

Pharmaceuticals**Not Your Ordinary Labels: Advanced Labeling Tips for Pharma**

2009 NOV 16 -- Print On Demand (POD), label reconciliation, and other advanced labeling options help pharma meet regulatory, quality, and inventory management requirements

In the pharmaceutical industry, "simple" adhesive labels are anything but simple.

Unlike ordinary pre-printed adhesive labels stored in inventory in a manufacturer's warehouse, the labels used within the pharmaceutical industry are kept under lock and key in secure areas to protect against theft, bootlegging, and counterfeiting. Labels are only handled by authorized personnel, who must sign them in and out under the tightest scrutiny. In addition, the exact count of all labels - both used and unused - must be accounted for daily under the U.S. FDA's "current good manufacturing practices" (cGMP).

Changing FDA regulations also affect labeling requirements and often render pre-printed labels "obsolete." For this reason, labels are often printed in small quantities to avoid large upfront costs and wasted inventory, and quick turnaround is demanded for replacement labels to keep products moving out the door. Finally, these "simple" labels must be made of the proper substrates, adhesives and inks to remain adhered and legible for the life of the product so as to safeguard the consumer and protect the manufacturer from liability.

Although label requirements are admittedly the last item a pharmaceutical manufacturer thinks of when bringing a product to market, it is clear that labels play a vital role in the industry. By following the following advanced label printing tips and techniques, manufacturers can meet regulatory, quality, and inventory management requirements more easily than ever.

#### Print On Demand for Labels

Perhaps the most significant development in label printing in the last decade is the introduction of Print On Demand (POD). Although widely adopted in recent years within the book publishing industry, POD has only recently established a foothold with label printers as the technology has been adapted for label printing, and more shops make the capital investment in the equipment.

POD label presses are full-color digital print systems that offer greater flexibility than conventional presses, specifically in terms of job setup and changeover times. For the pharmaceutical industry, POD printing of labels reduces lead times, improves supply chain management, equates to shorter run lengths and minimal stock holding, and satisfies the requirements of variable data and other last minute changes.

"POD provides greater flexibility, faster turnaround time and the ability to make last second changes and adjustments," says Barrie O'Brien of American Label & Tag, a Canton, MI-based manufacturer of custom labels, tags, decals and nameplates that is now offering POD for labels. "For the pharmaceutical industry, the ability to quickly produce and receive custom labels is appealing when compared to the longer runs of labels using conventional label presses."

#### Label Reconciliation

Satisfying the U.S. FDA's "current good manufacturing practices" (cGMP) as efficiently as possible is a must in the pharmaceutical industry. But one area that can cause undue heartache is failing to achieve full label reconciliation, which falls under cGMP guidelines. Full label reconciliation, or accounting for all labels used and unused, can help to deter label theft and misuse.

"We have to account for every pharmaceutical label used and unused as required by the FDA," says Samir Shah, Vice President of Regulatory Affairs at The Harvard Drug Group, a premier secondary supplier of generic and brand pharmaceuticals, major OTCs, and vitamins. "Reverse numbering on the back of each peel-off-label, by vendors such as American Label & Tag, helps us to efficiently achieve this. There's no need to open or rewind the label rolls, and the last label on the roll tells us exactly how many are left by looking at the back of the label."

Full material traceability, or back-tracking the supply chain and handling of all a product's raw materials, can also help to prevent or limit potential recall if there's ever a question of sub-par product, materials or processes. This protects both the manufacturer and the consumer, according to Barrie O'Brien, co-owner of American Label & Tag.

Companies like American Label & Tag, for instance, can provide full material traceability for labels with a unique bar code system issued to all incoming raw materials from suppliers. The bar coding stays with the material in-house. Label bar code testing and verification also ensures that all are readable before shipment, which safeguards against potential returns to the manufacturer, according to O'Brien.

#### One-Stop Shop Capability

Despite POD's potential, traditional label printing is still less expensive for longer production runs - if turnaround time is not an issue. Yet with expensive inventory, limited lifespan, and frequent FDA changes, the clock is always ticking on pharma products, so to speak.

When turnaround time is of the essence, an expert "one-stop shop" label printer can eliminate bottlenecks and expedite delivery. By definition, a label printer that must outsource any aspect of the project automatically delays turnaround time. Outsourcing a die, for example, will add a week or two; not to mention opening the possibility that the die maker could be backlogged or fail to deliver as expected.

Instead, label printers that are vertically integrated with all the capabilities from design to die making to shipping can turn jobs around much faster. With the addition of POD, turnaround time has never been faster.

"From label design and graphics to plate making, set up, and proofing, relying on a one-stop shop has allowed us to quickly make any necessary changes," says Shah. "When speed is critical, they can deliver labeling within three days. That gives us peace of mind, helps us stay FDA-compliant, and gets our needed medicines in the hands of customers as quickly as possible."

And getting the right labels to the manufacturing site is just part of the job, according to O'Brien. Companies such as American Label & Tag can apply their extensive expertise over many decades of label design and printing to work in partnership with the manufacturer to produce the right label, while pointing out efficiencies to keep costs down.

"For cost efficiency, pharma manufacturers not only need to know how many labels are on a roll, but also how big the roll is, which way it's oriented, and how it's going on and coming off," says O'Brien. "An effective labeling partner will look at all the factors, including consolidating or standardizing where possible to deliver the best product at the best price."

### Advanced Labeling Specifications

Beyond simple labeling choices are a number of advanced options that pharma manufacturers should consider.

#### Product and Brand Security

Tamper-evident labels, with nicks or perforations that cause the label to fall apart when tampered with, are common in the pharma industry. While these are usually sufficient, more advanced security options should be offered by a reliable label vendor.

"Micro text, visible watermarks, color shifting inks, holograms, and difficult alignments are becoming viable options to protect pharmaceutical product from counterfeiting and bootlegging, which is a particular problem overseas," says O'Brien. "Also, more covert means such as hidden overprints, graphic characters, encrypted codes, and invisible inks or images detectable only in ultra-violet light are options as well."

#### Label substrate and adhesive expertise

Since pharmaceuticals may last for years, some labeling must remain legible and fade-resistant for up to four years. Other labeling, such as that used in internal manufacturing processes, may be designed for easy removal or repositioning.

"For label substrate and glue/adhesive requirements that can vary widely, it's best to work with a partner who can explore your needs and guide you to the best options," says O'Brien, whose company has refined its label substrate and glue expertise by working with industry giants such as 3M for decades. "For safety and economy in pharma, simple paper, film, or plastic substrates are a good place to start. A liquid UV coating can also provide a protective glossy coat that reduces smudging."

American Label & Tag, Inc. is a quality manufacturer of custom labels, tags, decals, and nameplates. It maintains all FDA approvals for its labeling products, including cGMP.

For more info, visit [www.americanlabel.com](http://www.americanlabel.com); call 800-641-8247; Fax 734-454-7606; or write to American Label and Tag at P.O. Box 85488 Westland, MI 48185-0488.

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