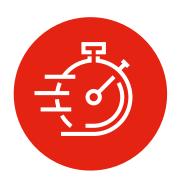


Your ISO 13485:2016 transition toolkit

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.

You can read the full press release on our website.

Our expert assessors have undergone rigorous training so that they are ready to support you through the transition and beyond.

Use our resources to **support** your transition



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

OMS 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

Next steps



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

Talk to BSI now

Audit



BSI Group America Inc.

12950 Worldgate Drive, Suite 800, Herndon, VA 20170 USA

T: +1 800 862 4977/703 437 9000

F: +1 703 437 9001

E: us.medicaldevices@bsigroup.com

BSI Group - EMEA

Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP United Kingdom

T: +44 345 080 9000

F: +44 1908 814920

E: eu.medicaldevices@bsigroup.com

BSI Group Asia Pac

BSI Group - Hong Kong 23rd Floor, Cambridge House TaiKoo Place, 979 King's Road, Island East, Hong Kong

T: +852 3149 3320 F: +852 2743 8727

E: hk@bsigroup.com