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Advena Ltd are active members of the European Association of Authorised Representatives (EAAR) who have representatives on most of the major European policy making committees, including those for device vigilance, clinical trials, emerging technologies, IVD devices and there are contacts with the Global Harmonization Policy Committee for Europe. Appropriate information from these meetings will be reported in these reports.



Opportunity to meet and network;

We will be at the FIME show (www.FIMESHOW.com) at Miami Beach Convention Centre, August 13 to 15, I have a booth # 2438. I send, with this report, a complimentary ticket so you are able to attend and enjoy some humidity! Just print off, you can either register on-line or on the day.

I am making a presentation on “Achieving Regulatory Compliance in Europe” at 9.00 am on Friday 15th August in meeting room C225.

Client's Regulatory Update – July 2008

1 EUROPEAN DEVICE REGULATION INTERPRETATIONS

We have been notified that some of the new members of the EU, particularly Poland, have been asking to see Declarations of Conformity for products and insisting that such documents list the range of product LOT or Serial Numbers to which the Declaration covers. One of our clients actually had shipments held up until they provided an amended Declaration that listed this data.

However, this may be the tip of the iceberg, as other countries have been showing signs now that Declarations should refer to particular product batches/LOTs/Serial Numbers rather than being generic for a particular product type and catalogue number as previously interpreted and widely accepted. It appears that the requirement for this is actually embedded within the annexes of the Medical Device Directive but never been required before.

Now we hear that one UK Notified Body are asking that Declarations of Conformity provide for “...- identification of a given number of products or identification from which

batch/lot or production date the declaration is valid....". I suppose this could be interpreted as covering either a time period of manufacture or actual batch/serial numbers.

It would be wise to be prepared for this, but not do anything until requested. But do remember that Declarations must **always** list the descriptions and catalogue numbers to which the document refers to, not just a generic name.

2 NOTED DURING RECENT EXTERNAL (NOTIFIED BODY AND FDA) AUDITS

- Requirements that manufacturers have process validation data (*for those processes having a resulting output that cannot be verified by subsequent monitoring, measurement or inspection*) is being extended to most all suppliers/subcontractors of critical items or services.
- Root cause analysis expected of all corrective actions/complaints
- Record keeping procedures to specify requirements for records of approved suppliers, even for very small companies.
- Post market surveillance (proactive) processes must be taken seriously and records available during audit. Some auditors are asking for a regular search of the FDA web site for vigilance reports to see if any relate to the particular manufacturer's products. (On this web site search for "MAUDE" to get the link to this listing or type <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM>)
- Emphasis on "quality objectives" being set and monitored, this be audited for and that such objectives are to be shown to *".....meet the requirements of the quality management system..."*.
- The words *"...advisory notes...."* to be now *"...field safety corrective actions...."* in vigilance and complaint reporting procedures.

3 IVD's

These are notes from the EU IVD Technical Working Group Meeting in June

Proposed CTS Revision

The revised text had undergone legal consultation and various problems have arisen, in particular that the changes proposed now may mean only an amendment of the CTS without a complete replacement of the existing document. They also criticised the document as being too technical to be understood by many users.

The UK Competent Authority complained that the document referred to reference materials that may no longer exist and suggested general reference to NIBSC reference materials.

vCJD assays in Annex II and the CTS.

Agreed that changes are needed but problems arise that;

- There are not enough human samples and animal models may not have relevance.
- Not enough products on the market to compare.
- No confirmation assay.
- Specifications may only be vague at this stage.

To be discussed at the next meeting with experts from member states and organisations/manufacturers familiar with the topic.

Global harmonisation task force (GHTF) re IVD classification and conformity assessment procedures

In April the EU blocked the adoption of the GHTF documents (especially the one on Conformity Assessment) due to absence of a CTS and of batch release testing. Now, however, it was agreed that the EU should adopt the GHTF document but will communicate to the GHTF to require these amendments:

- The text of the guidance should be modified to make clear that the described requirements are not the maximum what an authority may request for assessment of a product (p.4 # 4 and p.15 # 3)
- The guidance requirements for “Pre market Approval” should ensure that verification of manufactured products (batch release) is a Post Market Activity and should therefore not be addressed in the guidance describing the Pre Market Assessment.
- CTS describing the Minimal Requirements for Performance Evaluation should be addressed.

IVD Directive and predictive testing

The subject as to whether predictive testing is covered by the European IVD Directive was discussed. Several opinions were given, and there was no consensus. It was agreed to discuss again.

Definition of a kit – CE marking of components

It was discussed as to whether it is required to put the CE mark on individual kit components. Opinions differed so opinion will be sought whether there are technical reasons why CE marking each component is not practicable!!.

Next meeting will be on November 20

4 US and FDA

This is to alert to manufacturers and users to the possibility that the x-rays used during CT examinations may cause some implanted and external electronic medical devices to malfunction, and that manufacturers provide recommendations to reduce the potential risk.

For other news see;

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTopic/cdrhnew.cfm>

For a search of incidents see;

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.cfm>

5 UK MHRA REPORT (Remember if you are contracted with us to be your Authorised Representative the MHRA is your “Competent Authority”)

Various alerts about specific devices.

For full details see <http://www.mhra.gov.uk/index.htm>

6 CANADA

It has been commented that the GMDN has great impact on medical devices. They are concerned with duplication, investment, harmonization, implementation, including the limitation in implementation. The challenge in the next 3 years will be how the GHTF and Health Canada can harmonize device nomenclature.

Health Canada is joining discussions to try and determine the most appropriate way to move forward with the recognition of the 3rd edition of IEC 60601-1 and its associated standards.

There is a recognized backlog of IVDD License Request Evaluations, this is being worked on to improve timing.

Health Canada is currently revising its approach to Post-Market Surveillance and Vigilance, which is considered part of the Progressive Licensing Project.

Bill C-307 (Phthalate Control Act) was ready for second reading of the Senate of Canada. The current version of the Bill was supported in Parliament by all political parties. The current version of the Bill will protect Canadians from **unnecessary exposure to DEHP in medical devices** but will also ensure that Canadians have continued access to needed medical devices when DEHP-free devices are not available or appropriate. The Bill will require Health Canada to take the following actions

Full information at;

<http://www.hc-sc.gc.ca/dhp-mps/md-im/index-eng.php>

7 STANDARDS UP-DATE.

The close of 2008 is expected to see the publication of ISO 9001:2008. However, changes to the existing ISO 9001:2000 are thought to be minor and, in principle, there will be no new requirements introduced. What is expected in the updated standard are clarifications to the existing requirements of ISO 9001:2000 and changes that intend to improve consistency with ISO 14001:2004.

There will be a 36-month transition period following the publication of the revised standard, so certification bodies can follow their normal cycle and won't issue ISO 9001:2008 until the time of re-certification. This prevents additional costs being incurred, either to the certification body or to the client. After this period, certification to ISO 9001:2000 will no longer be valid, but prior to this, certification to both ISO 9001:2000 and ISO 9001:2008 will carry the same weight.

Note; We can obtain any standard at about 50% price for clients. Please enquire.

Publications;

BS EN Publications	
BS EN 62353:2008	Medical electrical equipment. Recurrent test and test after repair of medical electrical equipment.
Amendments to British Standards	
BS EN ISO 11737:-	Sterilization of medical devices. Microbiological methods.
BS EN ISO 11737-1:2006	Determination of a population of microorganisms on products.
British Standards proposed for obsolescence	
BS 1619:-	Re-usable hypodermic syringes for insulin injection.
BS 1619-2:1988	Specification for syringes for use with insulin of strength 100 units per millilitre. This standard has been re-proposed for obsolescence for a further period as it is no longer relevant.
BS 3522: 1962	Specification for hypodermic surgical mounted needles (Luer fitting)

British Standards under review.	
BS 6001:-	Sampling procedures for inspection by attributes.
BS 6001-3:2005 (ISO 2859-3:2005)	Specification for skip-lot sampling procedures.
BS 6001-4:2005 (ISO 2859-5:2005)	System of sequential sampling plans indexed by acceptance quality limit (AQL) for lot-by-lot inspection.
BS EN ISO 3823:-	Dental rotary instruments. Burs.
BS EN ISO 3823-2:2003	Finishing burs.
BS EN ISO 9394:1998	Ophthalmic optics. Contact lenses and contact lens care products. Determination of biocompatibility by ocular study with rabbit eyes.
BS EN ISO 14408:2005	Tracheal tubes designed for laser surgery. Requirements for marking and accompanying information.
New work started	
BS EN 60335-2-109	Particular requirements for UV radiation water treatment appliances.
BS EN 60601:-	Medical electrical equipment.
BS EN 60601-2-11 (Revision)	Particular requirements for the safety and essential performance of gamma beam therapy equipment. Will supersede BS EN 60601-2-11:1998.
BS ISO 11140:-	Sterilization of health care products. Chemical indicators.
BS ISO 11140-6	Class 2 indicators and process challenge devices for use in performance testing for steam sterilizers.
Standards out for public comment	
08/30133979 DC BS ISO 23409	Male condoms. Requirements and test methods for condoms made from synthetic materials.
08/30149952 DC BS EN 60601-2-54	Medical electrical equipment. Part 2-54. Particular requirements for basic safety and essential performance of X-ray equipment for radiography and radioscopy.
08/30183534 DC BS EN 61000-4-6 AMD	Electromagnetic compatibility (EMC). Part 4-6. Testing and measurement techniques. Immunity to conducted disturbances, induced by radio-frequency fields.
Standards not issued for public comment	
IEC/TR 80002	Medical device software. Guidance on the application of ISO 14971 to medical device software.
ISO Publications	
ISO 4074:-	Natural latex rubber condoms. Requirements and test methods.
ISO 5832:-	Implants for surgery. Metallic materials.
ISO 5832-1:-	Wrought stainless steel.
ISO 7176:-	Wheelchairs.
ISO 7176-5:2008 (Edition 2.)	Determination of dimensions, mass and manoeuvring space.
ISO 13356:2008-(Edition 2.)	Implants for surgery. Ceramic materials based on yttria-stabilized tetragonal zirconia. (Y-TZP)

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