bsi. | Medical Devices

Talk to us
+44 (0)345 080 9000
eu.medicaldevices@bsigroup.com

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Update on European Regulation, Electronic Cigarettes

There is a great interest in the regulation of nicotine-containing products (NCP), either to help smokers break their dependence to nicotine that comes from tobacco products or simply as a replacement. A relatively recent newcomer is the eCigarette.

Two directives apply in the regulation of Nicotine Containing Products:

- Tobacco Products Directive 2014/40/EU (http://ec.europa.eu/health/tobacco/products/index_en.htm)
- Medicinal Products Directive 2001/83/EC (http://ec.europa.eu/health/documents/eudralex/vol-1/index_en.htm)

Only one directive can be applied for any particular product and the appropriate directive will be determined by the manufacturer's claims and specifications.

Tobacco Products Directive

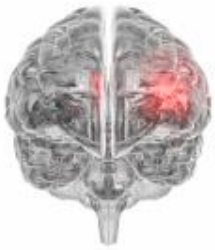
The Tobacco Products Directive (TPD) applies if the eCigarette manufacturer doesn't make medical claims and the following criteria are satisfied:

- Maximum cartridge / tank size 2 ml
- Maximum refill container volume 10 ml
- Maximum concentration 20 mg/ml nicotine.

In this case, the European Member States are required to apply the measures set out in the TPD from 20 May 2016. The Member State's nominated Competent Authority will be responsible for regulation and oversight. There is no requirement for Notified body involvement with eCigarettes regulated under the TPD.

To read further advise please visit the MHRA website - E-cigarettes: regulations for consumer products: www.gov.uk/guidance/e-cigarettes-

New ISO 13485 Training



ISO 13485:2016 Transition

This comprehensive course introduces you to the new requirements and explores the changes between ISO 13485:2003/ EN 13485:2012 and the latest standard.

With greater attention on the organization's ability to meet applicable customer and regulatory requirements, ISO 13485:2016 focuses on the entire supply chain of the medical device industry, with added emphasis on risk management.

You'll be able to identify the gaps in your current Quality Management System (QMS) and start planning your transition and certification to comply with ISO 13485:2016.

ISO 13485:2016 Auditor

regulations-for-consumer-products

Medicinal Product Directive

Addiction to a chemical substance is a medical condition and any product which claims to treat an addiction with supportive clinical data falls under the Medicinal Product Directive (MDP). eCigarettes which do not meet the criteria set above for the TPD are regulated under the MPD.

The manufacturer must obtain a marketing authorisation for medicinal products for human use (http://ec.europa.eu/health/human-use/legal-framework/index_en.htm) for the nicotine-containing product (NCP). The Notified Body has no involvement in the approval of the marketing authorization for medicinal product. However, as an electronic cigarette contains components such as a battery and heating element, legislation relating to medical devices is also relevant. Since, in many cases, the delivery / administration part of the electronic cigarette supplied separately from the nicotine-containing product will be regarded as a medical device, it will require to be CE marked under the medical device regulations.

Applications for the NCP (medicinal product) and the delivery system supplied separately to NCP (device) may run in parallel.

A CE certificate can be issued once all Notified Body and Medicines Agency conformity assessments have been successfully completed.

NEW Complementary Webinars on the regulatory changes in Europe

Update on the Proposed EU Medical Device Regulation.

Paul Brooks, Thursday 14th April, 2016. 4pm GMT.

Raise your awareness of the current state of the proposed EU Medical Devices Regulation (MDR) by hearing chapter by chapter what's and what's likely to be in the MDR basis and how this will likely impact manufacturers.

The current three Directives on active implantable medical devices (AIMD), medical devices (MDD) and in-vitro diagnostic medical devices (IVDD) are to be replaced by two Regulations, one covering all medical devices, the other covering IVDs. Both Regulations are in the final stages of the legislative procedure and are expected in 2016, allowing them to come into effect by the end of 2016, or early 2017.

This webinar will help you to consider what actions you need to start

Refresher

Are you an existing auditor with knowledge of ISO 13485 wishing to update your audit programme in line with ISO 13485:2016?

This course will refresh your auditing techniques and help you prepare to audit against requirements.

With a transition period of 3 years, it's important to get up to speed so you can ensure your organization is ready to comply with new requirements. Through audit scenarios, you'll identify opportunities for improvement and build on your reporting skills.

To book your course visit: bsigroup.com/training

Listen back to the latest ISO 13485:2016 Webinars

Publication of the Medical Device International Standard, ISO 13485

The published standard is now available, and this webinar introduced you to the final standard and guided you through the BSI transition plans.
The webinar highlighted the actions you should be taking now and how to plan for the

now to be prepared for the change in requirements; the webinar will outline the new requirements so that medical device manufacturers can start planning their resources to ensure uninterrupted CE Marking and EU market access during and after the transitional period of the new regulation.

The Future of Standards in Europe - harmonization and other recognitions of standards
Paul Sim, Wednesday 4th May, 2016. 4pm GMT.
A harmonized standard is a European standard developed by a recognized European Standards Organization: CEN, CENELEC or ETSI, created following a request from the European Commission. Manufacturers, economic operators or conformity assessment bodies use harmonized standards to demonstrate that products, services or processes comply with EU legislation.

New to the MDR is the instrument of Common Specifications (CS). These can be adopted by implementing acts where no harmonized standards exist or where relevant harmonized standards are not sufficient.

This webinar will discuss how the introduction of CS sits with harmonized standards and how organizations can utilize both to maximum effect.

Register Online

All registrants will be sent a link to the recorded webinar and presentation slides after the event.

implementation of the standard.

New Versions of ISO 13485 AND ISO 9001, what do you need to consider.

The new revision ISO 13485:2016 does NOT align with the revised high level structure, Annex SL, used in ISO 9001:2015. For those medical device manufacturers who hold dual certification, you will need to be aware and start to consider and develop transition plans to allow for a smooth migration from previous versions of the standards to the two newly released versions.

This webinar discussed the considerations needed to transition to the new standards within your organisation taking into account the now different structures.

Listen Back Now