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Medical Devices - ISO 13485 Standard

As the world's population gets increasingly older, the need to replace body parts that wear out is also increasing, hence the need for medical devices i.e. the spare parts. According to an article in the Business Standards, BSI's magazine, there are over 10,000 different groups of medical device types, covering almost every part of the human body. Manufacture of these types of devices is supported by ISO 13485 – the International Medical Device Quality Management System Standard. This standard was recently updated to ISO 13485:2003 and is aligned with ISO 9001:2000. The medical devices industry is a highly regulated and technical business. The laws and guidelines are constantly changing and it is therefore crucial that companies have the relevant knowledge to ensure compliance. Medical devices are used to treat people with varying degrees of illness and product quality is vital. To achieve this, all divisions of industry must learn and discuss quality related issues. According to a news article in the IQA's – "Quality Professional" magazine, a new group has been formed called the Medical Device Quality Group (MDQG). This is a joint venture between the IQA and the biomedical division of the ASQ (American Society for Quality). The new group is intended as a forum to share knowledge and expertise between quality professionals in the UK and US. For more information please see the "Business Standards" or "Quality Professional" magazines.

Who will run the Internet?

According to a recent article in "The Register" a meeting in Geneva will define what is, what was and what shall become of the global electronic medium known as the Internet. The World Summit on the Information Society, organised by the International Telecommunications Union (ITU), will see heads of over 60 governments getting together, discussing and hopefully agreeing on some principles of where we go from here. There is a divide across the world over who should be in charge of running the Net's vital infrastructure. The United States, Europe and other English-speaking partners such as Australia favour the existing private-company organisation, ICANN, whereas the developing nations such as China, India, South Africa and others all want a recognised international body to run the show, ITU. The outcome of this meeting will probably be known in the new year. For more information please see www.theregister.co.uk

CMMI for Software and Systems Process Improvement

One on-going change in the Capability Maturity Model world is the continuing integration of the models for Software and Systems Engineering. The resulting model, the Capability Maturity Model Integrated (CMMI), is a powerful tool to lever process improvement into an organisation in a structured and visible way. The model defines the key elements of effective processes for the two disciplines and is based on those processes proven by experience to be effective in practice. It carefully builds on the



concepts of process capability and organisational maturity to allow organisations to focus on improving an individual process or on a relevant set of processes. In either case a series of levels are defined that provide a valuable roadmap for improvement efforts. The Software Engineering Institute at the Carnegie Mellon University have made it clear that the CMMI will be the way forward for the key disciplines and they will not be developing the original CMM-SW further. To find out more about the model and its potential please visit www.sei.cmu.edu/cmm/cmmi or www.dnv.com

Company Newsletters

Producing a company newsletter can be one of the best ways of building a good relationship with your customers and also generating sales. According to an article in "The Guardian" a newsletter is a good sales promotion vehicle. Organisations, which consider using newsletters as a method of promotion/marketing, should commit themselves to producing a newsletter regularly and to a high standard. Newsletters can be in the form of printed-paper or electronic. Whichever method used, it must capture the audience's attention. In the case of the paper version, it must grab the customer's attention before they throw it in the bin, or in the case of the electronic version, it has to be pretty distinctive to avoid being deleted as one of the vast numbers of emails received. QM&T can offer help and advice on producing newsletters and can even produce a dedicated company newsletter with your own logo, news material and any special offers. For more information please visit www.qmt.co.uk

Toy Safety Standard

Christmas is the busiest period for buying toys, and it is important for customers to look out for the European Standard BS EN 71 on toys and packaging. Standards play an essential role in the design and manufacture of toys, and BS EN 71 shows that the toy has been tested to European toy safety standards. There are eight

separate parts to BS EN 71. For example, Part six (BS EN 71-6) covers age warning labelling, whereas part eight (BS EN 71-8:2003) refers specifically to play equipment and is a new addition this year. Before toys reach the shelves of UK shops, they undergo a number of safety tests in the design and manufacture process. Different types of toys, and even different parts of the same toy, must meet certain specifications outlined in BS EN 71 before they can be considered safe for children. Safety testing might include setting a teddy bear alight to check that it does not burn too quickly, and (BS EN 71-2:2003) ensures that certain flammable materials, which create the greatest risk, are banned from all toys. For more information please see www.bsi-global.com

Poor Quality Pictures Using CCTV

CCTV pictures are often of poor quality and the problem of tackling crime using CCTV has led to a FBI initiated project involving 3000 visitors to a British Science museum. The problem has always been the difficulty of determining the identity of the suspect as the quality of the film has been often poor. The research is to be carried out by Sheffield University scientists who are hoping to develop a system that can identify a face caught on CCTV and match it with that of a suspect. The project will involve building a database of the facial variations among the general public. The pictures will be used to develop mathematical techniques to calculate the frequency of sets of facial characteristics. The results should help the police and a jury determine the likelihood of a match between a CCTV picture and the suspect. This could mean that a suspect is not detained unfairly or that an offender that is guilty of a serious crime would not escape conviction. The scientists are hoping this system to produce results that can be used in court in a similar way to DNA. For more information please see BBC news.



Parent's Appearance can Influence their Children's Health

According to a recent report, the appearance of our parents can cause us health problems in the future. The research was carried out on seven thousand people born in March 1958 - and at ages 7, 11, 16, 23 and 33. The results were published in the Journal of Epidemiology and Community Health. The research suggested that having a short mother and an overweight father could result in an underweight baby, who then grows into an overweight adult, with an increased risk of heart disease, high blood pressure and diabetes. This reinforces the need for men and women to maintain a healthy weight throughout their life. For more information please see BBC news.

Mobile Phone Crackdown

It was recently reported that the Scotland Yard have launched a new initiative to cut mobile phone crime, using a specialist unit called the National Mobile Phone Crime Unit (NMPCU), dedicated to dealing with handset theft. Currently, in UK, when mobile phones are reported lost or stolen, once a call has been made to the police, that handset would be blocked across all networks in the country. However, they can still be used abroad, where criminal gangs steal the handsets to be exported to counties such as Africa, Asia and other parts of Europe, where handset prices aren't subsidised as they are in the UK. With the new initiative it is hoped that they could extend their practice internationally to stop the handset being traded in other counties. For more information please see www.silicon.com

Top Spammers are the Pill Pushers

Health related email messages, mainly those marketing diet pills and Viagra, were the top spam offenders of last month's emails. A new study issued in December 2003 by anti-spam software maker Clearswift showed that unwanted email messages relating to health increased significantly and yet more surprising the pornography-oriented spam, actually decreased over that same period.

Clearswift's study surveyed 15,000 customers who received unwanted emails, then randomly selected 1,000 of those emails and categorised spam messages based on their contents. Clearswift's Spam Index, a monthly report that surveys the frequency of unwanted email, found that health related messages accounted for nearly 50 per cent of all spam, porn-related messages accounted for 14 per cent, whilst finance related messages accounted for 12.5 per cent and direct product spam, which often markets products such as toys and electronics represented only 10.5 per cent of unwanted emails last month. Spam continues to be a major problem facing the Internet. The UK introduced its anti-spam law early in December and President Bush also signed the so-called Can-Spam bill, which is the first federal law regulating spam. Legal issues among businesses and widespread distribution of parental control software has made pornography the most actively blocked form of spam. For more information please see www.silicon.com

Recognition of ISO/TS 16949:2002 - We are Unanimous

In the usually highly competitive world of the automotive industry, unanimity seems to have broken out, well at least in the quality sense, it has. The three huge giants, Daimler Chrysler, Ford Motor Company and General Motors Corp. have joined forces to agree the quality criteria for their suppliers, namely, they are strongly urging their suppliers (I think in automotive speak, this means "you will do it") to meet the requirements of ISO TS 16949 by 10 December 2006. However, reading between the lines this effectively means December 2004.

The agreement between QS9000 and ISO, Geneva, to include ISO9000:1994 text in the QS9000, 3rd edition standards document will expire in December 2006 and ISO/TS 16949:2002 will replace QS9000. This standard provides a single supplier to vehicle manufacturers a single quality management system, which is

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recognised by all IATF-participating companies. ISO/TS 16949:2002 was released in March 2002 and is based on ISO 9001:2000. The benefits of this standard include:

- Improved and consistent registrar oversight and auditor training
- Process based audits, focusing on customer satisfaction
- Global acceptance of the standard
- Improvements learned through QS9000 implementation

More information on this standard can be obtained from www.iaob.org or www.alag.org or www.qmt.co.uk.