Medical Device Single Audit Program (MDSAP)

Mid-Pilot Status Report

(MDSAP Pilot Study: 01 January 2014 – 31 December 2016)

Purpose: The purpose of this report is to document the mid-pilot status of the objectives and performance goals defined to develop the infrastructure, processes, training, and stakeholder commitment necessary to launch the operational phase of the Medical Device Single Audit Program (MDSAP) on 01 January 2017.

Goal: The goal of the Medical Device Single Audit Program (MDSAP) Pilot Study is to provide objective evidence confirming "proof-of-concept" that a regulatory audit of a medical device manufacturer conducted by an MDSAP recognized auditing organization (AO) can fulfill the needs of multiple regulatory jurisdictions (Australia, Brazil, Canada, Japan, and the United States of America).

A. STATUS OF MDSAP PILOT ACCELERATED PROJECT PLAN OBJECTIVES:

(1) The MDSAP recognition of Canadian Medical Device Conformity Assessment System (CMDCAS) auditing organizations

a. Application review and Head Office Assessments: 3-5 AOs by May 2014, 3-5 AOs by December 2014, 3-5 AOs by May 2015, and any remainder of the 13 CMDCAS AOs by December 2015

Table 1 demonstrates that the first six month target for application reviews and assessments of head offices was met. However, the second six month target fell short by one auditing organization; and the third six month target fell short by two auditing organizations. All thirteen (13) eligible CMDCAS registrars have committed to submitting applications prior to the conclusion of calendar year 2015. Table 2 lists the projections of the remaining seven CMDCAS registrars that will be applying in 2015. It is anticipated that application reviews and assessments of the head offices of all eligible CMDCAS registrars will be complete prior to the conclusion of the MDSAP Pilot.

Table 1 – Status of Auditing Organizations Authorized to conduct MDSAP Audits as of July 2015

Auditing Organization (AO)	Application Receipt	Head Office Assessment	Witnessed Audits	Surveillance Assessment 1
BSI Group America Inc.	2014 01 03	2014 02 25-28	WA 1 2014 09 22-25 WA 2 2015 04 14-17 WA 3 2015 05 12-20	2015 02 24-26
TŰV SŰD America Inc.	2014 01 09	2014 03 11-14	WA 1 2014 10 14-17 WA 2 2015 01 19-23 WA 3 2015 04 28-29	2015 04 07-10
SAI Global Cert. Services PTY Ltd.	2014 01 27	2014 05 26-29	WA 1 Voluntary moratorium WA 2 Voluntary moratorium WA 3 Voluntary moratorium	Voluntary moratorium

LNE G-MED	2014 04 30	2014 10 20-24	WA 1 2015 07 20-23 WA 2 TBD WA 3 TBD	2015 10 20-22
TŰV USA Inc.	2014 06 10	2014 08 05-08	WA 1 TBD WA 2 TBD WA 3 TBD	2015 08 17-19
Intertek Testing Services NA Inc.	2014 09 30	2015 02 24-27	WA 1 2015 09 29-10 02 WA 2 TBD WA 3 TBD	2016 02 TBD

Table 2 – Status of Auditing Organizations awaiting authorization to conduct MDSAP Audits as of July 2015

Auditing Organization (AO)	Application Receipt (or Target)	Head Office Assessment	Witnessed Audits	Surveillance Assessment 1
UL, LLC	2014 04 02	TBD	TBD	TBD
DQS MED GmbH	(2015 07 31)	TBD	TBD	TBD
NSAI	(2015 08 31)	TBD	TBD	TBD
TŰV Rheinland of NA Inc.	(2015 07 31)	TBD	TBD	TBD
DEKRA Certification B.V.	(2015 09 30)	TBD	TBD	TBD
SGS UK Ltd.	(2015 12 01)	TBD	TBD	TBD
LRQA Inc.	(2015 12 31)	TBD	TBD	TBD

b. Witness Audits for each of the respective 3-5 AOs within 6 months of their Head Office Audit

Table 1 demonstrates that although witnessed audits were not scheduled within six months of the Head Office audits, two of the six auditing organizations that are authorized to conduct MDSAP audits have completed all three prerequisite (to recognition) witnessed audits; and two of the remaining auditing organizations authorized to conduct MDSAP audits have completed or have scheduled their first witnessed audit. On 17 July 2015, one AO entered a voluntary moratorium regarding engagement in the program.

c. Completion of several Surveillance Assessments of AOs prior to the completion of the Pilot.

Table 1 demonstrates that two surveillance assessments have been completed to date with an additional surveillance assessment scheduled to be completed by 19 August 2015. All surveillance assessments have been accomplished or are scheduled to be accomplished within target timeframes.

d. Recognition of an AO will occur after successful application review and completion at a minimum of one (1) successful certification assessment and at a minimum one (1) successful assessment by the MDSAP Regulatory Authority(ies) during a witness audit of the AO auditing a medical device manufacturer(s) using the MDSAP audit process and reporting requirements.

This objective has been modified to establish more stringent recognition criteria (e.g. three prerequisite witnessed audits v. one as originally planned) consistent with IMDRF/MDSAP WG/N11 FINAL: 2014[1]. A technical review[2] of assessment activities will be conducted at the conclusion of the pilot to confirm prerequisite MDSAP recognition requirements have been met. Two of the six auditing organizations that are authorized to conduct MDSAP audits have completed all prerequisite recognition requirements including three witnessed audits.

(2) The analysis and evaluation of the results of the implementation of MDSAP program requirements and processes to confirm "proof-of-concept".

Program performance indicators, prospective target results, performance measurements and metrics have been established[3] and summarized in Table 3. Data is being generated, analyzed, and archived. Results will be used to support final approval of the program; as well as changes to the program. Progress against these targets is summarized below.

(3) The identification and correction of existing and potential weaknesses within the MDSAP program based on study findings.

A comprehensive MDSAP quality management system has been established[4]; and policies and procedures have been posted to the web. This QMS includes policies and procedures for complaints and feedback; internal assessments of MDSAP processes; dispute resolution; as well as, corrective and preventive action. Internal and external stakeholders are encouraged to use the processes defined in the MDSAP QMS to communicate concerns.

On 23 June 2015, an MDSAP Forum was held. The forum included representatives of the participating regulatory authorities, auditing organizations, and manufacturers that have participated in the program to date. As a result of forum discussions (as well as subsequent discussions with AOs and regulatory authorities), fifteen (15) specific areas of MDSAP program concern were identified. Forty-six (46) specific tasks were identified to address these concerns. Initial solutions to these concerns have been identified and Deliverable Development Teams have been assigned to investigate the feasibility of these solutions and propose final solutions.

(4) Enable a fully operational program no later than 2016.

Two auditing organizations have completed the prerequisite MDSAP recognition requirements. Objective evidence relative to the completion of these assessment activities (demonstrating requirements have been met) will be assembled and reviewed by a Technical Review and Recognition Committee (TRRC). Prior to the conclusion of the pilot, final recommendations will be provided to the

[1] MDSAP Assessment and Decision Process for the Recognition of an Auditing Organization

[2] MDSAP AS P0017 Technical Reviews and Recognition Decision Making

[3] MDSAP P0007.002 Proof of Concept for MDSAP Pilot

[4] MDSAP QMS Procedures and Forms

Regulatory Authority Council[5] for a final recognition decision. An additional four auditing organizations are on schedule to complete all prerequisite MDSAP recognition requirements and have a recognition decision rendered prior to the conclusion of the pilot. Seven auditing organizations (Table 2) will be in various stages of assessment at the conclusion the Pilot. It is feasible that a percentage of these auditing organizations will complete all prerequisite MDSAP recognition requirements prior to 31 December 2016. As of 01 January 2017, MDSAP will be open to additional Auditing Organization applicants outside of the Health Canada CMDCAS registrars.

B. STATUS OF EACH PROOF OF CONCEPT CRITERION CITED IN MDSAP P0007.002 PROOF OF CONCEPT FOR MDSAP PILOT:

Table 3 – MDSAP Proof of Concept Criteria (PoCC)

PoCC No.	Performance Indicator	Targets	Performance Measurement	Metric
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 & Exchange Form	# of satisfactory reports / # reports evaluated
2.	Whether the evidence provided in audit and nonconformity reports, for **common** QMS requirements, supports the findings and NC grades	> 80% consistency in the conclusions of the regulators	By a comparison of the evaluations of audit evidence and NC grading performed by different RA on the **same** sampled reports	# consistent reports among regulators / # reports on which comparison was performed
3.	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	# reports suitable for regulatory decisions / # reports evaluated by RAs
4.	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	# of audit tasks requiring corrections / # of audit model tasks
5.	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	# of assessment tasks for which a NC is raised / # of assessment model tasks
6.	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	duration of witnessed audit / calculated MDSAP audit duration
7.	Whether a sufficient number of candidate AOs are recognised	> 75% of Health Canada MD Licences could be assessed by candidate AOs	By determining the # of MD Licenses supported by a CMDCAS/ MDSAP QMS cert from a Registrar that is a candidate AO	# of MDL supported by CMDCAS / MDSAP AO cert / # of MDLs

[5] MDSAP P0009.006: Regulatory Authority Council (RAC) Appointment

8.	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	# of MDMs that have applied to participate / # of CMDCAS clients of all candidate AOs

PoCC 1 (> 70% of the sampled and evaluated reports comply): As of 23 July 2015, approximately ten (10) MDSAP audits of medical device manufacturers have been conducted; and six (6) audit report packages have been received. The participating regulatory authorities are completing reviews of the reports that have been received to date using MDSAP F0007.1.001 Audit Report Evaluation Assessment Tool. No final evaluations of reports by participating regulatory authorities are complete. It is too early to project whether target goals will be met.

PoCC 2 (> 80% consistency in the conclusions of the regulators): As of 23 July 2015, approximately ten (10) MDSAP audits of medical device manufacturers have been conducted; and six (6) audit report packages have been received. The participating regulatory authorities are completing reviews of the reports that have been received to date using MDSAP F0007.1.001 Audit Report Evaluation Assessment Tool; and Nonconformity Grading and Exchange forms (NCGEFs) are also being evaluated. No final evaluations of reports by participating regulatory authorities are complete. It is too early to project whether target goals will be met.

PoCC 3 (> 80% of reports evaluated would substantiate regulatory decisions): As of 23 July 2015, approximately ten (10) MDSAP audits of medical device manufacturers have been conducted; and six (6) audit report packages have been received. The participating regulatory authorities are completing reviews of the reports that have been received to date using MDSAP F0007.1.001 Audit Report Evaluation Assessment Tool. Nonconformity Grading and Exchange forms (NCGEFs) are also being evaluated. No final evaluations of reports by participating regulatory authorities are complete. It is too early to project whether target goals will be met.

PoCC 4 (< 5% of audit model tasks requires a correction or corrective action): As of 23 July 2015, no requests have been received from AOs or RAs to adjust the audit model tasks or audit model process or task sequence. The performance target of less than 5% of audit model tasks requiring correction or corrective action is being met. During the MDSAP forum, challenges were expressed by AO representatives regarding the application of the MDSAP audit model to team audits. The MDSAP team is investigating solutions to this concern.

PoCC 5 (< 25% of assessment model tasks require a correction or corrective action): As of 23 July 2015, no requests have been received from AOs or RAs to adjust the assessment model tasks or assessment model process or task sequence. The performance target of less than 25% of audit model tasks requiring correction or corrective action is being met.

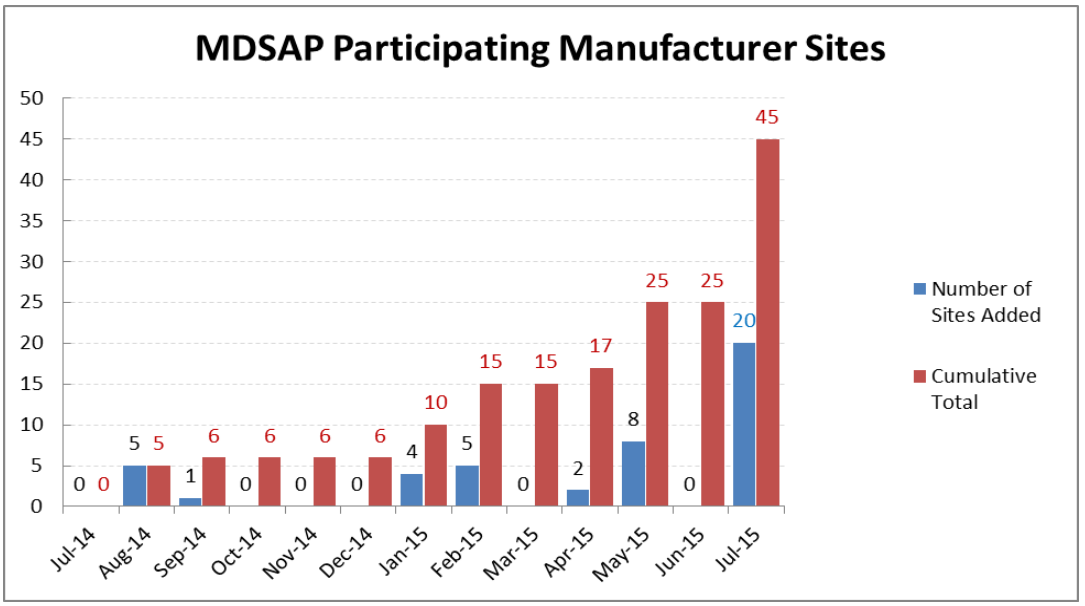
PoCC 6 (The duration for an MDSAP audit is ≥ 100% and ≤ 120% of the calculated duration): As of 23 July 2015, there have been seven (7) witnessed audits. All witnessed audits were accomplished within calculated audit times. No adjustments to calculated audit times were necessary. During the MDSAP

forum, challenges were expressed regarding the calculation of the time necessary to conduct surveillance audits. The scope of a surveillance audit as defined by MDSAP is less predictive than MDSAP certification and recertification audits. The MDSAP team is investigating solutions to this concern. To date, we are meeting target performance goals.

PoCC 7 (> 75% of Health Canada MD Licenses could be assessed by candidate AOs): Of the thirteen (13) eligible CMDCAS registrars (AOs), six (6) have been authorized to conduct MDSAP audits. Of the six AOs authorized to conduct MDSAP audits, one (1) has voluntarily entered a moratorium regarding program participation. The remaining five (5) AOs authorized to conduct MDSAP audits account for the certification of approximately 60% of the approximate 3.3k Health Canada licensed manufacturers of Class II, III, and IV devices (subject to annual audit). With the participation of the remaining auditing organizations in 2015, it is feasible the target of 75% of Health Canada licensed manufacturers of Class II, III, and IV devices being assessed by MDSAP auditing organizations can be met at the conclusion of the pilot. The potential exists for approximately 97.9% of Health Canada licensed manufacturers of Class II, III, and IV devices being assessed by MDSAP auditing organizations at the conclusion of the pilot – based on the projected 2015 application commitments. Although the current coverage of 60% is encouraging, at this point in time, it is too early to project whether target goals will be met.

PoCC 8 (The number of MDMs that have applied to participate is >10% of a candidate AO's CMDCAS clients): As of 23 July 2015, forty-five (45) medical device manufacturing sites have requested participation in the MDSAP program. Table 4 demonstrates the progression (over time) of the participation of medical device manufacturing sites in the program. As more AOs become authorized to conduct MDSAP audits, a continuation of the positive slope is anticipated. It is too early to project whether target goals will be met.

Table 4



Conclusions:

Accelerated Project Plan Objectives:

Of the seven (7) accelerated project plan objectives, two (2) do not impact the viability of the MDSAP program beyond the achievement of target timeframes (1a – 1b). The timeframes defined in these objectives were dependent on AOs fulfilling commitments (e.g. application package submission, Stage 1 document submissions, etc.). Although the MDSAP team encouraged the AOs to fulfill these commitments, the MDSAP development team did not have ultimate control of the completion of these commitments. The mid-pilot status of objectives 1a – 1b will not negatively impact the final viability of the program.

The remaining five (5) project plan objectives are complete or are on schedule to be completed as planned.

Proof of Concept Criteria:

Of the eight (8) proof of concept criteria (PoCC), three have met target goals to date (PoCC No.s 4, 5, and 6); one (1) is on track to meet target goals (PoCC No. 7) by the end of the pilot; four (4) have not generated enough data and analysis to draw a conclusion (PoCC No.s 1-3, 8).

PoCC No.s 1-3 relate to the AOs' compliance with the policies and procedures relating to, and the effectiveness of, MDSAP audit reports and Nonconformity Grading and Exchange Forms. These are standardized fillable format forms that are unique the MDSAP program. Although the reports to date have not been completely analyzed against PoCC requirements, each report generated as a result of a witnessed audit has been assessed for compliance to applicable MDSAP policies and procedures. These initial assessments have led to nonconformities relative to report content as well as compliance with other policy and procedural requirements (e.g. one report representing multiple sites). This is an area where challenges were expected. Audit reporting to satisfy four (4) regulatory authorities is not something the AOs have experience with. We are monitoring the progress of each AO to assure the trend is moving consistently towards compliance with audit report policies and procedures. More experience is still needed in these areas.

PoCC No. 8 relates to the number of medical device manufacturing sites electing to participate in the program. Although Table 4 demonstrates a favorable trend, there is still one key factor affecting this outcome - manufacturer commitment to utilizing the program in order to decrease regulatory audits. The PoCC target of 10% means approximately three-hundred-thirty (330) medical device manufacturing sites have to express an interest in participating in the program by the end of 2016. As of 23 July 2015, forty-five (45) manufacturing sites have expressed interest in participating in the program. Program participation by medical device manufacturers appears to be the primary challenge at the mid-pilot review. **Manufacturer participation is vital for the success of the program.**