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# MedtechBusiness

Business intelligence for the medical technology sector

Issue 19 June 2011

## *Dispatches* questions medical implant safety

Many patients are "acting as guinea pigs" for medical implants and undergoing traumatic device failure and revision surgery due to inadequate regulation, a Channel 4 documentary has claimed.

ABHI and other voices from the UK medical devices sector have responded by drawing attention to the strong record of European medical device regulation and the industry's support for changes to the EU legislation that are currently in process.

*Dispatches: The Truth About Going Under the Knife* looked at devices such as metal hip replacements, pacemaker-defibrillators and cochlear implants that have been recalled following widespread use, requiring their extraction from many patients. It pointed to weak EU medical device regulation as an underlying problem.

Drawing on recent *BMJ* studies, the programme argued that most implantable devices are launched after being tested only in the laboratory and not within the body. The foremost example discussed was the ASR hip replacement from DePuy, where the gradual shedding of metal from the implant surfaces caused complications in many patients more than two years after implantation.

The programme called for greater reliance on clinical testing for any

new brand of implantable medical device, and better access to trial data and clinical records for surgeons and patients alike.

Dr Deborah Cohen, Investigations Editor at the *BMJ*, said: "This story shows the power that companies have in deciding the fate of their devices, their hold over surgeons, the lack of regulatory power in Europe, and the lack of premarket clinical studies."

More bluntly, Dr Carl Heneghan, a GP and Clinical Reader at the University of Oxford, remarked: "Patients are acting as guinea pigs, and that's not good enough."

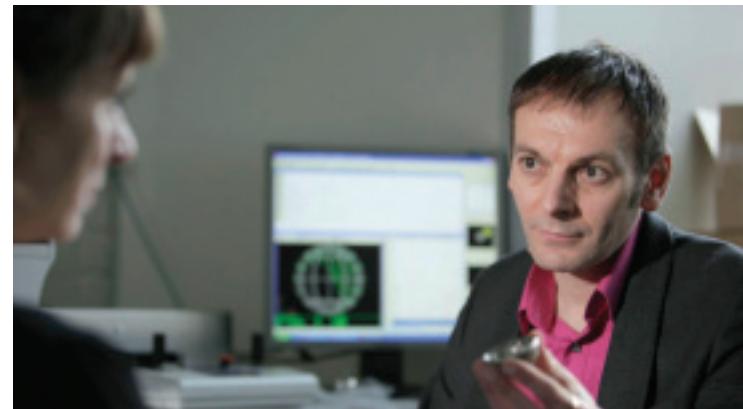
Responses from the UK medtech industry have been vigorous and thorough. ABHI Chief Executive Peter Ellingworth and Eucomed Chief Executive John Wilkinson wrote to the *BMJ*, responding to its criticisms of the regulatory system and the industry. They noted: "The EU system is ahead in terms of patient access as European patients benefit from the latest in safe technology nearly 2 years ahead of their US counterparts and up to 5 years ahead of Japanese patients."

They argued that current reforms to the Medical Devices Directive, which are supported by the industry, address the concerns raised; and that the industry's ethical standards are shown by the ABHI Code of Conduct.

The letter concluded: "We think that much of your criticism of the regulatory system and of industry behaviour is alarmist and fails to take account of both the strong positive track record of the medical technology industry and the regulatory controls applying to it, as well as recent developments and reforms which are in the process of being made both by the authorities and by industry."

Medical device regulatory expert Tarlok Bola noted: "The key difficulty that exists for manufacturers in ensuring compliance is that different national CAs are inconsistent in their interpretation and application of the MD Directive. Sweden's view of the ISO 13485 standard is the most recent example of these inconsistencies. The strengthening of the mechanism to resolve such inconsistencies between CAs is therefore essential."

Paul Saunders, Account Director



Channel 4's *Dispatches* programme

at recruitment, training and business intelligence consultancy Wound Care People, added: "The recent *Dispatches* programme was a sensationalist approach to an issue that industry takes very seriously, patient safety. If we can develop a more proactive, balanced approach, then we have a chance of people seeing the full picture."

"A possible way to address this is by industry helping the consumer and the clinicians to understand that there is a life-cycle for products from innovation to discontinuation. If we can be seen as adding value at the top and removing outmoded technologies at the bottom, then we can start to show the improved outcomes and whole-system benefits that these technologies bring."

For more analysis of the regulatory issues, see 'Viewpoint from ABHI' (page 7) and 'Not mentioned in *Dispatches*' (pages 8–9).

# MedtechBusiness says...

The trouble with innovation is that it's kind of *new*. Nobody likes that. For the medical technologies industry, putting forward solutions that drive changes in healthcare delivery is a tough game in a time of economic trouble. Is it even worth it?

A recent Channel 4 *Dispatches* programme used the example of the ASR hip replacement to argue that the pace of medical device innovation involves too many risks for patients. But these safety issues are not ones about which the industry has been either ignorant or complacent. The pressure for rapid innovation in medical solutions comes from the healthcare system and the public. Companies have to juggle conflicting customer priorities: *we want it safer, we want it cheaper, we want it better, we want it now.*

Last month, it was reported that an implanted neurostimulation device has enabled a young American to walk again two years after his spine was broken by a hit-and-run driver. Former baseball star Rob Summers said: "This procedure has completely changed my life. To be able to pick up my foot and step down again was unbelievable." That's the other side of innovation.

Our article on page 10 examines the threats posed to medtech innovation by healthcare budget cuts and commoditisation. A visit to your local supermarket will demonstrate the problem: high-quality and niche products are abandoned in favour of what is cheapest and most in demand.

But, as our news section illustrates, the health system can only meet the growing demand by developing personalised solutions that empower patients to manage their own healthcare. Through management of the innovation process, demonstrating benefits to the health system and building new solutions through 'open innovation', the medtech industry can help to bring sustainable health to a far greater number of people.

Innovation is a tough game – but it's the only game in town.



Chris Ross, Editor

## TSB and MRC invest in personalised healthcare

Seven major new research projects that bridge life science sectors to develop innovative personalised medicine in the UK will be supported by joint funding of £3.7 million from the Technology Strategy Board (TSB) and the Medical Research Council (MRC).

Northern Ireland-based diagnostics specialist Randox Laboratories is among the life science companies leading the projects, which include developing new uses of biomarkers to predict reactions to drugs and business models for the co-development and commercialisation

of drugs and companion diagnostics.

The investment is the first to be made through the new Stratified Medicine Innovation Platform (SMIP), which will oversee the investment of over £50 million of government funding over five years to support innovation in such areas as tumour profiling and biomarker development.

Managed by the TSB, the SMIP brings together representatives of the English and Scottish Government health departments, the MRC, NICE, Cancer Research UK and Arthritis Research UK.

## Industry agrees on ethical practices

Nine medtech industry associations from around the world have committed to advancing ethical business practices by signing a 'Global Compliance Statement on Interactions Between Medical Technology Companies and Healthcare Professionals (HCPs)'.

The agreement, first signed in 2010 by US industry association AdvaMed and European associations Eucomed (for medical devices) and EDMA (for diagnostics), now includes another six industry associations.

The extended agreement represents a major step forward in the establishment of global standards for ethical business practices between medtech suppliers and HCPs, reflecting the worldwide reach of medical innovation.

The new signatories are COCIR (European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry), IMEDA (International Medical Devices Manufacturers Association) and industry associations in Canada, Australia, New Zealand and South Africa.



John Wilkinson

The nine associations will work together to encourage companies to adopt compliance programmes and policies consistent with the applicable industry codes, and to provide guidance to companies on ethical business conduct relating to interactions with HCPs.

John Wilkinson, Chief Executive of Eucomed, said the agreement was "an important milestone in our mission to provide consistent transparency and ethical standards across international borders". He added: "This is the way forward if the medical technology industry is to keep on delivering modern, safe and effective medical technology and care to patients across the globe."

## BMA calls for 'integrated' health reform

The Health and Social Care Bill should be changed to reduce its emphasis on competition between providers, or else be withdrawn, the BMA has said.

In its formal response to the NHS Future Forum, the body leading the Government's 'listening exercise', the BMA warns that its members are seriously concerned about the effects of enforcing competition.

It recommend the development of more integrated services based on "more mature" commissioning, with greater collaboration between NHS providers.



Dr Hamish Meldrum

The BMA calls for a system whereby clinical networks of specialists and primary care professionals work together alongside GP consortia to design patient pathways and commission services.

The submission recommends that the primary role of Monitor be amended to protecting and promoting high-quality, comprehensive, integrated services, not promoting competition; and that GP consortia should have an explicit duty to involve all relevant clinical staff in commissioning.

Dr Hamish Meldrum, the BMA's Chairman of Council, said: "We know that the NHS has to become more efficient, and that we need a step change in improvements in public health. Increasing and enforcing competition is not the answer. Instead, we are putting forward recommendations that aim to maximise the potential for positive change in the proposals, by genuinely giving more say to patients and to clinicians."

# Eucomed calls for eHealth 'voice'

European medtech industry association Eucomed has called on healthcare providers in the EU to ensure that electronic healthcare (eHealth) has a strong 'voice', a unified technical framework and effective reimbursement.

In its position paper *Overcoming barriers to eHealth*, Eucomed argues that the implementation of eHealth is a major priority for public health.

Eucomed states that eHealth programmes and policies in the EU need to meet several major goals, including:

- To ensure a framework for technical and semantic interoperability in the health sector that enables the standardisation and harmonisation of national and local eHealth systems.
- To ensure a value-based reimbursement and funding framework that properly compensates healthcare professionals for the use of eHealth technologies and remote services.
- To establish a leading European voice to argue the value of eHealth for the future of EU healthcare systems.

Anna Lefevre Skjöldebrand, Chair of the Eucomed eHealth Working Group, commented: "eHealth is transforming healthcare delivery across Europe and it is only a matter of time before we drop the 'e' in 'eHealth' and view it as the benchmark."

She added that "Eucomed and its members will become more involved and active in the eHealth arena."



Genesis DM eHealth monitor

# Boston Scientific wins stent patent lawsuit

Boston Scientific has won \$19.5 million in damages from Cordis, a Johnson & Johnson company, after a US jury trial resolved the patent dispute over the companies' small-vessel stents.

A jury in Delaware, USA, determined that the 2.25mm Cypher stent for small blood vessels (which gained FDA approval in September 2009) infringed a patent held by Boston Scientific for its Taxus Express Atom stent (approved a year earlier).

Boston Scientific was awarded \$18.5 million in lost profits and \$1 million in royalties. The company had sought \$34 million in damages – more than half of Cordis's \$60 million revenue from the

small-vessel Cypher stent.

Ironically, the original Cypher stent was the first drug-eluting stent approved for sale in the USA (in 2003), while the Taxus stent was approved a year later after being developed to challenge the Cypher stent's monopoly of the US market.

Boston Scientific sued Cordis for patent infringement over the similarity of their small-vessel stents in 2009. The Delaware court has now determined that the infringement was both real and intentional.

Referring to the extensive patent litigation of recent years, the judge commented that this could be "the last of the stent trials".



Copyright © 2009 Boston Scientific Corporation. All rights reserved. Taxus Express Atom

# Drug delivery study stresses patient experience

Pharmaceutical and medical device companies making combination products need to pay more attention to patient experience, according to a new study by technology design and development firm Cambridge Consultants.

A survey of healthcare providers and over 240 insulin-injecting diabetes patients showed that by paying better attention to device usability, companies could improve patient compliance and health outcomes.

The patients surveyed used combination products such as injection pens and insulin pumps daily. The study found that 75% of patients had been given a choice of drug delivery device; of these, 21% had done their own research. Among patients who had changed their devices, 'lifestyle' factors such as discretion and portability were the biggest influences. The healthcare

providers surveyed all believed that better device usability improves compliance.

"The findings challenge traditional industry conceptions about compliance and the patient experience," said Melanie Turie, Human Factors Team Leader at Cambridge Consultants. "The industry has been good at maximising drug efficacy but patient experience factors have not really been a primary focus. Only now are we seeing the patient experience take centre stage."

"Drug makers need to realise that if you consider the patient's broader needs throughout the development process – from conception to design, development and commercialisation – you are likely to have a more successful and effective product, resulting in improved compliance and therefore improved patient outcomes."

# Letter to Medtech Business

27 May 2011

Dear Sirs

The report in May's edition on Proact Medical's NICOM device was misleading about the status of guidance from NICE's new Medical Technologies Advisory Committee.

In March NICE published guidance recommending the use of Deltex Medical's CardioQ-ODM to manage intravenous fluids during major and high-risk surgery. This recommendation is specific to CardioQ-ODM and was based on a rigorous assessment of a substantial body of high-quality clinical evidence that using CardioQ-ODM during surgery reduces post-operative complications and, therefore, lengths of hospital stay.

The route to a NICE recommendation is transparent: manufacturers submit details of their product and its evidence base and NICE's committee decides whether and how to evaluate the product. The process from notification of CardioQ-ODM to its recommendation took a year and involved ten weeks' hard work for a small team, but only modest external costs.

The harder and more expensive part was, of course, the many years spent developing a safe and efficacious product that makes a real difference to patients and is supported by a robust evidence base of its clinical and economic benefits. We don't believe there are any short cuts, but do believe such investment will generate substantial returns for those medtech companies that are prepared to make it. So, if you want to claim a NICE recommendation for your product, go ahead and get one, but only if your product is good enough and proven so.

Yours faithfully

Ewan Phillips  
Chief Executive  
Deltex Medical

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# Paediatric CT systems showcased

Paediatric imaging applications of computed tomography (CT) scanners were showcased by two major diagnostic imaging specialists at the International Paediatric Radiology 2011 conference in London.

Toshiba presented the Aquilion ONE CT system with dose reduction capability and new paediatric software. Siemens presented the Somatom Definition Flash with new applications for dose reduction.

The new applications reflect the growing priority of minimising children's exposure to radiation, and of avoiding the costs and dangers of sedation in very young children.

Toshiba's Aquilion ONE features Adaptive Iterative Dose Reduction software, which reduces 'noise' to increase image quality at a lower radiation dose. In addition, the scanner can capture a structure up to 16cm wide – such as the heart or brain – in one rotation, potentially eliminating the need for sedation.

The Aquilion ONE now features dedicated paediatric software that allows the clinician to set 'child-sized' examinations by entering the patient's age or weight. A separate Paediatric Kit



Aquilion ONE



Somatom Definition Flash

includes a number of child-friendly accessories and features, including: an audio-visual instructional tool to help children maintain breath holds; child-sized table straps and cushion; and a small replica of the scanner to help the child understand the process.

The Somatom Definition Flash from Siemens Healthcare offers CT scans without sedation or breath holds, and with new applications for dose reduction. The system, which uses two X-ray tubes and detectors, is the world's fastest scanner. It has been used to scan infants in less than 1 second, at an X-ray dose of less than 1mSv. Using conventional CT technology, the procedure would take several seconds and require a dose 8–20 times higher.

The system has three new dose reduction applications:

- The Care kV function recommends the correct tube voltage for the patient's anatomy and adapts other parameters, allowing the dose to be reduced by up to 60%.
- The Care Child function reduces the voltage from its usual range (80–140kV) to only 70kV.
- The Safire (Sinogram Affirmed Iterative Reconstruction) function reduces the time required to reconstruct slice images, allowing a further 60% reduction in the dose.

## Blood glucose meter calculates doses

A new blood glucose monitoring system that can calculate appropriate mealtime insulin doses is now available in the UK.

The FreeStyle Insulin Blood Glucose Monitoring System from Abbott has received CE Mark approval.

Designed for people with diabetes who use mealtime (rapid-acting) insulin, the system has several features designed to enable patients to manage their condition more effectively – including a mealtime dose calculator for insulin, a user-friendly touch screen and an automated logbook.

The FreeStyle Insulin system also offers USB connectivity, options for personalisation and a specialised FreeStyle Auto-Assist software that provides reports, reminders and messages for patients, carers and clinicians.

A study found that only 41% of people with type 1 diabetes were able to calculate an appropriate insulin dose with adjustments for both carbohydrate intake and blood glucose levels.

Dr. David Kerr, Consultant Physician at Bournemouth Diabetes and Endocrine Centre, Royal



FreeStyle Insulin system

Bournemouth Hospital, commented: "For my patients who require insulin, the steps involved in the self-care of their diabetes can be complicated and overwhelming. Insulin is a powerful drug that needs to be dosed accurately and carefully or it can lead to significant adverse consequences."

"The introduction of new products that are created to make the difficult task of insulin dose calculation easier is important for people with diabetes and for their healthcare professionals."

"The FreeStyle Insulin Blood Glucose Monitoring System is a significant advance for people with diabetes who use insulin," said Heather L. Mason, Senior VP, Abbott Diabetes Care. "It has the potential to help change the way insulin users manage their diabetes, because it has been designed to translate glucose results into helpful information."

# NICE unsure of whole-body X-ray

The first draft guidance from the new NICE Diagnostics Assessment Programme says a new whole-body X-ray system has "plausible potential".

The provisional recommendations do not support routine NHS use of the EOS Low Dose 2D/3D X-ray imaging system from EOS Imaging – but recommend its use in research settings to explore its clinical benefits.

The EOS system uses a low radiation dose to take 2D X-ray images and 3D reconstructions of bones. By scanning a line at a time, it allows weight-bearing images of the whole body to be taken. This could assist the treatment of orthopaedic patients by showing relationships between skeletal areas, while cutting patient turnaround times.

Professor Adrian Newland, Chair of the Diagnostics Advisory Committee,

said: "This technology may have a number of potentially significant benefits for patients, and there is evidence to suggest that the system does confer some benefits in terms of reducing radiation dose. Also, simultaneous 2-view imaging may permit improved patient throughput.

However, he stated, there was "no available evidence" that the benefits of using the EOS system translated into "health benefits for patients" – in particular, no data regarding its diagnostic accuracy relative to conventional systems – and this, "together with the high cost of the system", had led the Committee to its provisional conclusion.

Professor Newland added that the EOS system has "plausible potential" to provide clinical benefits, and NICE

is recommending further research to establish whether it offers better health outcomes. Final guidance will be published in October 2011.



EOS X-ray

## NEWS IN BRIEF

### Mobile app for NHS Direct

A new mobile app for the Android and iPhone enables users to interact with the NHS Direct service.

The free app from Mobikats was commissioned by Transform Innovation, digital strategy advisers to NHS Direct. The user answers symptom-related questions and the app provides self-care advice, generates a call-back from a nurse advisor or suggests a course of action.

### 'Virtual hospital' trialled in UK

An e-health solution that provides a 'virtual hospital' for patients with long-term conditions is being trialled by a UK hospital trust, which will apply it to COPD patients at home. The CSC eMEDlink platform enables clinicians in primary and secondary care to conduct secure, remote audio-visual consultations with patients, carrying out virtual 'ward rounds'.

## Portable negative pressure system launched

The first pocket-sized, portable Negative Pressure Wound Therapy (NPWT) system is now available throughout the EU.

Smith & Nephew's PICO is a single-use therapy for acute and chronic



PICO system

wounds, high-risk surgical incisions and skin grafts.

PICO combines a disposable one-button pump with an advanced wound dressing that can be worn for up to seven days. It allows fluid management directly through the dressing, making NPWT available to a wider range of patients than was possible with canister-based treatments.

Preclinical studies have shown that PICO delivers negative pressure to the wound bed and removes exudates to the same extent as standard NPWT. The simplified technology means that it can readily be applied with minimal

administration and training.

"A system like PICO that combines the clinical effectiveness of NPWT with the known benefits of advanced wound care dressings is an ideal solution for appropriate patients, especially those at high risk in the critical days following surgery," said Professor Donald Hudson, Head of the Department of Plastic Surgery at the University of Cape Town, South Africa.

"PICO opens up some very interesting possibilities in treating many kinds of small to medium-sized wounds in both hospital and outpatient settings."

### Monitors share patient data

The new Peterborough City Hospital is the first UK hospital to install the IntelliVue MX800 iPC patient monitoring system from Philips Healthcare. The first such system to incorporate clinical informatics, the MX800 iPC facilitates the sharing of patient data between departments: clinicians can use it to access information from other bedside monitors or the hospital intranet.

## Ultrasound needle pierces endoscopy market

A new high-frequency ultrasound needle for endoscopy promises to improve the diagnosis of cancers in and around the gastro-intestinal tract.

The Expect Endoscopic Ultrasound Aspiration Needle from Boston Scientific has been launched in Europe and worldwide.

The needle is used to acquire tissue samples for diagnosing and staging malignant growths in the pancreas, liver, bile duct and intestine.

It combines endoscopic ultrasound imaging (EUS), used to produce detailed images of soft tissues and

organs, with fine needle aspiration (FNA), used to collect cytology samples for cancer diagnosis.

The Expect Needle has an echogenic pattern that aids needle visibility and precise guidance. Its cobalt chromium material has greater sharpness and deformation resistance than traditional stainless steel needles.

"Combining EUS with FNA offers powerful diagnostic capabilities that can help optimize malignancy management in the GI tract and inform appropriate treatment paths for the patient," said Robert H. Hawes, Professor of

Medicine, Medical University of South Carolina.

"The excellent visibility, sharpness and durability of the Expect Needle help obtain high-quality diagnostic samples easily and efficiently."



Expect Needle

### Skin repair spray launched in Middle East

ReCell Spray-On-Skin, a regenerative therapy for skin damage from UK company Avita Medical, has been launched in six Arabian Peninsula countries. ReCell enables the preparation in theatre of a suspension of cells derived from a small biopsy of the patient's own skin that can cover a wound area up to 80 times greater and regenerate skin of normal colour and texture.

# Breakthrough medical technologies

## Imaging breakthrough arms cancer research

A new imaging technology enables cancer researchers to visualise the structural and functional attributes of tumours *in vivo*, tracking tumour development and the effect of drug therapies.

The Veo LAZR photoacoustic imaging system from VisualSonics, a subsidiary of SonoSite, is now available worldwide and could contribute to cancer risk reduction, early detection and treatment.

The new system enables researchers to observe tumour progression from the earliest stages, measuring changes in the blood flow and oxygen level in real time.

Crucially, it can be used to track the effect of a drug on tumour growth without reliance on biopsy – offering a more efficient means to screen drugs during early stages of research.

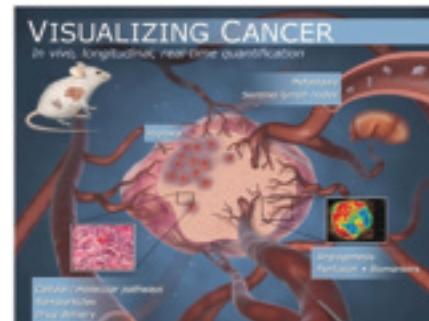
The device sends laser pulses through the skin into tissues where they are converted into heat, producing ultrasonic emissions that are captured by a probe and turned into images. This makes visible a wider range of cell components than could previously be imaged *in vivo*. Applications include targeted imaging of tumour biomarkers.

“The Veo LAZR is a crucial breakthrough, with wide-ranging implications for cancer research,” said

Professor Stanislav Emelianov, Department of Biomedical Engineering, University of Texas.

An early user of the new system, David A. Jaffray of the Ontario Cancer Institute, added: “Advanced imaging technologies like VisualSonics’ Veo LAZR photoacoustics system allow our scientists to see into the processes that sustain a disease like cancer. With this knowledge, we can design the next generation of therapies.”

SonoSite President and CEO Kevin M. Goodwin commented: “We believe that the Veo LAZR system will have a



VisualSonics poster

strong impact on the discovery of new cancer therapies, more efficient testing of therapies with never-before-seen insights into cancer and quantified measures of cancer progression, viewed from inside the tumour.”

## Skin cancer screening with an iPhone

The first mobile-connected dermatoscope has been launched in Europe and the USA.

handyscope from German company FotoFinder is an iPhone-based device for mobile skin cancer examinations.

Doctors can use an iPhone, handyscope and secure app to capture, save and share microscopic pictures of skin moles.

The handyscope device is attached to the iPhone and placed directly on the patient’s skin. High-resolution mole images with up to 20x magnification are captured and managed in the app and can be shown to the patient.

Unlike conventional hand-held dermatoscopes, handyscope enables doctors to avoid touching the skin and to evaluate moles on-screen. This makes home visits more comfortable for the patient.

Skin moles can be photographed and labelled with patient data and comments. The pictures can be shared with colleagues using the iPhone. This enables non-specialist doctors in rural areas to



handyscope

carry out initial skin cancer screening.

“We developed handyscope for those who want to take pictures of the skin and work with them later – doctors who miss the ‘capture and save’ function when using conventional hand-held dermatoscopes,” said Andreas Mayer, CEO of FotoFinder.

“For many years we have been speaking and publishing on ‘Mobile teledermoscopy – melanoma diagnosis by one click?’ And now I envision that the handyscope will do the job,” commented Prof. H. Peter Soyer, Dermatology Research Centre, University of Queensland, Australia.

German company FotoFinder Systems is a global supplier of imaging devices for skin cancer diagnosis.

## Spinal implant enables paralysed man to walk

An implanted neurostimulation device has enabled a man whose legs were paralysed in a car crash to walk again.

Rob Summers, aged 25, was a baseball star in the USA when a hit-and-run driver broke his spine and left him with no movement below the torso.

The implantation of a neurostimulation device in his lower back, followed by two years of intensive training, have enabled him to stand and even take steps. He has also regained bladder and bowel control.

This medical breakthrough offers hope of restored mobility and independence to many people paralysed by injury or stroke.

“This procedure has completely changed my life,” said Rob Summers. “To be able to pick up my foot and step down again was unbelievable, but beyond all of that my sense of well-being has changed.”

The treatment was the result of research funded by the Reeve

Foundation, which aims to find a way of restoring mobility to people with spinal injuries – such as the actor Christopher Reeve, who died in 2004.

The neurostimulation therapy builds on recent discoveries about the role of limb and spinal nerves in controlling movement. It proves that in humans (as was already known for other animals), movement is possible without the direct control of the brain.

Professor Susan Harkema from the University of Louisville, a neurologist involved in Summers’ treatment, said: “This is a breakthrough. It opens up a huge opportunity to improve the daily functioning of these individuals... but we have a long road ahead.”

Three other neurologists commented in *The Lancet* that “this novel phenomenon of electrically enabled motor control” has great potential, though further research into its applicability is needed. “We are entering a new era when the time has come for spinal-cord injured people to move.”

# Viewpoint FROM



Association of  
British Healthcare Industries

## Benefits of the European regulatory system

Many medical technology suppliers will have seen the recent media coverage surrounding medical device regulation. Whilst this may have caused some concern, it is important that industry continues to explain the benefits of the European regulatory system. A number of the claims made during the coverage were alarmist and failed to acknowledge many of the processes that are already in place to ensure that the Medical Devices Directives continue to deliver safe technologies to patients when they are needed. Instead of focusing on a few negative incidents, it is important to look at the true picture.

Europe is approaching almost 20 years of proven effectiveness of the Medical Devices Directives in regulating the safe introduction of new medical technology. Established in the 1990s, the EU system is seen globally as one of the best in the world. It takes its place alongside jurisdictions such as the US and Japan in setting a high level of patient safety.

The EU system is ahead in terms of patient access, getting safe technologies to patients ahead of other systems around the world. Recent research published by Dr Josh Makower shows that the regulatory process in Europe delivers treatments to patients faster than the US and Japan while not compromising patient safety.

Any system that regulates rapidly developing technologies such as medical devices needs to be revised

periodically. The original device legislation has been updated on several occasions. A further revision is currently under way – a fact that was virtually ignored in recent coverage. The anticipated reforms address many of the criticisms that were raised including the designation and control of Notified Bodies, the availability of information and the post-market follow-up.

The medical technology industry has consistently supported the need for regulation and we have argued in favour of the reforms. We think the evidence shows that the Directives fundamentally offer the necessary balance between protecting public health and allowing new medical technology onto the market. We agree with the Commission and Member States in that we see no need for radical change to the underlying regulatory system, but at the same time recognise that the system should evolve to introduce specific improvements including overall management and co-ordination by the Member States' competent authorities.

No-one would sensibly maintain that the introduction of medical technology is without risk or that unforeseen adverse events cannot occur. Regulation has to maintain a balance between the need to avoid inappropriate or defective products being introduced to the market and the need to avoid unnecessary delay in making available to clinicians and

patients new products that can save and enhance the quality of lives.

Criticism also touched on the relationships between the medtech industry and clinicians. ABHI has for many years operated a Code of Business Practice, which was comprehensively revised in 2008 in conjunction with the revision of a similar Code of Practice operated by Eucomed. These codes lay down, in strict terms, the way in which manufacturers and suppliers should interact with health professionals and purchasers of medical technology. It is a condition of membership of both ABHI and Eucomed that members adhere to these Codes, which are aimed at establishing and maintaining high standards of business ethics.

ABHI has been responding to media coverage and will continue to defend industry against criticism. Over the coming months we will be working to ensure that medical device regulation and its role in delivering safe technology to patients in a timely manner is fully understood.

### What next for the NHS reforms?

The Government's Health and Social Care Bill 'Listening Exercise' came to a close on May 31, meaning there will probably be a report to Cabinet in June prior to a formal announcement of any changes and a new timetable for the reforms.

The 'Listening Exercise' was the Government's response to opposition to the planned changes. The NHS Future Forum, a group of around 40 experts recruited to co-ordinate the exercise, held hundreds of sessions across the country to give people the chance to tell the Government what they think of the proposed reforms.

Once this group reports back, the Government will have to decide what to do next and formally respond. If the Bill is to undergo significant changes, the likelihood is that it will go back to a Commons committee for scrutiny by MPs before it moves to the House of Lords. This delay means it is unlikely to become law before early 2012.

ABHI continues to ensure that industry is well represented throughout this process. We took part in a number of listening sessions and provided a formal submission to the 'Listening Exercise'. We will continue to keep members up to speed on the changes as the legislative framework develops.

ABHI's Summer Dinner and Networking Dinner will look at the NHS reforms in greater detail. We will be joined by Health Minister Earl Howe, new head of the NHS Confederation Mike Farrar, former health minister Lord Hunt and *Health Service Journal* columnist Michael White.

**You can register to attend the ABHI dinner at: <https://www.abhi-events.org.uk/abhi/45/home>**

For more from ABHI visit: [www.abhi.org.uk](http://www.abhi.org.uk)



# Not mentioned in *Dispatches*



Channel 4's *Dispatches* programme on medical implants did not show how European medical device regulation is changing. Trevor Lewis argues that the medical devices directives are a work in progress, and that following the recent revision of directives, industry needs to be aware of their impending recast – which will have long-lasting and potentially fundamental effects.

If the regulatory system in Europe is to improve, a number of factors are needed. There has to be a mindset among all manufacturers to fully comply with or exceed the essential requirements of the directives. There is a need for more clinical investigations (both pre- and post-market), especially for higher-risk devices; and for greater transparency about the classification and presence on the market of all devices, especially higher-risk ones. The regulations should be enforced in an appropriate and proportionate way, with due regard to economic cost and the public health interest. Finally, all medtech industry representatives and other stakeholders need to work at improving the medical device directives, including the *In Vitro* Diagnostics Directive (IVDD).

## Not the whole story

So there is work to do to make the medical directives fulfil their intended purpose – but Channel 4's emotive *The Truth About Going Under the Knife*

missed out the numerous actions currently in train to improve this situation, both in Europe and beyond. The programme's major omissions are worth noting.

There was no significant discussion of the extensive pre-clinical tests undertaken by responsible implant manufacturers, such as finite element analysis, tribology testing, accelerated life testing, destructive testing, non-destructive testing, precision measurements, biocompatibility, toxicology and animal work.

It was not mentioned that the products cited in the programme were all placed on the market before the mandatory implementation of Directive 2007/47/EC on 21 March 2010 that revised the main device directives. There was no substantive mention or discussion of this recent revision, which:

- demands better compliance with the essential requirements (ERs)
- demands more clinical investigations for all products,

except where their omission can be scientifically justified

- demands more transparency for higher-risk products, especially with regulators and in regard to product vigilance measures including recalls
- demands more scrutiny by competent authorities when biologics, medicines or human or animal tissues are incorporated into medical devices
- has generally increased the expectations that competent authorities (CAs) and notified bodies (NBs) have of manufacturers, especially in design and post-market surveillance activities
- has led CAs to demand improved performance and standards from NBs.

reinforces all the above points, and is encouraging a very wide consultation process. Suggestions made include using the Central Management Committee to provide better co-ordination and consistency across all EU regulators, both CAs and NBs.

Nor was there any substantive mention of the UK Bribery Act 2010 (though the programme questions ethical behaviour in the industry) or its international equivalents, or of industry codes of business practice such as the one long established by ABHI and Eucomed.

*Dispatches* did not refer to the Global Harmonisation Task Force (GHTF) move to become a regulator-only group in preparation to ensure its greater influence in the drafting of appropriate, proportionate and cost-effective medical regulations all around the world (many of which are based on the EU model).

The programme also did not acknowledge that other countries, such as those in MEDA (including

There was also no substantive mention or discussion of the current fundamental review of the directives known as the Recast. The Recast



Algeria, Egypt, Israel, Jordan, Lebanon, Morocco, Palestine, Syria, Saudi Arabia and Tunisia), have closely examined the directives for adoption. Turkey has already done so in preparing to enter the EU. These countries have all opted to adopt the EU system or a close equivalent.

Finally, there was no clear and simple graphical representation to put the relatively small number of non-conforming products into the perspective of the huge number of devices that save lives and extend life in years, all over the world, without fault or concern.

### Keeping a balance

Industry should not just believe that it will all come right in the end. ABHI and Eucomed have been telling their members for some time that there could be significant opposition to the Recast from a minority who think it does not go far enough. However, few predicted such a depth of interest in, and attack on the fundamentals of, the 'New Approach' directives from various quarters – including the recent articles in the *British Medical Journal (BMJ)* related to the *Dispatches* programme, the withdrawal of ISO 13485 for quality management by Sweden, and the objection by the European Commission to the use of ISO 14971 for risk management of medical devices as a harmonised standard.

All medical technology companies, especially SMEs, need to get involved in regulation and look after their own and their patients' best interests. Some past directives, especially environmental ones, have changed in the last stages of their tortuous route through the European legislative process at the European Parliament and Council of Ministers. Companies must take nothing for granted and keep lobbying and putting their case forward until the final ink of the acceptable transposition document is very dry indeed.

Studies have shown the European system to be just as effective as the US Food and Drug Administration (FDA)

approach. Indeed, the FDA recently mooted a 'Class IIb' approach with more emphasis on design scrutiny and use of clinical investigation as part of the pre-market clearance approach, mimicking the Class IIb approach in Europe. A recent US research study by Dr Josh Makower indicates that the EU system helps to deliver innovation to the market more efficiently than the US system – without compromising patient safety. Indeed, a substantial majority of companies surveyed in the US considered the EU regulatory experience much better than its US counterpart.

Over-regulation denies patients the benefits of innovation – a situation much reported during the 1990s, when FDA Commissioner Dr David Kessler adopted a very tough stance. The Wilkerson Group report of June 1995, *Forces Reshaping the Performance and Contribution of the US Medical Device Industry*, is useful in this context. During the Kessler years, more than 100 products were denied to US citizens while being used safely in the EU and in other jurisdictions. The report provided useful statistics on the benefits of medical devices that we should keep in mind and promote to the general public.

### The need for evolution

While claims that the *Dispatches* programme was unnecessarily alarmist are justified, it is still true that all stakeholders can do better – and indeed, the process of improving the system through the revision and Recast of the directives is well under way. The need is not for undue attention to *Dispatches*, but for focus on the vitally important Recast currently being discussed. We are clearly at an important time in the history of EU medical device legislation: the Recast will affect all devices and all patients for a long time to come – probably for 15 years, maybe for 20. It is not something the Commission will want to repeat in a hurry either – as was indicated by the Commission's Director of Consumer

Affairs, Jacqueline Minor, when she said "We don't want to do it again" at a conference in Brussels earlier this year.

Some protagonists, including those writing for the *BMJ*, appear to be comfortable suggesting a pharmaceutical approach to medical device regulation – including the much vaunted (but often inappropriate) use of extensive double-blind randomised clinical trials as the central requirement for regulatory clearance. But a more measured and cautious approach is required in the best interests of patients, so they can receive cost-effective innovations in a timely manner. The highest-risk products must be subject to the most rigorous requirements and extensive clinical investigations – but this is actually a minority of devices, probably fewer than 10%. Most medical devices can be adequately tested with small-scale comparative clinical investigations and extensive pre-clinical testing and simulation. An extensive, comprehensive scientific literature search and report by an appropriately qualified person is always required.

The current position that the medical device regulatory world finds itself in causes me much concern. The focus should be on making the current system more productive and more rigorously used and enforced, not reinventing it. In Europe, while our medical device regulation is long-established, it can be improved. If we do not collectively evolve it further we risk losing a really good system – and doing so mainly because too many stakeholders (CAs, NBs and manufacturers alike) have not rigorously implemented them. We need a mix of sticks and carrots to improve the unfortunate perception that programmes like *Dispatches* create in the minds of consumers.

Most important of all, if industry and regulators do not make good progress in the next few years then a worse alternative is very likely: that those currently demanding a prescriptive and draconian style of regulation, with excessive demands and requirements, will prevail.

**Trevor Lewis is a medical device regulatory expert and Principal Consultant at Medical Device Consultancy (MDC).**

### ABHI comments

Peter Ellingworth, Chief Executive of the Association of British Healthcare Industries (ABHI), commented:

"All patients should be able to feel confident that the medical devices used in their treatment are of the highest quality and safety. At the same time, patients need to be assured of timely access to medical technologies that can allow them to live healthy, productive lives."

"Europe is approaching almost 20 years of proven effectiveness of the Medical Devices Directive in regulating the safe introduction of new medical technology. ABHI has consistently supported the need for regulation of medical technology, and we argued in favour of the reforms currently proposed by the Commission and some Member States.

"The anticipated reforms address most of the criticisms raised by the *BMJ* and the TV programme *Dispatches* with regards to the regulatory framework: overall management and co-ordination of the system by Member States' Competent Authorities, designation and control of Notified Bodies, availability of information and requirements for pre-market testing and post-market surveillance."





# Innovation in danger



The pressures of healthcare cost-cutting and commoditisation threaten the vital role of product innovation in taking healthcare forward. Claudia Graeve looks at how the medical technology sector can rise to the challenge.

The medical technology industry is increasingly under pressure to justify the value of the innovation it provides to healthcare systems around the world. Companies need to respond to this pressure by increasing their capabilities to manage a wider variety of stakeholders, improving the robustness of their innovation pipelines and managing the process of innovation throughout the company.

## Warm words

A quick search of the websites of some of the world's biggest medical device and diagnostics companies in 2011 allows no doubt that innovation is deeply scripted into the hearts and minds of the industry:

- ... bringing innovative ideas, products and services to advance the health and well-being of people (Johnson & Johnson)
- ... a global leader offering

*innovative products and solutions... (3M)*

- ... to continuously develop innovations... (GE Healthcare)
- *Our innovations combine state-of-the-art... solutions (Siemens Healthcare)*
- ... global healthcare products leader dedicated to innovation (Covidien)

If it is so vital, why has there lately been so much anxiety in the industry about the prospects for innovation?

## Increasing pressure

Healthcare costs have risen steadily and faster than overall GDP over the past 50 years or so (see the OECD *Health Data*, October 2010). This growing burden on public spending has been exacerbated by weak economic performance in recent years. Healthcare budget constraints imposed by governments around the world

have resulted in pressure on device manufacturers to justify the value of new products.

*New* is not necessarily *innovative*. Like-for-like replacement of older versions of a product with newer ones is experiencing pushback on pricing. Improved and advanced solutions that are ahead of their time, economically viable, possessing widespread appeal and like nothing done or experienced before require validation and justification in terms of patient outcomes and health economics.

Throughout the world, new policies and regulations are being set up to allow a better understanding of the value of innovation to the healthcare system. Comparative effectiveness research, Health Technology Assessment (HTA) and cost-effectiveness are some of the tools that are being explored to this end.

These are the brutal facts of the pressures faced by healthcare innovation. In the light of this increased scrutiny, what should medical technology companies do to rise to the challenge?

## Towards a new dynamic

Living up to the new reality requires companies to press ahead and go much further in expanding their innovation abilities and finding even smarter, more differentiated ways of offering both incremental innovation (developments of existing technologies that further advance existing healthcare solutions) and disruptive innovation (radically new technologies that create new healthcare solutions).

Insight into the company's own value drivers of innovation can release untapped potential. However, an internal focus is not enough. Expanding our understanding of the

value of innovation to the different stakeholders in today's healthcare systems will prove crucial in developing effective responses to the outside pressures. Policy makers, healthcare providers, payers, clinicians and patients need to be appreciated and recognised for their requirements and needs.

Four dynamic principles are currently emerging among medtech companies seeking to play a part in the innovative healthcare of the near future:

#### **1. Show more evidence of benefit to the healthcare system.**

For a new product to be recognised as innovative, its benefits have to be demonstrated in terms that are meaningful to the relevant audiences. Hence medtech companies are intensifying their efforts to compile solid dossiers for new product assessments by decision makers. In addition, they have integrated the new requirements for innovation into their development criteria: there is now a widespread consensus that innovative products need to demonstrate improved cost-effectiveness for healthcare providers and payers.

Much hope has been pinned on health economic modelling as a tool to quantify the unique contributions of the medtech sector. However, medical technology spans different stages of disease management – from prevention and detection to diagnosis, treatment and rehabilitation. Modelling is complex, and is perhaps more a necessary component of the overall solution than a solution in itself.

Success stories are coming through, as the example of Deltex Medical Group shows. This company, with an annual turnover of £6 million, manufactures and markets the CardioQ oesophageal Doppler monitoring (ODM) device, which has been demonstrated to reduce the complications and shorten the hospital stays associated with major surgery, and could save the NHS an estimated £1 billion a year. Having established a substantial evidence base to support its product from a clinical and economic perspective, it recently celebrated a major breakthrough with a recommendation by NICE to adopt the new technology for patients undergoing major or high-risk surgery. The recommendation sent the company's share price up by 48%.

There is no room for complacency or hesitation: the game is up and the stakes are high. Take a moment to reflect on your company's choices.

Have you tapped into all the possibilities of managing the different stakeholders, building a robust innovation pipeline, and scrutinising your innovation process from end to end?

#### **2. Build a stronger innovation pipeline.**

In addition to demonstrating the benefits of new products, medical technology companies – especially larger ones – have a number of options at their disposal to ramp up the robustness of their innovation pipeline.

In-house development and external acquisitions of start-up ventures are two classic means of sourcing innovation that the sector has used extensively. Furthermore, the idea of venture incubators is powerful – as the Philips Healthcare Incubator, created in 2006, illustrates. Bridging the gap between research and development on the one hand and the business units on the other, an incubator offers the necessary room for non-traditional ways of working and exploration of niche markets.

True to its quest for 'open innovation', which it broadly defines as "actively leveraging its deep competencies, know-how and IP to work with selected companies and organizations with the purpose of creating win-win propositions," Philips has also recently helped to set up and invested in a \$250 million venture fund. This fund invests in innovative early and growth-stage healthcare technology companies in Europe and the US in the areas of home healthcare solutions, sleep improvement techniques, image-guided interventions and clinical decision support, with particular emphasis on cardiology, oncology and women's health.

Medtronic has explored a different approach to new venture incubation by founding and financing MD Start in 2009. MD Start is one of the first corporate and venture capital backed accelerators in Europe to be focused on medical devices. Independent of its founders Medtronic and Sofinnova Partners, it aims to leverage the

competencies of its strategic partners in order to bring ideas that pass the initial screening process through proof of concept to new company incorporation and preparation for external funding.

#### **3. Develop breakthrough innovations.**

The pursuit of breakthrough innovation encompasses more than technological innovation. Today's healthcare systems cry out for more disruption, for new business models and modes of service delivery. When technological enablers for the diagnosis and treatment of infectious diseases (such as antibiotics) first appeared, patient care was transferred largely from hospitals to practitioners. That business model innovation had a profound impact on the healthcare system and freed up potential to tackle other diseases or ailments. Given the current high-cost system, a new wave of business model innovation could prove extremely beneficial – to patients, healthcare providers and innovators. Could wireless network technology play a similar enabling role?

Value chain innovation offers another form of potentially disruptive change. GE Healthcare achieved this when its sophisticated, high-price ultrasound devices met with limited market success in China in 2002. The company re-invented its entire value chain, from R&D to sales and service, and launched a small, portable ultrasound device for a fraction of the original price. GE subsequently marketed the same product in the developed world.

#### **4. Manage the innovation process.**

Disruptive and incremental innovation alike are processes that span across a company. Like every business process, they occur in a number of steps – and each step offers the potential to increase

the value of innovation by doing the right things in the correct way.

For each step from ideation to project selection, product development and commercialisation, a distinct set of capabilities is required. Companies that focus on the relevant capabilities and perform them well are able to release the hidden value potential of their innovations:

- Combining a detailed product understanding of emerging technologies with rigorous decision-making about which projects to select and which to drop can provide a competitive edge.
- Engaging continuously with lead users of an unproven technology during the development phase is paramount in proving its validity.
- Commercialisation is crucial to making sure that innovative products can be successful in the marketplace. It requires the company to work seamlessly across functional boundaries, involve and align internal departments in different geographies, and execute product launches in a co-ordinated way (with thorough preparation and follow-up) to ensure market penetration.

#### **Seize the day**

Many years of successful medical technology innovation lie behind us. The medtech industry has fared well and proven itself and its value to society over a considerable timespan. If the sector can nurture the culture of innovation and enhance it with skills and capabilities found outside its own boundaries, it will be stronger and better-prepared for the future.

But there is no room for complacency or hesitation: the game is up and the stakes are high. Take a moment to reflect on your company's choices. Have you tapped into all the possibilities of managing the different stakeholders, building a robust innovation pipeline, and scrutinising your innovation process from end to end?

Let's make it a bright future for all our sakes.

**Dr. Claudia Graeve** is a strategy practitioner with Graeve Consulting, advising medical technology companies on business planning, marketing and strategic planning.

# Clinical buy-in is key to sales and marketing success



Doctors.net.uk explains how to influence the most important stakeholders. By Simon Grime, Head of Healthcare, Doctors.net.uk

Multiple stakeholders are now involved in the purchasing process for medical devices and technologies, from the CEO to legal departments, technical teams to finance and reimbursement and procurement experts. However, without the buy-in from the clinician who will use the technology, their deliberations are in vain. The key challenge therefore is:

## ***How do medical technology companies foster genuine engagement with vital doctor groups, without extending the sales force?***

### **The Engagement Challenge**

It's a simple fact that technology companies now tend to have fewer sales people on the ground, especially compared to the pharma industry, and as a result, individual representatives have large geographical territories and a range of important stakeholders to cover.

Whilst organisations undoubtedly have key relationships with groups of doctors already, the ability to extend that group and regularly engage with them, in an environment of trust, and to target them with clinically relevant educational information to support their brand proposition, and be able to measure rapid progress, is not easy.

Yet building those long-term relationships with doctors, engaging them in their preferred channels, and gaining their trust is crucial if organisations wish to position themselves as thought leaders in their field. It is only by doing this that they will be able to effectively move from simply selling products to selling a "solution", thus positioning themselves differently, to mitigate against the threat from low cost competition.

### **Taking it online**

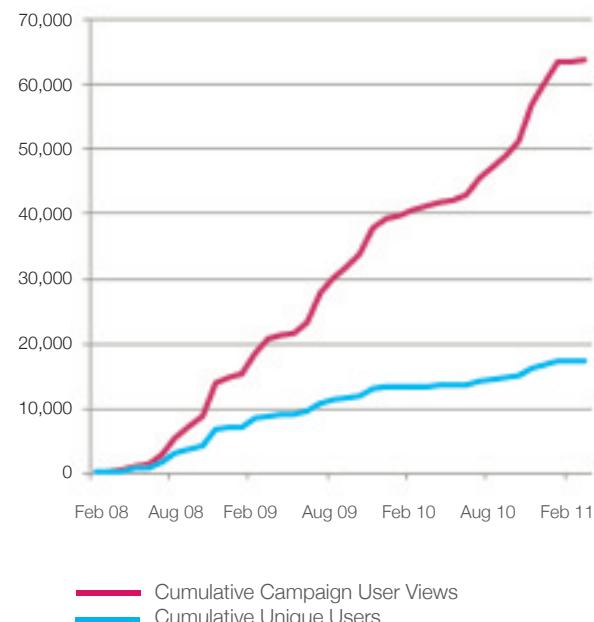
Digital channels to doctors are an important part of the answer. Several are already well established among the medical community and research shows that doctors, in the UK and

globally, have readily adopted online networks and increasingly turn to such channels for professional information on medical technologies and discussions with their peers.

For doctors, the use of such channels has many advantages. Not least, it enables them to 'self-serve' their own information needs and access information at their own convenience, as well as knowing they will see information relevant to their own speciality.

Within the Doctors.net.uk channel for example, it is possible for organisations to research opinion of key clinical groups and gather insight to inform and assist in the tailoring of an education and engagement programme and actually measure the change in awareness, and knowledge levels on key topics.

Increasing impact and engagement over time



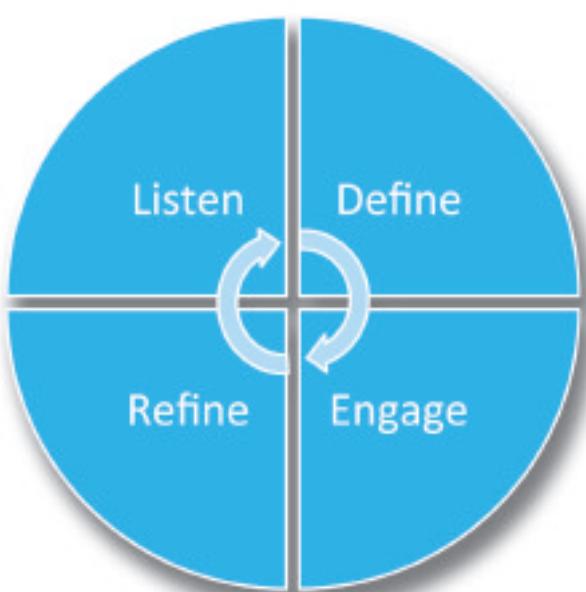


## Designing an effective programme

By providing a targeted and sustained programme of educational messages and information and marrying educational information with a business proposition, programmes can be integrated and aligned with the sales force activities. The insight gained from doctors activity and engagement in the educational resources in the programmes, provides valuable and complementary data to aid the focus of sales teams in different territories.

Before launching a programme, it is key to establish what doctors are saying about the key issues and product areas, and what information and resources they need. These insights help inform the thinking and enable us to ensure that our engagement programmes are timely, relevant, and deliver measurable results that really add value and improve clinical knowledge.

An intergrated approach to clinical engagement



By demonstrating a clear understanding of doctors' thinking and providing new and interesting information that meets their specific needs, the channel enables medical device companies to establish themselves as thought leaders and experts in their field. This sets them apart from the competition and helps to put them at the forefront of doctors' minds in key procedures and conditions.

Phasing the educational programme over a twelve month period or longer, with new types of resource being introduced throughout, encourages even greater participation and discussion among doctors. Through monitoring the performance and engagement levels in the different resources and messages, the engagement can be continually optimised.

Integrating this educational approach into the planning for product sales drives and launches, helps to engage the target clinician with key information around the topic well in advance of any launch and enables a measurable change in doctors' knowledge, to coincide with the critical milestones. This means organisations need to start planning their strategic launches earlier and to be prepared to invest in the relationship development, albeit much less than the cost of a sales force

The results of digital engagement programmes are impressive, with key players in the sector now starting to gain real competitive advantage through engaging with doctor groups in this way.

**Doctors.net.uk offers a range of commercial packages for market research and insight gathering, plus education and engagement**

**For more information on how you can use Doctors.net.uk, please contact Simon Grime, Head of Healthcare, Doctors.net.uk, simon.grime@mess.doctors.org.uk**



# Medtech Business *events*



## Medilink East Midlands Innovation Day 2011

East Midlands Conference Centre, Nottingham, 11 May 2011

This event had the theme 'Fit for the future'. In a time of economic crisis, with the health system in turmoil, having valuable scientific insights is not enough to ensure the success of life science companies. Now more than ever, innovation means finding better ways to deliver value to a changing customer base.

Over 300 representatives of the East Midlands' medtech, biotech and pharma sectors gathered for a day of presentations and discussions, culminating in the presentation of the Medilink East Midlands Business Awards 2011.

The day's events were presented by science broadcaster Vivienne Parry OBE – who told the delegates that her experiences of live broadcasting had taught her both the value of taking risks and the need to be well prepared.

Throughout the day, an exhibition by service providers to the life science sector – from innovation specialist Healthcare and Bioscience iNet to legal and regulatory affairs consultancies, academic and industry partners and life science incubators.

### Spin cycle

Vivienne Parry's opening talk described the profound changes taking place

in healthcare: demographic and economic pressures are driving a shift to home-based care and preventative treatment, while technological changes are making possible the development of miniaturised 'smart' devices and diagnostics. The NHS, she said, is on a 'spin cycle' of change to deliver reduced costs and higher quality of care. She drew out two underlying messages: the growing value of co-production (for example, of drugs and drug delivery devices) and the need for the industry to engage with a wider range of stakeholders.

Jeremy Russell, Director of Praestantia Medical Ltd, addressed the question: "Is the medtech industry fit for the future?" In a provocative SWOT analysis of the UK medtech sector, he identified its key weaknesses as a focus on products rather than solutions; a failure to plan in sufficient depth, leaving key aspects such as reimbursement and regulation to be 'retrofitted'; and a 'Some day my prince will come' approach to customer targeting. The way forward, he argued, lies in better management of the innovation process: the benefits of a technology must be demonstrable, and the planning must be thorough, rigorous and broad.

A number of service providers to industry gave 5-minute 'soapbox presentations' (with an ending time enforced by a gong), including:

- Nick Merryfield of NHIS (National Health Information Service) on the value to suppliers of NHS data focused on providing customer insights.
- Chris Penfold of Design Cognition on new technologies that enable the design of more customer-focused, interactive packaging for drugs and devices.
- Joachim Grevel of BAST on the value to manufacturers of computer modelling to generate optimal trial designs and support investment decisions.
- Heike Passauer from development agency Baden-Württemberg International on how it can help UK life science companies build their presence in Germany.

In the afternoon, a panel of health reform specialists discussed the question "Is the NHS fit for business?" They outlined the potential benefits to suppliers of an NHS focused on outcomes and 'value for money'.

On the difficult question of how to get innovative products into the NHS, their suggestions included: focusing on the cost-benefit equation; building alliances with patient groups; identifying a 'human story' to back up a product; lobbying NICE; and as a last resort, undercutting your competitors on price.

### Best and brightest

In the evening, a gala dinner accompanied the presentation of the Medilink East Midlands Business Awards 2011. The choice of theme



Vivienne Parry moderating a panel discussion

music (New Order's 'Regret') underlined the difficulty of selecting winners from a dynamic regional sector. The winners will be entered for the Medilink UK national awards.

The Start-up Award was won by Platelet Solutions, a supplier of user-friendly blood tests for platelet function based on a new technology.

Morningside Pharmaceuticals collected the Export award in recognition of its success in selling drugs and medical devices to private, public and aid sector customers in over 80 countries.

The Partnership with the NHS Award went to Optima-Life for its partnership with Glenfield Hospital Leicester in developing a system to evaluate the exercise capacity of chronic heart failure patients.

Scientific camera manufacturer XCAM won the Innovation Award for its development of a CCD camera used to photograph viruses.

Finally, and to strong applause, Monica Healthcare won the Outstanding Achievement Award for its home-based foetal monitor, which has gained FDA approval. CEO Carl Barratt said: "This award is well-deserved regional and national recognition and great technical and market validation of our product, of which we are all very proud."



Winners of the Medilink East Midlands Business Awards 2011

*Nobody really knows what impact the government's changes will have on us, but we do know that fit-for-purpose teams must be built to move fluidly with the NHS; 'the fluid process', delivers teams of people who demonstrate boundary-less behaviours. They have the skills and attitude to work beyond redundant methods, and produce results in sync with an evolving NHS.*

# The road to reward



Attracting and retaining talent is a major challenge for UK employers. The battle to increase productivity while delivering cost-efficiencies is driving change in companies' employee benefit strategies. *MB* provides an overview of employee benefits.

Popular HR wisdom, backed up by respected psychologists and employment commentators, suggests that money is not generally the main motivator for employees. Satisfaction in the workplace depends on much more than our annual salary and, according to American psychologist Abraham Maslow, is only one of many 'hygiene factors' that determine whether or not we are happy at work. Maslow's *Theory of Human Motivation* included his acclaimed 'Hierarchy of Needs', which outlined the most fundamental requirements for human satisfaction. It was written in 1943. Despite vast societal and technological evolution since then, its most salient messages still appear to resonate today.

The concept of benefits beyond salary is cemented into the modern workplace. 'Employee benefits', defined by the Chartered Institute of Personnel and Development (CIPD) as "non-cash provisions within the pay and benefits package, although they have a financial value or cost for employers", have traditionally been regarded as a vital component in staff retention. In many cases they have been considered a moral obligation for employers.

In the 1970s, employers increasingly looked towards developing more generous benefits packages rather than rewarding employees via basic salary. But in recent years, as tax legislation has tightened its grip on non-cash provisions, the attraction of certain

benefits over salary has been diluted. In response, employers have begun to adopt a more individualistic approach to how employees are rewarded and transferred more of the risk – and cost – of benefits onto their workers. For example, the days of Final Salary pension schemes are now all but over and have been replaced by the offer of money purchase plans for employees. At the same time, more employers are moving from fixed benefits to flexible and voluntary arrangements.

There is little doubt that the global economic downturn has had a demonstrable impact on the employment market and, by association, the employee benefits landscape. Across the board, companies are adopting a twin focus in which they are trying to balance a drive for productivity gains against the need to deliver cost-efficiencies. As such, employers need to attract and retain talent but, at the same time, secure the best possible return on investment with their human resource. Sustaining staff motivation and employee engagement during turbulent times is a major challenge for modern businesses. Benefits are, of course, one of the key weapons employers have at their disposal to address employee engagement; but with a widespread determination to control costs, companies are needing to be more creative in how they shape employee benefits packages.

## Total rewards

The past year has seen a significant shift in the way companies are designing and presenting benefits packages to employees. According to a survey carried out by the UK magazine *Employee Benefits*, there is a growing trend towards the use of 'Total Reward' strategies among British companies. The poll, conducted in March 2011, showed that 45% of respondents received a benefits package that had been presented to them as a Total Reward scheme – an increase from 29% in 2010. CIPD defines Total Reward as a concept that "encompasses all aspects of work that are valued by employees, including elements such as learning and development and/or attractive working environment, in addition to the wider pay and benefits package."

Total Reward is considered to be distinct from Strategic Reward, which, according to CIPD, is based on "the design and implementation of long-term reward policies and practices to closely support and advance business or organisational objectives, as well as employee aspirations." But, says CIPD, strategic and total reward may often work in partnership. "An organisation might adopt a total reward approach encompassing the provision of both cutting edge training programmes together with flexible working options – as well as more traditional aspects of the pay and benefits package, in order

to recruit, retain and motivate the high quality staff that are best placed to help it secure its business objectives."

Changes to benefits packages are being driven by market dynamics in the wider business environment. The Employee Benefits 2011 survey identified the following issues as being instrumental in determining benefits packages this year:

- Improving the perceived value of the benefits package.
- A drive to control costs across the organisation.
- Making benefits expenditure more cost-effective.
- Matching benefits to employee need.
- Ensuring benefits are competitive.
- Improving the effectiveness of the benefits package.
- Harmonising benefit terms and conditions across the organisation.
- Drive to reduce costs across the organisation.
- Managing pension costs or deficits.
- Encouraging pension scheme take-up.

These findings illustrate a diversity of considerations for managers responsible for employee benefits, and highlight the tensions between fixed, flexible and voluntary arrangements – as well as the challenges of balancing individual rewards for star performers against the desire for an organisation-wide template.

## Feeling the benefit

Traditionally, employee benefits packages generally comprised the usual suspects: pensions, paid holidays and company cars. But today, the benefits market has expanded to include a wide array of arrangements that match the changing needs of modern society. So what kinds of benefits are included in a contemporary Total Rewards plan? The most common benefit is Life Assurance/Death in Service, which seems to be offered to all employees by the vast majority of employers. Alongside this, and perhaps in line with the thinking behind a Total Reward approach, most companies consider training and development to be an employee benefit and, again in the main, provide it to all members of staff. It is arguable whether employees themselves regard this as a significant benefit or simply as a natural and expected aspect of any job of work.

Behind Life Assurance and training and development, the Employee Benefits survey showed that more than two thirds of benefits packages (70%) include counselling/Employee

Assistance Programmes (EAPs) – a benefit that appears to reflect modern demands in an era where many individuals are burdened with high levels of debt and stress, as well as being exposed to increasing instances of redundancy. The survey's authors say that EAPs have now become a mainstay of many employers' core benefits, having grown in popularity in the past few years. In 2004 only 30% of its survey respondents' benefits packages included EAPs. Other popular benefits include childcare vouchers, extra holidays for long service and the option of additional voluntary pension contributions.

Outside of the core options, companies offer a wide range of additional benefits to their employees on an all-inclusive or selective basis (for examples, see box on right).

## Taxing measures

Some employee benefits attract preferential tax treatment, often in line with government policy to support lifestyle choices – for example, childcare

vouchers and cycle-to-work schemes. Alternatively, employees may enter into a salary sacrifice arrangement. Under such agreements, an employee gives up part of his/her gross salary in return for the employer agreeing to provide a benefit. For example, under a pension salary sacrifice arrangement, a member of staff gives up a percentage of their salary while the employer makes an equivalent contribution to the employee's pension. The employee saves on income tax, while both employer and employee save on National Insurance contributions. However, salary sacrifice agreements may have implications for other provisions such as working tax credits or the national minimum wage. CIPD advises parties considering such arrangements to visit the HM Revenue and Customs website for further information.

**Next month, MB looks at incentives and motivation. For further information on employee benefits, go to [www.cipd.co.uk](http://www.cipd.co.uk). To download a copy of *The Benefits Research 2011*, visit [www.employeebenefits.co.uk](http://www.employeebenefits.co.uk).**

## Typical benefits

- Income protection
- Private medical insurance
- Optical care
- Health screening
- Personal accident insurance
- Concierge services
- Season ticket travel loan
- Bicycle rental/loan
- Retail discounts
- Car parking
- Dental insurance
- 'Give as you earn'/payroll giving
- Student grants/repayments
- Professional body subscriptions
- Lunch vouchers/subsidised staff canteen
- Gym membership
- Pet insurance



# corporate rewards

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# Cards on the table



Sales teams love to talk, but how can a meeting be focused on achieving genuine team development? Allan Mackintosh explains a low-cost strategy to unlock the power of team meetings.

I am passionate about team development and totally convinced that when a team is developed properly, it can really enhance the performance of the individuals within that team. If all individuals develop and achieve their targets and goals, that ensures the team will achieve its own objectives, targets and goals.

However, I get very frustrated when I hear talk of 'team development' – because that is what it is in many ways, just talk. Many organisations and managers within them talk a good game when it comes to team development. They think that just holding regular meetings and keeping 'communication levels' high will be enough to develop the team to its full potential. Some firmly believe that a night out at the pub having a few drinks will enhance team 'bonding' and hence make them all more productive. Nothing could be further from the truth!

Having worked in and alongside many teams, from professional sports teams through to sales teams and executive boards, I know that without regular review of team results, processes and behaviours, teams will never get anywhere near their full potential. In fact, look behind the scenes with many teams and you will find cliques, in-fighting, 'back-stabbing' and 'corridor conferences'. The team visit to the pub will only enhance this, not change it. Of course, these pathological behaviours will never be effectively challenged within a regular 'manager-run' meeting either. This is not a healthy situation, and certainly will not enhance either team or individual performance.

## Nothing to spare

So what are the challenges that managers face in developing their teams – and what can be done to support them?

**Look behind the scenes with many teams and you will find cliques, in-fighting, 'back-stabbing' and 'corridor conferences'. The team visit to the pub will only enhance this, not change it.**

- Time.** The pressure is on for results, so time for team meetings is limited and the agendas are crammed with 'business' items. No time is put aside within these meetings for team development.
- Money.** Cash is tight. The recession has caused training budgets to be slashed. Bringing in external team development specialists or taking the team away for outdoor team development sessions won't happen in the near (or medium-term) future, simply because the money isn't there.
- Training.** As regards team skills such as leadership, coaching and facilitation, there are few training courses being run internally. There may be internal training resources such as company books and videos, but little attention is being paid to these due to challenge number one – time! There are numerous external courses, but again time and money are limited.

I interviewed a number of managers recently, and the key challenges they highlighted were:

## Rules of engagement

What is the solution to these challenges? It was recognised by all the managers I spoke to that development of the team was vital if better results were to be achieved – and if a solution could be found that supported the development of the team in a timely, cost-effective and productive way, it would be well worth looking at.

I got my thinking cap on, and wrote down some key principles that would have to be kept in mind when creating a suitable solution:

- The solution must be affordable and be a ‘no-brainer’ as regards cost.
- Any intervention must be able to work within a limited amount of time and to be used within a regular business meeting.
- It should be easy to use and not reliant on external ‘experts’.
- Every member of the team must be involved and have opportunity to contribute.
- An action plan to move the team forward must be produced.
- It must be a motivational experience and hopefully a bit of fun!

## A dynamic resource

Coaching cards, whereby a coach uses a set of cards to get individuals talking about their situation and how they feel about it, have been used by coaches for several years now. Typically, the individual being coached picks a card, analyses the question, statement or picture and then states their feelings, thoughts and comments. The cards are a catalyst to enable the individual to think and talk freely. I asked myself: *Why can't we apply this idea to team meetings?* The answer, as you may have guessed, was: *Why not?*

So I designed two sets of what I call ‘team cards’: an ‘Original’ set composed of 52 questions about teams, and a ‘Provocateur’ set composed of 52 fairly provocative statements

The diagram shows four cards from the 'Team Cards' series. The top-left card is titled 'TEAM-CARDS ORIGINAL' and features a stylized figure holding a globe. The text on the card reads: 'To what level does every team member understand the team's goals and targets?' and 'Get everyone to write them down now.' The top-right card has the text: 'How well does everyone understand the team rules and regulations?' The bottom-left card is titled 'TEAM CARDS PROVOCATEUR' and features a similar stylized figure. The text on this card reads: 'I have no idea what the vision for this team is and neither does the manager.' The bottom-right card has the text: 'There are no processes in place to:' followed by two points: 'a) reward adherence to the contract, and' and 'b) manage non-adherence to the contract.'

about teams. The ‘Original’ set is for newly established teams, while the ‘Provocateur’ set is for more established teams who are more open to expressing their views and, importantly, more open to constructive feedback. All the questions and statements relate to critical aspects of team working.

## Let's talk it over

The rules of a ‘team cards’ session are simple:

- There must be a facilitator, a timekeeper and an action taker (three different people). The facilitator does not need to be the team’s manager, just someone who can effectively facilitate a group or team discussion.
- The individuals within the team must agree to be as open, as honest and as constructive as they can.
- Time must be allowed within the meeting for the cards to be used effectively. An hour and a half to two hours is recommended.

- The facilitator shuffles the cards and asks a team member to pick a card. Although the cards are picked ‘blind’ it is important (for psychological reasons) that they are picked by team members, not dealt by the facilitator.
- The team member reads the card’s question or statement and then answers the question or comments on the statement.
- The facilitator then encourages discussion and debate around the question or statement, while the action taker records any team development action points that arise from the discussions.
- This process continues until each member of the team has picked a card and commented on the question or statement. Trials have shown that each member of a team of six should have two opportunities to pick and comment on a card within a two-hour session.

## Play your cards right

The feedback from team sessions so far has been excellent. Enough time has been found in regular business meetings; individuals feel motivated; the cards are very cost-effective, so there are no real budget implications; action plans have been constructed; and overall the teams are ready to use the cards on a regular basis. All this without a single ‘rope course’, human table football game or expensive team development consultant like me in sight!

**Allan Mackintosh is an Account Management Performance Coach with Grunenthal UK Ltd and the author of *The Successful Coaching Manager* (Troubador Press).**

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# My Medtech Business



David T. Davison

**David T. Davison is the Managing Director of 1<sup>st</sup> Call Mobility. Based in Harlow, Essex, 1<sup>st</sup> Call Mobility sources equipment for the support and transport of bariatric patients, and provides the equipment on loan to UK hospitals and clinics.**

**What is driving the equipment loan service market at present in the UK? What are the challenges it faces?**

Currently some hospitals carry equipment for heavier people – but they tend only to have one or two chairs and possibly a couple of commodes suitable for patients weighing up to 40 stone. The body dynamics of morbidly obese or bariatric patients change significantly once they get beyond 25 stone. For instance, a suitable chair for someone who is 40 stone and has a large 'shelf' or layer of fat at the back is totally different from a chair for the same weight for a patient who has a large pannus at the front but no 'shelf' at the back. So we need to provide many different styles and sizes of chairs for bariatric patients. With a person up to about 20 stone, one chair tends to fit all; but in our business, we need to have a chair for somebody 22 inches wide, a different one for somebody 24 inches wide, and so on up to 40 inches wide; and the same is true of commodes and beds. So it's very difficult for hospitals to keep a big enough range of products in stock,

and in fact they have neither the funding nor the storage space to do that. So that's really the driving force: they get people in of varying sizes and shapes and they have to cater for them.

**Do you think loans will become a more common arrangement for non-disposable hospital equipment in the future? If so, how will that affect the commercial model for medical equipment OEMs?**

In principle, loans will stay at a similar level as they are now. The biggest challenge for companies like ours is having the space available to store the products, the huge costs of providing decontamination facilities, the logistics of providing products around the whole country within four hours, and of course the capital cost of purchasing the equipment. In the last year we've invested £2 million in the business so that we can remain market leaders and ensure that the products we're providing are the best available.

We're currently seeing hospitals hiring equipment for perhaps three to six months and then buying the

equipment they see is the most hired. So if they realise they're hiring a chair that's 28 inches wide regularly, they'll end up buying those chairs, and the hiring side will drop off for a while.

But the problems a hospital faces are the capital expense of buying products and, more importantly, the cost of maintenance. Every time a piece of equipment comes off hire, it goes through a rigorous decontamination and maintenance process, and almost without fail it will have some form of damage or fault that needs putting right. We regularly see hospitals that have purchased specialist products and after only a few months these have become unserviceable – a slight crack has become a tear in the fabric and so on – so within a few months they have to rent again.

Our idea is that it's actually cheaper in the long term for them to rent, and know that it's available when they want it and they have a full range of equipment, than it is to buy.

**People talk about 'the obesity crisis' in UK healthcare, but is it a crisis or an ongoing long-term**

**issue? Do you think the market for bariatric medical equipment will stabilise and potentially decline in the future?**

The obesity crisis is known to be a growing problem. There are more very large people than there were 20 years ago, and they have higher expectations of being able to live a normal life. That is not true in the developing world. It's clear that our diet in the West is a significant cause of obesity, and I don't see that changing for many years to come. Companies are generally building healthcare equipment that is stronger and heavier than it used to be. Over the next 10 years, a weight of 15–20 stone will perhaps become the norm.

However, what we term 'bariatric' is in excess of 25 stone. And at that level, the Government and the NHS are investing a lot of money in providing care. So while the general population will get bigger, with a major rise in the number of people up to 20 stone or so, I think at the higher levels of obesity the numbers – because of the amount of intervention – will stabilise and possibly fall slightly in the years to come.

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# Fresh faces, fresh fundraising, fresh success!

The first few months of 2011 have been busy ones for the medical and scientific recruitment specialists Kirkham Young.

Following the growth of the team at the end of 2010, the company was delighted to reveal its new-look website as part of its ongoing programme of progression.

"We all had great fun with the photo shoot at the offices," commented Scientific Manager Alan Dias. "It is always a little unnerving being followed around by a photographer for the day, but I think

it's really important that our customers can see us as naturally as possible.

People are the foundation of our business, and searching for a new role can be a daunting prospect – being able to visualise who is on the end of the phone should help to alleviate some of that apprehension!"

Although the company covers sales and marketing vacancies across the UK it is committed to supporting a range of causes locally, and both the scientific and the medical recruitment teams at Kirkham Young are delighted



The Kirkham Young team

to support a range of charities again this year with fundraising events, corporate donations and sponsorship of local junior sports teams.

This year Kirkham Young was also able to increase its annual donation to the local children's hospice Demelza James, which provides a hospice at home service to local families in East Sussex and Kent.

With great team morale and an enviable client base, it is no wonder that this company is looking to further strengthen its team: it is currently recruiting for an additional recruitment consultant to join its highly successful scientific division.



## RECRUITMENT

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Ortho Executive partner companies exclusively within the orthopaedic industry, with a commitment to securing the 'right fit' talent by providing a focussed, insightful and professional service to our clients and candidates. With offices in both the UK and Australia, our consultants have global orthopaedic industry experience, making us well placed to offer a specialised recruitment service both domestically and globally. If you are an individual looking for a new challenge in your career, or a company seeking a partner who can offer a fresh approach to your recruitment needs, we look forward to hearing from you.

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# Siemens appoints new ultrasound Sales Managers

Siemens Healthcare has appointed three new Ultrasound Regional Sales Managers in the UK.

Brian Kane, Michael Asare and Zaheer Ali will promote the Acuson range of diagnostic ultrasound systems and support customers in Scotland, London and the South East, East

Anglia and the Midlands.

Brian Kane has worked in medical sales for over 20 years, with experience in the orthopaedics and pharmaceuticals sectors. He will cover Siemens' entire ultrasound customer base in Scotland.

Michael Asare joins Siemens from



L-R: Michael Asare, Zaheer Ali and Brian Kane

Ethicon Endo-Surgery, where he has worked as a Sales Manager of capital equipment for over three years. He will drive sales in South London and the South East region.

Zaheer Ali has worked for diagnostic and therapeutic device supplier Medrad for six years. He will be responsible for North London and areas including East Anglia, Cambridge, Northampton and Milton Keynes.

"We are delighted to welcome three new additions to the Ultrasound team," said Sanjay Srivastava, UK Ultrasound Business Manager, Siemens Healthcare. "Each of them brings a wealth of experience and will further strengthen our focus in the ultrasound marketplace following the recent establishment of our new Clinical Products division."

## GE Healthcare appoints two executives

UK-based corporation GE Healthcare has appointed two new members to its leadership team.

Tom Gentile joins GE Healthcare as President and CEO of Healthcare Systems, and Mike Swinford has been appointed President and CEO of the new Global Services business.

The appointments are intended to drive further differentiation of the company's global product and service offerings.

Tom Gentile is currently VP of GE Aviation's Services division. In 13 years with GE, he has also held leadership

roles in GE Capital's businesses. He previously held strategic and leadership roles with McKinsey & Company, CBS and General Motors. In his new role Gentile succeeds Omar Ishrak, who is leaving GE to lead Medtronic.

John Dineen, President and CEO of GE Healthcare, said: "Tom has built his career building business solutions for multi-national companies, across a wide range of industries. He has the proven track record in developing technologies to help his customers solve some of their industry's toughest problems."

Mike Swinford has been Services

leader for GE Healthcare's North American division since 2005. Before that he held a number of services, quality and supply chain roles with GE Healthcare. The new Global Services business will create new global service platforms across product lines.

"As we've expanded our commercial activities around the world we believe it makes good, profitable business sense to drive service growth across our global product lines," John Dineen commented. "Mike has the credentials and business acumen to lead this valuable business."

## Royal visit to surgical instrument firm

Sheffield-based manufacturer of bespoke surgical instruments Platts & Nisbett has received a visit from Prince Edward, The Earl of Wessex.

His Royal Highness was given a tour of the factory to see surgical instruments being made by hand and meet its apprentice-trained craftsmen.

The company offers an in-house service to craft individual instruments according to a surgeon's exact specifications. This enables it to meet unusual requirements, such as left-handed instruments and bariatric devices.



Prince Edward with Alyson Nisbett

Alyson Nisbett, Managing Director of Platts & Nisbett, said: "It was a real pleasure to show His Royal Highness around Platts & Nisbett,

and for him to see first-hand our dedication to quality and traditional manufacturing.

"The logistics and the marketplace may change over the years, but the core values of our company will never alter, which is why we not only retain our staff, but our products continue to be a popular choice with clinicians."

Platts & Nisbett supplies surgical instruments to the NHS, private sector hospitals and decontamination units, as well as distributors and OEMs in the UK and overseas.

## Remtec strengthens its board

Life science recruitment company Remtec has strengthened its board with two new appointments: John Morley has been promoted to Business Development Director and Lorna Rutter to Operations Director/ Company Secretary.

John Morley worked as an analytical chemist with Johnson Matthey before moving into life science laboratory sales with Sarstedt and then joining Remtec in 2005. He specialises in recruiting senior professionals across Europe in technical areas of the medical technology sector.

Lorna Rutter worked for an IT consultancy as Project/Office Manager before joining Remtec in 2006 as Office Manager. She will be responsible for managing the company's day-to-day operations, leading its financial functions, developing and implementing its organisational policies and practices, and contributing to its strategic development.

Nigel Job, CEO and founder of Remtec, said: "John and Lorna have both been with Remtec for over five years and have been instrumental in getting the business to where it is today. This promotion is in recognition of that contribution, and the contribution I am sure that they will make to our continued growth."

Remtec is a specialist European medical technology and life science recruitment consultancy, offering executive search and selection services to a wide range of companies in the UK and across Europe.



John Morley and Lorna Rutter