

REMOTE CONTROL

For a water-tight supply chain, track and trace must begin at the very earliest stages of clinical trials.

Frances Penwill-Cook reports.

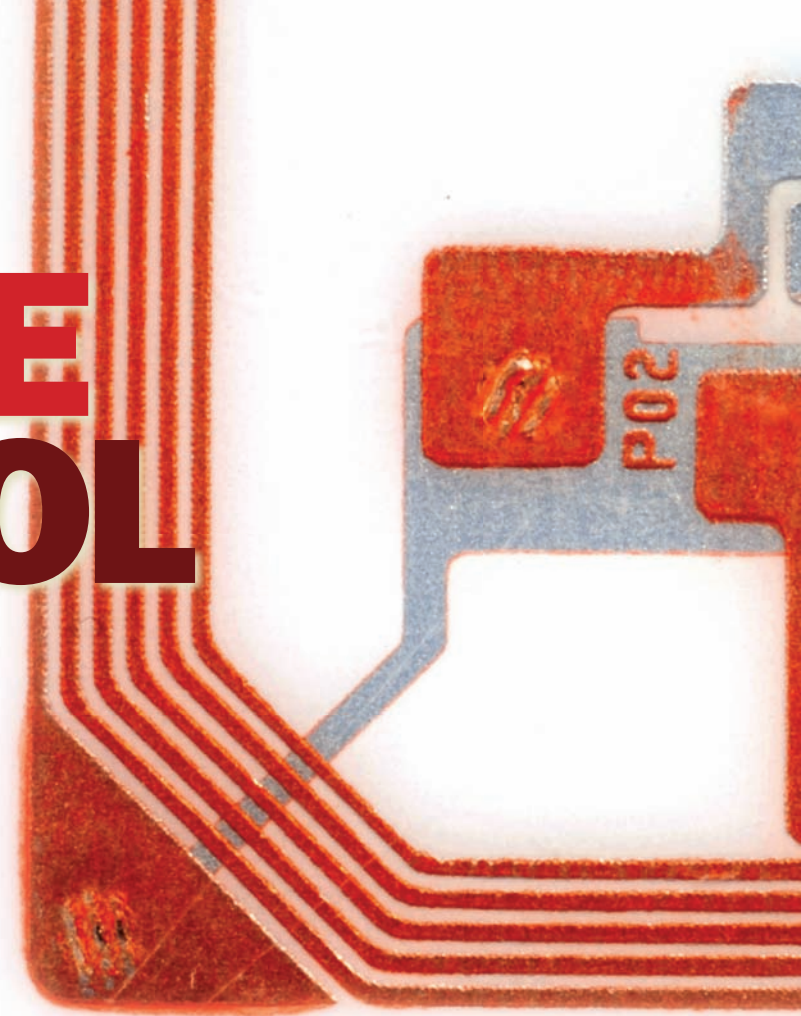
In early 2009, US Food and Drug Administration (FDA) associate commissioner for policy and planning Jeffrey E Shuren said that the 'existing supply chain safety system for FDA-regulated products is not adequate'. Ensuring good practice of the manufacture of clinical trials materials and fulfilling the roles of good clinical practice has come under the microscope of EU legislation.

GMP and GCP are not new concepts but recent developments in legislation have narrowed the interface between the two areas. If good standard practices aren't upheld at the beginning of the supply chain, things can go horribly wrong later on. It seems that the two greatest challenges that must be overcome arise from the globalisation of the industry and the lack of take-up of the latest technologies designed to alleviate these problems, such as traceability.

Non-profit healthcare organisation GS1 Healthcare's director Ulrike Kreysa says that the global movement of drugs, and the truly global nature of clinical trials of investigational products, is creating much of today's problems. 'The lack of global harmonisation for product identification is an obstacle for traceability across borders,' she explains.

GMP and GCP are not new concepts but developments in legislation have narrowed the interface between them.

Combine this with ineffective and inconsistent data collection and the problem becomes multiplied. RFID Journal editor Mark Roberti says it is the cost of data collection of drug pedigrees or e-pedigrees that are difficult to maintain. 'We lose chain of custody as items move through the supply chain, which is exploited by counterfeiters and others,' he says.



Finding harmony

To ensure technological advancements can fulfill their true potential in the market place, GS1 identified a need for global standards in the healthcare industry to effectively manage complex issues of security, traceability and efficiency. Along these lines, in April 2009 it approved the Global Traceability Standard for Healthcare (GTSH).

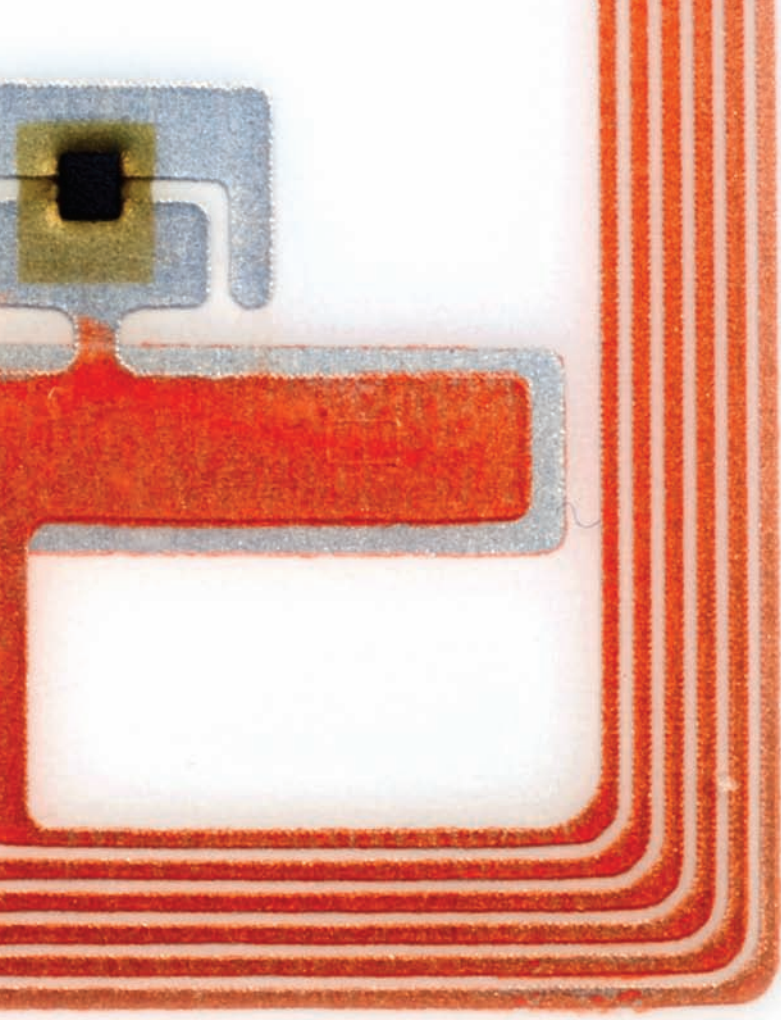
GS1 Traceability Director Healthcare, and facilitator of the global traceability work team of the GS1 Healthcare User Group Janice Kite, says GTSH has been developed to counter costly and inefficient standard solutions with input from more than 100 representatives from all stakeholder groups from about 30 different countries.

'GTSH is the first publication on traceability for healthcare that provides a foundational framework and defines the minimum requirements for all stakeholders,' she explains.

GTSH is now available for download and, to support implementation, the GTSH Implementation Guideline was published on 24 April. GS1's phase two guidelines will be a big step towards the smooth running of automatic identification technologies and end-to-end traceability becoming reality.

Combating counterfeiting

With the World Health Organization (WHO) estimating that 10% of medication globally is fake – a figure that reaches 50% in some countries – counterfeiting is a serious business that injures and kills thousands of people each year. 'By introducing track and trace, you make it much



authentication through its review of medicines distribution in Europe,' says Ager.

RFID woes

Although viewed as a great technology for the future, for now there remain security concerns relating to RFID. RFID Security's Mike Ahmadi says that the benefits of RFID in healthcare are obvious to all but his concerns lie with security issues relating to the easier collection of product data. 'An RFID tag can be read or written surreptitiously by anyone who, for example, happens to brush past a cardholder with a small portable reader,' he explains.

Another issue with RFID implementation is that it could potentially make labelling and packaging companies' work even more complicated than it is already, with ever-decreasing lead times. 'You would have to get all the label information synched with the RFID tag and barcode on the label,' says Roberti.

'There is the possibility of one day using an interactive tag that displays the data written to an RFID tag.'

harder for criminals to get bogus drugs into the legitimate supply chain and therefore into the hands – I should say, bodies – of consumers,' says Roberti.

In February 2004 the FDA released Combating Counterfeit Drugs, a report that cited 2D barcodes and RFID as the 'technology most likely to bring mass serialisation into widespread use'. It also recognised, however, that in the long term, it would take 'considerable planning, experience and investment of resources' to deploy RFID throughout the supply chain and so the focus turned to barcoding.

'The AIDC Application Standards for medical products, which are in the final phase of approval, have been developed by the user community who put forward barcodes as 'preferred options' and EPC/RFID as the 'additional option', says Kreysa. 'Standards, of course, develop further in time, but this is the current situation.'

In 2008 the European Federation of Pharmaceutical Industries and Associations (EFPIA) announced its support for pan-European and industry-wide solution to create a 'more transparent supply chain'. It too championed 2D data-matrix barcoding as each pack's unique number makes it harder for counterfeiters to successfully copy and bring their fakes to market.

EFPIA director-general Brian Ager urges stakeholders to support the implementation. 'We strongly urge the European Commission to consider the benefits to all stakeholders of medicines traceability and

For now RFID is the long-term future but industry expects say new technologies go even further. 'There is the possibility of one day using an interactive tag that displays the data written to an RFID tag,' says Roberti. 'A development firm, VRF Holdings, has created a tag for apparel retailers to mark down tags electronically. This could potentially be used to transfer critical information to labels that are easily changeable.'

Future technologies

For Ahmadi, it is near field communication (NFC) technology and Apple's iPhone that are part of healthcare's data capture future. To capitalise on this, he recently set up iPhone Biotech. Ahmadi says Apple is extending its capability by allowing device manufacturers to access the device's dock connector.

'This same technology could be used to create a device that would connect to the iPhone and scan RFID codes as drugs are passed from point to point,' he explains. 'This would build in the already-existing iPhone applications that read 2D barcodes that are used in the pharmaceutical industry.'

'As NFC technology becomes more ubiquitous, I can see the iPhone becoming a viable candidate for the requisite 'always available' tracking and data collection device the pharmaceutical industry needs to help meet the growing challenges of the supply chain system.' **WPF**

■ *This article was first published on www.pharmaceutical-technology.com*