Medical Device Single Audit Program (MDSAP)

Final Pilot Report: 29 June 2017

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

Purpose: The purpose of this report is to document the final 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).

Goal: The goal of the Medical Device Single Audit Program (MDSAP) Pilot Study was 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 (i.e. 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 lists the status of all thirteen (13) participating AOs as of 31 December 2016 (conclusion of the Pilot).

- Three (3) AOs have completed all recognition criteria and are recognized to conduct independent MDSAP audits on behalf of the coalition of regulatory authorities.
- Eight (8) AOs have obtained authorization to conduct the three (3) specified Witnessed Audits in support of recognition; and are at various stages of completion of the three (3) specified Witnessed Audits.
- Two (2) AOs have completed Stage 2 assessment and are awaiting authorization to conduct the three (3) specified Witnessed Audits. This authorization will be granted upon satisfactory completion of Stage 1 and Stage 2 nonconformity (NC) responses, as applicable.

The first six month target (January 2014 – May 2014) for completion of application reviews and head office assessments was met. However, the second six month target (June 2014 – December 2014) fell short by one AO and the third six month target (January 2015 – June 2015) fell short by two AOs. No additional AOs underwent completion of both an application review and a Head Office assessment during the fourth six month target (July 2015 – December 2015). This performance target was not met.

Although not all target dates were met, application reviews and Head Office assessments for all thirteen (13) eligible CMDCAS registrars were completed prior to the conclusion of the MDSAP Pilot.

Table 1 – Status of Auditing Organizations as of 31 December 2016

Auditing Organization (AO)	Application Receipt	Head Office Assessment	Witnessed Audits Complete or Scheduled	Surveillance Assessment 1/2
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 2016 02 16-18
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 2016 04 06-08
Intertek Testing Services NA Inc.*	2014 09 30	2015 02 24-27	WA 1 2015 11 03-01 WA 2 2016 01 26-29 WA 3 2016 06 05-10	2016 03 28-30
LNE G-MED**	2014 04 30	2014 10 20-24	WA 1 2015 07 20-23 WA 2 2015 03 14-21 WA 3 TBD	2015 10 20-22 2016 11 02-04
SAI Global Cert. Services PTY Ltd.**	2014 01 27	2014 05 26-29	WA 1 2016 08 15-19 WA 2 TBD WA 3 TBD	2016 09 21-23
TŰV USA Inc.**	2014 06 10	2014 08 05-08	WA 1 2016 10 17-21 WA 2 2017 05 or 06 (TBD) WA 3 TBD	2015 08 17-19 2016 10 10-11
DQS MED GmbH**	2015 10 21	2016 04 25-28	WA 1 2017 01 23-27 WA 2 TBD WA 3 TBD	2017 04 26-28
DEKRA Certification B.V.**	2015 12 11	2016 04 04-07	WA 1 2017 02 06-10 WA 2 TBD WA 3 TBD	2017 04
UL, LLC**	2014 04 02	2016 08 08-12	WA 1 2016 10 03-07 WA 2 2016 12 19-23 WA 3 2017 02 13-17	2017 08 14-18
SGS UK Ltd.**	2015 10 21	2016 09 26-30	WA 1 2106 11 15-12 01 WA 2 TBD WA 3 TBD	2017 09
TŰV Rheinland of NA Inc.**	2015 09 29	2016 05 31 – 06 03	WA 1 2017 02 06-10 WA 2 2017 03 13-17 WA 3 2017 03 20-24	2017 05
NSAI***	2016 03 21	2016 06 27-30	WA 1 TBD WA 2 TBD WA 3 TBD	2017 06

LRQA Inc.***	2015 11 23	2016 04 11-14	WA 1 TBD WA 2 TBD WA 3 TBD	2017 04

* Completed all recognition criteria

** Authorized to conduct Witnessed Audits to support recognition

*** Upon satisfactory closure of all Nonconformities (NCs) cited in Stage 1 and Stage 2, Regulatory Authorities (RAs) to grant authorization to conduct Witnessed Audits

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 assessments, three (3) of the eleven (11) auditing organizations that are authorized to conduct MDSAP audits have completed all three prerequisite (to recognition) Witnessed Audits; and two (2) of the remaining auditing organizations authorized to conduct MDSAP audits completed two (2) Witnessed Audits. All AOs authorized to conduct MDSAP audits have at least one Witnessed Audit scheduled. Two (2) AOs awaiting authorization to conduct Witnessed Audits have not scheduled any Witnessed Audits. This performance target was not met. Variables affecting the scheduling of Witnessed Audits are beyond the control of the MDSAP development team.

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

Table 1 demonstrates that ten (10) surveillance assessments (six (6) Surveillance 1 and four (4) Surveillance 2) were completed prior to the conclusion of the Pilot. This performance target was met.

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 consistent with IMDRF/MDSAP WG/N11 FINAL: 2014[1] (i.e. three prerequisite Witnessed Audits v. one as originally planned). Three (3) of the eleven (11) auditing organizations that are authorized to conduct MDSAP audits have completed all prerequisite recognition requirements including three (3) Witnessed Audits. A technical review[2] has been held for three (3) of the AOs and recommendations for recognition have been approved. This performance target was met.

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

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

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

Program performance indicators, prospective target results, performance measurements and metrics have been established[3] and summarized in Table 2. Data has been (and continues to be) 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. This performance target was met.

(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. All policies and procedures have been updated to reflect changes necessitated by the implementation of ISO/IEC 17021-1:2015 and ISO 13485:2016.

On 23 June 2015 and 21 June 2016, MDSAP Fora were held. The fora included representatives of the participating regulatory authorities, auditing organizations, and manufacturers that have participated in the program to date. As a result of fora discussions (as well as subsequent discussions with AOs and regulatory authorities), fifteen (15) specific areas of MDSAP program concern were identified. Over eighty (80) specific tasks were identified to address these concerns. Initial solutions to most of these concerns have been identified and implemented; and Deliverable Development Teams have been assigned to investigate proposed final solutions for the remaining concerns.

On 08 – 10 December 2015 and 12 – 15 December 2016, Auditing Organization/Regulatory Authority meetings were held. These meetings included representatives of all participating auditing organizations and regulatory authorities. As a result of meeting discussions, eleven (11) general areas of MDSAP program questions or concerns were identified; with approximately fifty (50) specific questions or concerns cited. Initial solutions to most of these concerns have been identified and implemented; and Deliverable Development Teams have been assigned to investigate proposed final solutions for the remaining concerns.

Examples of changes made based on Pilot results include revisions to the MDSAP Audit Model and Companion Document; revision of the Audit Time Calculation Procedure; and automatic notifications (RSS) have been established when webpage changes are made. This performance target was met.

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

Three (3) auditing organizations have completed the prerequisite MDSAP recognition requirements. Objective evidence relative to the completion of these assessment activities (demonstrating requirements have been met) was assembled and reviewed by a Technical Review and Recognition Committee (TRRC)[2]. Final recommendations for the recognition of these three (3) auditing organizations

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

[4] MDSAP QMS Procedures and Forms

have been approved by the Regulatory Authority Council[5]. An additional four (4) auditing organizations are on schedule to complete all prerequisite MDSAP recognition requirements and have a recognition decision rendered prior to 30 September 2017. Six (6) auditing organizations are completing Witnessed Audit obligations; and are targeted for recognition in CY 2017. Although not at full capacity, MDSAP was operational on 01 January 2017. As of 01 January 2017, MDSAP was open to additional Auditing Organization applicants outside of the Health Canada CMDCAS registrars. This performance target was met.

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

Table 2 – 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~~	Prior to the conclusion of the Pilot, PoCC No. 2 was eliminated. Please refer to discussion below.	~~By a comparison of ons of nce and NC by different RA on the **same** sampled reports~~	~~# consistent reports among regulators / # reports on which comparison was performed~~
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	# reports "fit for purpose" for all RAs / # reports evaluated by RAs
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	# of audit tasks requiring corrections / # of audit model tasks
4.	Whether the assessment model and task sequence appropriately assesses MDSAP	< 25% of assessment model tasks require a correction or	By RA self-evaluation and AOs feedback about the application	# of assessment tasks for which a NC

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

	requirements	corrective action	of the assessment tasks at HO, CL assessments and at witnessed audits	is raised / # 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	duration of witnessed audit / calculated MDSAP audit duration
6.	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
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	# of MDMs that have applied to participate / # of CMDCAS clients of all candidate AOs

PoCC 1 (> 70% of the sampled and evaluated reports comply): During the MDSAP Pilot, one-hundred-seventy-two (172) audit reports were generated. A statistical method based on a population proportion formula was used to determine the sample size of reports to be evaluated. Based on this statistical method, one-hundred-eight (108) audit reports were randomly sampled and evaluated according to MDSAP F0007.1.002 "Audit Report Evaluation Assessment Tool". The result of the evaluation showed that 88% of the audit reports complied with specified MDSAP policies and expectations. This performance target was met.

Original PoCC 2 (> 80% consistency in the conclusions of the regulators): Prior to 31 December 2016, it was determined that since each regulatory authority reviews audit reports against different regulatory criteria, it was not possible for regulatory authorities to reach consistency in report review conclusions. It was determined that this PoCC would be eliminated.

PoCC 2 (> 80% of reports evaluated would substantiate regulatory decisions): MDSAP audit reports that included the regulatory requirements of all five (5) participating regulatory jurisdictions* within the audit criteria; and that were generated between 01 February 2016 and 31 December 2016** were selected for this evaluation. In total, ninety-three (93) audit reports that met selection criteria were issued during this period. Based on our statistical methodology, sixty-one (61) audit reports were

randomly sampled for evaluation. Each audit report was evaluated by each of the four (4) remaining Regulatory Authorities (sans Health Canada) to determine if the reports could be used to support regulatory decisions. The cumulative results of this evaluation demonstrated that of the sample of sixty-one (61) audit reports, thirty-six (36) could be used for regulatory decisions by all four (4) regulatory authorities participating in this evaluation. This represents 59% of the total reports evaluated. This performance target was not met cumulatively. However, individual evaluation results demonstrated that the evaluated reports met specified acceptance criteria for three (3) of the four (4) participating regulatory authorities.

* It was subsequently determined that Health Canada would be excluded from this Performance Indicator evaluation. Health Canada receives and reacts to QMS Certificates for regulatory decisions (as opposed to audit reports).

** MDSAP audit reports generated after 01 February 2016 included Japanese requirements (where applicable).

PoCC 3 (< 5% of audit model tasks require a correction or corrective action): As of 31 December 2016, no formal requests have been received from AOs or RAs to adjust the audit model tasks or audit model process or task sequence. Revisions were made to the audit model and companion document based on revisions to ISO 13485:2016; as well as to eliminate duplicative audit tasks. This performance target was met.

PoCC 4 (< 25% of assessment model tasks require a correction or corrective action): As of 31 December 2016, no formal requests have been received from AOs or RAs to adjust the assessment model tasks or assessment model process or task sequence. Due to anecdotal reports and ancillary document revisions, revisions to the assessment model will be investigated. This performance target was met.

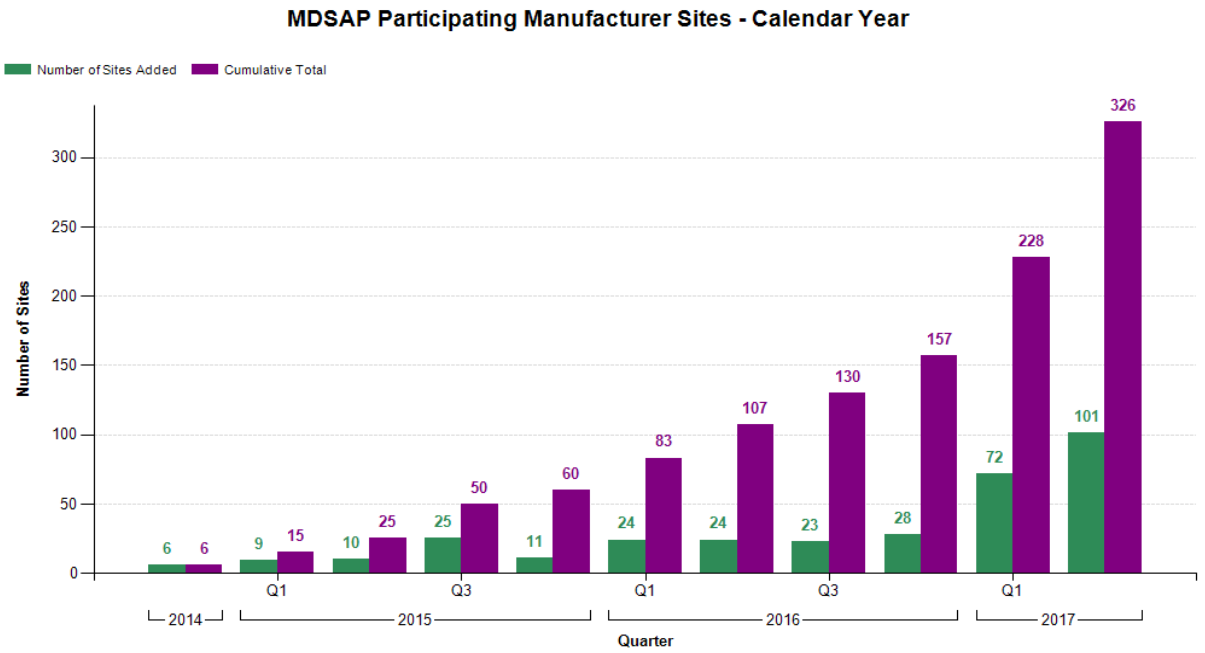
PoCC 5 (The duration for an MDSAP audit is ≥ 100% and ≤ 120% of the calculated duration): As of 31 December 2016, there have been sixteen (16) witnessed audits. All witnessed audits were accomplished within calculated audit times; or, voluntarily terminated early by the manufacturer (n = 1). No other adjustments to calculated audit times were necessary. The performance target was met.

PoCC 6 (> 75% of Health Canada MD Licenses could be assessed by candidate AOs): Of the thirteen (13) eligible CMDCAS registrars (AOs), eleven (11) have been authorized to conduct MDSAP audits – a percentage of which must be witnessed by regulatory authority representatives. These eleven (11) AOs account for the certification of approximately 95% of the approximate 3,300 Health Canada licensed manufacturers of Class II, III, and IV devices (subject to annual audit). The performance target was met.

PoCC 7 (The number of MDMs that have applied to participate is >10% of a candidate AOs CMDCAS clients): As of 31 December 2016, One-hundred-sixty-one (161) medical device manufacturing sites have requested participation in the MDSAP program. Table 3 demonstrates the progression (over time) of the participation of medical device manufacturing sites in the program. Four (4) sites cited in CY 17 Q1 notified the program of participation in CY 16 Q4; and were not added to the tally until CY 17 Q1 due to end of CY 16 personnel holiday leave impacting data input. One-hundred-sixty one (161) participating

sites represent less than five (5) % of the approximately 3,300 Health Canada licensed manufacturers of Class II, III, and IV devices (subject to annual audit). For this PoCC, all sites were assumed to be CMDCAS participants. This performance target was not met.

Table 3



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 development team encouraged the AOs to fulfill these commitments, the MDSAP team did not have ultimate control over the completion of these commitments. The final pilot status of objectives 1a – 1b do not negatively impact the final viability of the program.

The remaining five (5) project plan objectives are complete and met performance targets.

Proof of Concept Criteria:

Of the eight (8) proof of concept criteria (PoCC), one (1) was eliminated as it was determined that since each regulatory authority reviews audit reports against different regulatory criteria, it was not possible for regulatory authorities to reach consistency in report review conclusions (original PoCC No.2); five (5) have met performance targets (PoCC No.s 1, 3, 4, 5, and 6); and, two (2) did not meet its performance target (PoCC No. 2 and PoCC No. 7 – discussed below).

PoCC No. 2 relates to the use of audit reports to substantiate regulatory decisions. Although this performance target was not met *cumulatively*, evaluation results demonstrated MDSAP audit reports met the acceptance criteria for three (3) of the four (4) *individual* regulatory authorities that base regulatory decisions on findings documented within audit reports. In addition, a qualitative evaluation demonstrated that many reports that did not originally meet acceptance criteria could be used for regulatory decisions after obtaining additional information/clarification from the auditing organizations. Program changes have been implemented to mitigate deficiencies identified in the audit reports. For example, two annexes have been added to the MDSAP Audit Model (i.e. "Audit of Technical Documentation" and "Audit of Requirements for Sterile Medical Devices"); and the standardized audit report template was revised to provide additional specificity.

PoCC No. 7 relates to the number of medical device manufacturing sites electing to participate in the program. Although Table 3 demonstrates a favorable trend, there is still one key factor affecting this outcome - manufacturer commitment to utilizing the program. The PoCC target of 10% meant approximately three-hundred-thirty (330) medical device manufacturing sites had to express an interest in participating in the program by the end of 2016. As of 31 December 2016, one-hundred-sixty-one (161) manufacturing sites have participated in the program.

Program participation by medical device manufacturers continues to be the primary challenge at the conclusion of the MDSAP Pilot (just as it was at the mid-Pilot review)***. It is anticipated that the 04 December 2015 Health Canada announcement of its plan to transition from CMDCAS to MDSAP[6] will continue to stimulate additional manufacturer participation. In order to assure a smooth transition from CMDCAS to MDSAP, manufacturers are encouraged to transition sooner than later. Early participation will help mitigate potential burdens on auditing organization capacities as the end of the transition period approaches.

***Following the conclusion of the Pilot, a positive trend in terms of the number of manufacturing sites seeking participation was identified (refer to Table 3, CY 17 Q1 and Q2). During the six (6) months since the conclusion of the Pilot, the number of participating manufacturing sites has doubled.

[6] http://www.hc-sc.gc.ca/dhp-mps/md-im/activit/int/mdsap-trans-notice-avis-eng.php