



Bulletin

Issue:	MPD_ISO 13485 and MDSAP transition
Date:	Aug 02, 2016
To:	TUV USA/TUV NORD ISO 13485 Certified clients
From:	Bradley Chen
Re:	ISO 13485:2003 to ISO 13485:2016 / CMDCAS to MDSAP transition

Dear Valued Customer:

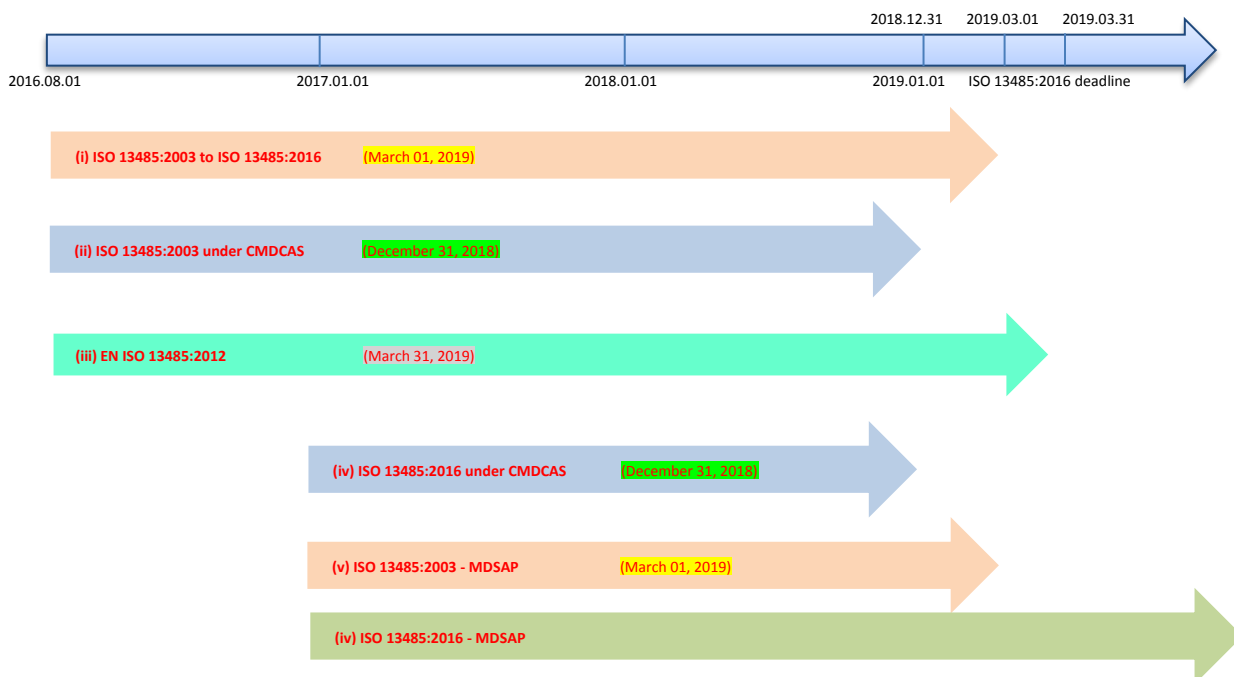
ISO 13485:2016

ISO 13485:2016 was published on March 01, 2016. The transition period from ISO 13485:2003 to the new 2016 version is three (3) years from the date of publication of the 2016 version of the standard.

Medical Device Signal Audit Program (MDSAP)

In accordance with the direction received from Health Canada, all clients certified to ISO 13485:2003 (under CMDCAS) need to transition the CMDCAS Certificate to an MDSAP Certificate, latest December 31, 2018.

The following is the official deadline and transition time for both certification schemes:





TUV USA, Inc. / TUV NORD will be happy to work with you to complete your transition.

Based on the type of certification scheme you have with TUV USA / TUV NORD, it is recommended that you start planning to transition your ISO 13485:2003 to ISO 13485:2016 as soon as possible.

If you have CMDCAS please plan to transition it to the MDSAP program as well.

We will inform you in our next bulletin the following:

- 1) When we will be starting to issue the new ISO 13485:2016 certificates
- 2) The deadline of submitting your transition plan to the ISO 13485:2016 and/or MDSAP Program

If you have any questions, please feel free to contact the undersigned.

Thank you.

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