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ISO 13485:2016 specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements.

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~~INTERNATIONAL ISO STANDARD 13485~~

The following is a major revision of the ISO 13485:2016 standard. ISO 13485:2016 replaces ISO 13485:2003 and ISO 13485:2012. The revised ISO 13485:2016 was published on 1 st March 2016. The standard is aligned with ISO 9001:2008 and not ISO 9001:2015. This misalignment is due to the revision of both standards being completed in parallel to one another.

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The following is a major revision of the ISO 13485:2016 standard. ISO 13485:2016 replaces ISO 13485:2003 and ISO 13485:2012. The revised ISO 13485:2016 was published on 1st March 2016. The standard is aligned with ISO 9001:2008 and not ISO 9001:2015. This misalignment is due to the revision of both standards being completed in parallel to one another.

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?In Europe, ISO 13485 Standard designated as EN ISO 13485:2016 is seen as the de facto standard for the medical device industry. ?Addresses most or all of the quality system requirements in markets including Europe,

Australia, Japan, Canada, South Korea and Brazil, etc.

~~ISO 13485:2016 QUALITY MANAGEMENT SYSTEMS STANDARD~~
ISO 13485, Medical devices — Quality management systems — Requirements for regulatory purposes, is the International Standard for quality management systems for the medical devices sector. Published in 2016, it is designed to work with other management systems in a way that is efficient and transparent.

~~ISO - FDA plans to use ISO 13485 for medical devices ...~~
This standard supersedes earlier documents such as EN 46001 (1993 and 1996) and EN 46002 (1996), the previously published ISO 13485 (1996 and 2003), and ISO 13488 (also 1996). The current ISO 13485 edition was published on 1 March 2016.

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

~~ISO 13485 Medical Devices | NSF International~~
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.

~~NEW ISO 13485:2016 GUIDANCE PUBLISHED - Pacific BioLabs~~
a Final Draft International Standard (FDIS)/ISO 13485 on 29th of October 2015 for balloting by ISO member countries. The revised standard ISO 13485:2016 was published on 1st March 2016. Summary of the key changes The ISO 13485 revision includes significant changes in a number of important areas. The following sections offer a summary of these ...

~~ISO 13485:2016 Revision Factsheet~~
Surprising a lot of insiders, ISO pushed ahead with publication of its revised medical device quality management system standard, ISO 13485:2016, despite some controversy that many thought would cause ISO to delay its release. You can purchase the official release here, from ISO, for $158 (158 CHF).

~~ISO 13485:2016 Published - Quick First Look - Oxebridge ...~~
The current version of the standard is ISO 13485:2016, Medical devices – Quality management systems – Requirements for regulatory purposes. It can be purchased from the ISO website for its international version, or from a national standardization organization (e.g. SNV in Switzerland) for the recognized version in a given jurisdiction.

~~Understanding ISO 13485 - Certification of a Quality ...~~
SS ISO 13485 : 2016 6 COPYRIGHT National Foreword This Singapore Standard was prepared by the Biomedical Standards Committee. This standard is identical with ISO 13485:2016, published by the International Organization for Standardization. Attention is drawn to the following: 1.

~~SINGAPORE STANDARD Medical devices Quality management ...~~
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