

6 pharmaceutical packaging trends to look for in 2018



2018 will be a year of change for the pharmaceutical labeling and packaging industry. Up and down the supply chain, the pharmaceutical industry will work hard to achieve traceability per DSCSA standards. Greater consumer demand and a heightened focus of customization at the patient level will force smaller batches and shorter lead times for packagers. Through all of the changes, quality management remains top-of-mind for pharmaceutical packaging manufacturers.

Here are six trends pharmaceutical packagers need look out for in 2018:

1. DSCSA regulations will increase industry focus on serialization, security and quality

With implementation deadlines on the horizon for the 2013 [Drug Supply Chain Security Act \(DSCSA\)](#), all segments of the pharmaceutical supply chain are pushing to meet the new federal verification, serialization and transaction documentation regulations on time.

The DSCSA is a law aimed at preventing counterfeit products from infiltrating the supply chain — a problem that [costs the industry almost \\$40 billion annually](#). The law comes with a 10-year timeline of gradual deadlines for all segments of the pharmaceutical distribution supply chain, from manufacturers to packagers to distributors.

The next big deadline —originally set for November 27, 2017— requires manufacturers to include serialized numerical identifiers (SNIs) at the product- and pallet-level. This allows for the verification of each unit from raw material to finished, saleable product throughout the supply chain.

The [FDA recently released a draft guidance document](#) pushing enforcement of that deadline from November 27, 2017 to November 27, 2018, citing concerns about the industry's readiness to meet the requirements by the original date.

Once the one-year grace period expires, it is likely that a zero-tolerance policy will take its place. The pharmaceutical industry should take this time to get their ducks in a row.

The ability to track and trace all products at the individual level offers you many benefits beyond simply achieving compliance. [Integrating serialization into your packaging operations now](#) not only prepares you for November 2018 — it also gives you heightened transparency into your operations, enhancing trust with partners and the end-user.

2. Greater consumer demand and increased focus on personalized care

At the same time as the pharmaceutical industry's regulatory landscape is shifting, consumer demand is expanding and transforming.

The Affordable Care Act (ACA) has allowed for almost 30 million more Americans to obtain insurance. This, coupled with an aging population, has resulted in an [increased global demand for pharmaceuticals](#). And as consumer demand expands, its needs are also changing. There's a [greater focus on personalized medicine](#) — one-size-fits-all no longer cuts it. This means smaller batches and shorter lead times for manufacturers up and down the supply chain.

For pharmaceutical packagers in particular, this will result in more continuous, localized production in the coming year. Customized medication necessitates label and packaging manufacturers to handle smaller batches with shorter lead times. And, because the batches are smaller, there is a shift toward packaging goods much closer to the point of sale for more efficient distribution.



3. Rise in use of contract packaging companies

As the market changes and regulations stiffen, pharmaceutical manufacturers are hard-pressed to keep up with their packaging needs. The cost of replacing legacy equipment in the face of stricter regulations is high. Pharmaceutical packaging itself is increasing in complexity.

That's why more pharmaceutical manufacturers are turning to specialized contract packagers (CPs) to ensure a higher level of speed and accuracy in their packaging operations. This allows pharma companies to focus on their core competencies —developing drugs— and leave the mounting complexities of pharmaceutical packaging to the experts.

With greater flexibility, shorter lead times and a wide portfolio of capabilities (i.e., blister packs, RFID tags, tamper-evident solutions, etc.), [specialized pharmaceutical packaging companies](#) are able to provide full-service solutions that pharma manufacturers just can't. And because outsourcing packaging can [reduce total supply chain costs by 25 to 50 percent](#), we're likely to see more and more pharma companies partner with CPs for their packaging needs.

4. Data management and cybersecurity emerge as primary concerns

To track and trace all products from raw material to finished product per DSCSA, [data must be](#)

[collected, stored and transferred](#) down the pharmaceutical distribution supply chain. This calls for robust and integrated data management solutions. But, in the pharmaceutical industry, these enterprise software solutions must come with equally [robust cybersecurity precautions](#) to prevent counterfeiting and security breaches as the data moves from organization to organization in the supply chain.

All legs of the supply chain are concerned with ensuring the security of their facility and the verifiability of their data. Because of this, beginning-to-end data management and cybersecurity solutions throughout the supply chain will be a key concern throughout the implementation of the DSCSA regulations in 2018 and beyond.

5. Growing use of smart packaging for identification and patient engagement

More and more pharmaceutical packagers are using smart labeling technology —namely radio frequency identification (RFID) and near field communication (NFC) tags— to track products and engage with patients.

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RFID tags for product- and pallet-level identification

In addition to 2D barcodes, [RFID tags are increasingly used](#) to track packages and pallets throughout the pharmaceutical supply chain. The main advantage RFID tags have over barcodes is that they eliminate the need for line-of-sight identification. All the goods within a pallet of packaged goods can be identified simultaneously, so long as it is close enough to the RFID reader. Basically, RFID tags allow you to identify entire truckloads worth of packaged product at once, and that information can immediately integrate with your data management software. Beyond ease of identification, RFID labels are extremely difficult to counterfeit — of great import in pharmaceutical packaging.

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NFC tags emerging as leading-edge solution for medication adherence

NFC labels have far-reaching implications in terms of improving medication adherence. [Small, programmable NFC tags](#) embedded in labels enable pharmaceutical companies to communicate key information to consumers. Just by tapping their NFC-enabled smartphones to the label, patients can access dosage and usage information in real time from your company's cloud server. Moreover, you can track interactions with NFC labels, and report on the success of various patient engagement or marketing campaigns.

6. Accountability of pharmaceutical packaging manufacturers

Accountability will be key in 2018. By the end of 2018, every package and homogenous case that leaves your facility must be uniquely identified with an SNI — and you must be able to trace each

package's progression throughout your facility with the utmost accuracy.

While there are [many factors to consider](#) as your organization gears up to meet these deadlines—from choosing enterprise-level considerations all the way down to upgrading legacy equipment, and everything in between—it's important not to lose sight of the employees who will be running your serialization implementation strategy day to day. After all, the quality of your labels and packaging will only be as good as the employees producing it.

As regulations change, tried-and-true standards like the [FDA's current good manufacturing principles \(cGMPs\)](#) and [International Standards Organization \(ISO\) 13485](#) will go a long way in ensuring every label, package and pallet that leaves your facility is made to the highest quality.

Training, buy-in and quality management will be key to your organization's success as it attempts to put processes in place to ensure total traceability of every product that cycles through your facility. With the right strategy, quality management system and comprehensive training plan, you should be able to complete any verification requests your facility receives.

Looking forward, pharmaceutical packagers want to be at the leading edge of label technology, quality management, employee training and serialization. Not only will leading the pack on this charge help you achieve compliance in the coming year — it also offers you a competitive advantage in cross-organizational collaboration up and down the supply chain for years to come.