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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 standards were introduced. The ISO working group was also

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Last revision published in 2016 and the transition period for migration to this version has not yet ended (due date 31st Mar 2019). This is indeed a unique situation – a new revision to an ISO management system standard started before the transition

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to the previous version has been completed.

Another Revision of ISO 13485 starts in
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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

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of accredited certifications to the new ISO 13485:2016 can now be effected within the scope of a regular surveillance or recertification audit.

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