



Medical  
Devices

Talk to us  
**+44 (0)845 080 9000**  
[eu.medicaldevices@bsigroup.com](mailto:eu.medicaldevices@bsigroup.com)

## BSI Medical Device Newsletter: July 2015



Welcome to the July Medical Device Newsletter 2015

### Report on the update of the Revision of the Medical Device Directives

Gert Bos, BSI Head of Regulatory & Clinical Affairs

On June 19, the EPSCO (Employment, Social Policy, Health and Consumer Affairs Council configuration) meeting was successful in finding a path forward in negotiations and finalisation of the legislation. Whilst we received a consolidated version of the MDR a week before the meeting, the IVDR document was ready only days before the debate and vote.

As the recitals are not yet in place, Council agreed on the core text only, which allows two processes to run in parallel:

1. The fine-tuning of some text and addition of the recitals that motivate the reasons and considerations around the changes in the regulatory system.
2. The negotiations to start.

Once the final Council view is completed and the first reading vote finished, negotiations might be advanced enough to

### Medical Device Single Audit Program

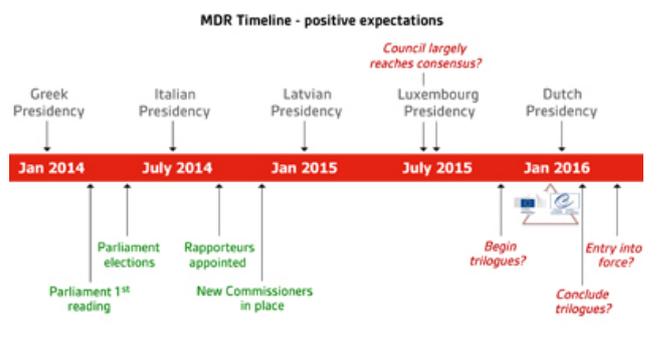
The Medical Device Single Audit Program (MDSAP) is a foundational international initiative led by Regulatory Authorities of the International Medical Device Regulatory Forum (IMDRF) to implement a certification program where recognized third party Auditing Organizations (AO) can conduct a single audit of a medical device manufacturer that will be accepted by multiple regulators to address various QMS/GMP requirements.

Four of the Regulatory Authorities (Australian TGA, Brazilian ANVISA, Health Canada and US FDA) have decided to proceed with a three year MDSAP pilot. BSI is fully supporting the MDSAP pilot and participating in the process as an AO.

finish and agree on the two documents shortly after a quick second reading in Parliament and Council.

The Luxemburg presidency is ready to start from 1 July 2015, meeting with key stakeholders to obtain input into the final stage; the Dutch presidency will follow and will hopefully be able to help finalise the new ruling, ready to support the continuing work. Following a positive scenario, legislation may be finished towards the middle of 2016.

In the consolidated versions, the Council added a lot of detail on clinical evaluation, scrutiny measures, reprocessing and more. Many elements are not contradicting the concerns from Parliament, but rather finding some alternative solutions moving forward. Comparing the views of Parliament and Council indicates the feasibility of reaching consensus, and we might indeed see the end of the eight year legislative process within 12 months' time.



## New BSI webinars available

To help you keep up to date with a rapidly changing regulatory environment we have published a webinar schedule for the whole of 2015. The full list of webinars can be seen on our website, and the following webinars are open for registration:

[> ISO 13485 and ISO 9001, with both changing are you prepared?](#) (28 July 2015 - 16:00 GMT)

[> Will your product be reclassified under the new MDR? Lessons you need to hear](#) (9 Sept 2015 - 16:00 GMT)

If you missed previous webinars on the [Requirements for a 'Person Responsible for Regulatory Compliance'](#), [ISO 13485 - The new revision](#), and the overview of [ISO 14971 Risk](#)

Japan recently announced its participation in the MDSAP pilot; Europe and the WHO are officially participating as observers.

---

## BSI Whitepapers



Negotiating the innovation and regulatory conundrum

bsi. making excellence a habit

[The proposed EU regulations for medical and in vitro diagnostic devices](#)

[Generating clinical evaluation reports: A guide to effectively analysing medical device safety and performance](#)

[Effective post-market surveillance](#)

[What you need to know about the FDA's UDI system final rule](#)

[Engaging Stakeholders in the Home Medical Device Market](#)

[Negotiating the Innovation and Regulatory Conundrum](#)

[The growing role of human factors and usability engineering for medical devices](#)

---

## [BSI Global Medical Device Group](#)

[Management](#) or any others, you can listen back on our [website](#).

---

## Update on the revision of ISO 13485

The working group (WG) met in Denver in June 2015 to review the 800+ comments received on DIS2 ISO 13485. The WG reviewed each comment and on completion of the meeting, a rough draft of an FDIS document was compiled. IMDRF submitted a request for consideration by the WG to the classification on non-conformities as defined in GHTF SG3:N19, Quality management system –Medical devices - Nonconformity Grading System for Regulatory Purposes and Information Exchange document and how this relates to the clause structuring of ISO 13485 and the MDSAP Program.

In order to support companies operating integrated management systems i.e. ISO 13485, ISO 9001 etc., a Japanese colleague of the WG (with approved access to the FDIS text from 9001) is collating a correlation matrix using the clause references from ISO 13485:2003, ISO 13485:2015:16 and ISO 9001:2015 FDIS.

AAMI, the secretariat for WG, are currently editing and correcting the FDIS draft developed during the meeting and will include the correlation matrix. This will be circulated to the members of the WG who attended the Denver meeting for each to review prior to attending a further WG meeting in the United Kingdom, during the third week of August 2015. From the meeting it is anticipated that the FDIS text will be finalised and following ISO procedures will be released middle/late September 2015 for voting.

Based on the above and a presumption of a positive vote at the FDIS stage which is a straight YES/NO vote, publication of the 3rd revision of ISO 13485 could occur late 2015/early 2016.

Keep up to date with the development of the standard via our [revision website](#).

If you missed the webinar in May, Paul Sim talked through the current status of the revision and how the standard will



This group is for professionals who design, develop, manufacture or distribute or related services, or are involved in developing medical device standards or regulations.

Don't forget to [sign up](#) if you haven't already.

---

### Medical device training

We run online, public or inhouse training courses. For training at your place of work, call us on +44 (0) 845 086 9000.

[View all training courses](#)

---

### Meet BSI in person

Some of the events BSI are attending and speaking at in June are below. For a full list of event we will be speaking at please see our [events page](#).

---

proceed, you can [listen back to the webinar](#).

---

## BSI Shop

Purchase a range of documents and training products from the BSI Shop now

[Find out more](#) ▶

---

For all general enquiries call +44 845 080 9000 or [visit the BSI Medical Devices website](#)

**Our mailing address is:**

BSI  
Kitemark Court, Davy Avenue  
Knowlhill  
Milton Keynes, MK5 8PP  
United Kingdom

You have received this email because you have purchased a product or service from BSI, opted-in to a third party list or opted in to marketing emails. If you wish to unsubscribe please click on the 'one-click unsubscribe' link located below. Some of BSI's services include a customer newsletter/eshot as part of that service. This ensures that you are made aware of any changes to that particular services.

Please note that this inbox is not monitored so don't use "reply to" or "reply all" in your email. Should you wish to talk to us, please call +44 845 086 9001 or email [marketing.services@bsigroup.com](mailto:marketing.services@bsigroup.com).

The British Standards Institution (BSI, a company incorporated by Royal Charter), performs the National Standards Body activity (NSB) in the UK. BSI, together with other BSI Group Companies, also offers a broad portfolio of business solutions other than the NSB activity that help businesses worldwide to improve results through Standards-based best practice (such as certification, self-assessment tools, software, product testing, information products and training).

We respect your right to privacy - [view our privacy policy](#)

[Unsubscribe from this list](#) | [Update subscription preferences](#)

Join us     