



## Advena Ltd.

Thorne Widgery House,  
33 Bridge Street  
Hereford HR4 9DQ, UK

✉ Westbury Court, Westbury St,  
Leominster HR 6 8NT UK

☎ +44-(0)1568-620080

☎ +44-(0)1568-620078

✉ [john@advenamedical.com](mailto:john@advenamedical.com)

✉ 2626 Valley View Lane; Suite #4  
Farmers Branch, Dallas, TX 75234, USA

☎ +1-972-742-4934

✉ [judy@advenamedical.com](mailto:judy@advenamedical.com)

*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.*



## **IMPORTANT ANNOUNCEMENTS**

### **USA OPERATION**

Advena Ltd have set up a new office close to Dallas, Texas, USA, and are now offering services in the USA that include;

- FDA 510(k) submissions.
- US Agent service.
- Internal auditing.
- Compliance training.
- Small business document control.
- US import documentation

USA Contact Judy Burton at [judy@advenamedical.com](mailto:judy@advenamedical.com)

### **AUSTRALIAN CO-OPERATION**

An agreement has been reached with an Australian medical device consultant who will be able to assist with registrations, etc., in Australia. Contact for this service is via the Advena Ltd. UK office.

## **Client's Regulatory Update – August 2008**

The August period is usually slow for regulatory activity so some of the news is rather sparse this month.

### **1 BAR CODING**

We have been informed about a UK National Health Service initiative concerning bar coding of medicines and healthcare product. At the moment we are unsure of the impact this may have upon manufacturers selling devices into the UK, they appear to be working on demonstrator projects at the moment.

We will be watching development which is referred to as GS1 and there is a document available named "Coding for Success" at [http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_066082](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_066082)

This states that it is new guidance to promote and support use of auto identification (barcoding and similar technologies) to increase patient safety and improve efficiency.

They state that there is evidence of real improvements to patient safety when coding systems are used to match patients to their care – reduced medication errors, reduced risk of wrong site surgery, accurate track and trace of surgical instruments, equipment and other devices and much better record keeping. They also refer to using coding to manage supplies and purchasing electronically so as to dramatically cut costs and improve efficiency.

### **2 CANADA**

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

**The web site has information on the release of the proposed GHTF (Global Harmonization Task Force)<sup>1</sup> Guidance: (PD)N17R7: Quality management system - Medical devices - Guidance on the control of products and services obtained from suppliers**

This was released by the GHTF Steering Committee for consultation and is being posted on the Health Canada Website for information and comment.

*They state;..... existing regulatory requirements require manufacturers to control products and services obtained from suppliers. These requirements call for the type and extent of controls to be established and documented within the organization's quality management system. Control could be defined and documented in the form of contractual arrangements, quality plans or other types of documents.*

*Therefore, when a medical device manufacturer chooses to utilize suppliers, the manufacturer should ensure control over any product or service obtained from such suppliers as defined within the quality management system (QMS).*

*This document provides guidance for medical device manufacturers on control of products and services obtained from suppliers.....*

All comments forwarded to Health Canada will be transmitted to the GHTF as is, with the disclaimer that they are provided for information and do not necessarily represent the views of Health Canada, except as specifically indicated in separate comments.

As appropriate, organizations may alternatively provide comments to local affiliate associations in Australia, Europe, Japan or the U.S. for their input directly to GHTF.

Comments provided to Health Canada should be submitted no later than 15 September 2008 in order to allow sufficient time for their assessment and subsequent transmission to the GHTF.

### 3 FDA

Some medical device safety info from the FDA, see <http://www.fda.gov/cdrh/medicaldevicesafety/>

They report;

***Serious adverse events associated with unretrieved device fragments*** (UDFs) and they provide recommendations to mitigate these events.

A UDF is a fragment of a medical device that has separated unintentionally and remains in the patient after a procedure. Patients may not be aware that this has occurred. The Center for Devices and Radiological Health (CDRH) receives nearly 1000 adverse event reports each year related to UDFs. These have included more than 200 different medical devices and numerous medical specialties.

The adverse events reported included local tissue reaction, infection, perforation and obstruction of blood vessels, and death. Contributing factors may include biocompatibility of the device materials, location of the fragment, potential migration of the fragment, and patient anatomy. During MRI procedures, magnetic fields may cause metallic fragments to migrate, and radiofrequency fields may cause them to heat, causing internal tissue damage and/or burns.

#### ***Possible Malfunction of Electronic Medical Devices Caused by Computed Tomography (CT) Scanning;***

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

They say it is possible that this interference is being reported more frequently now because of the increased utilization of CT, the higher dose-rate capability of newer CT machines, an increase in the number of patients with implanted and externally worn electronic medical devices, and better reporting systems.

***Institute for Safe Medication Practices (ISMP)*** highlighted several potential safety problems when hospitals switch from multiple dose vials of insulin to insulin pens.

#### 4 OTHER POST MARKET SURVEILLANCE ISSUES

Health Canada are reporting issues with Silicon Gel Breast Implants; <http://www.hc-sc.gc.ca/dhp-mps/md-im/update-miseajour/index-eng.php>

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FDA are reporting problems with (at <http://www.fda.gov/cdrh/index.html>)

- Mobile Oxygen Storage Tanks
- Carotid Stent and Monorail Delivery System.
- Extracorporeal Blood Pumping Systems.

UK MHRA are reporting problem with;

Baby sleep monitors; <http://www.mhra.gov.uk/NewsCentre/Pressreleases/CON023330>

Procedure packs;

<http://www.mhra.gov.uk/Safetyinformation/Safetywarningsalertsandrecalls/FieldSafetyNoticesformedicaldevices/CON023334>

Sutures;

<http://www.mhra.gov.uk/Safetyinformation/Safetywarningsalertsandrecalls/FieldSafetyNoticesformedicaldevices/CON023328>

Endoscopic applicators;

<http://www.mhra.gov.uk/Safetyinformation/Safetywarningsalertsandrecalls/FieldSafetyNoticesformedicaldevices/CON023307>

Ventilator circuits;

<http://www.mhra.gov.uk/Publications/Safetywarnings/MedicalDeviceAlerts/CON023087>

Hygiene chair; entrapment of genitals!!

<http://www.mhra.gov.uk/Publications/Safetywarnings/MedicalDeviceAlerts/CON023082>

**Full list of MHRA alerts is at**

**<http://www.mhra.gov.uk/Publications/Safetywarnings/MedicalDeviceAlerts/CON2033928>**

## 5 STANDARDS UP-DATE.

*Interesting web site that keeps you up-to-date with adopted standards that are harmonised with the EU Directives;*

[http://ec.europa.eu/enterprise/medical\\_devices/guide-stds-directives/abhs\\_n\\_106\\_snapshot\\_july\\_2008.pdf](http://ec.europa.eu/enterprise/medical_devices/guide-stds-directives/abhs_n_106_snapshot_july_2008.pdf)

### *Publications;*

<b>BS EN Publications</b>	
<b>BS EN 1650:2008</b>	Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas. Test methods and requirements. (phase 2, step 1) Supersedes BS EN 1650:1998
<b>BS EN 15546:-</b>	Small bore collectors for liquids and gases and healthcare applications.
<b>BS EN 15546-1 :2008</b>	General requirements
<b>BS EN 60601:-</b>	Medical electrical equipment.
<b>BS EN 60601-1-9:2008</b>	General requirements for basic safety and essential performance. Collateral standard. Requirements for environmentally conscious design.
<b>Drafts for development</b>	
<b>DD ISO/TS 22367:2008</b>	Medical laboratories. Reduction of error through risk management
<b>Amendments to British Standards</b>	
<b>BS EN 15333:-</b>	Respiratory equipment. Open-circuit umbilical supplied compressed gas driving apparatus.
<b>BS EN 15333-1:2008</b>	Demand apparatus
<b>New work started</b>	
<b>BS EN 1639 (Revision)</b>	Dentistry. Medical devices for dentistry. Instruments. Will supersede BS EN 1639:2004
<b>BS EN 1640 (Revision)</b>	Dentistry. Medical devices for dentistry. Equipment. Will supersede BS EN 1640:2004
<b>BS EN 1642 (Revision)</b>	Dentistry. Medical devices for dentistry. Materials. Will supersede BS EN 1641:2004
<b>BS EN 1642 (Revision)</b>	Dentistry. Medical devices for dentistry. Dental implants.
<b>Draft British Standards for public comment.</b>	
<b>08/30170500 DC BS EN 60601-2-33</b>	Medical electrical equipment. Part 2-33 Particular requirements for basic safety and essential performance of magnetic resonance equipment for medical diagnosis.
<b>08/30174059 DC BS ISO 81062-2</b>	Non-invasive sphygmomanometers. Part 2. Clinical validation of automated measuring type.
<b>Documents not issued for public comment</b>	
<b>ISO 2898:-</b>	Plastics. Plasticized poly(vinyl chloride) (PVC-P) moulding and extrusion materials.
<b>ISO 2898-2</b>	Preparation of test specimens and determination of properties.

<b>IEC Publications</b>	
<b>IEC 62220:-</b>	Medical electrical equipment. Characteristics of digital X-ray imaging devices.
<b>IEC 62220-1-3:2008</b>	Determination of the detective quantum efficiency. Detectors used in Dynamic Imaging.
<b>ISO Publications</b>	
<b>ISO 5364:2008-08 (Edition 4)</b>	Anaesthetic and respiratory equipment. Oropharyngeal airways.
<b>ISO 11143:2008-08 (Edition 2)</b>	Dentistry. Amalgam separators.
<b>ISO 12189:2008</b>	Implants for surgery. Mechanical testing of implantable spinal devices. Fatigue test method for spinal implant assemblies using an anterior support.
<b>ISO 13408:-</b>	Aseptic processing of health care products.
<b>ISO 13408-1:2008 (Edition 2)</b>	General requirements.
<b>ISO 15223:-</b>	Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied.
<b>ISO 15223-1:-</b>	General requirements. AMENDMENT 1:June 2008 to ISO 15223-1:2007.

John Adcock  
Advena Ltd.  
August 2008

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