The new ISO 13485:2016
BSI’s Best Practice Transition Journey
5 Key Steps for a Successful Transition

Don’t delay – start working on your transition today

1. Talk to your BSI Client Manager
   • Discuss your challenges and timelines
   • Review the latest webinars and whitepapers on the BSI website for background information

2. Consider BSI’s Training programme
   • Understand the new requirements faster and in greater detail by attending our transition training course, aimed at the new ISO 13485:2016 requirements

3. Communicate with your organization
   • Talk to your leadership team about the new requirements
   • BSI ISO 13485:2016 senior management briefing can help your managers understand the implications of the new standard
   • Communicate the revision to your wider organization to gain buy in
   • Send regular updates on progress
   • Agree strategy and confirm readiness

4. Set up an Internal Project Team
   • Conduct a gap analysis against your current system
   • Create an implementation plan and monitor progress
   • Take a fresh look at your QMS
   • Update your documentation to reflect the new standard and implement the additional requirements
   • Agree an updated visit schedule with BSI Client Manager

5. Gap Transition Assessment
   • Consider a gap assessment to help you identify any weaknesses prior to formal assessment

Transition to the new standard as soon as possible to gain the additional benefits.

ISO 13485:2016 Transition Timeline

2016 2017 2018 2019

February 2016 New ISO publication
March 2016 Start of three year transition period to 28th February 2019

Visit our website to find out the latest information
bsigroup.com/ISO13485revision

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