ISO13485 Certification for Medical Device Dealers in Singapore

Medical Devices Branch

2 March 2021

MD Dealers Control

Dealer's Licensing

Local companies who manufacture, import or supply devices by wholesale are required to be licensed by HSA

Types of Dealer License – based on company's activities

Local manufacturing	Importing	Wholesale (including export)
Manufacturer's License	Importer's License	Wholesaler's License

Pre-requisite

ISO certificate is a pre-requisite for Manufacturer's License

Manufacturer's License	Importer's License	Wholesaler's License
ISO 13485 certificate **OR** Declaration of conformity to a QMS (for Class A dealers only)	GDPMDS* SS 620** certificate **OR** ISO 13485 certificate (with scope of storage & distribution) **OR** Declaration of conformity to a QMS (for Class A dealers only)	

** Good Distribution Practice for Medical Devices*

*** Singapore Standard SS 620 : 2016 – Good Distribution Practice for Medical Devices - Requirements*

Accreditation for GDPMDS Certification

- All GDPMDS certification performed by 3rd party certification bodies (CBs)
  - Currently 10 accredited CBs
  - All CBs must be accredited by the Singapore Accreditation Council (SAC)

- Witnessed Assessment Program: Certification bodies issuing GDPMDS certificates shall be subjected to witnessed assessments by HSA
  - Ensure GDPMDS technical requirements are being appropriately applied
  - Develop consistency in interpretation amongst certification bodies

Accreditation for ISO13485 Certification

- Globally, medical device regulators are moving towards leveraging ISO13485 audit reports/certification from comparable regulators in other jurisdictions (e.g. MDSAP under IMDRF)
  - Minimise duplication of effort and avoid performing multiple ISO13485 audits of same manufacturing facility
  - Need for a robust ISO13485 certification locally with oversight from the regulatory body (i.e. HSA)

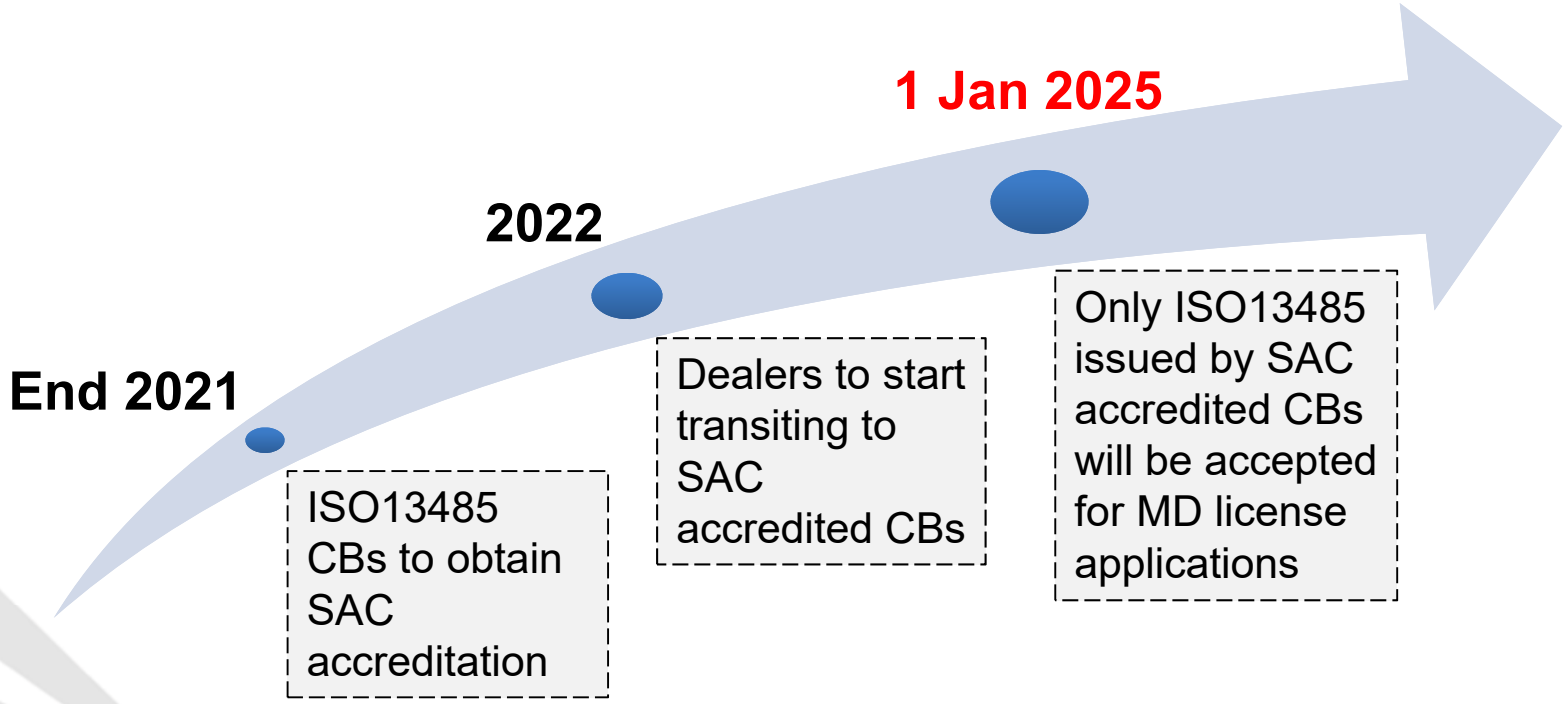
- SAC has an accreditation system for CBs issuing ISO13485 certificates
  - Currently CBs opt in voluntarily for this accreditation

- HSA will require all CBs that issue ISO13485 for local medical device regulatory purposes to get themselves accredited by SAC
  - To ensure consistency and quality in the certification process across various CBs
  - To ensure the ISO13485 certification locally is in line with international medical device regulatory principles

- HSA will implement a witnessed assessment program for these CBs similar to the current approach for GDPMDS certification

Proposed Implementation Plan for Accredited ISO13485 Certification

Proposed Implementation Timelines



Thank You

Key Discussion Points from Webinar

SAC accreditation

- List of SAC accredited CBs for MDQMS (i.e. ISO13485) can be found on SAC's website below. This list will be updated upon addition of new accredited CBs.
  https://www.sac-accreditations.gov.sg/Pages/Homepage.aspx
  (Scheme: Management Systems Certification Bodies > Medical Device-Quality Management System)

- SAC accreditation applies only to CBs that issue ISO13485 certificates for local medical device regulatory purposes. This is not applicable to dealers (i.e. companies).

Witness Assessment by HSA

- The purpose of witness assessments is for HSA to assess the ISO 13485 audits conducted by the CB. This is not intended to audit of the company.

- Witness Assessment audit is not a compliance audit. During the audit, HSA typically observes and assesses the CB's performance to ensure consistency and robustness of the audit and ISO 13485 certification process for regulatory purposes.

- Where necessary (e.g. when there is evidence of potential non-compliance reported to HSA), HSA may perform compliance audits on medical device companies locally as provided for in the Regulations.

Key Discussion Points from Webinar

Implementation Plan

- Dealers who use ISO 13485 certificates as pre-requisite for their medical device dealer's licences are given 3 years transition period (2022 - 2024). If the dealer's current CB do not get themselves accredited before your next recertification audit that falls in the period (2022 - 2024), dealers should plan to transit to a SAC accredited CB for recertification.

- Dealers are advised to check with your current CB on their plan to obtain the SAC accreditation before your next recertification cycle.

- From **1 Jan 2025**, only ISO13485 certificates issued by SAC accredited CBs or MDSAP certificate will be accepted for HSA medical device dealer license applications.