



ISO Revisions



➤ The new ISO 13485:2016
BSI's Best Practice Transition Journey

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...making excellence a habit.™

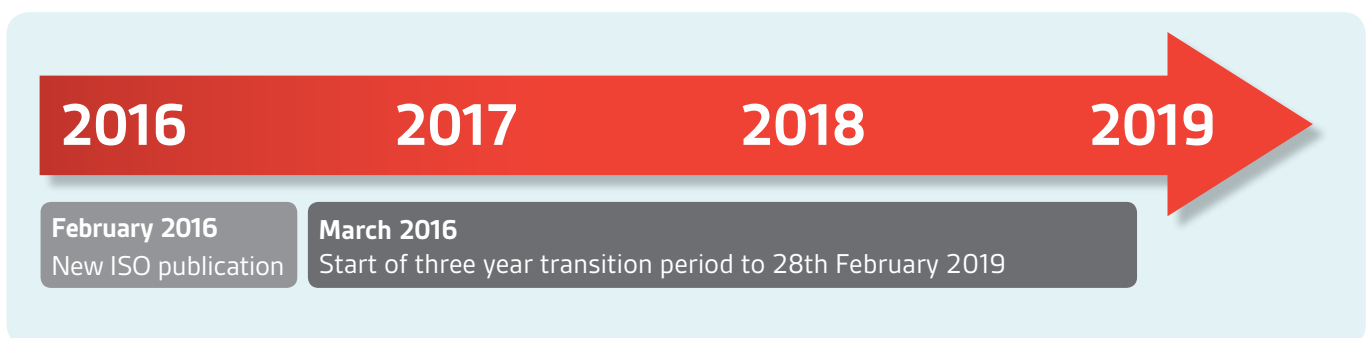
➤ 5 Key Steps for a Successful Transition

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



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to find out the latest information**

bsigroup.com/dispositivi-medici/ISO13485Revision