IMDRF International Medical Device Regulators Forum

Medical Device Single Audit Program (MDSAP) Pilot Update

Fábio P. Quintino

MDSAP RAC – Chair

Manager - Medical Devices, Sanitizing Products and Cosmetics inspection Office

General Office of Sanitary Inspection / ANVISA

MDSAP Pilot Consortium

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Observers

World Health Organization

- *03/2013*: Accelerated plan to develop the basic structure for the 3 year pilot program starting on 01/01/2014

- *Pilot started **13** eligible Auditing Organizations Acredited under the CMDCAS – Canadian Medical Device Conformity Assesment System*

AOs Authorized to Perform MDSAP Audits

1 - BSI Group America Inc.
2 - TŰV SŰD America Inc.
3 - SAI Global Cert. Services PTY Ltd.
4 - LNE G-MED
5 - TŰV USA Inc.
6 - Intertek Testing Services NA Inc.

AOs Audit Progress

Approximately fifty-eight (85) MDSAP audits of medical device manufacturers have been conducted up to August 2016

AOs Under Authorization Process

Auditing Organization (AO)	Head Office Assessment on Target
UL, LLC	2016-Aug
DQS MED GmbH	2016-Apr
NSAI	2016-Jun
TŰV Rheinland of NA Inc.	2016-May
DEKRA Certification B.V.	2016-Apr
SGS UK Ltd.	2016-Sep
LRQA Inc.	2016-Apr

Perspectives

It is anticipated that all application reviews and assessments for Authorization purposes will be completed for all eligible CMDCAS registrars prior to the conclusion of the MDSAP Pilot.

Perspectives

It is expected at this point that 1/3 of the auditing organizations under the pilot will complete all prerequisite MDSAP recognition requirements prior to 31 December 2016.

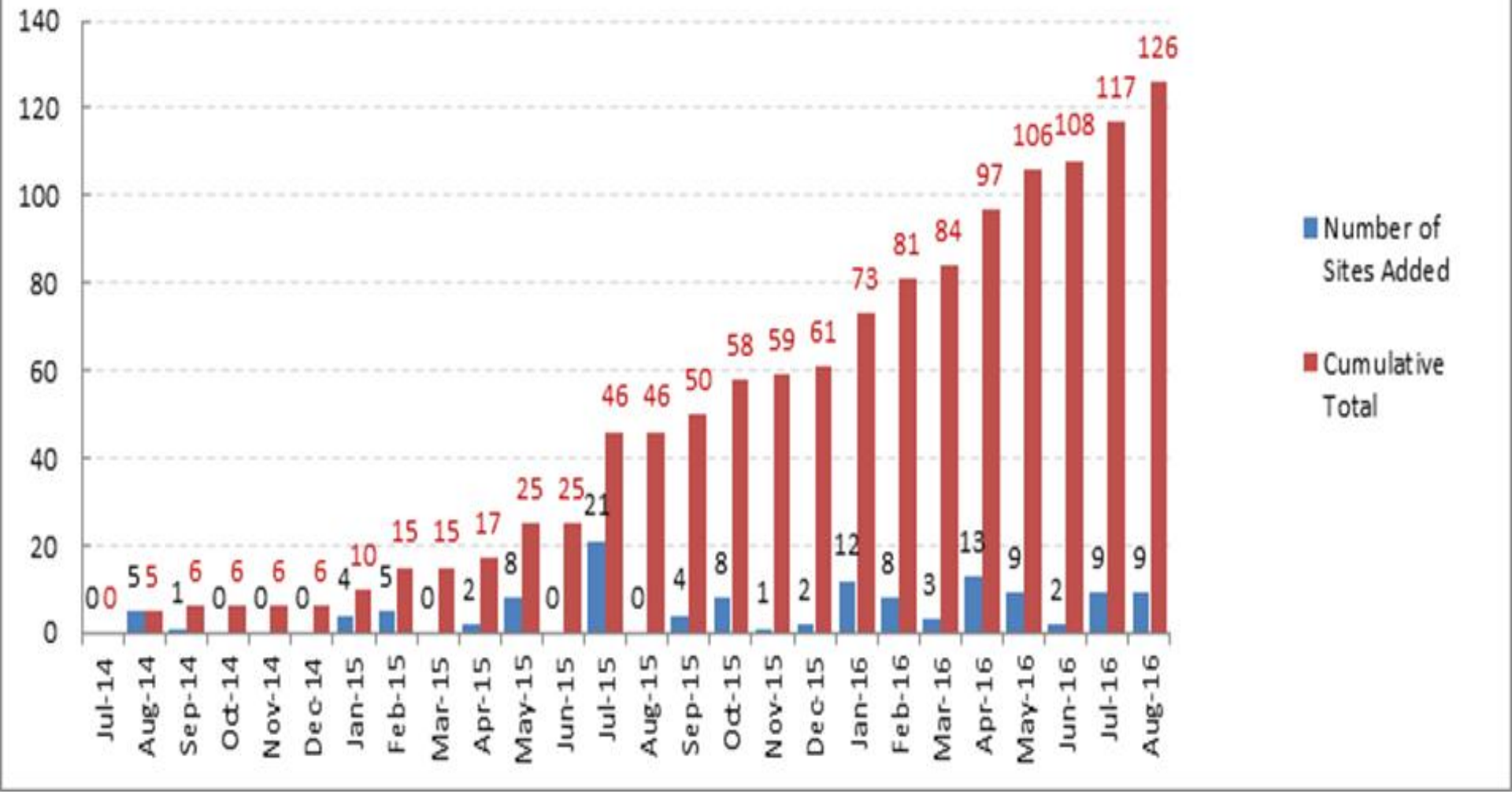
Perspectives

On 01 January 2017, MDSAP will be open to additional Auditing Organizations applicants other than the Health Canada CMDCAS registrars

Perspectives

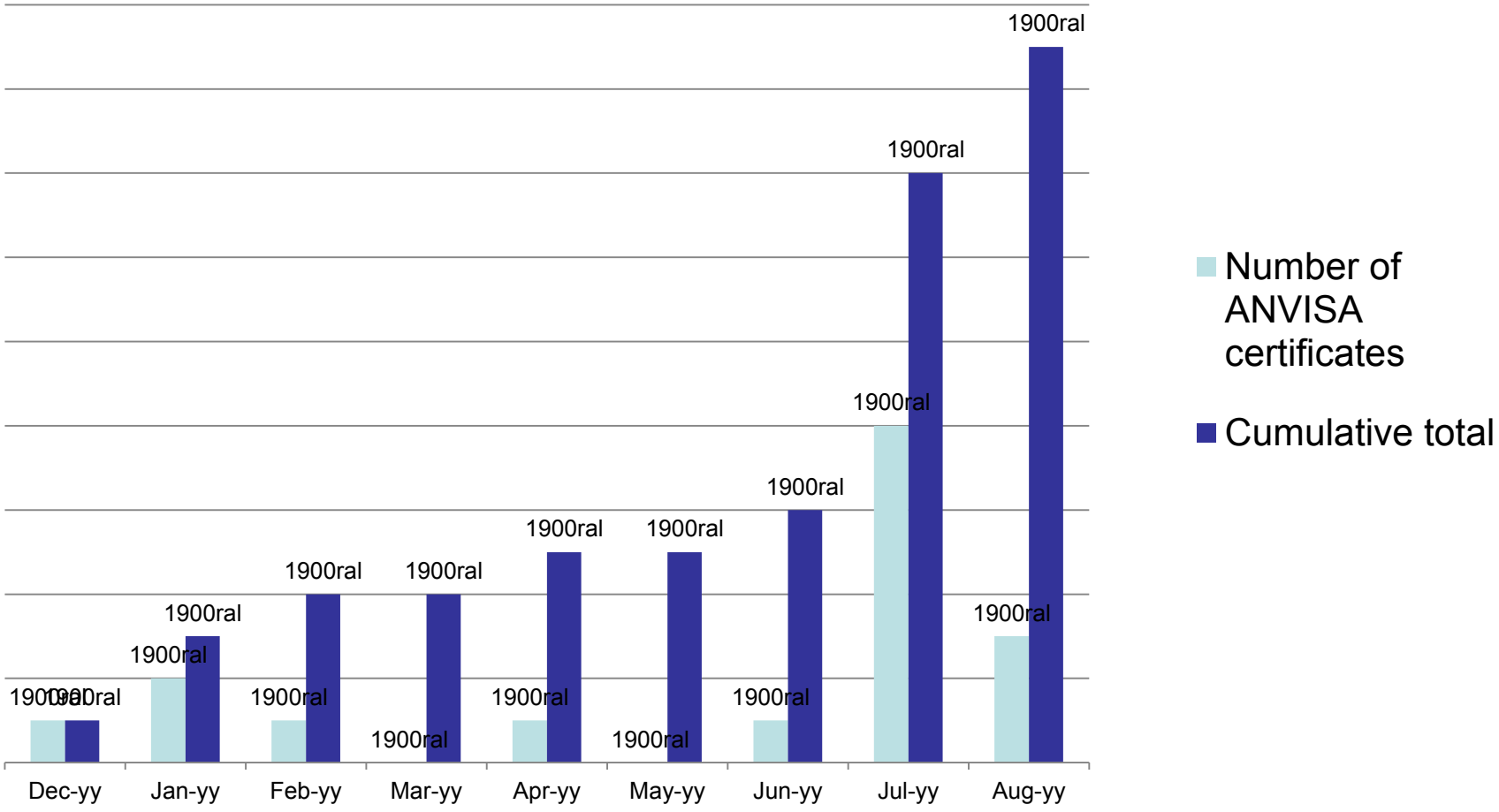
As more AOs become authorized to conduct MDSAP audits, a increase of the number of manufacturers in the program is anticipated.

MDSAP Participating Manufacturer Sites



Remarks from Participating RAs

Certificates issued by ANVISA using MDSAP reports



Trial acceptance of MDSAP audit reports in Japan

- By following a notification from MHLW issued in June 2016, PMDA reduces manufacturers' burden in its QMS inspection processes as a trial, when MDSAP audit reports are submitted. The trial period is from June 22nd to December 31st, 2016.
- The content of the trial includes reduction of manufacturer's QMS documents required to be submitted to PMDA for its off-site inspection.
- PMDA will perform the trial acceptance without any additional fee.
- MHLW/PMDA encourages manufacturers to participate in the trial and to provide feedback to it.
- Please see the details of the trial below:

http://www.pmda.go.jp/english/review-services/gmp-qms- gctp/0004.html

厚生労働省
Ministry of Health, Labour and Welfare

pmda

CHALLENGES

Consolidation and expansion of the program in the operational phase

Improve program attractiveness for manufacturers, including small and medium enterprises

Thank you