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## Medical Labeling

### Dedicated lines and facilities are critical when converting these high-quality functional labels.

By [Steve Katz](#)

Medical labeling is unlike other sectors of the labeling industry. Here, it's not about shelf appeal, eye-catching sheen, or labels that "pop." And there's no talk about the seven seconds it takes to catch and hold a consumer's attention. It's the reverse in this niche – it's function over form.

Labeling for the medical industry is taken seriously. Like pharmaceutical labeling, and to a lesser extent food, nutraceuticals, and health and beauty, there are legal guidelines that must be adhered to, and when not followed accordingly, consequences are potentially dire. We're talking about the labels for intravenous and blood bags, syringes, bodily fluid containers, and patients charts containing data – like one's medical history, just to name a few.



Schreiner MediPharm's Pharma-Comb labels

The niche is specialized – there are some converters who work only in the medical and pharmaceutical labeling space, while there are others who take it on as a part of the comprehensive product portfolio.

#### Quality is key

Like any other market, medical labels come in a wide variety of shapes and sizes, and some require special considerations for converting. One aspect that stands out – that converters point to – is the importance of quality control.

Gene Dul is president of Schreiner MediPharm L.P., Blauvelt, NY, USA, the US division of Munich, Germany, based Schreiner MediPharm, a global manufacturer of specialty labels for the medical and pharmaceutical industries. He says converting these medical and pharmaceutical labels requires a great deal of knowledge and know-how. "Printing such sophisticated, multi-functional labels demands comprehensive expertise in material and adhesion technologies, dispensing, printing and decutting techniques, as well as sound knowledge of the complex processes and requirements in the medical/pharmaceutical industry."

Quality, Dul says, is of primary importance in medical labeling. "First, the high quality demands of the pharmaceutical industry have to be considered. Schreiner MediPharm strictly complies with the cGMP (current Good Manufacturing Practice) rules to guarantee maximum product quality and to meet the requirements imposed by health authorities for bringing products to market. This includes in-process controls and 100 percent camera inspections. In addition, post-printing capabilities, printing of variable data, backside printing and special varnishes, such as the printing of tactile elements like Braille, for example, also play an important role," he says.

Tim Mlnarik is the business development manager for Brunswick, OH, USA, based ID Images, a converter that specializes in variable information printed (VIP) labels. The company is quite active in the medical labeling business. He says that from a manufacturing process standpoint (quality, scheduling, etc.), ID Images uses the same process for medical and non-medical applications alike. "Requirements will vary from customer to customer. Some customers may require a quality audit as part of the 'qualification' process or expect COC or COA (Certificates of Compliance/Certificates of Analysis) with shipments. Or some customers may require additional labeling information," he says.

HP Mile, Syracuse, NY, USA, is a converter that was founded specifically to service the medical and pharmaceutical industries. Michael Brady, president, says that for HP Mile, quality is of paramount importance. "I tell my employees that it is either 100 percent or it's a failure. There is no 'good enough' when it comes to printing medical labels. Accountability and traceability for every component and step that has gone into printing each label is very important. Our process for each job is the same. Everything is spelled out in a 'job bag' where all the pertinent records for each order are kept. The job bag stays with each order throughout the entire process, from order-entry through shipping. Retains from each job are filed with the job bag and kept for several years," he explains.

Brady emphasizes that for HP Mile, having a top-notch, electronic inspection system goes a long way in achieving the company's goals of printing the highest quality product. "We have always had the most up-to-date equipment to perform a 200 percent electronic inspection of our labels. We have been very happy with our relationship with AB Graphic International. We use their SR1300s with integrated Fleyevision video systems. The technology changes quite rapidly, and that is why we continually upgrade both the hardware and software with regard to our electronic inspection systems," he says.

As a label converter that specializes in the medical arena, HP Mile has always had a dedication to quality. But Brady says that taking steps to become ISO certified has really made a difference. "Since day one, our employees have been continually trained in pharmaceutical cGMPs. And in 2008 we decided to begin the process of attaining ISO 9001:2008 certification. This helped us to formalize our Quality System, which is our basis for continual improvement. The ISO certification gives us a 'stamp of approval'. This allows some companies to do business with us without having to send their own Q/A team in to do a full audit. It eliminates a hurdle and expense to begin doing business with us. And it serves as a way to give potential and existing customers a level of comfort in knowing that we have a quality system in place that has been approved by ISO, the International Organization for Standardization," says Brady.

For medical label customers, dead-on accuracy is mission critical, notes Eric Bartell, business development manager, labeling, for GBS Corporation, North Canton,

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OH, USA, a provider of pressure sensitive products to several Fortune 500 medical device and pharmaceutical companies. Bartell says that these customers have unique challenges in their industry that directly affect how GBS manufactures labels for them. "Our focus is to provide defect-free product to the end user. We have developed written, detailed, quality procedures and specialized work instructions for each customer based on their individual requirements. As we continually strive toward process excellence, we review and refine these quality procedures. ISO 9001 and cGMP process procedures help to ensure that this is achieved. We are finding that customers want to be able to rely on the quality of our processes, thus eliminating the need for incoming receiving inspection of our products," Bartell says.

#### Extended content, security and function

In medical labeling, it's fair to say that the use of electronic inspection systems is not a trend, but a must-have, in order to compete in the market. And converters in this field are eager to explore additional options and procedures with the goal being continuous improvement. Not only that, but the nature of medical labels often requires printing in multiple languages, as well as the addition of lengthy usage instructions. In addition, due to the sensitive nature of medical labeling content, it should come as no surprise that the adding of security features to medical labels is becoming increasingly more prevalent.

"GBS continually strives to stay abreast of trends by providing improved product and processes," says Eric Bartell. "Certainly, automated visual inspection systems are no longer a luxury. They are a necessity. Additionally, we are moving toward Six Sigma and process excellence. More than ever before, we are constantly evaluating and refining our processes.

"Extended text labels and RFID are good examples of applications that require specialized equipment and capabilities. Additionally, we have taken intentional steps in the layout of our facility to provide segregation of part numbers throughout our processes to avoid any possibility of co-mingling part numbers. In essence, we have created very secure areas in each of our departments," Bartell adds.

HP Mile's Michael Brady says, "We see an increasing need to provide more sophisticated security levels on labels and to assist our customers in the area of accountability. We currently back number each label and provide different machine readable or visual codes to assure correct labels and/or product. For security, we also use various photo-luminescent varnishes that are detected only when exposed to certain light frequencies."

Gene Dul also sees additional features being added as security measures, providing both brand protection and patient safety. "New developments like 2D bar coding and the integration of anti-counterfeiting features are some of the current trends in pharmaceutical labeling," he says. Dul says Schreiner MediPharm develops and converts a wide variety of specialty labels with innovative, value-added benefits such as labels with integrated hangers, labels with removable documentation parts as well as multi-page labels. Additionally, the product portfolio includes syringe labels with integrated needle protection as well as anti-tampering and counterfeiting protection systems.

"Patient safety is definitely an issue," Dul points out. "Pharmaceutical labels should ideally help to ensure that healthcare personnel is able to easily and reliably mark medications for clear identification and traceability of the drug up to the time of administration. In addition, track and trace serialization helps to optimize the supply chain processes," he says.

While some would think that RFID would be a perfect fit for medical labeling, it hasn't caught on as once anticipated, notes Eric Bartell. He says, "Interestingly, we have not seen as much activity in this market as we expected. We are involved in RFID in other market segments, but the medical device and pharmaceutical market has been moving in that direction much slower than we estimated. We do have a few key clients that are starting to look at the feasibility of RFID for internal inventory tracking."



Schreiner MediPharm's Needle-Trap system

Another important feature of some medical labels is their ability to provide a function. Schreiner MediPharm offers several functional medical products, and recently introduced its Needle-Trap labels. The Needle-Trap system features an integrated safety mechanism that is a component of the self-adhesive syringe label. The design allows the needle to be safely and easily secured after it has been used and enables healthcare providers to use their same injection technique and disposal process. The labels can be integrated into conventional labeling systems and are adaptable to the most common syringe types. The Needle-Trap received FDA 510(k) clearance for marketing in the US and has won an award from FINAT, the international label manufacturers' and converters' association.

"Many products have come out in recent years to help reduce the risk of needlestick injuries," says Gene Dul. "Unfortunately, such products often require major packaging design changes that can be quite expensive for manufacturers and difficult for users. Because the Needle-Trap system is integrated into the label, major changes are unnecessary. This integration makes it an effective, economical and convenient solution for the pharmaceutical industry as well as healthcare providers."

Jay Ziegler, director of sales and marketing for Tapecon, a printing and converting company based in Buffalo, NY, USA, says that while the company prints and converts a broad range of products, Tapecon's largest market is medical and medical devices. And some of the products they're converting provide medical functions – and are somewhat complex. "While we are involved in primary and secondary labels, we focus on specialty products that generally are functional. Our engineering and converting expertise lends itself well to more complex applications," Ziegler says.

"One category of products are single-use diagnostics such as sterilization indicators and disposable thermometers. Another includes our patented IV hang label that is a functional label with an integrated hanger that gets applied to glass IV vials. We also produce durable decals, overlays, membrane switches and fabricated functional parts for medical equipment," he explains.

Tapecon's medical products also have security and other functional features that Ziegler says has the company well positioned. "We can print as fine as 1-point microtext, fluorescing varnishes and apply registered security holograms and EAS tags behind labels for security and anti-counterfeiting measures. We also have experience with coatings for marking such as DataLase and CodeStream. In addition, we have perfected a process to print Braille rather than embossing. The European Union 2001/83/EC requires all new pharmaceutical packaging to include Braille by November 2010. The US follows much of Europe's packaging trends, so we see this as a nice opportunity," he says.

#### Dedicated systems and facilities

For GBS, systems are the key, Bartell says. "Our systems allow us to retain and access records for several years. This is critical for our customers. They need to be able to track the raw materials down to the lot number and manufacture date in the event of a non-conformance. Additionally, our systems allow our customers access to real-time inventory of their product in any of our distribution centers. They can create and access important information such as trending, current revision verification, shipment tracking, and schedule product releases," he says.

HP Mile was founded to deal specifically with the pharmaceutical and medical industry, and having a facility dedicated to this specific market has been a real asset, says Michael Brady. "Our concept is to have production equipment and personnel assigned to a single customer. This allows us to customize equipment to meet specific requirements and to have the best people to run that equipment. Our people are extremely familiar with the needs and wishes of the customer and this assures consistency. These dedicated work areas become an adjunct of our customer's operation and allow us to respond instantly to changing requirements or production problems. We work closely with customer production scheduling and imprint lot/expiration date on most orders. This allows improved print quality, labeling speed, and eliminates the need for the customer to perform an additional inspection. In addition, it allows us the flexibility to change our production schedule at a moment's notice, and we can deliver complete orders including back numbering within hours – not days," he says, adding that HP Mile is often does deliver complete orders within 24 hours.



One of HP Mile's customer-specific dedicated lines

### Market health

While medical labeling certainly differs from its consumer goods counterparts, there are a few market segments where one can see some commonalities. In particular, it can be said that food or household goods, for example, and medical/pharmaceutical labels are similar in that they are necessities, and do well in standing up to recessionary times.

While no market is recession proof, this market certainly seems recession resistant, says Eric Bartell. "Individuals don't postpone getting a stent or buying their prescriptions because the economy is in a downturn. And we have seen an interesting trend: Our customers are consolidating their supplier base and we are seeing more opportunities to capture business that may have previously been sourced outside of GBS. The increase in business has been significant."

"The healthcare industry has been more resilient than other industries," says Schreiner's Gene Dul. "But still, due to increasingly strict regulations in many countries as well as cost pressure and consolidation trends within the healthcare industry, there are a lot of challenges pharma companies have to cope with. In the US, the current healthcare bill might have implications as well," he says.

ID Images' Tim Mlnarik also points to healthcare legislation as a potentially stifling force. He says, "Historically, non-discretionary healthcare procedures and treatments have been resistant to recessions. However, when consumers (patients) shoulder more of the healthcare costs with higher deductibles, higher co-pays and the like, people are holding off, pushing back or questioning the need for various tests and procedures. Discretionary or elective healthcare items such as cosmetic surgeries, Botox and Lasik eye surgeries have been impacted by the recession," he says.

Mlnarik also proposes that universal healthcare may have the potential to provide a boost to medical labeling, as it would precipitate "more standards and record keeping requirements, which will drive labeling needs," he says.

The medical market will continue to be a growth area, Mlnarik believes, and he provides some interesting facts and figures to support this. He emphasizes that the demographics of baby boomers points to an aging population, and one that will be more reliant on healthcare.

"By 2030 all (baby boomers) will be on Medicare," he says. "Hospital and doctor visits are expected to double. The average lifespan continues to lengthen with increased chronic conditions," Mlnarik states, noting that 62 percent of the elderly have at least one chronic condition, and an estimated 33 percent of elderly Americans take 8 or more medications.

"In addition, nearly 4 billion prescriptions were written last year alone, and this number is growing over 10 percent each year," he says, adding that there's been an increase in direct to consumer advertising for drugs and medical devices.

So, while healthcare continues to be a divisive issue, the population will continue to rely on modern medicine. And through it all, converters will continue to carefully manufacture quality, functional products that promote health and safety for both patients and practitioners alike.