

Conversion Arrangement for ISO 13485:2016

The International Organization for Standardization (ISO) has officially released the ISO 13485:2016 on 1 March 2016. As per ISO, organizations certified to ISO 13485:2003 are granted a three-year transition period to migrate to the new edition (http://www.iso.org/iso/iso_13485_medical_devices_2016.pdf). ISO 13485:2003 will not be valid from 1 March 2019.

Conversion Arrangement for HKQAA Certified Clients

HKQAA will assist certified clients to upgrade their quality management system via an on-going approach. From 1 March 2017 onwards, all audits of HKQAA certified clients will automatically become conversion audits if the clients do not indicate they want the audits in ISO 13485:2003.

Conversion audits shall be mandatory after 1 December 2017 in order to ensure that conversion can be completed before the deadline. The issuance of ISO 13485:2016 certificate will be arranged after all requirements in the new version are covered in the conversion audits.

If your organization wants to have a separate conversion audit, please contact our Customer Service for arrangement.

We will endeavor to assist you to ensure a smooth transition to meet the requirements of the new standard.