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Manufacturers holding only ISO 13485 certification with BSI are required to transition to ISO 13485:2016/EN ISO 13485:2016 by 28th February, 2019. The harmonization of EN ISO 13485:2016 is another step towards compliance to the recently published Medical Devices and IVD Regulations, which will supe current Directives in three and five years, respectively.

The key changes of the new ISO 13485:2016
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the revision of ISO 13485 was the first since the standard’s last revision in 2003, the ISO working group responsible for the revision faced the significant task of addressing nearly a decade of changes in technology and regulatory requirements. TÜV SÜD ISO 13485:2016 Revision Factsheet A quick guide to th ISO 13485:2016 standard ...

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The new 2016 revision of ISO 13485, the leading international standard for medical devices, is finally in front of us. Now we can see exactly what has changed and what needs to be done to achieve compliance with the new version. Alignment. The new version of ISO 13485 is aligned with ISO 9001:2008, whi challenges for organizations ...

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Another Revision of ISO 13485 starts in 2019
For more information about the changes, see our ISO 13485:2016 factsheet, which is available for download here. The necessary transition of your certificate is as follows: Since the official publication of ISO 13485:2016 on March 1, 2016, the transition of accredited certifications to the new ISO 13485:2016 ca effected within the scope of a regular surveillance or recertification audit.

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This did not create a significant problem for medical device manufacturers but, for component manufacturers, logistics companies and the like, working to ISO 13485:2016 for medical device sector customers and to ISO 9001:2015, with its HLS – High Level Structure – for their other customers created needles additional administrative burden and, frankly, was a waste of time.

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ISO 13485:2016 Revision Factsheet A quick guide to the revised ISO 13485:2016 standard Choose certainty Add value In addition, during the years since the publication of ISO 13485:2003, existing management standards continued to evolve and new management systems

INTERNATIONAL ISO STANDARD 13485
ISO 13485:2016 can also be used by suppliers or external parties that provide product, including quality management system-related services to such organizations. Requirements of ISO 13485:2016 are applicable to organizations regardless of their size and regardless of their type except where explicitly stat

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ISO 13485:2016 Gap Analysis Factsheet. A Lloyd’s Register gap analysis assessment examines and reports on your management system’s readiness for migration or assessment to ISO 13485:2016. It focuses on how your management system has addressed or plans to address, the changes introduced in th of the standard.

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All ISO standards are reviewed every five years to establish if a revision is required in order to keep it current and relevant for the marketplace. ISO 13485:2016 is designed to respond to the latest quality management system practices, including changes in technology and regulatory requirements and expecta

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