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MDSAP: WHAT DOES IT MEAN FOR MEDICAL DEVICE MANUFACTURERS?

BOSCON 2019

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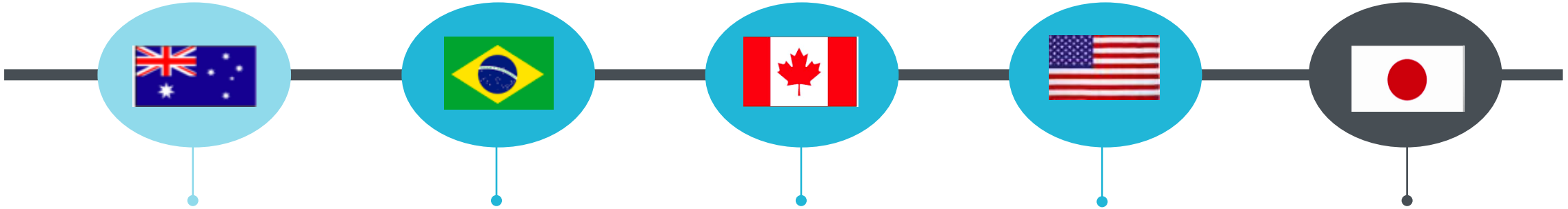
WHAT IS MDSAP?

- MDSAP is Medical Device Single Audit Program
- Program that allows a single regulatory audit of a QMS that satisfies the requirements of multiple regulatory jurisdictions
- Audits are conducted by Auditing Organizations (AOs) authorized by the participating Regulatory Authorities
- Program's main mission is to "…jointly leverage regulatory resources to manage an efficient, effective, and sustainable single audit program focused on the oversight of medical device manufacturers"

MDSAP AUDIT CRITERIA

ISO 13485 + Applicable Regulations



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

CMDR SOR-98-282 Part 1

Quality System Regulation 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 (Subparts A to D)

MHLW Ministerial Ordinance No. 169

Official observer: WHO

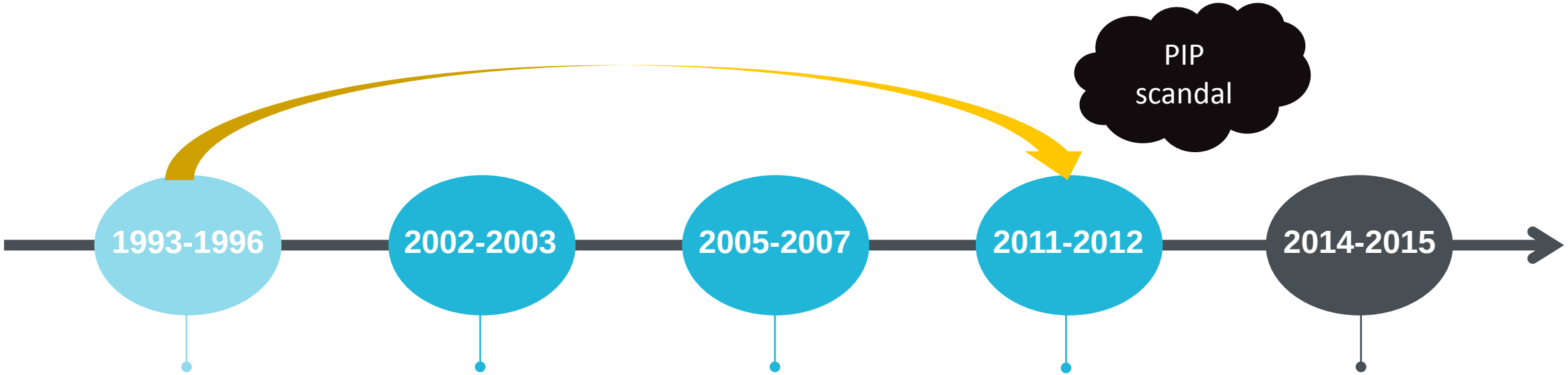
HOW DO PARTICIPATING REGULATORS USE MDSAP PROGRAM?

Jurisdiction	Use of MDSAP Reports/Certificates
Australia	Where regulations do not require a TGA Conformity Assessment Certificate (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.
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	MDSAP certificate is required to apply for a license for Class 2, 3 or 4 devices (CMDR, section 32(2)(f), (3)(j), 4(p), 34, and 43.1)
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.
United States	CDRH will accept MDSAP audit reports as a substitute for FDA routine inspections.

WHY WAS THE MDSAP PROGRAM DEVELOPED?

- Enable appropriate regulatory oversight of medical device manufacturers' quality management systems while minimizing regulatory burden on industry;
- Promote more efficient and flexible use of regulatory resources through work-sharing and mutual acceptance among regulators while respecting the sovereignty of each authority;
- Promote globally, in the longer term, a greater alignment of regulatory approaches and technical requirements based on international standards and best practices;
- Promote consistency, predictability and transparency of regulatory programs by standardizing;
  - the practices and procedures of participating regulators for the oversight of third party auditing organizations, and
  - the practices and procedures of participating third party auditing organizations; and
  - Leverage, where appropriate, existing requirements and procedures for conformity assessment.

BACKGROUND OF MDSAP PROGRAM



GHTF work by governments and industry reps of Australia, Canada, Japan, the European Union, and USA to encourage a convergence in standards and regulatory practices

ISO 13485 published in 1996

Health Canada launches mandatory **CMDCAS** Program

ISO 13485 + CMDR requirements

Recognized registrars

FDA launches voluntary **Accredited Persons (AP) Inspection Program**

21 CFR Part 820

JPAL revised Japanese legislation – MO169 based on ISO 13485

Australia TGA and US FDA start attending CMDCAS RB Forum meetings

HC-TGA QMS MOU

FDA launches **PMAP Program** single inspection for US and Canada

GHTF replaced by **IMDRF**

Members are: Australia, Brazil, Canada, China, Europe, Japan, Russia, Singapore, South Korea, and USA, Observer: WHO

FDA launches ISO 13485:2003 Voluntary Audit Report Submission Program

MDSAP Pilot phase starts 1st Jan 2014 with Australia, Brazil, Canada and USA as participating jurisdictions

Japan officially joined MDSAP Pilot in June 2015

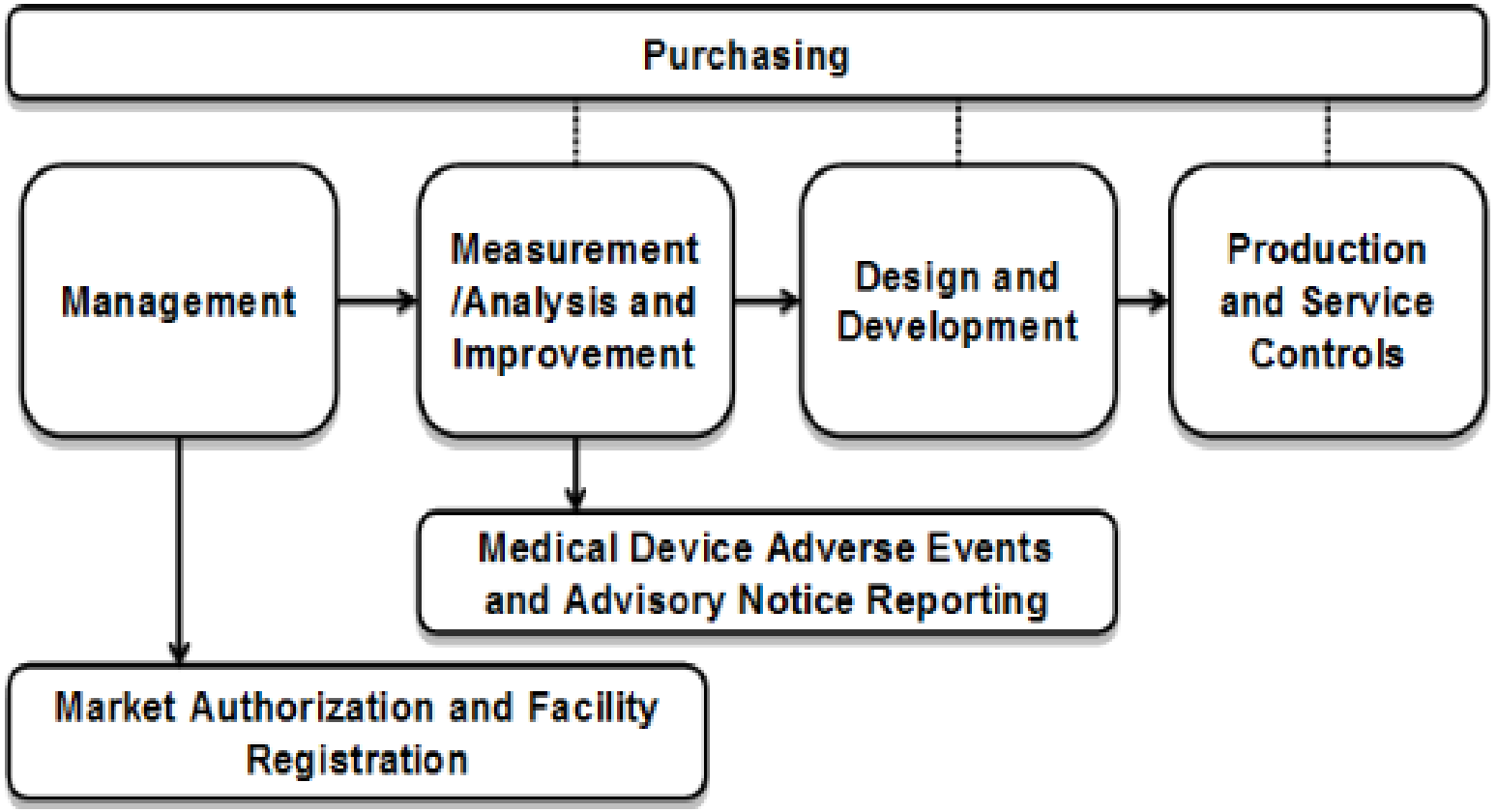
HC announces **CMDCAS to MDSAP transition**

MDSAP PROGRAM MAIN FEATURES AND DIFFERENCES WITH PREVIOUS REGULATORY PROGRAMS

- MDSAP Pilot addressed concerns/interests of the regulators:
  - Does not introduce any new requirement - you should already be meeting regulatory requirements, the main difference with previous 3rd party programs is how audits are performed
  - Notifications to Regulatory Authorities (RAs), e.g. that manufacturer has joined/left the program
  - Sequence designed to ensure appropriate coverage and scrutiny of all relevant requirements in a consistent and predictable manner – Audit Model (see next slide)
  - Audit duration not based on headcount – depends on scope and applicable jurisdictions
  - NC grading 1-5 based on rules in GHTF N19 and prescribed timeline for responses to findings
  - Audit report fillable pdf form imposed to Auditing Organizations
  - All audit reports made available to regulators, not only upon request
  - Unannounced audits
  - Direct oversight by regulators over Auditing Organizations

MDSAP AUDIT MODEL

- Prescriptive Process-Based Approach
- Risk focused
- Four primary processes and three supporting process defined
- Mandatory Sequence For Auditing Primary Processes
- Audit task sets prescribed for Each Process
- Emphasis on consideration of linkages between processes
- Prescribed sampling methodology



MDSAP FINDINGS: 2 STEP PROCESS

A two-step approach that leads to calculation of a final grade for each nonconformity

Step 1 - A Nonconformity Grading Matrix, which provides an initial grade

Step 2 - Additional escalation rules are applied, to determine a final grade

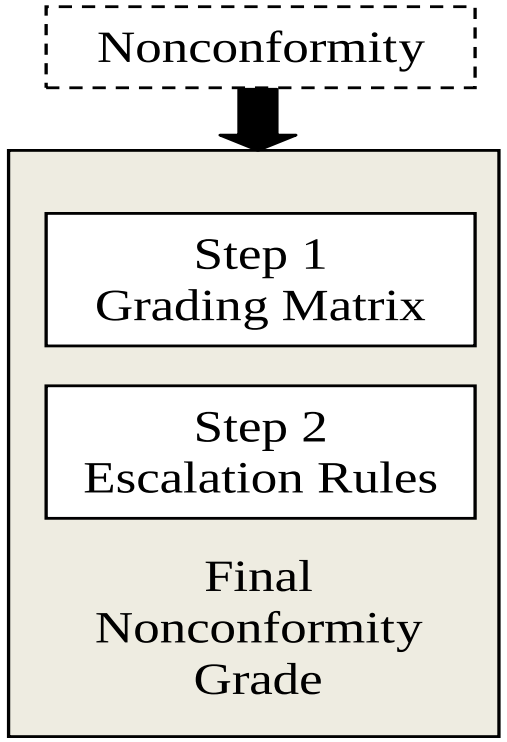


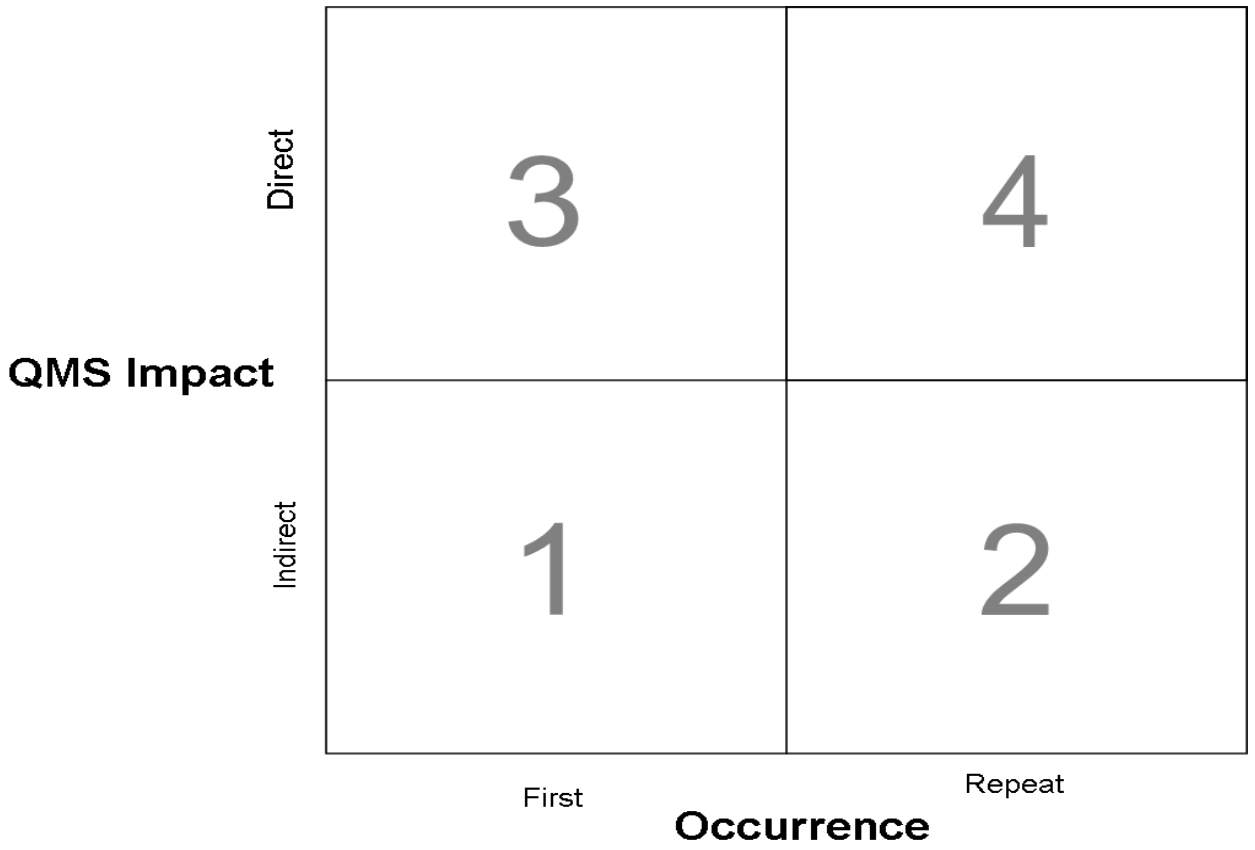
Figure 1: Grading Overview

STEP 1: GRADING MATRIX

Grade the non-conformances based on

(1) Direct vs. indirect impact on potential to affect safety or performance &

(2) First vs. repeat occurrences of the finding



STEP 2: ESCALATION

Step 1 grade is increased by 1 for each rule:

- **Rule 1: Absence of a documented process or procedure**

  The absence of a documented process or procedure will fundamentally affect consistency and effective implementation of any process.

- **Rule 2: Release of a Nonconforming Medical Device**

  A nonconformity which resulted in the release of a nonconforming medical device to the market is direct evidence of a QMS failure. This rule in the grading system is assessing the QMS non-conformity at a higher risk, because nonconforming product is on the market and outside the control of the manufacturer's QMS.

  Note: Does not apply to controlled concessions.

UNANNOUNCED AUDITS

Auditing Organizations shall carry out unannounced audits if previous audits indicate serious and/or frequent nonconformities.

An unannounced audit shall occur following any audit that results in:

- 1 ≤ # of NCs graded as 5

or,

- 2 < # of NCs graded as a 4

MDSAP PROGRAM RECENT AND FUTURE

End of MDSAP Pilot phase - 31st Dec 2016

Final Pilot Report: 29 June 2017

"Proof-of-concept"

Mitigation measures to address stakeholder concerns and challenges

- CMDCAS to MDSAP transition rules adjusted
- Audit duration reductions

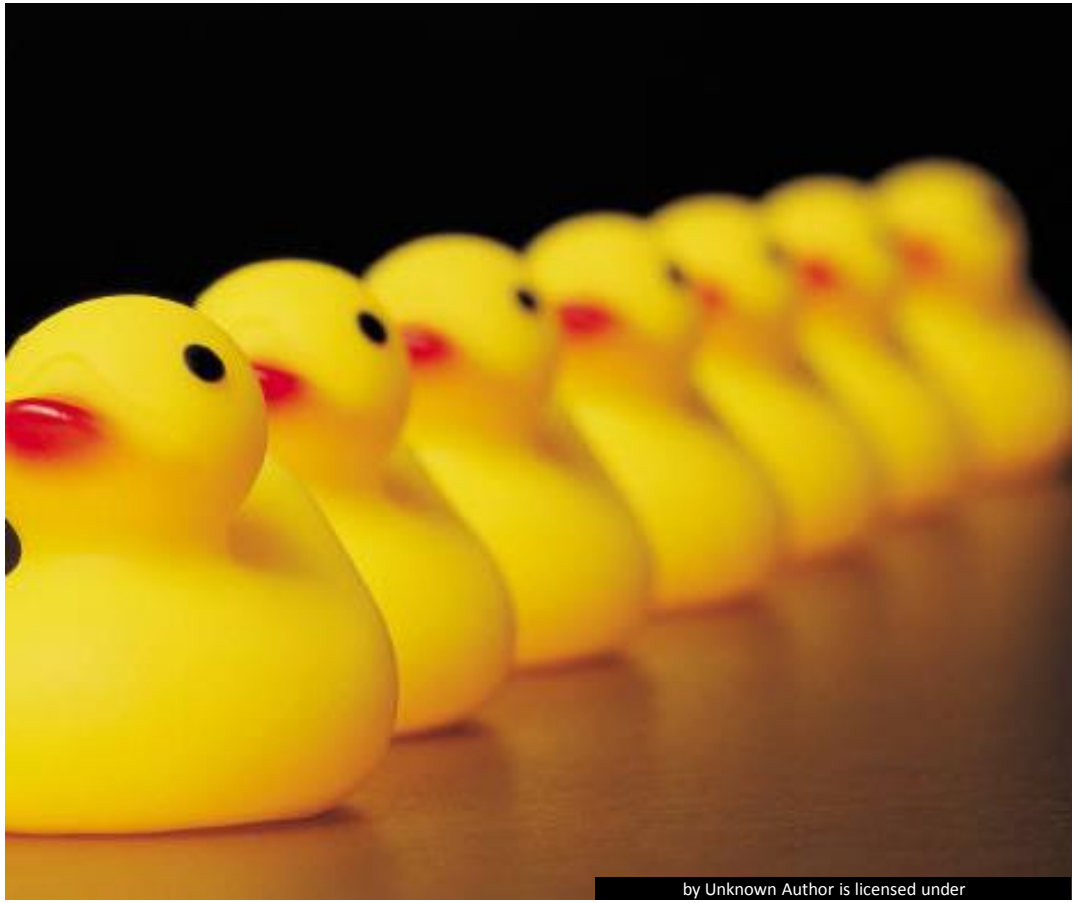
- End of CMDCAS to MDSAP transition period - 31st Dec 2018
- Expectations for Class 1 devices clarified
- Regulatory Exchange Platform (REPs) IT portal goes live

- Audit Model under revision
- Procedure for grading of NCs expected to be revised
- Several topics under discussion

Use of MDSAP Program by other regulators?

PREPARING FOR MDSAP AUDIT

- Be prepared to expertly demonstrate that you have satisfied all regulatory requirements applicable to your devices, including:
  - Regulatory roles per jurisdiction
  - Device classification
  - Market clearance
  - Change notification
  - Reporting device adverse event and field corrective action/recalls



PREPARING FOR MDSAP AUDIT

- Understand the scope and context for the upcoming MDSAP audit
- Perform a gap analysis & create an action plan
- Train personnel on MDSAP audit model, regulatory requirements, and/or new/revised processes
- Perform an internal audit against all relevant regulatory requirements
- Conduct a management review

RESOURCES

- IMDRF Home Page: http://www.imdrf.org
- MDSAP Home Page: https://www.fda.gov/MedicalDevices/InternationalPrograms/MDSAPPilot/
- Q&A Document on MDSAP Program: https://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM430563.pdf
- Audit Model: https://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM390382.pdf
- Companion Document: https://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM390383.pdf
- GHTF N19 NC Grading System: https://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM468937.pdf

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