



ISO Revisions



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

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...making excellence a habit.™

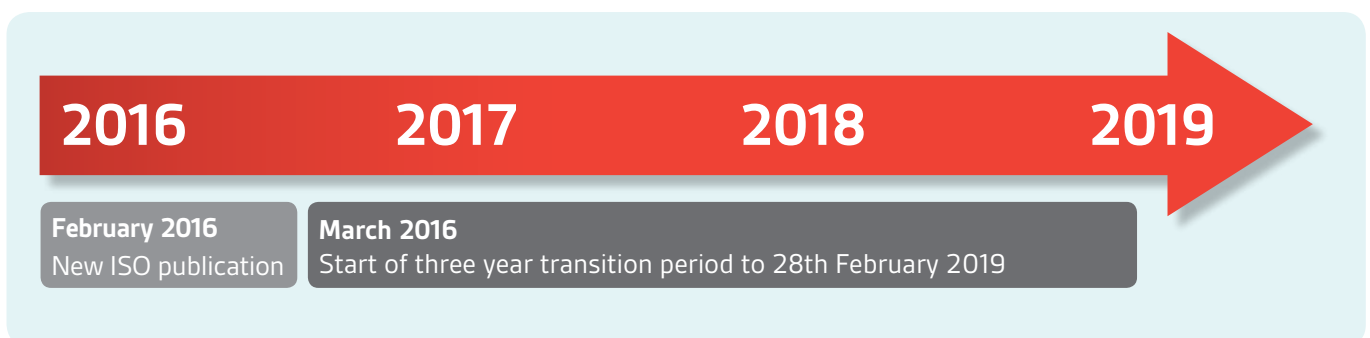
# ➤ 5 Key Steps for a Successful Transition

**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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[bsigroup.com/ISO13485revision](http://bsigroup.com/ISO13485revision)