MDSAP – ONE YEAR LATER

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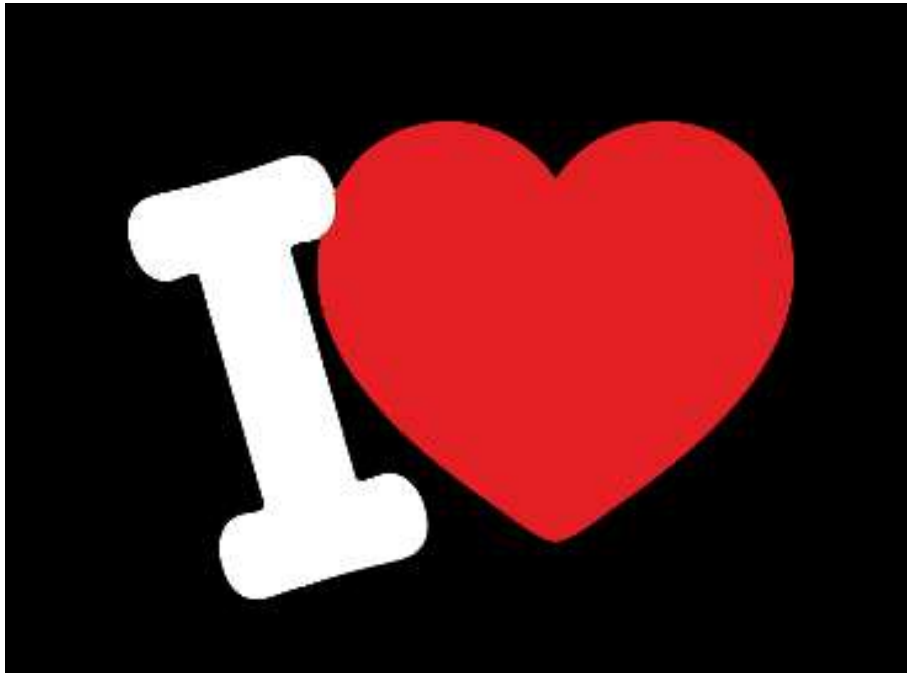


MDSAP

Tried to participate in the pilot program from the 1st day I heard about MDSAP from Kim Trautman

October 2016

Participated in MDSAP Pilot Program – ISO 13485:2003

- October 2016 Cert Audit at Main Campus
- February 2017 Cert Audit at Satellite
- Not pilot program audit

Surveillance Audit -October 2017

Surveillance Audit to upgrade to ISO 13485:2016 - October 2018

Since I retired……..

Asked by client to address their nonconformity for internal audits which led to developing a compliant audit process

My partner, Ed and I began performing MDSAP compliant internal audits in 2018

What I Want to Answer

- Update on Canada
- Who should participate
- What to expect in the audit
- Grading system for nonconformities
- Getting Started
- Preparation recommendations
- Certification vs. Surveillance

HEALTH CANADA

Health Canada

3000 companies met the deadline

Stuck to their guns with the December 31, 2018 drop dead date – sort of

- Submit valid MDSAP certificate
  - or
- Submit evidence that an MDSAP audit was successfully completed (but no certificate issued)
  - or
- Submit evidence that an MDSAP audit would occur in 2019 along with a valid ISO 13485 certificate

WHO SHOULD PARTICIPATE?

Who should participate?

- Any firm that wants to continue to sell in Canada

- Any firm that distributes in USA, Canada, Brazil, Australia or Japan and is tired of audits and expenses
  - For example To obtain and ANVISA audit you must apply and pay for the audit (about $25K). You then go into a queue that is up to 5 years long
  - If you want to expedite you can hire an attorney in Brazil and sue the government to expedite the audit and then get the audit in about 2 years.
  - You pay all expenses for the auditor(s) when you do finally get the audit

1 Jan. 2017

Any firm that would like to avoid routine QSIT inspections from FDA as MDSAP went live January 1, 2017

FDA announced on July 8, 2019 that MDSAP is considered acceptable based on the 3- year pilot and will continue to accept MDSAP in lieu of routine inspections

8 July 2019

REMEMBER

NOT a replacement for:

- Initial Inspections
- For Cause inspection
- Electronic Product Radiation Control (EPRC) inspection

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.

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

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

If you are not in all these markets

You can still participate in MDSAP

The countries you do not sell in currently are excluded from the audit scope and certificate

You can add them later with follow up audit activities

What happens in the EU?

Europe (EU) has been participating in MDSAP as an official observer

- Concerns is that it would be difficult to obtain agreement among all member states

There is optimism the EU will join the program

- MDSAP's aim to harmonize quality system compliance (ultimately increasing the safety and efficacy of medical devices) could serve as a way for EU to increase quality consistency across its member states

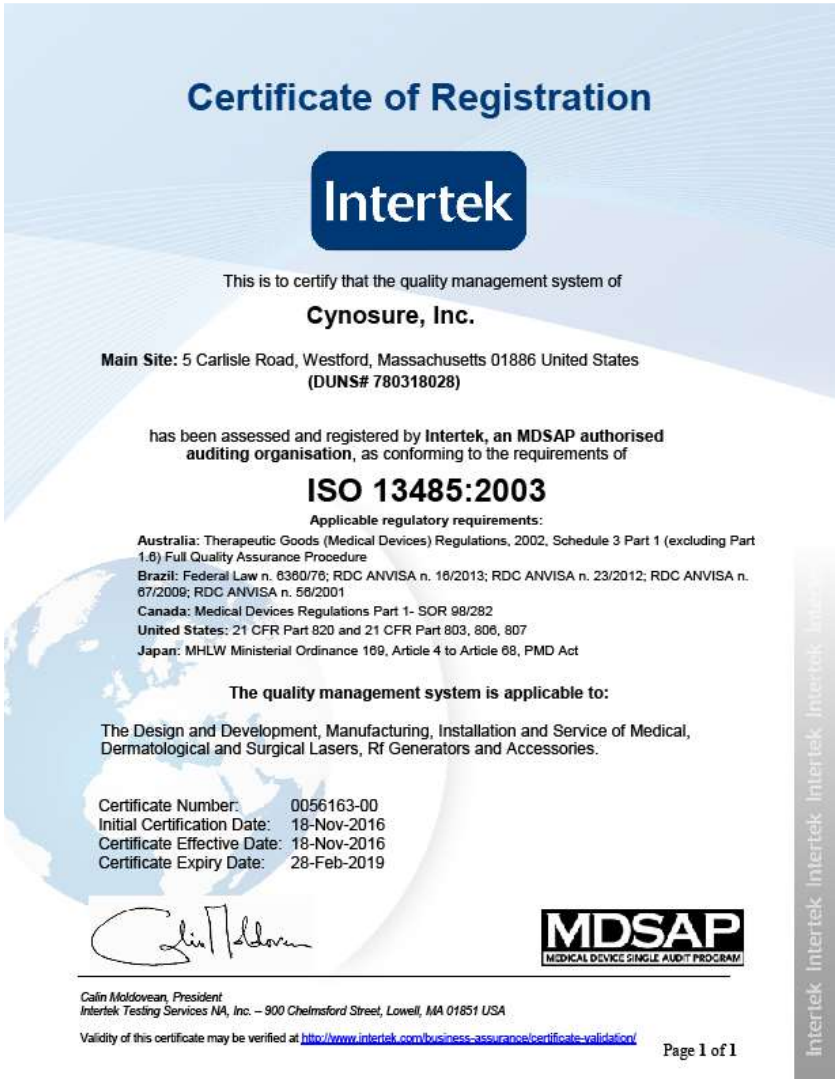
BUT..

Given EU focus on updating MDR regulations, this may not be soon

Registrars auditing to MDSAP already have 13485 and MDD (and soon to be MDR) baked into the current process

ISO 13485 audit is conducted in conjunction with the MDSAP audit

Cynosure's original certificate



Certificate of Registration

Intertek

This is to certify that the quality management system of

Cynosure, Inc.

Main Site: 5 Carlisle Road, Westford, Massachusetts 01886 United States
(DUNS# 780318028)

has been assessed and registered by **Intertek, an MDSAP authorised auditing organisation**, as conforming to the requirements of

ISO 13485:2003

Applicable regulatory requirements:

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) Full Quality Assurance Procedure
Brazil: Federal Law n. 6360/76; RDC ANVISA n. 16/2013; RDC ANVISA n. 23/2012; RDC ANVISA n. 67/2009; RDC ANVISA n. 56/2001
Canada: Medical Devices Regulations Part 1- SOR 98/282
United States: 21 CFR Part 820 and 21 CFR Part 803, 806, 807
Japan: MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act

The quality management system is applicable to:

The Design and Development, Manufacturing, Installation and Service of Medical, Dermatological and Surgical Lasers, Rf Generators and Accessories.

Certificate Number: 0056163-00
Initial Certification Date: 18-Nov-2016
Certificate Effective Date: 18-Nov-2016
Certificate Expiry Date: 28-Feb-2019

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Calin Moldovean, President
Intertek Testing Services NA, Inc. – 900 Chelmsford Street, Lowell, MA 01851 USA

Validity of this certificate may be verified at http://www.intertek.com/business-assurance/certificate-validation/

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MDSAP Audit

- Based on 3 year cycle (similar to ISO 13485)
  - **Initial Certification Audit of entire quality management system (QMS)**
    - Stage 1: preparation review
    - Stage 2: registration audit
  - **Annual Surveillance Audits – partial coverage**
  - **Recertification audit in 3rd year**
- Non-conformance findings are graded for severity

WHAT TO EXPECT

MDSAP Audit

- Audit duration is based on the elements to be covered in the audit (up to 94), not on number of employees (as in ISO 13485)
  - **A pre-determined amount of time is allocated to each task (range: 15 – 44 minutes)**
    - reduced for no sterilization, service, installation or implants (¾ hr. each), or design (5 hrs)
    - increased for critical supplier visits (4 hours each), outstanding NCRs (15 min. each)

Audit Duration Range examples

Stage 1 Audit	Stage 2 Audit & Recertification	Annual Surveillance Audits
Typically 1 day	**6 ½ on-site man-days**: Including design, sterilization, service, installation & implants in scope	**3 ½ – 5 on-site man-days**: Including design, sterilization, service, installation & implants in scope
	5 ½ on-site man-days: Not including the above	**3 – 4 ½ on-site man-days:** Not including the above

MDSAP (7) Audit Elements

- Number of audit tasks:
  - **Management (11)**
  - **Device Marketing Authorization and Facility Registration (3)**
  - **Measurement, Analysis and Improvement (16)**
  - **Medical Device Adverse Events and Advisory Notices Reporting (2)**
  - **Design and Development (17)**
  - **Production and Service Controls (29)**
  - **Purchasing (16)**

MDSAP Audit Style

100% Prescriptive

Follows a Step by Step series of questions that are asked in order

Questions are in an Audit Checklist and does not vary from the flow of the checklist

- Cannot rearrange order of processes

Does link to other processes during each sections

- For example, may ask to see a CAPA during NCR review

The questions and order of questions are all in the Companion Document

Companion Document

You should love this

The audit is predictable

You can prepare documents in advance

You can queue up your subject matter experts

You will not be jumping around trying to guess where the audit is going

1st –QMS Questions Based on ISO 13485

Process: Management

1		Verify that a quality manual, management review, and quality management system procedures and instructions have been defined and documented.
1	USA	Confirm the organization has established a quality plan which defines the quality practices, resources, and activities relevant to devices that are designed and manufactured
2		Confirm top management has documented the appointment of a management representative. Verify the responsibilities of the management representative include ensuring that quality management system requirements are effectively established and maintained, reporting to top management on the performance of the quality management system, and ensuring the promotion of awareness of regulatory requirements throughout the organization.
3		Verify that a quality policy and objectives have been set at relevant functions and levels within the organization. Ensure the quality objectives are measurable and consistent with the quality policy. Confirm appropriate measures are taken to achieve the quality objectives.

2nd – Country Specific Questions

5	Canada	Verify that the roles and responsibilities of any regulatory correspondents, importers, distributors, or providers of a service are clearly documented in the organization's quality management system and are qualified as suppliers and controlled.

5	EU	Has the manufacturer changed their EU Authorized Representative? Do they have process to advise us, their Notified Body, of this substantial

3rd – Links to other processes

	Link	During audit of the firm's Purchasing process, ensure that management has assured the appropriate level of control over suppliers, including an assessment of the relationship between supplied products and product risk.

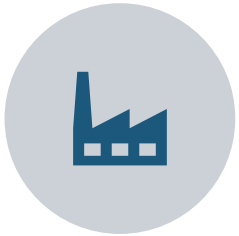
Risk assessment

- Focus on Risk related to the processes. Especially evident in ISO 13485:2016

- For example:
  - Verify that the system for monitoring and measure of product characteristic is capable of demonstrating conformity. ***Confirm that product risk is considered in the type and extent of product monitoring activities.*** (page 74)

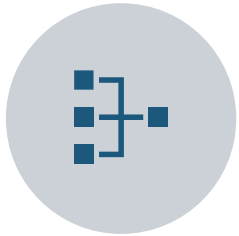
  - Confirm that the manufacturer has established and maintained a file for each type of device (DMR) ***Confirm that the manufacturer determined the extent of traceability based on the risk posed by the device.*** (page 78)

Outsourced Processes



OEM MANUFACTURERS

VENDORS (COMPONENTS)



OUTSOURCED PROCESSES (STERILIZATION)

ENGINEERING SERVICES

REGULATORY SERVICES (3RD PARTY REGISTRARS)

STORAGE FACILITIES

CONSULTANTS

Focus on Supplier agreements and Supplier Controls especially as it relates to RISK

During audit of the organization's purchasing process, ensure that management has assured the appropriate level of control over suppliers, including an assessment of the relationship between supplied products and product risk. (pg. 8)

For example: Does the agreement with a sterilization supplier specify what happens if there is deviation in the sterilization cycle?

Examples

Australia – if an Australia sponsor undertakes an activity that is outsourced….verify that the roles and responsibilities of the sponsor are documented in the QMS and the sponsor is controlled as a supplier (pg 8)

Brazil – there is no exception to design control. If design activities are outsourced, verify that the manufacturer has a complete device master record for the device and records of design transfer to production. (pg 50)

During the audit, the audit team should consider reviewing supplied product that have the highest risk (pg 56)

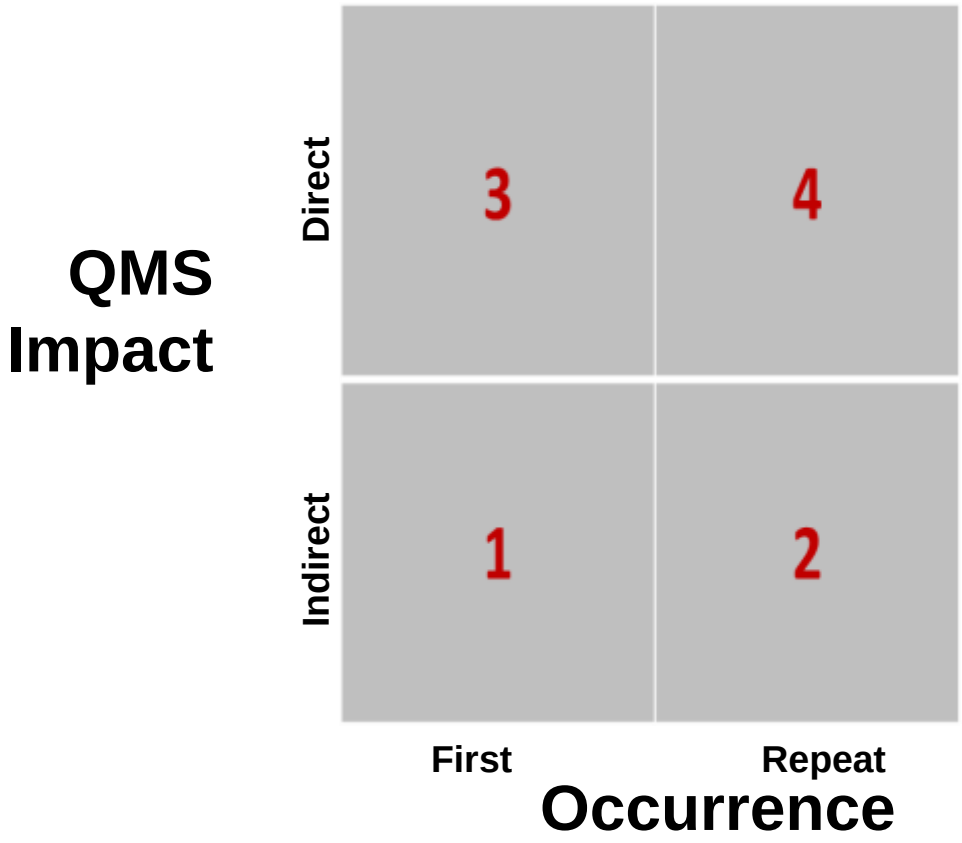
Non-Conformities Grading

- Major / Minor terminology no longer exists

- GHTF/SG3/N19:2012, *Quality management system: Medical devices - Nonconformity Grading System for Regulatory Purposes and Information Exchange*

- Nonconformities identified during an audit will be grade on a scale from 1 (least critical) to 4 (most critical)

Grading System



Escalation

- Escalation: the grade can be increased by 1 each if:
  - Absence of a documented process/procedure
  - Release of a nonconforming medical device
  - Repeat finding

Indirect vs direct

ISO Clause 6.3 and below is considered “indirect”

- Management Responsibilities
- Document Control

ISO Clause 6.4 and above considered “direct”

- Product Realization
- Measurement and Improvements

Example for Indirect

- Management review did not cover all the elements per ISO standard and SOP
- This was a nonconformity 2 years ago

1+1 = 2

- Nonconforming material is not being handled properly
- This led to nonconforming material being sent to a customer
- No SOP for how to handle nonconforming material
- This was a nonconformity 1 year ago

3+1+1+1 = 6

THEN WHAT?

Grade 4-6 findings

- 15 days to respond with corrective action plan
- 30 days to correct
- Expect unannounced audit to follow up

Grade 1-3 findings

- 15 days to respond with corrective action plan
- Implementation within 90 days


STAR

Companion Document

What is the Companion Document?

This is your GUIDEBOOK and it is FREE!

https://www.fda.gov/media/88275/download

And there is a very nice “plain English” guide published by FDA

https://www.fda.gov/media/87544/download

If you don’t have a highlighted, redlined, dog-eared, coffee stained copy of this in your possession, then you are probably not ready for your MDSAP Audit

Format

- Each process has a chapter that includes:
  - Purpose
  - Expected outcomes for the auditor
  - Audit Tasks and Links to other processes
- Audit Tasks are numbered and correspond to the auditor's checklist
- Section to explain what should be assessed during each audit task
- Country specific requirements

Example: Task 8 of Management

Verify that procedures have been defined, documented, and implemented for the control of documents and records of both internal and external origin required by the quality management system. Confirm the organization retains records and at least one obsolete copy of controlled documents for a period of time at least equivalent to the lifetime of the device, but not less than two years from the date of product release.

Clause and Regulation: [ISO 13485:2016: 4.1.4, 4.2.1, 4.2.4, 4.2.5; TG(MD)R Sch3 P1 1.4(4); RDC ANVISA 16/2013: 3.1; MHLW MO169: 5, 6, 8, 9,; 21 CFR 820.40, 820.180]

Additional Country Requirements

- Australia (TGA)
  - Confirm that Quality Management System documentation and records in relation to a device described in TG(MD)R Sch3 P1 1.9 are retained by the manufacturer for at least 5 years.

- Brazil (ANVISA)
  - Verify that change records include a description of the change, identification of the affected documents, the signature of the approving individual(s), the approval date, and when the change becomes effective [RDC ANVISA 16/2013: 3.1.5].
  - Confirm that the manufacturer maintains a master list of the approved and effective documents [RDC ANVISA 16/2013: 3.1.5
  - Verify that electronic records and documents have backups [RDC ANVISA 16/2013: 3.1.6].

Additional Country Requirements

Japan (MHLW)

- Confirm that Quality Management System documentation and records in relation to a device are retained for the following periods (5 years for training records and documentation). [MHLW MO169: 8.4, 9.3, 67, 68].
- (1) 15 years for ‘specially designated maintenance control required medical devices’ [or one year plus the shelf life for products when the shelf life or the expiry date (hereinafter simply referred to as the "shelf life") plus one year exceeds 15 years]
- (2) 5 years for the products other than the ‘specially designated maintenance control required medical devices’ (or one year plus the shelf life for the products of which the shelf life plus one year exceeds 5 years).

Additional Country Requirements

United States (FDA)

- Verify that electronic records and documents have backups [21 CFR 820.180].

Assessing Conformity

- Confirm that the organization has defined, documented, and implemented procedures for control of quality management system documents and records. Evidence that these controls are effective can be ascertained through the audit of the other quality management system processes. For example, evidence that the document controls process is ineffective might be the observation of obsolete procedures being used or required records being unavailable.

- Ensure at least one copy of obsolete controlled documents is maintained.


A Beautiful
THING


Prepare

What to do!

Read the Companion Document cover to cover

ALL OF IT (twice, thrice, more!)

This will help you understand the overall flavor of the audit

Look for Risk related activities as this may be unfamiliar territory

Highlight all the Audit tasks in each section

Hard copy then e-Copy – THIS IS YOUR TRAINING TOOL

Ask your notified body if they will provide you with the audit checklist (probably NOT but won't hurt to ask)

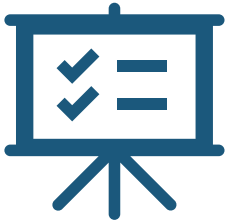
If NOT, you can create your own – you will need it going forward for internal audits anyway

How do I create my own checklist?


Copy
Paste

Review and Update your QM and SOPs

Quality Manual must address all applicable regulations



Procedures must include country specific requirements

For example: does your Supplier Quality SOP address consultants and design control activities?

Do you have an SOP that has addresses each countries registrations requirements?

Meeting

Explain!

- Meet with the appropriate dept. heads to explain the new audit style – you need to prep your organization
- DO NOT COMPLAIN ABOUT THIS. It is your job.
- Focus:
  - Audit “Tasks” that you have highlighted in the eCopy
    - Don’t hand out the entire document….Select the pertinent sections for each dept head
  - Discuss what Risk related activities means
- QA may need to hold some hands on this especially for “old-timers” who have been through lots of audits

Pre-Audit?

- There are consultants who can perform a pre-audit and provide training
  - I googled “ Hire an MDSAP Consultant” and got 20,800 hits
- FDA website has free training
  - https://www.fda.gov/medical-devices/medical-device-single-audit-program-mdsap/mdsap-training-material
- May also use the Companion document and/or the audit checklist and perform internal audit(s) on your own


Yes
No
Maybe
ARE
YOU
READY
?

The Certification Audit

- 0.5 day of desk audit (1 auditor)
  - Quality Manual
  - Top Level procedures (I sent 37 total SOPs)
- 4.5 days of on-site audit (2 auditors)
- Total of 9.5 (audit days)
- This is based on number of elements covered (full quality system)
- Scope was MDSAP, ISO 13485, and Medical Device Directive (MDD or in rare cases MDR)

The Certification Audit – Satellite Campus

- No Desk Audit
- Scope did not include processes managed from the main campus
- 3.5 days of on-site audit (2 auditors) - Total of 7 (audit days)
- Based on number of elements covered
  - No Management Processes
  - No Design Control

The 1st Surveillance Audit

- No Desk Audit
- 5.0 days of on-site audit (2 auditors)
  - Both sites
  - Included ½ day of travel
- Total of 9 audit days
- Scope was MDSAP, ISO 13485(surveillance) and Medical Device Directive (MDD)

The Desk Audit

- After the Desk Audit, you will receive a list of “things missing” from the SOPs
- Example:

  7.3.7 Control of design and development changes - Additional Country requirement: Australia

  Verify that the manufacturer has a process or procedure for notifying the auditing organization of a substantial change to the design process or the range of products to be manufactured [TG(MD)R Sch3 Cl1.5].

The Desk Audit

UPDATE YOUR SOPS IMMEDIATELY WITH THE “MISSING THINGS”

TRAIN YOUR STAFF

THE UPDATES ARE VERIFIED DURING THE AUDIT

The Site Audit

Two Auditors Worked separately

- You need 2 conference rooms
- Subject matter experts queued up

There is NO changing of the audit flow

- For example, we asked to have Purchasing moved to earlier in the week which was a no-go

The audit moves at a fast pace

PRE-GAME

- All procedures queued up electronically or paper (ask the auditor before he/she arrives for preference)

Pre-game

Matrix of all your registrations by product / country (with registration number in the matrix)

Objective evidence to show that your products are registered

Paper Copies or electronic copies

Copies of your establishment registrations by country

Be prepared to log into the website and pull up your registrations

SOP in place for interacting with regulatory agencies

I call this the Registration and Reporting SOP

Pre-Game

Documentation like you would support an ISO or QSIT

Distributor / Subsidiary agreements

Considered an outsourced process

Quality Agreements

I know you don't believe me but you need a quality agreement with your subsidiary offices.

Supplier Agreements

Qualifications per your Vendor List

Supplier / Quality Agreements

Pre-Game

Change Control

Documented Risk Assessment for significant changes

Decisions on when to notify a government agency of a change

- For example, a change to a critical component will require notification to INMETRO and ultimately ANVISA

Other

Translated Manuals / Labeling

Translated GUI

UDI

- confirm MDR reports contain the UDI (pg 47)
- Confirm that product realization includes a plan for UDI (pg 66)

War Room?

- Decided not to have a war room
- Set up a IM communication tool (SLACK) and a DropBox for documents
- Didn’t miss the War room but REALLY happy to have SLACK set up
  - Learn to use expanded desktop to present items to auditors to avoid IM messages popping up during audit!!!


DON’T FEAR THE AUDIT.

The Audit

Very promptly started and stuck to a strict schedule

Followed Audit Task Checklist to the letter and typed into the checklist during the audit

If you understand the Audit Tasks this is very direct

Seemed to be some overlap between the two auditors

For example, metrics were reviewed in Management Review and also reviewed in Monitoring and Measurement

Did spend time on the production floor

Process Control

Calibration

The Audit

- Focus on Risk Activities
- Focus on outsourced processes
- Focus on Validation
  - Design
  - Process
- Focus on Change management and associated risks
- Found multiple times where the subject matter expert for particular topics was required in both rooms
  - Had to improvise!

- We did bring in lunch and spent that time chatting with the Auditors

Example of findings

- **Finding: (Grade 3)**
- Could not determine that records of installation are maintained when installation activities are carried out by distributors.
-
- **Requirement:**
- 7.5.1.2.2 Installation activities
  If appropriate, the organization shall establish documented requirements which contain acceptance criteria for installing and verifying the installation of the medical device. If the agreed customer requirements allow installation to be performed other than by the organization or its authorized agent, the organization shall provide documented requirements for installation and verification. Records of installation and verification performed by the organization or its authorized agent shall be maintained

Example of findings

- **Finding: (Grade 3)**
- Internal audit insufficient as it did not entail all member country requirements and internal auditor did not exhibit appropriate qualifications
-
- **Requirement:**
- 6.2, 8.2.4 Internal Audit
  Verify that internal audits of the quality management system are being conducted according to planned arrangements and documented procedures to ensure the quality management system is in compliance with the established quality management system requirements and applicable regulatory requirements, and to determine the effectiveness of the quality system. Confirm that the internal audits include provisions for auditor training and independence over the areas being audited, corrections, corrective actions, follow-up activities, and the verification of corrective actions.

Example of findings

- **Finding: (Grade 3)**
- Process for documenting nonconforming product is not effectively implemented

- **Requirement:**
- 8.3 Control of nonconforming product
- *The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery*

Example of findings

- **Finding: (Grade 3)**
- Process is not effective/Use of Obsolete Document

- **Requirement:**
- 4.2.3 Control of documents
- Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4.

THEN WHAT?

Grade 4-6 findings

- 15 days to respond with corrective action plan
- 30 days to correct
- Expect unannounced audit to follow up

Grade 1-3 findings

- 15 days to respond with corrective action plan
- Implementation with in 90 days

Well acquainted with the Companion Document

Use as a training tool for other departments

Obtain or develop a checklist of the tasks

Review your SOPs against the Companion Document for country specific tasks

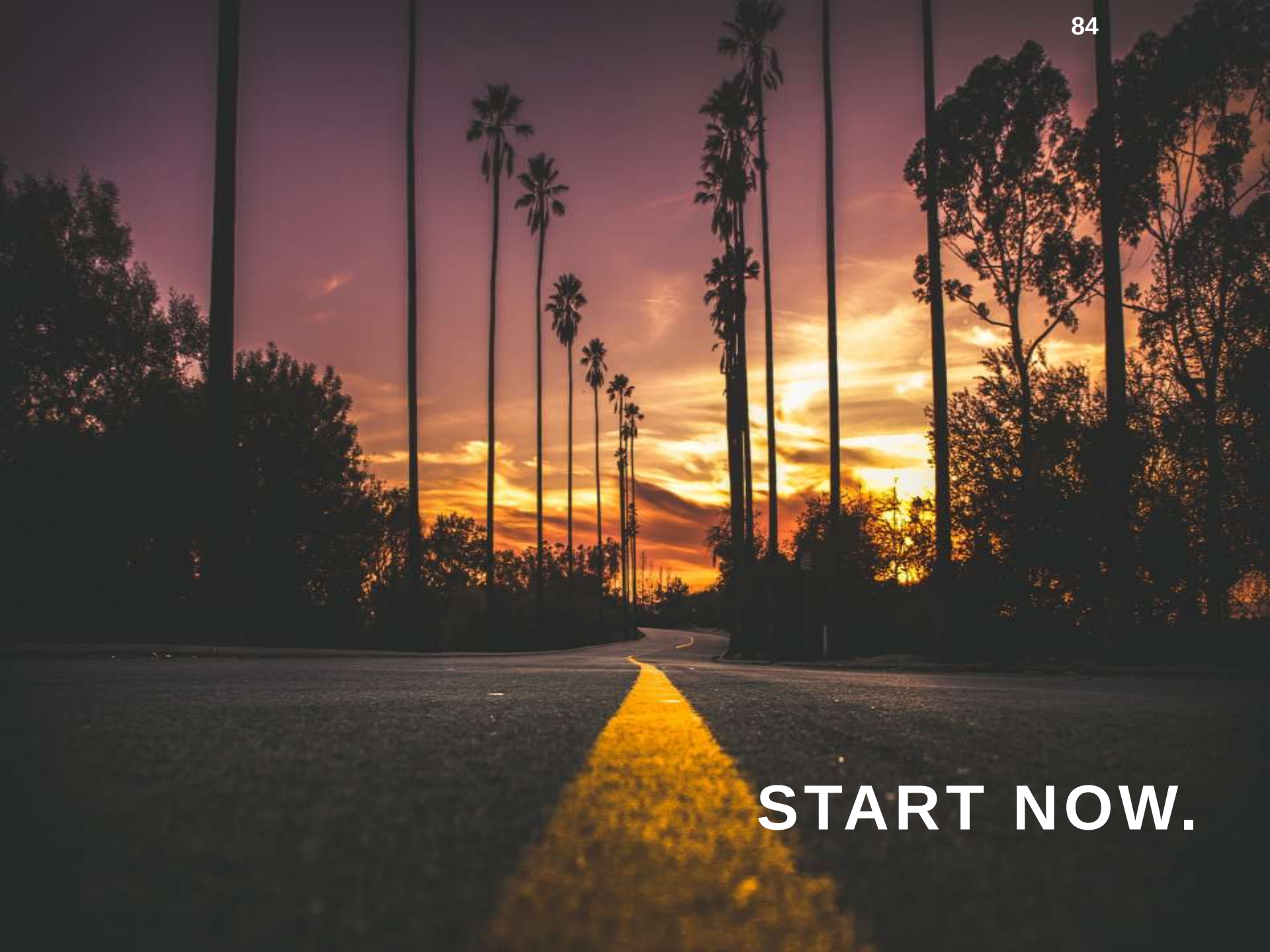
Create an SOP for communicating with the various countries' regulatory agencies

Create a matrix of all registrations - Must also have e-Copies of all registrations

Review agreements with outsourced processes

Review processes for how risk is addressed For example:

- Change Control
- Non-Conforming material
- Customer complaints


START NOW.