MDSAP for the Medical Device Professional

Real Life Experiences

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Real Life Experiences Agenda

What to do to get ready?

What has worked well?

And not so much…

Intro to MDSAP What to do to get ready?

- Do You Need MDSAP?
- Getting to Know the AO's
- Prepare for Audit
- The Audit
- The Aftermath

Do You NEED MDSAP?

If you currently DON'T HAVE a CMDCAS Registrar, make sure MDSAP is for you (some reasons you may not need/want it):

- ❑ Do you ONLY have a Canadian *Establishment* License (for Canadian Class I)
- ❑ Don't have and not currently planning to apply for Canadian Class II, III, or IV Medical Device License
- ❑ Not the LEGAL manufacturer for medical devices marketed to Canada
- ❑ Prefer Annual ANVISA (Brazil), TGA (Australia), PMDA (Japan) audits

Getting To Know the AOs

- ❑Start with your current (CMDCAS) Registrar / Notified Body
  - 15 CMDCAS Registrars, 12 authorised to do MDSAP
  - 55 MDD Notified Bodies, 13 authorised to do MDSAP
- ❑What do you mean you don't have CMDCAS?
  - Startup – still working on device design, or plan to begin Canadian shipping Jan 2019
  - Plan to apply for Canadian Class II, III, or IV License this year (2018)
- ❑Bookmark & revisit: https://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM429978.pdf - last update 3 DEC 2017
  - (List of those AO's authorized and recognized to conduct MDSAP audits.
- ❑Interview, get RFQ application, network (ASQ, RAPS, etc., local)

Getting to Know the AO's

- ❑Interview, Fill out (lengthy) questionnaire of AOs, get Quotes
  - First test: if 16-45 FTEs, if audit duration reduced 10%, if ≤15 FTEs, 20%, surv/recert 20% reduction
  - Find out what the queue is (Stage I AND Stage II)
  - Will the AO share the audit checklist?
  - How many MDSAP auditors & where do auditors (there will be 2) come from (AO may be local, 1 auditor may be from Iowa – has impact on queue & cost)
  - Don't Blow The "HTRJ" Opportunity
- ❑Let Management know how much this is going to cost (audit + etc.)
- ❑Let Management know _____ may have to wait (EDMS, next 510(k), etc.)
- ❑Let Management know pro's and con's (ex. EU not participating)
- ❑Let Management help make AO Selection

Prepare for the Audit

Understand your Scope (Products, Countries, Critical Sub, Legal Mfr)

Product	Marketed to	Act as	Current Assess	MDSAP
CPAP Blower	USA	Mfr	FDA Insp	Yes
CPAP Blower	Canada	Mfr	CMDCAS	Yes
CPAP Blower	Brazil	Mfr	INMETRO	Yes
CPAP Mask	Brazil	Mfr	ANVISA	Yes
Mouthguard	USA	Mfr	FDA Insp	Yes
Mouthguard	Canada	Legal Mfr	Est. Lic	No
CPAP Mask	OBL Mfr	Contract Mfr	CMDCAS	Yes
CPAP Mask	OBL Mfr	OutsrcDesign	Brazil	Yes

Prepare for the Audit

- The Companion Document (13485:2003 or 13485:2016) is the foundation of everything MDSAP
- Decide if Internal, External (Consultant), or a Combination
  - How much time before Stage I/Stage II?
  - If external, be careful of Consultants insisting you need SOPs
- Gap Analysis using Companion vs. existing SOPs
  - Most likely SOPs will address majority of FDA QSR and ISO 13485 already
  - Gaps may be lack of detail on country regulatory requirements
  - Gaps may be 13485:2016 related if recently upgraded

Prepare for the Audit

Typical Gaps:

- ❑ "CMDR" SOP doesn't address all applicable requirements
  - Requirements for applying for a license, annual update of license not clear
  - Requirements for how to do a recall or issue advisory notice
- ❑ SOPs not meeting 'gotcha' country / 13485:2016 requirements:
  - SOP for notifying of substantial change doesn't address TGA
  - SOP allows design control exceptions…or if design outsourced, no requirements for complete DMR and records of design transfer to production ANVISA
  - SOP of installation doesn't cover non-staff or contractors (esp. foreign) 7.5.1.2.2, contractors not treated as suppliers 7.4.1) no qual agreement
  - Only SOP with Risk Management for Design, no RM throughout

Distribute the “Wealth”

- ❑Matrix of “Gaps”, What SOP, What Section covers what req’t, SMEs
- ❑Prepare MDSAP Process/Task Buckets with Matrix results

Process	Task	Country	Requirement	SOP	Sect	SME
Design	11	Australia	Validation incl clinical evaluation	7.3.2	6.5	Dr. Bob
Design	16	Brazil	Transfer includes s/w src code	7.3.3	5.4	Karen
Adverse	1	Brazil	Complaint feedback to Brazil Legal Rep	8.2.1	7.2	Dave
Production	7	USA	Proc val req’d sterilization, aseptic proc., injection molding, welding	7.5.2	8.5	Larry
Production	4	Brazil	Pest Control pgm – chemicals vs. quality	6.4.1	3.4	Nancy

Distribute the “Wealth”

- ❑Recruit Internal Auditors from other depts independent of process

Process	Internal Auditor
Adverse Events	Sam from Accounting
Production	Karen from Software Development
Purchasing	Craig from Marketing

- ❑Train Internal Auditors on Country Requirements by Process/Bucket

Internal Auditor	Process	Country Requirement
Sam (Accounting)	Adverse Events	TGA requires report 48 hrs
Karen (SWDevt)	Production	UDI requirements per 21 CFR 830

Distribute the “Wealth”

Once trained, Internal Auditors conduct audits of all processes

- ❑ Make AO’s checklist yours or create one from Companion
- ❑ Verify Gaps are no longer – or, if still, take CAPA
- ❑ Allows Depts/SMEs to get familiar with MDSAP audit
- ❑ Allows Backroom (if applicable) prepare/correct Bucket Matrix
- ❑ Allows all participants to experience ‘the audit speed/culture’
- ❑ Practice using all tools (Dropbox, Skype, IM/Slack, Zello/Headsets)
- ❑ Can use qualified consultant for this if resource limited (sometimes called ‘Preaudit’)

The Audit – Stage I

- ❑ Generally takes 0.5-1 day, off-site, 1 auditor
- ❑ Request Q Manual and Top Tier SOPs (hint: if the main Complaint SOP doesn't handle Brazil complaints, send top tier plus the 2nd tier)
- ❑ Receive deficiency report of gaps – mostly with country requirements
- ❑ If Stage I no deficiencies, doesn't mean none in Stage II
- ❑ Disposition: Ready for Stage II, Ready if deficiencies addressed, Not Ready

The Audit – Stage II

- ❑ Two auditors, start together, swiftly split up
- ❑ Best to have rooms for each auditor, ½ a Backroom for each audit
- ❑ For those companies used to controlling audit, a rude awakening
- ❑ Audit starts on time, proceeds according to plan, few detours
- ❑ Like going to Shakespearian Play – Checklist as per Companion Doc is script
- ❑ Hit Process Modules in order, Tasks in Order
- ❑ Have to stick to time/task (15-44 min) or will get behind

The Audit – Stage II

- Not a lot of time. "Show me the SOP that addresses _____"
- If it doesn't pop up on the screen or brought in swiftly, it's destined to be a NC.
- Entire audit is typed/entered on auditor laptop using MDSAP forms, spreadsheets, etc. Not much wiggle room.
- Like with most 'canned software', occasionally there may be glitches
- Auditor CAN'T bypass a question, go out of order, etc.
- Auditor CAN'T Exit and come back to it.

The Audit – Stage II

- Don't expect auditors to 'give benefit of doubt' (examples):
  - No SOP that says 'for USA, we won't distribute until 510(k) clears, because 'that's the way we've always done it.'
  - No evidence a 510(k) clearance not required – don't expect auditors to be 'regulatory guru's'. If you don't have documentation justifying no 510(k), they have to give a NC.
  - Watch Outlook emails and IMs showing up on "Audit Screen"
  - NC's written, supporting evidence entered, factored & graded:

The Audit – Stage II

- Nonconformities written, supporting evidence entered, graded:

Individual Nonconformity Information	
Nonconformity number or reference	
Statement of nonconformity	
Supporting evidence	

Nonconformity grading

QMS Impact	Repeat NC ?	Required Procedure Lacking ?	Nonconforming Products Released ?	MDSAP Grade	ISO 17021 Grade
○ Indirect ○ Direct	○ No ○ Yes	○ No ○ Yes	○ No ○ Yes		

☐ The organization detected and properly addressed the nonconformity prior to the audit

The Aftermath

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  - Watch Outlook emails and IMs showing up on “Audit Screen”
  - NC’s written, supporting evidence entered, factored & graded:

MDSAP What has worked well?

- Team approach – bucketizing requirements
- Earlier vs. Later
- Getting auditors who have done several
- Being flexible with AO on dates
- ‘Training’ Management on Process
- Precursor to EU-MDR/IVDR

What has worked well

- 2016 Statistics: 164 Audit Reports 46 No NCs, 118 1 or more NCs
- FDA has not indicated how many inspections have been deferred
- Audits take longer, cost more, but co-mingle FDA/CMDCAS/ANVISA/TGA in one ‘fun’ week (4-9 days) then subsequent surveillance and recert
- Drives Risk Management throughout QMS
- QA and RA have to work together
- Better control of critical suppliers/contract mfrs

MDSAP
Not So Much

- As we get closer to “the Crunch” (Oct, 2018)
- Small mfrs may drop out of Canada Jan 2019– not worth extra
- EU not joining – 25 May 2020 cert to EUMDR
- If NC also to MDD, do you get that too?
- Reports to ALL RAs regardless
- If your Stage II or Surveillance is a AO’s WA
- Gives FDA window into Management Review
- Do not adjust your set – when AO’s s/w goes kafluey