bsi. | Medical Devices

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BSI achieves accreditation to certify organizations to new ISO 13485:2016 standard

BSI has become one of the first certification bodies to be granted accreditation for the issue of quality management certificates against the requirements of ISO 13485:2016.

To gain accredited status, BSI's processes were independently reviewed by the United Kingdom Accreditation Service (UKAS). BSI is now able to issue UKAS accredited certificates to the latest edition of ISO 13485, the internationally recognized quality management systems standard for the medical device industry, to its clients.

Certification customers have until 28 February 2019 to transition from ISO 13485:2003 and the associated European Standard EN ISO 13485:2012; we recommend you start to plan your transition with urgency.

Gary Slack, Senior VP, Global Healthcare Solutions, BSI said: "ISO 13485 is the world's leading Medical Device standard, with over 27,000 certificates globally, therefore we're very proud to achieve accreditation from UKAS. We have invested heavily in making sure that we provide our clients with the best service possible to transition early to the standard."

BSI has developed a suite of materials, services and courses to help make the transition as smooth as possible, details can be found on our transition website: bsigroup.com/ISO13485Revision

Do you have questions about the new Clinical Evaluation Guidance?

The Clinical Evaluation guidance document, MEDDEV 2.7.1 Rev 4, includes new requirements and clarifications on existing requirements.

Sign up to our new, complimentary webinar to learn more about the key changes and clarifications to the guidance.

Sign up now

Don't have a copy of the ISO 13485:2016 standard?

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Visit the BSI Shop to purchase your copy of the new ISO 13485:2016.

How does the new standard align with the new Medical Device Regulations?

Join Acting Head of QMS, Stewart Brain, and QMS Specialist, Linda Moon, as they discuss the alignment between the new version of ISO 13485 and the new Medical Device and IVD Regulations in our new, complimentary webinar.

Sign up now

BSI Medical Devices LinkedIn

Join the BSI LinkedIn Group to stay informed and updated with the latest news.

Stay informed on key updates

Get the latest information and new resources on the MDR and IVDR by bookmarking our transition webpages:

Medical Device Regulation Transition page

In Vitro Diagnostic Regulation Transition page

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