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Medical Device Single Audit Program (MDSAP): One Audit, Multiple Market Access

Presented by Richard DeRisio

December 8, 2015

TÜV SÜD in numbers: Growing from strength to strength

1	One-stop technical solution provider
150	years of experience
800	locations worldwide
2,060	million Euro in sales revenue 2014
22,000	employees worldwide

Note: Figures have been rounded off.

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  - Management Service
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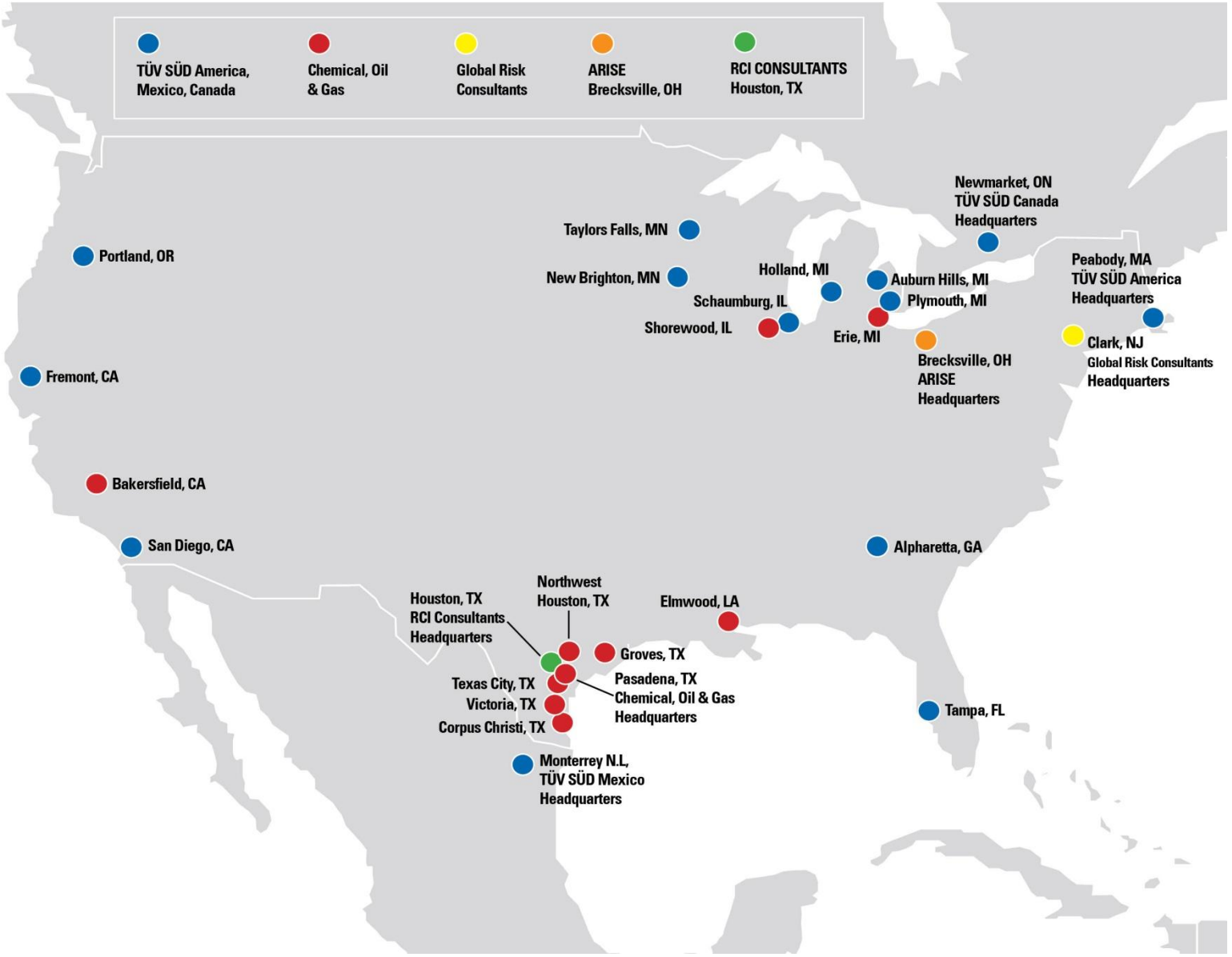
  - Global Risk Consultants (GRC)
  - RCI Consultants

TÜV SÜD America locations



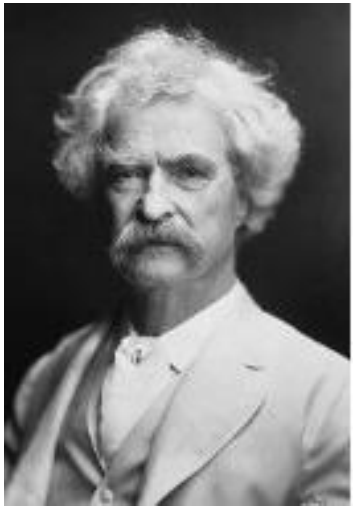
The Challenge of Brevity – Part 1

Mark Twain, like most writers, found it easier to write long than short. He received this telegram from a publisher:

NEED 2-PAGE SHORT STORY TWO DAYS.

Twain replied:

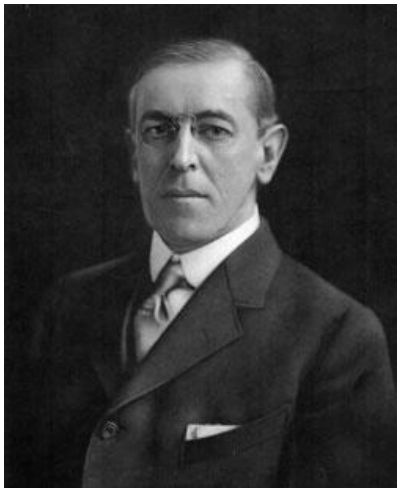
NO CAN DO 2 PAGES TWO DAYS. CAN DO 30 PAGES 2 DAYS. NEED 30 DAYS TO DO 2 PAGES.



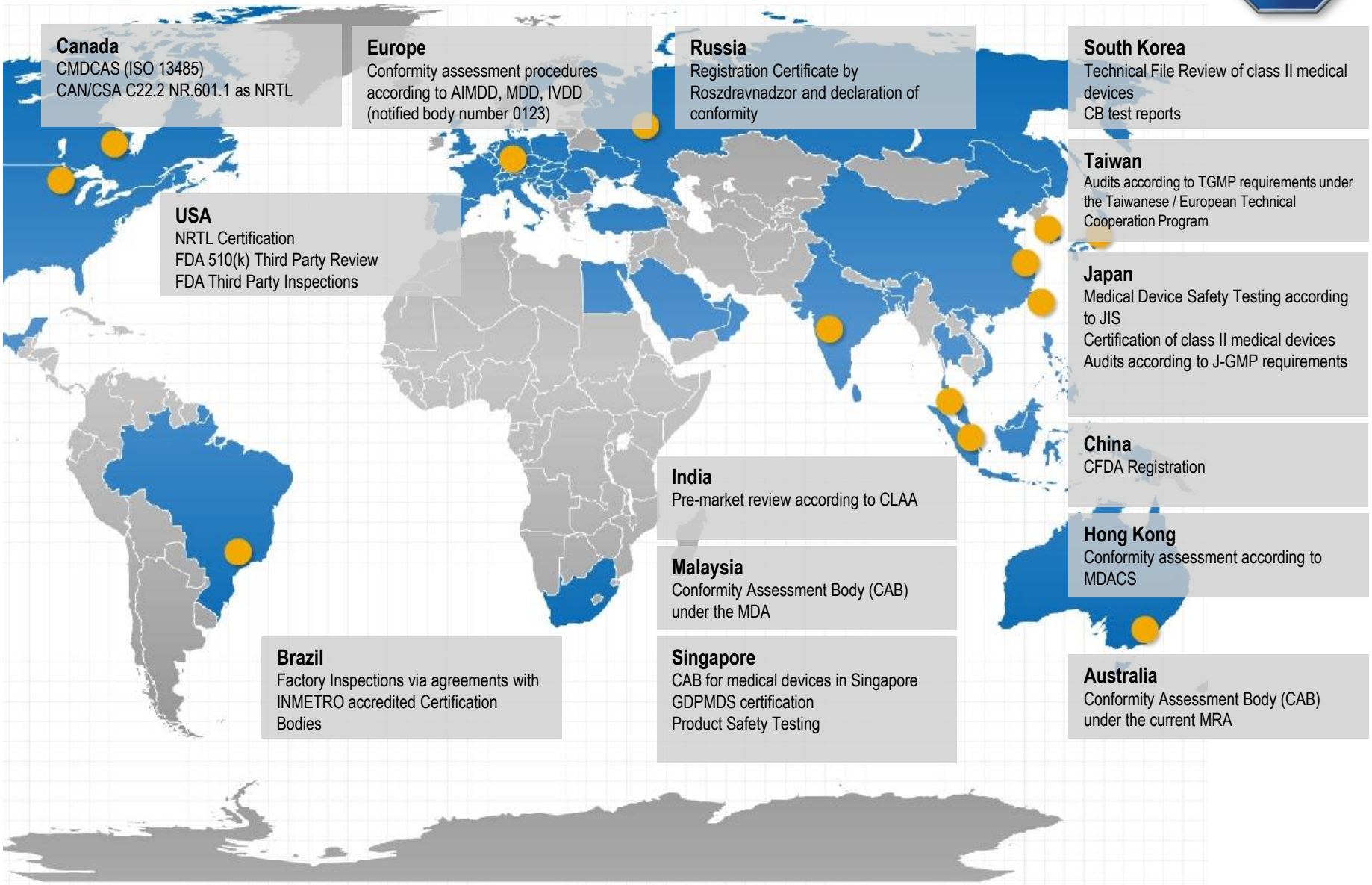
The Challenge of Brevity – Part 2

According to an anecdote published in 1918, Woodrow Wilson was asked about the amount of time he spent preparing speeches, and his response was illuminating:

"That depends on the length of the speech," answered the President. "If it is a ten-minute speech it takes me all of two weeks to prepare it; if it is a half-hour speech it takes me a week; if I can talk as long as I want to, it requires no preparation at all. I am ready now."



Market approval and certification – 400 Medical Experts In-house



Canada
CMDCAS (ISO 13485)
CAN/CSA C22.2 NR.601.1 as NRTL

Europe
Conformity assessment procedures according to AIMDD, MDD, IVDD (notified body number 0123)

Russia
Registration Certificate by Roszdravnadzor and declaration of conformity

South Korea
Technical File Review of class II medical devices
CB test reports

Taiwan
Audits according to TGMP requirements under the Taiwanese / European Technical Cooperation Program

USA
NRTL Certification
FDA 510(k) Third Party Review
FDA Third Party Inspections

Japan
Medical Device Safety Testing according to JIS
Certification of class II medical devices
Audits according to J-GMP requirements

China
CFDA Registration

India
Pre-market review according to CLAA

Hong Kong
Conformity assessment according to MDACS

Malaysia
Conformity Assessment Body (CAB) under the MDA

Brazil
Factory Inspections via agreements with INMETRO accredited Certification Bodies

Singapore
CAB for medical devices in Singapore
GDPMDS certification
Product Safety Testing

Australia
Conformity Assessment Body (CAB) under the current MRA

Market approval and certification

Our market approval services

- TÜV SÜD's foreign affairs department continuously scans the international regulatory environment and can keep you up to date with the latest regulatory changes concerning medical devices.
- Providing International Compliance Management (ICM) services, the foreign affairs team can provide step-by-step guidance on how to enter the maximum amount of global markets with your existing TÜV SÜD certification.

Overview

1. Overview of the MDSAP Program
2. MDSAP Objectives and Goals
3. The Mechanics of MDSAP Audits
4. Training and Qualifications of MDSAP Auditors
5. Advantages of Participating in the MDSAP Pilot Program

Medical Device Single Audit Program (MDSAP)

IMDRF International Medical Device Regulators Forum

One Single audit of a medical device manufacturer conducted by an MDSAP recognized Auditing Organization (certification body) to satisfy the needs of multiple regulatory jurisdictions.

Current participating regulators:

- Australia (TGA)
- Brazil (ANVISA)
- Canada (HC)
- Japan (MHLW/PMDA)
- U.S. (FDA)

Pilot phase has been started and will be finalized by the end of 2016. Audit reports issued during the pilot phase are recognized by the participating regulators.

✓ TÜV SÜD is authorized to perform MDSAP audits during this pilot phase

MDSAP Pilot Program and Transition

- Six Notified Bodies are in the Pilot Program, Office audits and witnessed audits are required (conducted by regulators):
  - TÜV SÜD
  - BSI
  - LNE G-Med
  - SAI Global Cert. Services
  - TÜV NORD
  - TÜV USA Inc.
- Pilot Program countries are USA, Canada, Brazil, Australia and now Japan.
- The European Commission is an Observer.
- Pilot will finish at the end of 2016; MDSAP will be fully operational in 2017.
- Once fully implemented, MDSAP will replace CMDCAS in Canada: MDSAP will be the only route to Health Canada approval effective January 1, 2019.

Late-Breaking News Regarding Japan's Participation in MDSAP

- Announcement on June 23, 2015 by the MHLW and PMDA that Japan is joining MDSAP:
  - Japan had been and active observer including participating on MDSAP office audits of Auditing Organizations participating in the MDSAP Pilot Program.
- A Transition Plan Has Been Announced:
  - The Audit Module and companion documents have been updated.
  - There are three new training modules for the particular Japanese regulatory requirements.
  - All MDSAP auditors will be trained quickly as MDSAP certificates that include Japan cannot be issued until the auditors and the Certification Body reviewers and Technical Certifiers are trained.
- Once the auditing organizations perform the audits, MHLW and PMDA will utilize these audit reports in both premarket and periodic postmarket audits in accordance with the regulations in Japan.

Late-Breaking News Regarding Japan's Participation in MDSAP Continued

- There is a three-month transition period beginning 1 November 2015 and ending on 1 February 2016.
  - We can perform MDSAP audits without including the Japan module until the end of the transition period.
  - After 1 February 2016, all MDSAP audits must include Japan, as applicable.
- If the AO has auditors trained on the Japan regulatory requirements, it is optional to include Japan during the transition period.
- The AO's Certification Body will need to notify the PMDA whenever an MDSAP audit is planned that includes Japan requirements.

Participating Regulator's Acceptance of MDSAP

USA

- The FDA will accept the MDSAP Pilot audit reports as a substitute for FDA routine inspections (biannual by policy). The FDA will not accept MDSAP for initial visits or "for cause" inspections.
- MDSAP is acceptable for first-time inspections for 510(k) products or sites that have a PMA and the new site does not require a pre-approval inspection.
- An organization must sign a contract for MDSAP before an FDA routine inspection is announced, otherwise the inspection will still occur. TÜV SÜD's U.S. Certification Body will send the regulators a form announcing the audit.

Regulator Acceptance of MDSAP

Canada

- Health Canada will use MDSAP in the same manner as CMDCAS
- 2015-12-04: **Notice: Transition Plan for the Medical Device Single Audit Program (MDSAP):**
  - "Health Canada intends to implement MDSAP as the sole mechanism for manufacturers to demonstrate compliance with the quality management system requirements of the *Medical Devices Regulations* (the Regulations). MDSAP will replace the current Canadian Medical Devices Conformity Assessment System (CMDCAS) program, even in situations when a manufacturer intends to sell only in Canada."
  - "This implementation will begin at the conclusion of the Pilot on January 1, 2017, and will span a period of two years. During this two year period, Health Canada will accept certificates issued under both CMDCAS and MDSAP. **As of January 1, 2019, only MDSAP certificates will be accepted"**

Participating Regulator's Acceptance of MDSAP

Brazil

- ANVISA plans to use MDSAP Pilot audits in lieu of a premarket inspection by ANVISA to grant ANVISA's GMP Certificate to manufacturers intending to put Class III or IV medical devices on the Brazilian market.
- Undergoing an MDSAP Pilot audit may accelerate ANVISA´s GMP certification process. There is a three-year or greater backlog for ANVISA to conduct its own audits.

Australia

- The TGA will take into account MDSAP Pilot audit reports when considering:
  - whether a manufacturer has demonstrated compliance with an Australian Conformity Assessment procedure.
  - whether to issue or maintain a TGA Conformity Assessment Certificate in relation to manufacturers of kinds of products prescribed in regulation1.
- Under some circumstances a manufacturer may avoid routine TGA inspections
- The TGA will accept MDSAP certificates as evidence of compliance with ISO13485:2003 where the Standard has been used to demonstrate partial compliance with the requirements of an Australian Conformity Assessment Procedure.

Japan

- MHLW and PMDA will utilize MDSAP audit reports in both premarket and periodic postmarket audits under the regulations in Japan.
- PMDA will accept an MDSAP audit report, in which the applicable regulations cover Japanese regulations, in order to avoid an on-site J-QMS audit. This is applicable to Manufacturing sites when they conduct:
  - Design,
  - Main Assembly,
  - Sterilization and/or
  - Domestic storage before final release of a medical device.

Will the European Union Ever Participate in MDSAP?

- The hope is that Europe will adopt IMDRF documents for use in their regulatory system.
- The consensus has been that the European Commission was only observing because the EU was in transition between the directives and the new medical device and IVD regulations.
- But now there is the realization that it will be very difficult to obtain agreement among all Member States.
- It is unlikely that Europe will ever be a full participant in MDSAP because of the difficulty in getting confidentially agreements with an additional 28 countries.

Will the European Union Ever Participate in MDSAP?

BUT THERE APPEAR TO BE MITIGATING FACTORS:

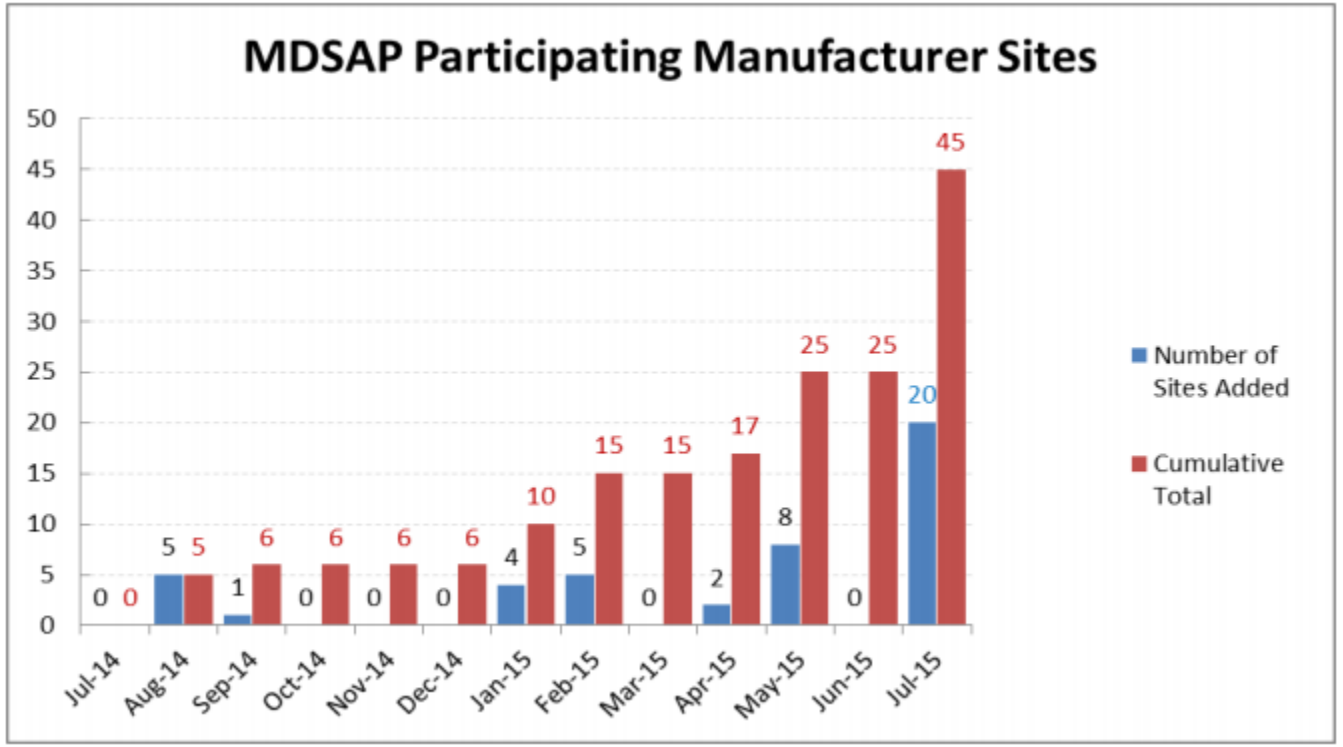
- The European Notified Bodies' participation in MDSAP is a strong link between the EU reliance upon EN ISO 13485 and MDSAP.
- Once the regulations are implemented, it will likely be apparent that if the EU member states can adopt one pan-European regulation, a global harmonized approach to Quality System compliance is reasonable.
- The European Commission's increased scrutiny regarding safety and effectiveness of devices sold in Europe is moving the Member States to a higher degree of consistency regarding regulatory rigor.
- This should make acceptance of a harmonized approach to Quality System compliance easier among the Member States.

Summary of Recent FDA Status Update Report

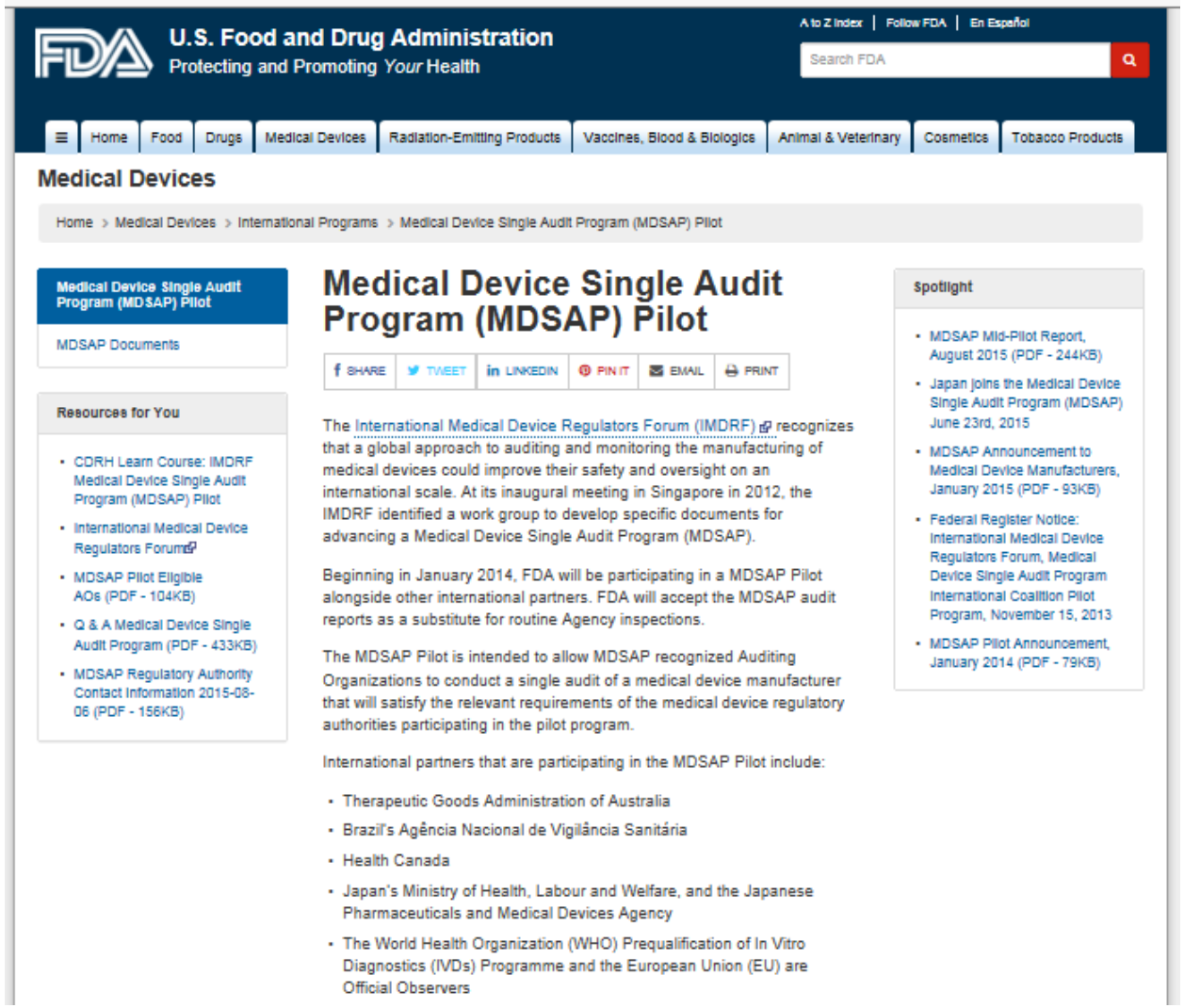
- In August 2015, FDA Published the “MDSAP Mid-Pilot Report”
- Contents include:
  - Status of Objectives
  - Status of Authorization of Auditing Organizations
  - Factors Used to Evaluate the Proof of Concept and Current Status of Each of the Criteria
  - Level of Participation by Medical Device Manufacturers

Summary of Recent FDA Status Update Report

As of 23 July 2015, forty-five (45) medical device manufacturing sites have requested participation in the MDSAP program.



MDSAP Documents – Guidance on FDA's Website



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Medical Devices

Home > Medical Devices > International Programs > Medical Device Single Audit Program (MDSAP) Pilot

Medical Device Single Audit Program (MDSAP) Pilot

MDSAP Documents

Resources for You

- CDRH Learn Course: IMDRF Medical Device Single Audit Program (MDSAP) Pilot
- International Medical Device Regulators Forum
- MDSAP Pilot Eligible AOs (PDF - 104KB)
- Q & A Medical Device Single Audit Program (PDF - 433KB)
- MDSAP Regulatory Authority Contact Information 2015-08-06 (PDF - 156KB)

Medical Device Single Audit Program (MDSAP) Pilot

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The International Medical Device Regulators Forum (IMDRF) recognizes that a global approach to auditing and monitoring the manufacturing of medical devices could improve their safety and oversight on an international scale. At its inaugural meeting in Singapore in 2012, the IMDRF identified a work group to develop specific documents for advancing a Medical Device Single Audit Program (MDSAP).

Beginning in January 2014, FDA will be participating in a MDSAP Pilot alongside other international partners. FDA will accept the MDSAP audit reports as a substitute for routine Agency inspections.

The MDSAP Pilot is intended to allow MDSAP recognized Auditing Organizations to conduct a single audit of a medical device manufacturer that will satisfy the relevant requirements of the medical device regulatory authorities participating in the pilot program.

International partners that are participating in the MDSAP Pilot include:

- Therapeutic Goods Administration of Australia
- Brazil's Agência Nacional de Vigilância Sanitária
- Health Canada
- Japan's Ministry of Health, Labour and Welfare, and the Japanese Pharmaceuticals and Medical Devices Agency
- The World Health Organization (WHO) Prequalification of In Vitro Diagnostics (IVDs) Programme and the European Union (EU) are Official Observers

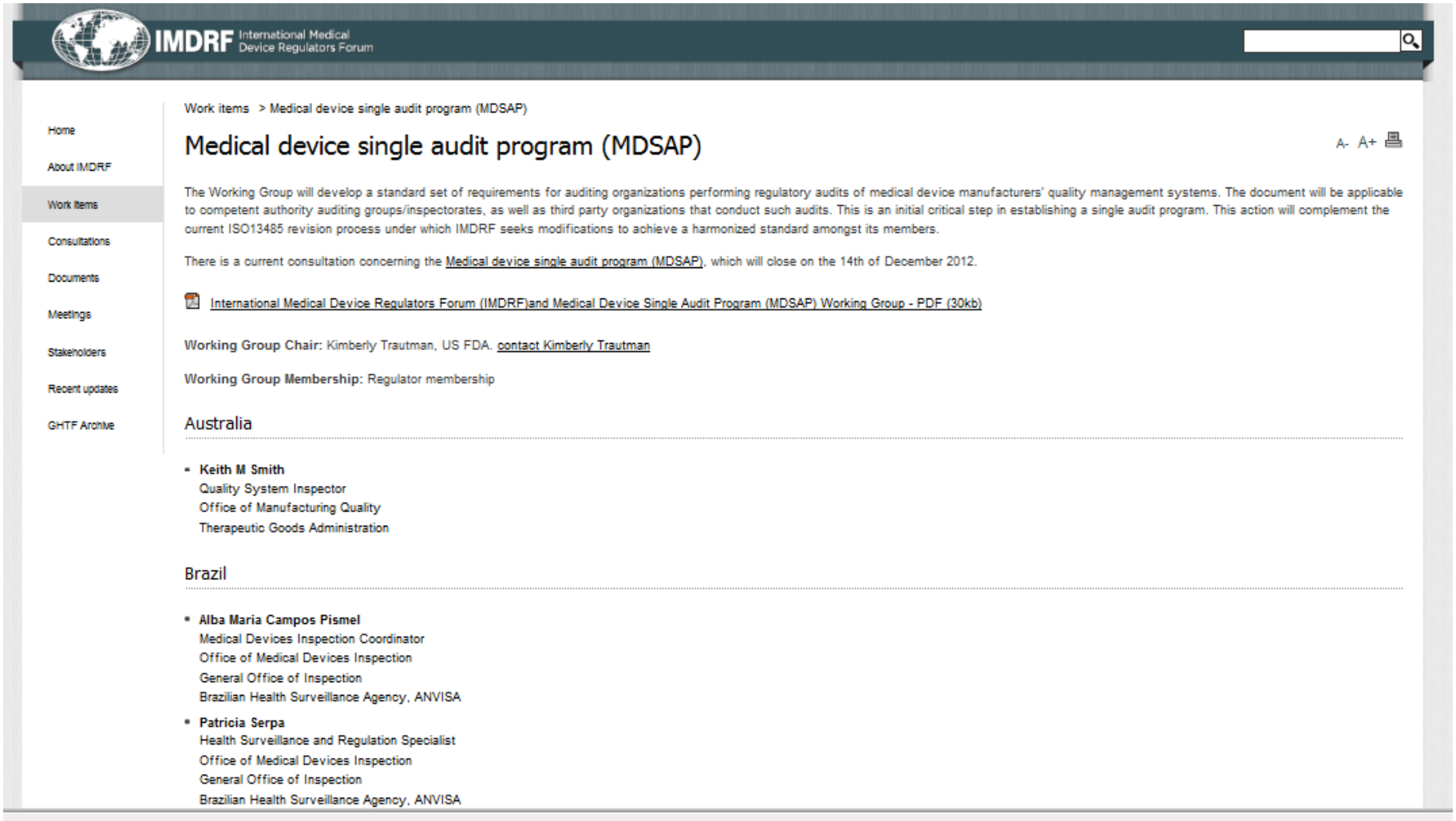
Spotlight

- MDSAP Mid-Pilot Report, August 2015 (PDF - 244KB)
- Japan joins the Medical Device Single Audit Program (MDSAP) June 23rd, 2015
- MDSAP Announcement to Medical Device Manufacturers, January 2015 (PDF - 93KB)
- Federal Register Notice: International Medical Device Regulators Forum, Medical Device Single Audit Program International Coalition Pilot Program, November 15, 2013
- MDSAP Pilot Announcement, January 2014 (PDF - 79KB)

http://www.fda.gov/medicaldevices/internationalprograms/mdsappilot/default.htm

MDSAP Resources on the IMDRF Website

http://www.imdrf.org/workitems/wi-mdsap.asp



IMDRF International Medical Device Regulators Forum

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Work items > Medical device single audit program (MDSAP)

Medical device single audit program (MDSAP)

A- A+

The Working Group will develop a standard set of requirements for auditing organizations performing regulatory audits of medical device manufacturers' quality management systems. The document will be applicable to competent authority auditing groups/inspectorates, as well as third party organizations that conduct such audits. This is an initial critical step in establishing a single audit program. This action will complement the current ISO13485 revision process under which IMDRF seeks modifications to achieve a harmonized standard amongst its members.

There is a current consultation concerning the Medical device single audit program (MDSAP), which will close on the 14th of December 2012.

International Medical Device Regulators Forum (IMDRF)and Medical Device Single Audit Program (MDSAP) Working Group - PDF (30kb)

Working Group Chair: Kimberly Trautman, US FDA. contact Kimberly Trautman

Working Group Membership: Regulator membership

Australia

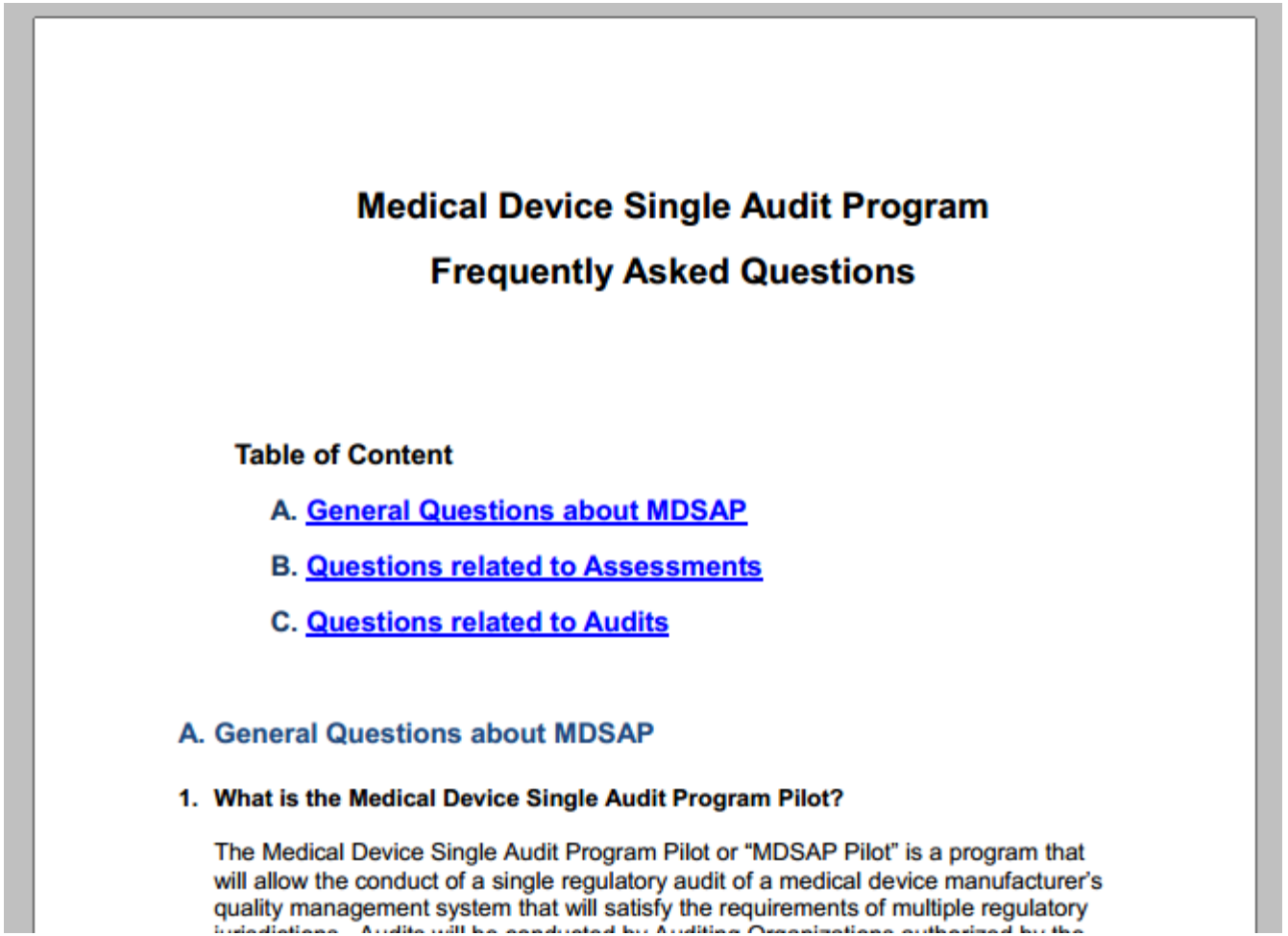
- **Keith M Smith**
  Quality System Inspector
  Office of Manufacturing Quality
  Therapeutic Goods Administration

Brazil

- **Alba Maria Campos Pismel**
  Medical Devices Inspection Coordinator
  Office of Medical Devices Inspection
  General Office of Inspection
  Brazilian Health Surveillance Agency, ANVISA
- **Patricia Serpa**
  Health Surveillance and Regulation Specialist
  Office of Medical Devices Inspection
  General Office of Inspection
  Brazilian Health Surveillance Agency, ANVISA

MDSAP Resources – FAQs

http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM430563.pdf



Medical Device Single Audit Program

Frequently Asked Questions

Table of Content

A. General Questions about MDSAP

1. What is the Medical Device Single Audit Program Pilot?

The Medical Device Single Audit Program Pilot or "MDSAP Pilot" is a program that will allow the conduct of a single regulatory audit of a medical device manufacturer's quality management system that will satisfy the requirements of multiple regulatory

Overview

1 Overview of the MDSAP Program

2 MDSAP Objectives and Goals

3 The Mechanics of MDSAP Audits

4 Training and Qualifications of MDSAP Auditors

5 Advantages of Participating in the MDSAP Pilot Program

MDSAP Objective

- *"The **overall objective** of the Medical Device Single Audit Program is to develop, manage, and oversee a single audit program that will **allow a single regulatory audit of a medical device manufacturer** conducted by an MDSAP recognized Auditing Organization* (certification body) ***to satisfy the needs of multiple regulatory jurisdictions**."*
- MDSAP will not require changes to country-specific regulations
- The audit is based on ISO 13485 plus regulatory-specific requirements of participating countries.

MDSAP Goals and Key Strategies

- A **single audit** program to satisfy the regulatory requirements of multiple participants
- **Appropriate, effective, efficient, and less burdensome regulatory oversight** of the quality management systems of medical device manufacturers
- **More efficient and flexible use of regulatory resources** through work-sharing and mutual acceptance among regulators while respecting the sovereignty of each authority.
- **Greater global alignment of regulatory approaches** and technical requirements based on consensus standards and best practices
- **Promote consistency, predictability, and transparency** of regulatory programs by standardizing work practices and oversight of third-party AOs.
- **Leverage**, where appropriate, existing conformity assessment structures

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Medical Device Single Audit Program (MDSAP)

- The Work Group developed a standard set of requirements for Auditing Organizations (certification bodies) performing regulatory audits of medical device manufacturers' quality management systems.
- The documents will be applicable to competent authority auditing groups/inspectorates, as well as third-party organizations that conduct such audits. This is an initial critical step in establishing a single audit program.
- **MDSAP will not require changes to country-specific regulations**

Audit Man-Day Calculations

- Audit time is based on “tasks” and not employee count
- There will be additive and subtractive adjustments
  - Adjustments specific to Design and Development (when applicable)
  - Adjustments specific to Production & Service Controls (when applicable)
  - Adjustments specific to assessment of previously cited nonconformities
  - Multiple Site Audits
  - Other adjustments based on ISO/IEC 17021
- Data will be collected during the pilot program. There could be a new man-day system in place at the end of the pilot program.

MDSAP Processes and Audit Sequence

Process approach with four primary processes:

1. Management;
2. Measurement, Analysis and Improvement;
3. Design and Development;
4. Production and Service Controls;

And a supporting process

- Purchasing

The MDSAP audit process has two additional supporting processes:

- Device Marketing Authorization and Facility Registration
- Medical Device Adverse Events and Advisory Notices Reporting.

At what frequency do MDSAP audits occur?

- MDSAP audits are conducted annually, according to a three-year certification cycle.
- The Initial Audit, also referred to as the “Initial Certification Audit” is a complete audit of a medical device manufacturer’s quality management system (QMS).
- The Initial Audit is followed by partial Surveillance Audits conducted once per year for two consecutive years.
- The cycle re-commences with a complete re-audit, also referred to as a “Recertification Audit” in the third year.
- Special Audits, Audits Conducted by Regulatory Authorities, and Unannounced Audits are potential extraordinary audits that may occur at any time within the audit cycle.

MDSAP Unannounced and Other Special Audits

- Regulatory Authorities themselves can perform special audits, including unannounced audits, anytime it deems necessary and within the purview of its jurisdiction
- Auditing Organizations shall carry out unannounced audits if previous audits indicate serious and/or frequent nonconformities.
- The timing of the unannounced audits should be unpredictable and in addition to the normally scheduled audits.

Working Groups Established a Foundation for MDSAP

- WG N3 – “Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition”
- WG N4 – “Competence and Training Requirements for Auditing Organizations,”
- WG N5 – “Regulatory Authority Assessment Method for the Recognition”
- WG N6 - “Regulatory Authority Assessor Competence and Training”

Implementation

Regulator 1

Regulator 2

Regulator 3

Regulation 1

Regulation 2

Regulation 3

Appointing Assessor

WG N6

Assessment Method

WG N5

Medical Device Auditing Organization

Assessor

WG N3

WG N4

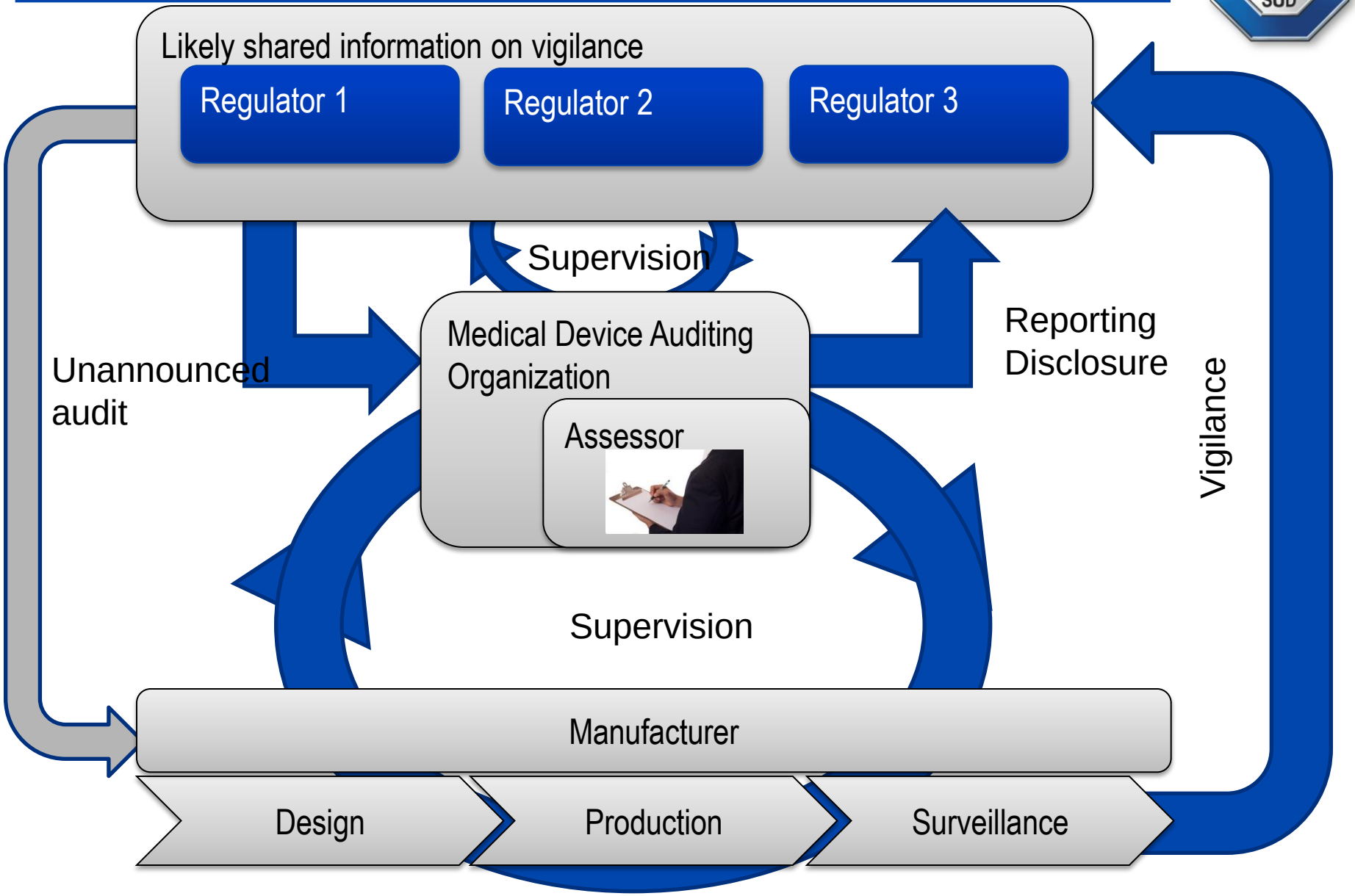
Manufacturer

Design

Production

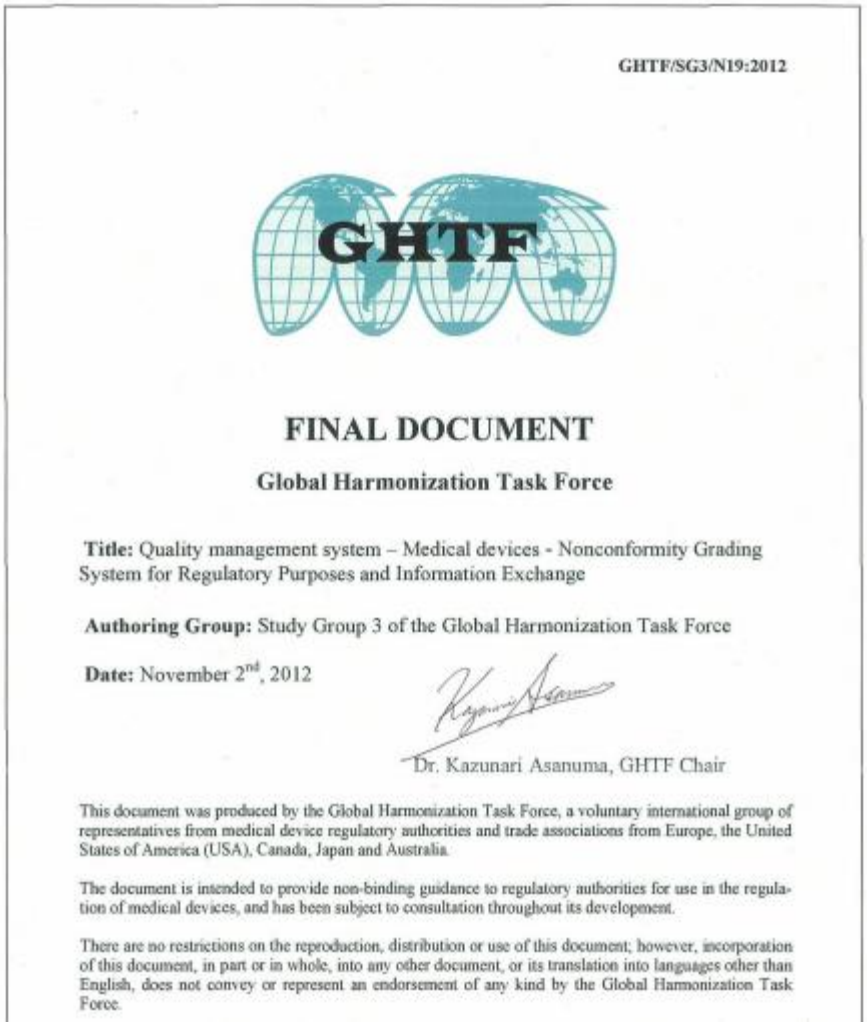
Surveillance

Implementation of MDSAP



GHTF/SG3/N19:2012

http://www.imdrf.org/docs/ghtf/final/sg3/technical-docs/ghtf-sg3-n19-2012-nonconformity-grading-121102.pdf



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

Dr. Kazunari Asanuma, GHTF Chair

This document was produced by the Global Harmonization Task Force, a voluntary international group of representatives from medical device regulatory authorities and trade associations from Europe, the United States of America (USA), Canada, Japan and Australia.

The document is intended to provide non-binding guidance to regulatory authorities for use in the regulation of medical devices, and has been subject to consultation throughout its development.

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MDSAP use of GHTF document SG3/N19

- Nonconformity grading system for regulatory purposes and information exchange
- Introduces a standardized nonconformity grading system for regulatory purposes that will enable exchange of information among regulatory authorities.
- Currently, the significance of a nonconformity may vary between regulatory authorities and Auditing Organizations.
- Current grading of nonconformities as major or minor does not provide enough detail for global information exchange.

Nonconformity Grading – Based on GHTF document SG3/N19

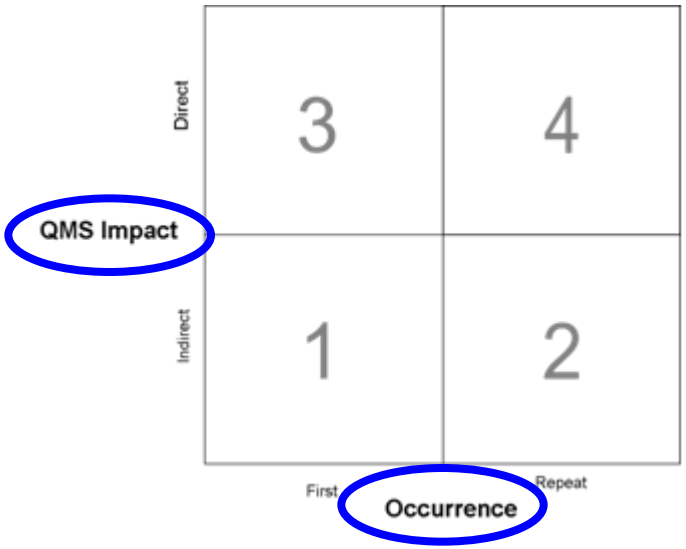
Indirect QMS Impact:

- ISO 13485:2003 clauses 4.1 through 6.3, are seen as **"enablers" (making it possible or feasible) for the QMS processes to operate**. These clauses are therefore considered to have indirect influence on medical device safety and performance.

Direct QMS impact:

- ISO 13485:2003 clauses 6.4 through 8.5, are seen as having direct influence on design, and manufacturing controls. These clauses are therefore **considered to have direct influence on medical device safety and performance**.

Grading a Nonconformity – Using GHTF document SG3/N19



Absence of documented process or procedure (add 1)

Release of Nonconforming Medical Device (add 1)

Nonconformity

Step 1
Grading Matrix

Step 2
Escalation Rules

Final
Nonconformity
Grade

Audit Report +
Regulatory Exchange form

MDSAP Operational Differences Compared to FDA and EU Audits

Nonconformity

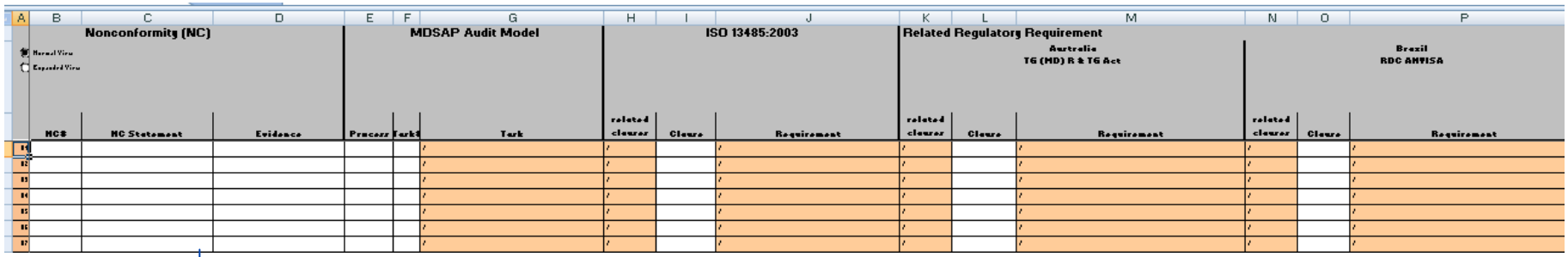
MDSAP Audit Model

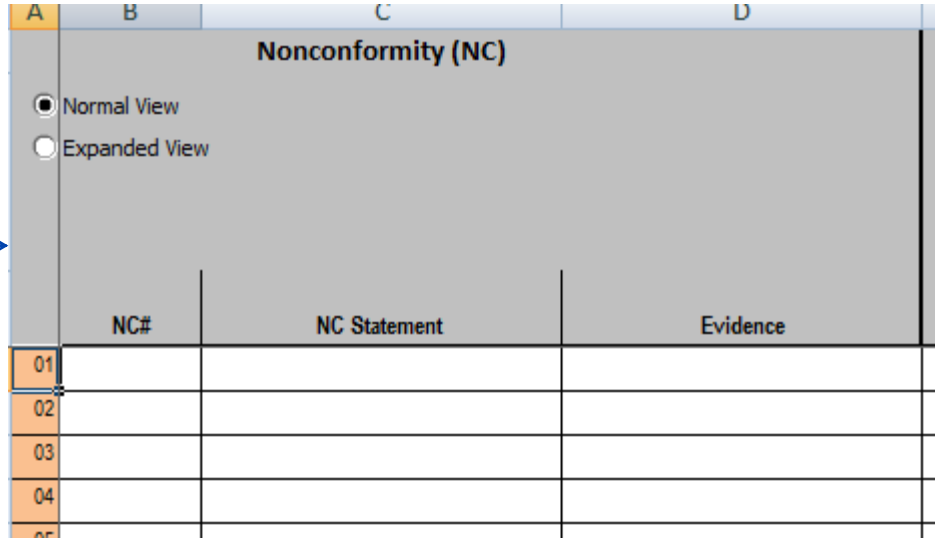
ISO 13485: 2003

Australia

Brazil

And More





Example of a Regulatory Audit Information Exchange Form

List of Nonconformities		Nonconformity Grading					Medical Device Country Specific Regulatory Requirements					
NC#	Nonconformity	ISO 13485 :2003 Clause	Step 1 Grade	Absence	Medical Device	Grade	EU	CAN	USA	AUS	JPN	OTHER
1	There is an absence of a Quality Policy in the organization.	5.3	1	+1		2						
2	Documented procedures for identifying training needs are not established.								21 CFR 820.25		Ord 169 (Article 23 subpart 2)	
3	The injection molding process has not been validated, as per procedure DOC12345 but has not resulted in nonconforming product being released to the market.	7.5.2	3			3	MDD (93/42/ EEC) (Annex II)					

Operational Requirements for Manufacturers and AO After the Audit

- The manufacturer must provide a remediation plan for each nonconformity within 15 calendar days from the date the nonconformity report was issued. The plan must include:
  - the outcome of the investigation of the nonconformity and its cause(s),
  - the planned correction(s), and
  - the planned corrective action(s) to prevent recurrence.
- D_0 = last day of audit
- Initial response due dates with correction plans, root cause analysis and corrective action plans:
  - D_0 + 15 calendar days for all nonconformity grades
- Final response due dates with evidence of effective implementation of corrections and corrective action:
  - D_0 + 30 calendar days for grades 4 or 5

Operational Requirements for Manufacturers and AO After the Audit

- If the audit identified one or more grade 5 nonconformities, or more than two grade 4 nonconformities, or a public health threat, or any fraudulent activity or counterfeit product, the Auditing Organization to inform the Regulatory Authorities within 5 working days.
- This level of nonconformities can result in an unannounced audit by the Auditing Organization.
- For Grade 4 or 5 nonconformities, manufacturers are expected to provide evidence to the Auditing Organization of implementation of the remediation actions addressing any grade 4 or 5 nonconformity within 30 days of the audit end date.
- Auditing Organizations are subsequently expected to provide the audit package, which includes the NC Grading and Exchange form, to a recognizing Regulatory Authority within 45 days of the end of audit.

Overview

1 Overview of the MDSAP Program

2 MDSAP Objectives and Goals

3 The Mechanics of MDSAP Audits

4 Training and Qualifications of MDSAP Auditors

5 Advantages of Participating in the MDSAP Pilot Program

Training Requirements for MDSAP Auditors

- **Status of TÜV SÜD MDSAP Authorizations:**
  - Worldwide: 15 to 20 auditors
  - U.S: 5 completed; all others in-process (Active, Nonactive, IVD)
- **Training Plan – Basic Quality Management System Modules**
  - Ten online modules; prospective candidates given access to the database
  - Each module has a mini-quiz that must be passed before proceeding to the next section.
  - Every slide must be reviewed – no skipping slides on the way to the mini-quiz
  - Presentations consist of slides and a concurrent recording.
  - There is a final exam with 20 to 25 questions per module
    - If the candidate fails the final exam, the training must be repeated.

Training Requirements for MDSAP Auditors (Continued)

- **Training Plan – Country-Specific Regulations**
  - 20 shorter training sections for participating countries
  - There is no quiz but the candidate needs to attest to having completed the training.
  - Ten presentations for FDA, 3 to 4 for Canada, Brazil, Australia and Japan
- **Training Certificates Can Be Printed Only Upon Successful Completion of Training**

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What is Preventing U.S. Companies from Adopting MDSAP?

- Lack of publicity and awareness of the program and its benefits.
- Company's Notified Body is not in the MDSAP Pilot Program.
- Possible concern about interacting with FDA in a different manner.
- FDA will now have visibility to areas previously not typically covered in depth:
  - Internal audits
  - Management reviews
  - Corrective actions associated with these two areas
- Hoping that FDA will not achieve its biennial inspection requirement and that FDA inspections will occur less frequently than two years vs. annual MDSAP audits.
- Possible assumption that FDA will raise the bar for MDSAP to a level of rigor not seen currently with the other MDSAP regulatory agencies.

My view: Get Over It! Sign Up and Get on Board!

Participating in the MDSAP Pilot Program / Benefits

- Any manufacturer may participate if a product falls under the scope of at least one participating Regulatory Authority and subject to their quality management system requirements.
- The manufacturer may be located anywhere in the world.
- Only the MDSAP participating countries will have direct access to the audit reports.
- Regulators will witness some audits to evaluate the Auditing Organizations, not the manufacturer.
- One benefit is your ability to provide feedback to the regulators and influence the future of the program at the end of the pilot phase.
- In case you are due for a routine inspection, you can potentially reduce overall inspection/audit expenses and resource assignments by acting now to incorporate MDSAP into your next Notified Body audit.

Advantages of MDSAP – Opinion of an Ex-Industry CA/RA/QA Guy

- The sheer efficiency of having one audit per year on a predictable schedule (assuming good compliance absent findings that could trigger an unannounced audit).
- For manufacturers of Class III devices, the ability to attain ANVISA QMS approval with a MDSAP audit vs. waiting years for an audit by the Brazilian government on their schedule (3 to 5 years) or via an injunction (faster but not considered a good practice).
- Potentially lower cost than what would accrue from paying for the audits and travel expenses for several of the separate agencies.
- For U.S. companies desiring to collaborate more closely with FDA, participating during this MDSAP pilot phase provides an opportunity to engage directly with FDA and your notified body by providing feedback on your experience with MDSAP

If I were still in industry, I would be signing up for MDSAP!!

Questions, Comments?

Questions?

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