PROJECT PLAN

PROOF OF CONCEPT FOR MEDICAL DEVICE SINGLE AUDIT PROGRAM (MDSAP) PILOT

Implementation Date: 2016-11-01

Revision Date: 2017-02-24

Section 1. Project Plan Summary

The goal of this project is to define the process to verify the proof of concept of the MDSAP Pilot.

An Acceleration Plan was developed to allow the launch of a three year pilot from January 2014 through December 2016. In order to analyse the results of the pilot, the development of prospective objectives and criteria to measure the success of the Pilot Study as well as the development of forms and methods for the collection of data during the Pilot Study is required to confirm the proof of concept.

The table in Section 2 defines performance indicators to be used to measure the success of the Pilot. The collection of data, sampling, methodology, frequency of measurement and verification, that defines if targets were met, is described in the narrative following the table.

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Section 2. Project Performance Evaluation

Table 2-1 Performance Indicators, Targets, Performance Measurements & Metrics during MDSAP Pilot

No.	Performance Indicator (what is to be measured)	Targets (what is the accepted performance target)	Performance Measurement (how will performance be measured)	Metric (how will the measurement be calculated or expressed)
1	Whether the format and content of audit and nonconformity reports comply with prescribed requirements	> 70% of the sampled and evaluated reports comply.	By a comparison of an evaluation of reports with the requirements of P0019 and the NC Grading & Reporting Form	$\frac{\#\text{ of satisfactory reports}}{\#\text{ reports evaluated}}$
2	Whether audit and nonconformity reports would substantiate regulatory decisions	> 80% of reports evaluated would substantiate regulatory decisions	By evaluation of the evidence in audit and nonconformity reports for their capability to substantiate regulatory decisions	$\frac{\#\text{ Reports that "fit for purpose" for all RAs}}{\#\text{ of reports evaluated}}$
3	Whether the audit model and task sequence appropriately assesses QMS and regulatory requirements	< 5% of audit model tasks requires a correction or corrective action.	By RA assessors observing the application of the audit tasks, as well as feedback from AOs.	$\frac{\#\text{ of audit tasks requiring corrections}}{\#\text{ of audit model tasks}}$
4	Whether the assessment model and task sequence appropriately assesses MDSAP requirements	< 25% of assessment model tasks require a correction or corrective action	By RA self-evaluation and AO's feedback about the application of the assessment tasks at HO, CL assessments and at witnessed audits.	$\frac{\#\text{ of assessment tasks for which a NC is raised.}}{\#\text{ of assessment model tasks}}$
5	Whether time provided in the audit duration model is suitable for evaluating and recording evidence of conformity / nonconformity with requirements	The duration for an MDSAP audit is ≥ 100% and ≤ 120% of the calculated duration	By observing the duration of witnessed audits and, at the conclusion, deducting the duration calculated by the AO to account for parallel activities	$\frac{\text{duration of witnessed audit}}{\text{calculated MDSAP audit duration}}$
6	Whether a sufficient number of candidate Auditing Organisations are recognised	> 75% of Health Canada MD Licences could be assessed by candidate Auditing Organisations	By determining the # of MD Licences supported by a CMDCAS/ MDSAP QMS cert from a Registrar that is a candidate AO	$\frac{\#\text{ of MDL sup'd by CMDCAS/MDSAP AO cert}}{\#\text{ of MDLs}}$
7	Whether a sufficient number of manufacturers participate in MDSAP	The number of MDMs that have applied to participate is >10% of a candidate AOs CMDCAS clients	By determining the number of MDMs that have applied to participate.	$\frac{\textbf{\# of MDMs that have applied to participate}}{\textbf{\# of CMDCAS clients of all candidate AOs}}$

2.2 Project Forms and Methods for the Collection of Data during the Pilot Study

Based on the table above, for each performance indicator, forms and methods for data collection during the Pilot Study will be developed. This will also include the evaluation method to verify if the targets were met.

The findings for this project will be summarized in a report on the results of the Pilot Study, as stated on the task # 8 of the MDSAP Project Acceleration Plan.

2.2.1 Performance Indicator 1 – Audit Reports and Non Conformity

a) Collection of data

Each RA will perform assessments of selected audit reports issued by AO's. The assessment will be performed based on data that will be collected using an assessment tool (see Attachment 1).

b) Sampling

If the pilot of the program generates more than 50 reports, then a valid statistical formula shall be used to determine the sample size of reports to be evaluated. The Lead Project Manager will select these reports based on the formula and randomly distribute them to the participating Regulatory Authorities.

If the pilot of the program generates less than 50 audit reports, all RAs will evaluate 100% of the reports.

Sampling of additional reports may be undertaken by any individual participating Regulatory Authority, however, the sampling must be random and encompass audit reports with and without nonconformities.

c) Source of document used as reference.

MDSAP AU P0019 - Quality Management System Audit Reports Policy

MDSAP AU F0019.1 - Medical Device Regulatory Audit Report

MDSAP AU F0019.2 - NC Grading and Exchange Form

MDSAP AU P0002 - Audit Model

MDSAP AU G0002.1 - Companion Document

d) Methodology

Each question in the assessment tool is weighted by points, with different weightings assigned according to the potential impact of missing or inadequate information when the report is to be used for making regulatory decisions. For this measurement, weightings will be distributed to ensure that any report may receive a maximum of 100 points.

A report will be considered "in compliance" if the minimum score in the assessment tool reaches 80 points.

e) Targets

The objective will be considered met when:

- A minimum of 70% of the reports evaluated have been found "in compliance" with the requirements of the MDSAP documents referenced under c) above.

2.2.2 Performance Indicator 2– Evaluation of Audit Reports and Non Conformity – Fit for Purpose

a) Collection of data

Each RA will evaluate selected audit reports issued by AO's for sufficiency of evidence of compliance with the regulatory requirements within their own jurisdiction.

Considering that the AO's auditors finished the Japanese regulatory requirements training on January 2016 and that only after that the reports could include these requirements the sample for this performance indicator will consider only reports from February 2016.

Therefore, all reports that have the 5 participating Regulatory Authorities on their scope from February 01st to December 31st, 2016 will be part of the sampling plan. The RAs will analyze the same sample in order to answer if the report "fit for purpose" for regulatory decision making.

b) Sampling

For the sampling plan, all reports that have the 5 participating Regulatory Authorities on their scope from February 01 to December 31 of 2016 must be considered

If the pilot of the program generates more than 50 reports, then a valid statistical formula shall be used to determine the sample size of reports for review. If the pilot of the program generates less than 50 audit reports, all reports will be distributed to the participating Regulatory Authorities for evaluation. The same sample will be evaluated by all participating Regulatory Authorities.

c) Source of document used as reference

MDSAP Regulatory Authorities regulations:

https://www.fda.gov/MedicalDevices/InternationalPrograms/MDSAPPilot/ucm453797.htm

d) Methodology

In order to calculate the Indicator, the number of reports that "fit the purpose" for all RAs will be divided by the total number of reports evaluated.

$$\text{Ex.:} \quad \frac{\text{\# reports that "fit for purpose" for all RAs}}{\text{\# of reports evaluated}}$$

e) Targets

The objective will be considered met when:

- 80% of evaluated reports are "fit for purpose" for use by RAs for regulatory decision making.

2.2.3 Performance Indicator 3 - Audit Model

a) Collection of data

Feedback from RA assessors and AO representatives will be compiled throughout the pilot and will focus on: the adequacy and completeness of MDSAP audit model tasks, guidance from the MDSAP audit model companion document, and the sequence in which audit tasks will be assessed. Assessors

will raise a NC under the MDSAP QMS if an Audit Model task does not fulfill regulatory requirements, or guidance in the Audit Model Companion document does not fulfill requirements, or the audit task sequence is not optimal.

b) Sampling

All nonconformities raised during the Pilot period will be taken into account.

c) Source of document used as reference

MDSAP AU P0002 - Audit Model

MDSAP AU G0002.1 - Companion Document

d) Methodology

The number of tasks in which nonconformity has been raised, requiring a correction or corrective action, divided by the total number of audit model tasks.

e) Targets

Less than 5% of Audit Model tasks require a correction or corrective action.

2.2.4 Performance Indicator 4 - Assessment Model

a) Collection of data

Feedback from RA assessors and AO representatives on the adequacy and completeness of the assessment tasks and the sequence of AO processes to be assessed will be compiled throughout the pilot. Assessors will raise a NC under the MDSAP QMS if an assessment model task does not adequately assess the requirements of ISO17021:2011 or the requirements of IMDRF N3 or N4.

b) Sampling

All nonconformities raised during the Pilot period will be taken into account.

c) Source of document used as reference

IMDRF MDSAP WG N5FINAL:2013 - Regulatory Authority Assessment Method for the Recognition and Monitoring of Medical Device Auditing Organizations

d) Methodology

The number of assessment tasks against which a nonconformity has been raised and that require a correction or corrective action, divided by the total number of assessment model tasks.

e) Targets

Less than 25% of Assessment Model tasks require a correction or corrective action.

2.2.5 Performance Indicator 5 - Audit Duration

a) Collection of data

Information regarding actual audit duration will be obtained from the audit reports.

The feedback from AO representatives and assessors who participated in witnessed audits (stage 2, S, Re audits, if applicable) on the duration taken to audit MDSAP requirements will be compiled throughout the pilot and also be considered as an input for this indicator.

b) Sampling

The duration of all witnessed MDSAP audits undertaken during the Pilot period will be taken into account.

c) Source of document used as reference

MDSAP AU P0008 - Audit Time Calculation Procedure

MDSAP AU F0008.1 - Audit Time Calculation Spreadsheet

d) Methodology

Assessor feedback will be evaluated to determine the minimum time spent on MDSAP audit tasks divided by the expected and calculated minimum audit duration.

(If actual audit time consistently exceeds the minimum audit duration then a change to the calculated audit duration should be investigated)

e) Targets

Time spent in MDSAP audits should be at minimum the time calculated according to the audit duration procedure and should not exceed calculated time by 20%.

2.2.6 Performance Indicator 6 – Recognition of Applicant Auditing Organisations

a) Collection of data

The Assessment Program Manager will supply information about the application review, initial assessments at the head office, critical locations and witnessed audits for candidate Auditing Organisations that occurred during the pilot.

b) Sampling

All candidate Auditing Organisations will be sampled.

c) Source of document used as reference

MDSAP AS F0005.2 - AO Assessment Program Management File

d) Methodology

The number of MD Licences supported by a CMDCAS/ MDSAP QMS cert from a Registrar, that is also a candidate AO, divided by the number of Health Canada Medical Device Licences.

e) Targets

The objective will be considered met if:

- a sufficient number of AOs recognized that would provide credible level of third party coverage of manufacturers, equivalent to 75% of Health Canada's medical device licences

2.2.7 Performance Indicator 7 – Participation by Manufacturers

a) Collection of data

The candidate Auditing Organisations will supply information about the total number of their existing CMDCAS clients and about the number of clients (existing and new) who have applied for participation in MDSAP during the pilot.

b) Sampling

All candidate AOs will be requested to provide the information.

c) Source of document used as reference

N/A

d) Methodology

The number of MDMs that apply to any candidate AO for participation in MDSAP, divided by the total number of CMDCAS clients of candidate AOs.

e) Targets

The objective will be met if:

- The number of MDMs that apply for participation in MDSAP represents more than 10% of the number of candidate AO's CMDCAS clients.

2.3 Assumptions

The execution of the MDSAP Pilot Project Acceleration Plan and the collection of metrics for analysis to support the pilot success as described in this document are contingent on (among others) sufficient:

- Participation by anticipated CMDCAS registrars;
- Preparation by participating CMDCAS registrars to be available for assessment activities at planned intervals;
- Participation by regulated medical device manufacturers; and,
- Availability of monetary and human resources by all participating regulatory authorities to accomplish planned assessment activities.

All of these variables (and others) may adversely impact the implementation and completion of the MDSAP Pilot Study and, in turn, the analysis of the Pilot Study described in this document.

Section 3. Attachment

3.1 Attachment 1: MDSAP F0007.1.002 Audit Report Evaluation Assessment Tool

Section 4. Document History

VERSION NO.	VERSION DATE	DESCRIPTION OF CHANGE	AUTHOR NAME/PROJECT MANAGER
001	2014-08-11	Initial Release	Alba M. C. L. Pismel
002	2014-08-26	Deleted paragraph listed under 2.2.2 d) methodology "…the point…regulator…" as per comment AP4 page 8 draft document. Updated index with 2.2.2 and 2.23. No transmittal will be submitted due that the change was a part of the initial comments before approved.	Liliane Brown
003	2017-02-24	The minimal score for compliance of the Performance Indicator 1 was changed from 90 to 80 points; Excluded Performance Indicator 2; Change in the item 2.2.3 (turns 2.2.2) a) Collection of data, b) Sampling and c) Methodology Changes on the Attachment 1: Audit Report Evaluation Assessment Tool: The tool was simplified and moved to an Excel file with automatic grade calculation.	Patricia Serpa / Maria Angela da Paz

Version 003

Approval

Approved: Signature on file_____ Date: 2017-03-02

CHAIR, MDSAP RAC