduct ANVISA audits for higher-risk devices.

Australia: TGA will use MDSAP to satisfy TGA requirements, considering MDSAP certificates as equivalent CE certificates.

Japan: MHLW will accept MDSAP in lieu of an on-site Japanese Quality Management System (J-QMS) audit.

Manufacturers cannot opt out of any particular market's regulation if they currently sell in that market. At the same time, manufacturers will not be audited to a regulation that is not applicable to their organization.

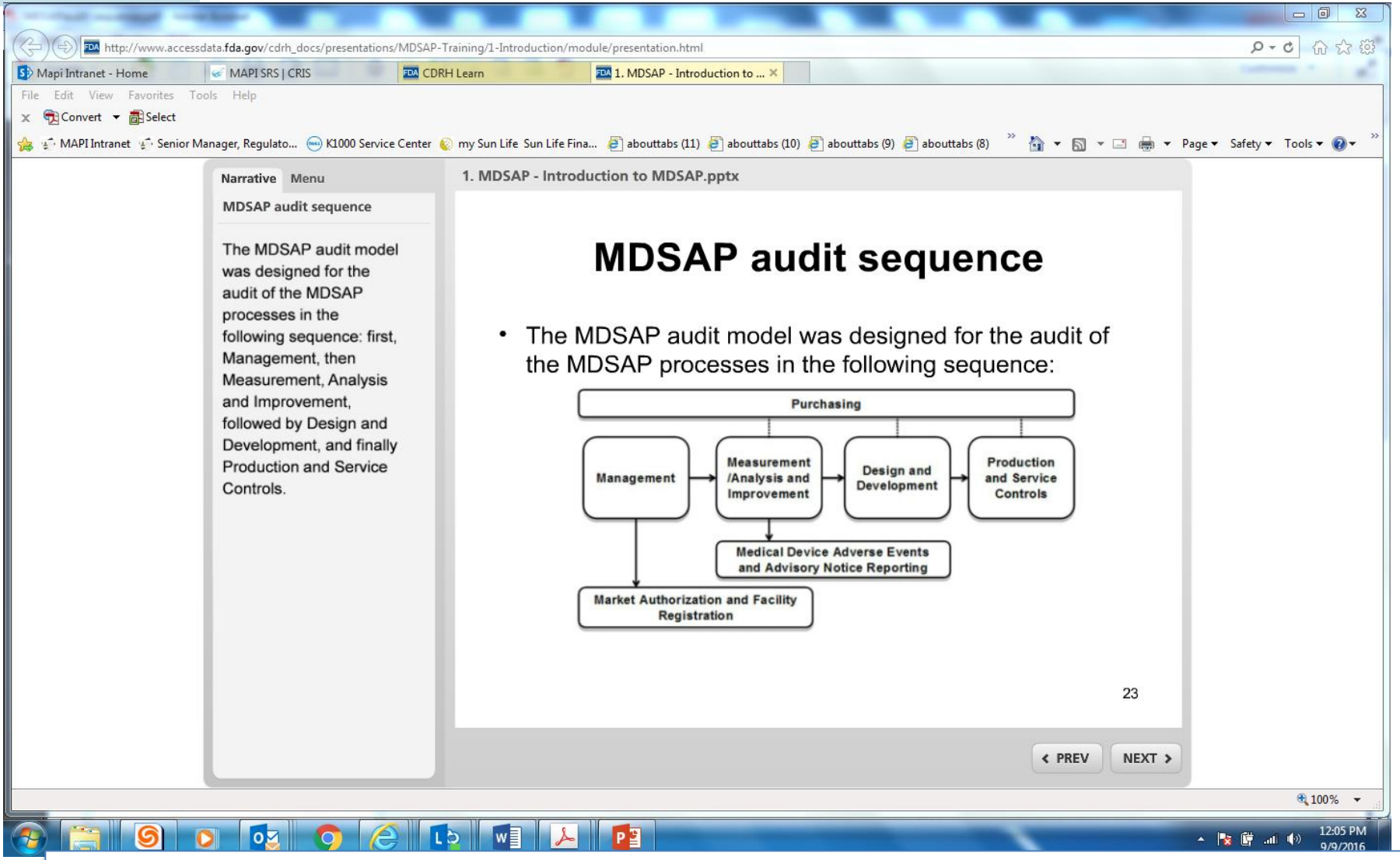
EU: MDSAP status

Europe (EU) is participating in the MDSAP pilot as an observer only

- concerns: difficult to obtain agreement among all member states (legal requirement)
- participation of European Notified Bodies in the program shows strong link between EU and MDSAP (ie CMDCAS registrars that are Notified Bodies)
- varying opinions whether EU will join; MDSAP's aim to harmonize quality system compliance (goal of increasing safety and efficacy of medical devices) may move EU to increase quality consistency across member states
- However – legal issues as above; also EU grappling with regulatory changes MDD – MDR, IVDD - IVDR

MDSAP - changes

- **Audit process**
  - **large amount of information, training on FDA website**
  - **MDSAP documents – audit procedures, forms** http://www.fda.gov/MedicalDevices/InternationalPrograms/MDSAPPilot/ucm377578.htm
  - MDSAP AU P0002.003 2015-10-06 and Companion Document MDSAP AU G0002.1.003
  - Audit approach/sequence
  - Country specific requirements



MDSAP - changes

- **Auditing Organization**
  - Communication, Quotation(s), Scheduling
  - New processes, AO specific
  - MDSAP documents - guidelines for audit time/days, dictate costs, increased over CMDCAS
  - Very significant change if companies not previously using third party auditing companies

- **Audit findings**
  - GHTF Grading system rather than major/minor non-conformances
  - Described in GHTF/SG3/N19:2013 -- Quality management system – Medical devices– Nonconformity Grading System for Regulatory Purposes and Information Exchange (PDF - 463KB)
  - Points assigned depending on direct or indirect influence on safety/performance; first or repeat occurrence; absence of documented process/procedure; release of nonconforming device
  - Maximum 5 points
  - Actions by AO, follow up, actions by manufacturer proportionate
  - AO will notify Regulatory Authorities within 5 days if: one or more grade 5, more than two grade 4, counterfeit product, public health threat or fraudulent activity

MDSAP - changes

- **Audit report**
  - **MDSAP AU P0019 documents**
  - Provided to regulators
  - FDA will triage every MDSAP report for potential OAI (Official Action Indicated)
    - AO to follow up the nonconformities – no 483
    - FDA prefers regulatory meeting, not Warning Letter
- **Audit certificate**
  - **MDSAP AU P0026 –** several documents
- **Audit follow up**
  - Post audit activity, obligations
  - Several documents

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ISO 13485:2016 – High level, key changes

- **Structure – same 8 clauses**
  - **Clause numbering**
    - Sub clause renumbering – reflects GHTF nonconformity grading system for MDSAP ie three digit sub-clause level
    - Eliminates subjective terms ie major, minor nonconformance
- **Definitions**
  - Some differences from previous version
  - Product, risk/risk management, complaint
  - Manufacturer, authorized representative, importer, distributor
  - from GHTF/SG1/N55:2009
  - Caveat: definitions not necessarily same as regulatory definitions

ISO 13485:2016 – High level, key changes - requirements

- **Quality management system** – Clause 4
  - expansion of risk management approach
  - Document/record control enhanced
  - Medical device file - articulated
- **Management responsibility** – Clause 5
  - Clarifications to quality planning, responsibility/authority, management representative, management review
- **Resource management** – Clause 6
  - Heightened documentation for personnel qualification/training/effectiveness
  - Work environment/contamination control requirements for sterile devices
- **Product realization** – Clause 7
  - Additional or enhanced: purchasing/vendor selection (incl. requalification), verification of product, design, cleanliness/sterilization, validation, ID/traceability, product preservation; analyze service records
- **Measurement, analysis and improvement** – Clause 8
  - Formalize/define methods of data analysis, feedback processes– production, post-production, funnel into risk management
  - Stronger controls: investigation, nonconforming products, CAPA, complaints, regulatory reporting

ISO 13485:2016 – High level, key changes - comments

- **Emphasis on risk management**
  - Very significant
  - Risk appears many times in the new standard
  - Risk based approach in all QMS processes, not just in product realization; includes outsourced processes, purchased product
- **Regulatory obligations - articulated**
  - Awareness of regulations
  - Reporting of recalls/advisory notices, incidents, notifications to regulators
  - a requirement of 13485 if it is a regulatory requirement ie regulatory requirements in any jurisdiction the company is selling must be incorporated
- **Process control**
  - Software validation used in manufacturing processes and used in QMS
  - Work environment/contamination control requirements for sterile devices
- **Nonconforming product - actions**
  - Differentiate actions depending on when discovered – before or after released
  - Regulatory implications
- **Still differences with US QS Regulation**
- **Many enhanced requirements consistent with ISO 14969:2004 (guidance on the application of ISO 13485:2003)**
  - if already following this closely, expect fewer changes needed

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MDSAP
– Impact on CMDCAS Recognized Registrars

Registrars must qualify to become **A**uditing **O**rganizations
Auditors must be trained and qualify to audit **MDSAP**

- Internal processes – many new, updated
- Implementation, internal training
- Auditor Qualifications
- Training – MDSAP processes; Auditing Organization processes; regulations for 5 participating jurisdictions
- Witness Audits
- - Client contracts for audits - challenges
- Time
- Cost
- Customer service
- Quotes, scheduling

Roles:

- MDSAP: Auditing Organization function more like a Regulator
- Although no consultation allowed by auditors previously under CMDCAS, this is more strictly delineated in MDSAP

ISO 13485:2016
– Impact on CMDCAS Recognized Registrars

Registrars must qualify to audit and issue certificates to ISO 13485:2016

- Internal processes – new, updates for revised standard
- Implementation
- Auditor Qualifications
- Training
- Witness Audits
- Time
- Cost
- Customer service
- Quotes, scheduling

Status: CMDCAS Recognized Registrars

ISO 13485:2016

Registrars in process of qualifying to audit to revised standard
Check websites
Communicate with contacts on status, expected timelines

MDSAP

Qualification as AO not meeting expected timelines

- MDSAP Pilot – ending December 2016
- manufacturers slow to embrace, enroll

Current list of Auditing Organizations available to conduct MDSAP audits.
http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM429978.pdf

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MDSAP – Impact on manufacturers

Selling in Canada only (Class II – IV devices) – MDSAP mandatory

Selling in Canada PLUS any other MDSAP participating country (US, Brazil, Australia, Japan) –MDSAP mandatory

- Planning
- Knowledge – understand MDSAP audit process
- Quotation(s)
- Audit scheduling
- Potential shortage of qualified AO's, auditors
  - To meet Health Canada mandatory timeline Jan/2019
- Audit days = double or more; min. 5 days
- Audit cost = double or more for one jurisdiction
  - Additional cost for more jurisdictions
  - Audit time calculated based on tasks
  - EU/CE mark in addition
- Time
- Resources: personnel, cost
- Updates to QMS documentation
- Host/participate in audit
- Manage post audit interface

MDSAP - Impact on manufacturers

Not selling in Canada?

- MDSAP not mandatory
- Weigh pros/cons

Selling in US only?

- MDSAP not mandatory
- Never been FDA inspected (many 510(k) holders)?
- N/A to Pre-Approval/Post-Approval Inspections (PMA devices)
- Weigh pros/cons

Selling in EU?

- Not participating (observer status)
- Additional audit cost
- potential visit coordination if Auditing Organization (AO) is also Notified Body (NB) – best strategy
- Alternate: if NB not AO = separate audit
    - More time, expense

ISO 13485:2016 - Impact on manufacturers

Selling in Canada

- ISO 13485:2016 transition for Health Canada
- Must submit certificate by March 1, 2019
  - to maintain existing Medical Device Licences Class II-IV
  - with applications for new Medical Device Licences

Selling in US only

ISO 13485 certificate not mandatory

Selling in EU too?

- EN ISO 13485:2016 issued
- Not yet added to list of harmonized standards - current EN ISO 13485:2012
- Complication with coming EU MDR, IVDR to replace MDD, IVDD
- References in EN ISO 13485:2016 will no longer apply (FYI also impacts EN ISO 14971:2012)
- New version of ISO 13485 and ISO 14971 will be needed
- messy
- Transition when announced by EU, NB's

Status: Manufacturers

ISO 13485:2016

Our experience:

Manufacturers starting to plan for/make revisions to QMS documentation, processes to align

Health Canada considers ISO 13485:2003 to be subsumed in ISO 13485:2016 – no contradictory requirements

- Even if next cyclic audit scope is ISO 13485:2003, references within the documentation may be to ISO 13485:2016
- Agreed also with registrar(s)

Can manage this change without delay; then it is done

MDSAP

- Skepticism - value added to them - large increase in costs vs CMDCAS
  - Especially for manufacturers selling only in Canada, or Canada + EU (as even more costs apply)
  - for manufacturers selling only into US; currently not FDA mandated; cannot replace all FDA inspections; now no fees FDA inspections; concern where never FDA inspected (eg many companies with 510(k) cleared devices)
- Slow to enroll in MDSAP Pilot; hence insufficient auditees for AO qualification
- Doubt re: implementation – but now Health Canada notice of timeline -Jan 2019

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Planning for ISO 13485:2016, MDSAP

- Buy the Standard – ISO 13485:2016
  - No revision to ISO 14969 (obsolete)
  - Instead, expect *ISO 13485:2016 Essentials - A Practical Handbook for Implementation* to be published (CSA formerly published such handbooks)
- Download MDSAP documents – FDA website
- Inform/educate
- Create a Quality Plan
  - Project leader, team
  - Timelines
  - Goals/objectives
  - Registrar/Auditing Organization interface
    - same or different third party?
    - audit scheduling – IMPORTANT
    - recertifications typically 3 months before expiration; possible to add at surveillance
    - ***anticipate shortage of qualified auditors/dates – concurrent MDSAP/ISO 13485:2016 burden on registrars/auditors***

Planning for ISO 13485:2016, MDSAP

- Determine resource requirements – people, costs/budget
- Gap analysis – existing QMS vs new std
  - Plan for new or revised processes
  - make changes soon even if not transitioning to 2016 std at next cyclic audit
- Training plan
- Implementation plan
- Internal audit; management review
- Registrar/AO Audits
- Follow up

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ISO 13485:2016

REVISED VERSION O F ISO 13485

On March 1st, 2016, the International Organization for Standardization (ISO) published the revised version of ISO 13485 titled "ISO 13485 – Medical Devices – Quality management systems – Requirements for regulatory purposes". This revised version will supersede ISO 13485:2003. This revised standard is referred to as ISO 13485:2016.

TRANSITION PERIOD

ISO will withdraw ISO 13485:2003 on March 1st, 2019, three years after the publication of ISO 13485:2016.

Health Canada has set March 1st 2019, as the transition date to ISO 13485:2016. **All manufacturers of class II, III, and IV medical devices holding licences or applying for new or amended licences must complete the transition to ISO 13485:2016 by March 1st, 2019.**

MDSAP

In accordance with Health Canada's announced MDSAP transition plan, CMDCAS certificates will no longer be accepted after December 31st 2018. Manufacturers will be required to submit valid MDSAP certificates by no later than January 1st, 2019 in order to maintain their medical device licences.

Good to Know

Health Canada Licences not supported by a valid MDSAP certificate as of January 1, 2019, will be subject to suspension.

Medical device licence applications containing CMDCAS certificates will not be accepted after January 1, 2019 by Health Canada.

All manufacturers must transition from CMDCAS to MDSAP certificates to meet the quality management system requirements of the *Canadian Medical Devices Regulations*. For manufacturers who only sell in Canada, the regulatory requirements of the other MDSAP participants (United States, Brazil, Australia, and Japan) will not be audited.

Registrars will not do certification/recertification audits to ISO 13485:2003 after March 1, 2018.

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ISO 13485:2016 changes: resources for information

- Purchase standard
  - iso.org
  - ISO 13485:2016 **annex A** Comparison of content between ISO 13485:2003 and ISO 13485:2016 Table A.1 clause by clause, pointing to the new or changed requirements
  - Analyses on many websites, some selling tools, services
- Note ISO 14969 (guidance for ISO 13485:2003) is obsolete, not being reissued for ISO 13485:2016
  - Expect ISO 13485:2016 Essentials
- Webinars
  - Registrar/Notified Body sites eg
    - BSI http://www.bsigroup.com/en-US/medical-devices/Resources/Webinars/
    - Intertek http://www.intertek.com/knowledge-education/webinars/
  - FDA News Webinar – Dan O'Leary webinar: ISO 13485:2016 – Preparing for Implementation
    - Contains **Activity Comparison**
    - www.fdanews.com
  - Others
- Training courses – many offerings
- White papers
  - Registrars eg
    - BSI http://www.bsigroup.com/en-US/medical-devices/Resources/Whitepapers-and-articles/
- Consultants – Mapi SRS

MDSAP – resources for detailed information

Health Canada

http://www.hc-sc.gc.ca/dhp-mps/md-im/activit/int/mdsap-trans-notice-avis-eng.php

FDA MDSAP Pilot

http://www.fda.gov/MedicalDevices/InternationalPrograms/MDSAPPilot/default.htm

FDA MDSAP Documents:

http://www.fda.gov/MedicalDevices/InternationalPrograms/MDSAPPilot/ucm377578.htm

FDA CDRH Training

http://www.fda.gov/Training/CDRHLearn/default.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

note: under Post Market Activities, scroll down to Inspections - Global Harmonization

Other offerings – various white papers, webinars, consultants

Thoughts/conclusions?

- Many changes
- Significant to QMS, how regulatory compliance is assessed
- Impact – resource, budget
- January 1, 2019 seems distant
  - Significant changes to certification process
- March 1, 2019 seems distant (ISO 13485:2016)
  - Significant changes to requirements, documentation
- Combine the planning
  - Practical, seamless
- Few Auditing Organizations, auditors at present
  - Behind expected timeline
  - Not all CMDCAS registrars plan to participate
- Should catch up in the next 6-12 months
- Availability of audit dates – compressed timeline
- Audit scheduling could be impacted
- Plan now, secure quotes/dates

Thank you!

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