

Frequently Asked Questions – For the conversion to ISO 13485:2016

- Q. What is the effective date of ISO 13485:2016?
A. The effective date of ISO 13485:2016 is 1 March 2016.
- Q. What will happen to my ISO 13485:2003 certificates?
A. ISO 13485:2003 certificate will become obsolete from 1 March 2019.
- Q. What are the key changes from ISO 13485:2003 to ISO 13485:2016?
A. Clients could refer to Table A.1 of ISO13485:2016 for the change outline.
- Q. Is there any transition period for conversion to ISO 13485:2016?
A. Organizations certified to ISO 13485:2003 are granted a three-year transition period to migrate to ISO 13485:2016. Two years after the publication of ISO 13485:2016, all certifications issued (new certificates or re-certifications) will be to ISO 13485:2016. During the transition period, ISO 13485:2016 will co-exist with ISO 13485:2003.
- Q. Is the representative of the certified organization required to have ISO 13485:2016 training to fulfill the ISO 13485:2016 conversion?
A. No, there is no requirement for the representative of the certified organization to have ISO 13485:2016 training to fulfill the ISO 13485:2016 conversion.
- Q. At what time will be the Conversion Audit scheduled?
A. 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.
- Q. What preparation is needed of the organizations for the Conversion audit?
A. The organizations shall update their relevant system documents and inform the relevant employees of the update.
- Q. Will nonconformity(ies) be raised against the ISO 13485:2016 standard during conversion audit?
A. Any discrepancy on the organization system's setting or implementation against the specific requirement of ISO 13485:2016 standard will be raised as nonconformities (NCs). If there are NCs raised, client is expected to submit the CAP in order to proceed the issuance of the ISO 13485:2016 certificate.