bsi. | Medical Devices

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January 2017 Medical Device Newsletter

BSI achieves accreditation from Standards Council of Canada to certify organizations to new ISO 13485:2016 standard.

BSI has become the first certification body to achieve 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 Standards Council of Canada (SCC). Under CMDCAS, only certification bodies accredited by SCC are eligible to certify medical device manufacturers' management systems. BSI is now able to issue both SCC and UKAS accredited certificates to the latest edition of ISO 13485 to its clients.

Existing BSI certification customers have until 28 February 2019 to transition from ISO 13485:2003 and the associated European Standard EN ISO 13485:2012. 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 page.

Manufacturers placing products on the Canadian market also need to be aware of the Medical Device Single Audit Program (MDSAP), which will be replacing CMDCAS from January 1 2019. You can find out more information in our full announcement, or by visiting our MDSAP webpage.

Further information will be provided via your normal BSI contacts, however, we recommend you start to plan your transition now and contact our planning team to ensure BSI can respond to your

Learn more about the new Regulations with our programme of webinars in 2017.

Listen to Product Specialist Susana Faria as she discusses Post Market Surveillance and Vigilance:

Post Market Surveillance and Vigilance - do you know the requirements? - 22 February, 4pm GMT

Find out more about roles and responsibilities under the new Medical Device Regulation with our Head of Notified Body, Suzie Halliday:

Roles and responsibilities in the Medical Device and IVD Regulations - 15 March, 4pm GMT

Sign up now

Stay up to date with the latest developments

Our transition webpages will be

timescales.

View the full announcement

Are you aware of the changes to the Unannounced Audit Visit schedule?

The European Commission Recommendation of 24 September 2013 (2013/473/EU) outlines the requirements for unannounced audits of manufacturers' premises as part of the scrutiny performed by Notified Bodies.

Recent changes have been made to the audit schedule, which is based on device classification. You can find more information in the table, below.

The new unannounced audit schedule will be implemented from January 2017.

Risk level	Details	New audit cycle
Higher risk products	AIMD, MDD Class III / IIb implantable devices	3 years
Lower risk products	MDD Class IIb / IIa / Is / Im	5 years
IVD products	Annex II List A / Annex II List B / Self-test (under Annex IV only)	5 years

You can find out more about unannounced audits by visiting our website:

Find out more

updated with the latest developments. Bookmark them now:

Medical Device Regulation transition page

In Vitro Diagnostic Regulation transition page

ISO 13485:2016 transition page

Medical Device Single Audit Program webpage

BSI Medical Devices LinkedIn

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

Visit the BSI Shop

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

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