

# A HUG to help you

Rich Hollander, senior director of packaging services, Pfizer Inc., visited Sydney late last year to assist with the start-up of a local HUG (Healthcare User Group) for Australia and New Zealand. He is co-chair of the global GS1 HUG and keen to develop the idea around the world. Rich Hollander spoke to MHD editor Charles Pauka whilst in Sydney.

According to Rich Hollander, Pfizer became involved in the GS1 HUG because it made sound business sense. "I am involved in the HUG, because we must establish global standards if the pharmaceutical and medical device supply chain is going to be effective in addressing patient safety concerns. While many global standards exist for automatic identification and electronic commerce, the healthcare industry needs differ from other industries from which these standards had been developed. In some instances new standards need to be developed or revised, and for some business requirements, we need to define which specific standards should be utilised. With these standards in place, we should all be able to achieve our objectives quicker and with a lower overall cost burden," he said.

"When it comes to the cost burden, while as an industry we always try to minimise costs, we also need to be aware of what it

will cost the industry if we don't take action. Both the global and local HUGs work hard to ensure standards around technology are developed based on clearly defined business and user requirements, and not based solely on what hardware or software suppliers believe the solutions to be."

Driven jointly by GS1 Australia and GS1 New Zealand, HUG Australasia will work together with the global HUG which includes representatives from 3M, B. Braun, Baxter, GSK, Johnson & Johnson, Novartis, Pfizer, Procter & Gamble, and Wyeth among others. The global HUG mission is to lead the healthcare industry to the effective utilisation and development of the GS1 System to improve patient safety. The initial primary focus for the group is automatic identification using GS1 standards for numbering structures and data carriers (e.g. bar codes and radio frequency identification).





HUG Australasia speakers (from left to right)  
 • Ken Nobbs, Manager - Supply Chain, NEHTA (National E-Health Transition Authority) • Gary Hartley, General Manager - Sector Development, GS1 New Zealand • Dr Bruce Anderson, Manager - Governance DHB Funding and Performance Directorate NZ Ministry of Health  
 • Rich Hollander, Senior Director of Packaging Services, Pfizer Inc., and Co-Chair, GS1 HUG  
 • Sue Schmid, General Manager - Member & Industry Support, GS1 Australia.

The group also covers Australia and New Zealand on topics related to patient safety in two key areas. The first is prevention of dispensing errors by employing automatic identification at the bedside and developing standards that enable users to do that in a common manner globally. This is so manufacturing sites around the world can get to market much faster, irrespective of whichever market they're servicing.

"The second area that we focus on is anti-counterfeiting, specifically utilising automatic identification technologies carrying a serial number to help authenticate the product as being genuine. This could be an individual product at a pharmacy level and wholesale level, as well as cases and pallets as they move through the supply chain," Rich Hollander said.

An RFID-enabled supply chain allows users to authenticate and track at every step in the chain. Pfizer is already piloting the use of this technology on individual packs, cases and pallets of Viagra distributed in the US market. This ongoing pilot project aims to provide a means for pharmacies and wholesalers to authenticate the product at any packaging level they choose, with the hope that it will also facilitate wholesalers' and retailers' ability to understand how to use the technology.

The global HUG is also developing a guideline for how manufacturers should code their packages in such a way that they can be used in hospitals at the bedside.

The way it is being approached is to first understand what the business need is: i.e. for bedside scanning of pharmaceutical products. Sub-sets might be solid dosages, injectables, pre-filled syringes, etc. How that individual type of product or package is utilised at the bedside would dictate what technology is used. For example, if the medication needs to be hands-free, then maybe RFID might make sense, otherwise a bar code might be a better option. If it needs a bar code, then what type of bar code? What type of data should be carried in the bar code? How big would the bar code need to be and in what type of scanning environment is it used?

"There is not a lot of bedside scanning going on in hospitals right now, so there will need to be expenditure on scanning equipment, servers and also on the software development that is going to have to take place. We recognise that different data carriers require different investments in scanning technology, but we also recognise that incrementally, from one technology to the next, it's not a huge amount. For example, when we talk about the incremental cost of a laser scanner versus an imaging scanner for two-dimensional codes, the differential is about \$150. When you consider the number of scanners required for a large sized hospital may be 300, the incremental cost is \$45,000, which by itself seems like a lot of money. However, if you compare that incremental cost with the rest of the hardware and software costs for a bedside scanning system for that same large hospital, the incremental cost becomes less significant. But the potential

value in that decision is significant, as using a two-dimensional code allows additional information to be encoded, and be captured when desirable," said Rich Hollander.

"Our desire is to utilise contemporary thinking as we develop these guidelines. We want to utilise technologies that are going to be forward compatible. When we start thinking about what we need today, for instance, we may only need product identification to be the data element that's carried in the bar code. At some point in the future we may need a lot number or expiration date for other reasons, or even a serial number. So we want to use a technology that is going to allow us to leverage what we have already invested in, and move forward with it," he said.

"We have developed a strategy for producing this end-point deliverable, which we call the AIDC Application Standard - Automatic Identification Data Capture Application Standard. We envision this to be a book which talks about different business use cases, and for those cases a guide to approaching the selection of data structure and data carrier. We have four work teams that will be feeding into this guideline, and we expect it to be ready in late 2008."

The global HUG has members from all parts in the supply chain, users of the GS1 standards, manufacturers, wholesalers, retailers, hospitals, academic institutions and regulatory agencies. The initiative was driven by frustrated users of the GS1 System, who recognised that GS1 offers a lot of standards that can easily be used in the health





care sector. They also recognised that from a user perspective, they didn't necessarily all understand the GS1 standards; how to utilise them and, more importantly, how to align GS1 standards globally rather than market by market, which had become the case until about a year ago before the global HUG was formed.

Some members from the healthcare industry went to the GS1 global office and asked for help. GS1 wasn't accustomed to taking a leading role with the healthcare industry at a global level. In fact the healthcare industry is recognised as being well behind in this area, which is understandable when compared to the massive resources of the consumer goods sector. So they decided to shine a spotlight on the healthcare sector and have helped establish the global Healthcare User Group.

"In May 2005, we held an informal gathering at the GS1 US offices with representatives from about 15 multinational companies, both pharmaceutical and medical devices. We conducted a brainstorming session to identify the key topics a HUG should work on. Once we categorised them, we realised the common theme was driven by a need to improve patient safety and the role that automatic identification could play, and that global standards were desperately needed," said Rich Hollander.

"We have very good representation from a manufacturer's perspective, both medical device and pharmaceutical. This has been easy to do because we have multinational companies with vested interests to make sure we do things consistently around the world. We have representation from the major trade organisations, both US and EU, for the wholesale sector and with respect to hospitals and retailers. Hospitals are coming in to explain their needs and business requirements to us, and as we develop these standards, we suspect they will be much more engaged in the process to make sure the standards still satisfy their needs." (Since last October, two hospital groups have joined the global HUG.)

The global HUG is comprised largely of US and European stakeholders in the supply chain, but also includes representation from

Japan. The global HUG conducts conferences every 3 to 4 months, alternating between US and European locations and attracting good representation from the entire supply chain. With each global HUG meeting, the organisation has grown in the number of participants and countries represented. These meetings combine presentations by supply chain stakeholders describing their business needs, as well as working sessions of the various work teams working on establishing the standards themselves.

The role of the local HUG is to help gather information at the country level and ensure it is fed to the global HUG and considered as standards are developed. Once these standards are agreed to globally, the local HUGs will work collaboratively towards their implementation as the business in that market warrants.

At the moment there are three local/regional HUGs: Switzerland, which has many projects going on in its hospitals; Australia, which has much to offer the global HUG, especially in data synchronisation; and Chile, which has a lot of activity going on in the area of auto ID for patient safety. Other local HUGs are in the planning stages right now.

Often the feedback from hospitals to the global HUG is: "we're not going to develop any systems until manufacturers start putting codes on their packages." Then manufacturers tell us: "we're not going to start putting codes on our packages until you show us that you are committed to developing the systems."

The global HUG is trying to mitigate one of the road blocks, which is to have a standard ready to utilise when manufacturers do say they'll put codes on packages, or if regulatory agencies come in and say they will mandate that manufacturers put codes on packages. As manufacturers start developing new packages or new technologies on packaging lines, the global HUG wants to make sure that they are aligned, and when the market decides it's the right time to start putting codes on packages, they have a standard to use.

"There is a software industry out there that helps with point-of-care administration, and there are many different ways of approaching it. They all feed off a data collection point at the bedside and our task is to make sure the feed can happen. This is to ensure that hospitals don't need to repackage or re-label products, which is often what they are doing because today, manufacturers don't consistently put the machine readable codes on the packages. Our focus is predominately on marking the packages in such a way that whatever system they choose, they will be able to pull in the data when they need it," said Rich Hollander.

"There are currently around fifteen commercially available BPOC (bar code point-of-care) systems that can be utilised in hospitals, to run everything from purchasing supplies, dispensing, verification, bedside dispensing and patient records.

"Global standards are important, so if there is a hub of activity anywhere in the world that is growing and understanding what the opportunities are, it is important to Pfizer to ensure that we as an organisation are aligned. We are also trying to influence stakeholders towards global standards. Many of our sites support over 75 markets, so if each market has its own standard for us to follow when it comes to automatic identification, common technical solutions are difficult to achieve. It's a cost for the manufacturer as well as others in the supply chain.

“What we are trying to do is utilise the global HUG as our lever into these markets and engage the regulatory authorities, trade organisations, manufacturers, wholesalers and stakeholders in the supply chain, so we can all get to the right place sooner. This requires education and a lot of what I do is educate, so that people understand that the business requirements we have around patient safety in Australia are no different to what goes on in a hospital in New York. The activity of dispensing a product at the bedside is the same, the types of packages that we are using are the same, so when it comes down to what type of technology we use, let’s use the most appropriate technology,” he said.

“The way I always look at it is this: review the business requirements collectively, put them on the table and break them down to the lowest common denominator, which in this case means ‘what type of data do you need to support all these business requirements?’ Then get the right people around the table to figure out what the right application identifier is, what the right data carrier is. Even if it’s a linear bar code: which linear bar code? Do we need to consider other data elements? (e.g. lot number, expiration date, serial number, etc.) This is the essence of the process used within the global HUG.

“So let’s all put the right minds around the table, discuss it, agree to it, and then we can move forward with it. Some markets may not move forward with us, or have a reason to do it today. Some day they may have a reason for it, and when they do, they’ll be able to go to this application standard, pull it off the shelf, and know that they should be using a certain data structure and carrier, and be able to move forward from there. The world will spin in the right direction if we have such a deliverable available for everybody to use.

“In the meantime, where we have growing regulatory pressures from the US, France, Spain, Italy, UK, Japan, Portugal etc., now is the time to let those regulatory authorities know what we are doing and how we are doing it, so that they can become part of our process. We don’t want them sitting on the sideline, we want them to be engaged with us. Through the global HUG we have a lot of regulatory engagement. They attend our conferences and are active in our work groups. They contribute to our process by bringing requirements that we may not have thought about yet. So they put them on the table for us to respond to, and we consider them and factor them into the standard. If we didn’t, then they would just choose to ignore everything we are doing and develop regulatory policy that might create undue burden to the supply chain. At the same time, we are educating them on how these standards would solve their problems, without having to develop new standards. At the end of the day if we have to develop new standards we will develop them through the GS1 standard setting process. But we believe that most of what we need for the healthcare industry already exists in GS1’s tool kit, we just need to figure out what the right ones for our industry are.” ■

