QMSMDD ISO 13485 IS NOW IN VERSION 2016

On March 1st, 2016, the *International Organization for Standardization* (ISO) published the revised version of ISO 13485 titled as "**ISO 13485 - Medical Devices - Quality management systems - Requirements for regulatory purposes**". This revised version will supersede the ISO 13485:2003 and new revised standard is referred to as ISO 13485:2016 which is the global standard for medical device quality management systems (QMS). According to a draft transition planning guidance, organizations will still be able to be accredited for either ISO 13485:2003 or ISO 13485:2016 for the first two years of the transition period. However, after the second year, new accreditation will only be given for ISO 13485:2016.

Both old and new medical device standards cover essentially the same topics. However there are some important differences

- Regulatory Requirements
- Risk based Approach
- Medical Device File
- Record Keeping
- Product Realization
- User training
- Design and Development Inputs
- Design and Development Verification and Validation
- Design and Development Changes
- Design and Development Transfer
- Purchasing
- Supplier Monitoring
- Purchased Product Risks
- Process validation
- Servicing
- Complaints
- Delivery of Nonconforming Device – Product
- Improvement