Your ISO 13485:2016 transition toolkit

Don’t delay – start your transition today.

The transition has started: ISO 13485:2016 was published in March 2016, with a transition period of three years. All existing ISO 13485 certificates must be transitioned to the new version of the standard by 28th February, 2019.

Transition with an accredited Certification Body

BSI is one of the first certification bodies to be accredited to ISO 13485:2016. Our expert assessors have undergone rigorous training so that they are ready to support you through the transition and beyond.

You can read the full press release on our website. Use our resources to support your transition.

bsi...making excellence a habit™
It is important that you start your transition. The transition requires you to prepare for, plan and implement the new requirements, undergo your transition audit and make any necessary adjustments before March 2019, to ensure you maintain uninterrupted certification to the standard.

It is important that you understand the changes to the standard so that you plan enough time and resource for a smooth transition. Use this toolkit to access all the resources you need to prepare for your transition.

Your Transition Toolkit

Understand
- QMS Brochure
- Webinars
- White papers
- Expert Commentary
- Senior Management Briefing

Prepare
- Best practice transition journey
- Training
- Readiness review
- ISO 13485 Frequently asked questions
- Pre-certification assessment

Audit

Next steps

We encourage you to book your transition as soon as possible, to gain the benefits of early certification.