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The latest edition of ISO 13485, the internationally recognized quality management systems standard for the medical device industry, with over 27,000 certificates globally, has been published, 25 February 2016. The standard provides an effective framework to meet the comprehensive requirements for a medical devices quality management system; for manufacturers and service providers to both comply and demonstrate their compliance to regulatory requirements.

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ISO 13485:2016 is the standard for a Quality Management System (“QMS”) for the design and manufacture of Medical Devices. Certification to the standard requires an organization’s quality management system to pass a third party Medical Device Single Audit Program, or “MDSAP” Audit.

ISO 13485, Medical devices – Quality management systems – Requirements for regulatory purposes, is an internationally agreed standard that sets out the requirements for a quality management system specific to the medical devices industry. It has recently been revised, with the new version published in March 2016.

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The current ISO 13485 edition was published on 1 March 2016.

On March 1, 2016 the International Organization for Standardization published the new edition of the ISO 13485 standard. Previously updated in 2003, the revision places more emphasis on the quality management system throughout the supply chain and product lifecycle, as well as on device usability and postmarket surveillance requirements.

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With the publication of ISO 13485:2016, TC 210 proves that there never needed to have been such overwhelming timidity when dealing with the ISO TMB, and that with enough leadership, any TC could have pushed back against the inane Annex SL and the other non-consensual demands of the non-elected ISO leadership.

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The International Organization for Standardization published the updated ISO 13485 medical devices quality management systems standard on March 1, 2016. The standard can be used by organizations involved in the production, post-production, storage, distribution, installation, servicing, final decommission and disposal of medical devices.

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