



Regulatory review

Your monthly medical device
update

March 2018



ISO 13485:2016

One year left to transition, don't jeopardize your certification

There's less than one year left to complete your transition to ISO 13485:2016. Manufacturers who haven't transitioned by 28 February 2019 risk losing their certification and potentially restricting their market access.

BSI will complete all upcoming audits to ISO 13485:2016; [we may need to add additional time or visits to complete your transition](#), but we will discuss this with you ahead of your visit.

What you need to do

Make sure you're prepared to complete your transition successfully by using our resources to prepare, and get more information about the transition by visiting our dedicated webpage: bsigroup.com/iso13485revision

[Find out more](#)

Re-register today to continue receiving our regular updates

Under the General Data Protection Regulation (GDPR), coming on 25 May 2018, we can only continue to email you if you request to hear from us. Re-register with us today to continue receiving our monthly updates and additional information about our products and services.

[Yes, please send me the medical devices updates](#)



Don't miss out - listen back to our recent webinars

Listen back to our experts discussing the current status of key standard harmonization, the latest updates on labelling, and the new Regulations' that the new Regulations will have on your QMS.

[Listen back](#)





Global market access:

Have you applied for MDSAP?

Manufacturers planning to sell into Canada from 2019 will need to have successfully completed an MDSAP assessment, following Health Canada's decision to replace their current CMDCAS market entry scheme with MDSAP from 1 January 2019. If you need replace your CMDCAS certification with MDSAP, you need to apply to an Auditing Organization (AO) - **you will not automatically be transitioned from CMDCAS to MDSAP.**



MDSAP is also accepted in Australia, Brazil, Japan and the US; each Regulatory Authority utilizes the Program in a slightly different way. While not compulsory in these jurisdictions, MDSAP provides an efficient and cost-effective route to market by combining the audits to each jurisdiction's requirements, reducing the disruption to your business from multiple audits and providing market access in up to five markets at one time. BSI is a recognized AO with a wealth of experience with MDSAP audits, and has approximately 100 qualified MDSAP assessors.

Find out more about the Program and BSI's role as an AO by reading our new brochure, listening back to our webinar or downloading our recent white paper, available on our dedicated webpage: bsigroup.com/mdsap

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