ISO 13485:2016

ISO 13485:2016 was issued in March 1, 2016. The International Accreditation Forum has agreed to a three year transition period. This means that accredited certificates issued to the 2003 version of the standard will be invalid on March 1, 2019.

Interestingly, this standard does not follow the Annex SL format that is evident in ISO 9001:2015 and other recently revised standards. In addition, whereas ISO 9001 is no longer requiring formal documented procedures or a quality manual, ISO 13485:2016 still has many requirements for documented procedures and a quality manual. The 2015 version of ISO 9001 no longer has a requirement for preventive action, but this requirement still exists in ISO 13485:2016.

ISO 13485:2016 also has new requirements for complaint handling (8.2.2) and reporting to regulatory authorities (8.2.3). The standard is applicable to organizations involved in design and development, production, storage, distribution, installation or servicing. Organizations are required to identify as either a manufacturer, importer, distributor or authorized representative in accordance with the applicable regulatory requirements.

In order to ensure timely transition, PJR will require that all organizations complete their transition audit by December 1, 2018. This will ensure sufficient time for corrective action closure, technical review, decision making and certificate issuance activities. PJR recommends aligning transition with your normal recertification audit. If you choose to transition on a surveillance audit, additional time may be required.