WHAT YOU NEED TO KNOW ABOUT PHARMACEUTICAL PACKAGING

Honeywell

ABSTRACT

With increased globalization, the pharmaceutical industry is facing new challenges – along with promising opportunities. Many drug manufacturers look to packaging innovations to stay ahead of the curve in meeting unmet needs in healthcare.

WHEN IT COMES TO PHARMACEUTICAL PACKAGING, DIFFERENT CATEGORIES OF USERS HAVE DISTINCT NEEDS.

Originators take the challenge and risk to develop new and novel therapeutic options with improved outcomes and/or lower side effects for patients than standard therapies. Specialized treatments for smaller patient populations and rare disease are highly prevalent in current drug pipelines. They require packaging solutions that enable design for intended use (DIU). This involves a shift in packaging operations to smaller batch sizes and shorter cycle times. Generic companies, on the other hand, make significant efforts in R&D to develop new formulations for active pharmaceutical ingredients that have already been on the market for a long time. They regard time-to-market (i.e., launch at day one after patent expiry) as a critical factor to obtain a competitive advantage.

Common to both originators and generic companies is the need to quickly arrive at flexible solutions for packaging operations and users (caregivers and patients).

Patient safety, usability and therapeutic outcomes, combined with adherence to therapies, traceability of both in-bound and outbound supplies, and productivity of pharmaceutical operations, have become key criteria for packaging selection.

INTRODUCTION

> The pharmaceutical industry is undergoing a significant shift from standard chemical active pharmaceutical ingredients (APIs) to therapeutic proteins.

IN THE FORESEEABLE FUTURE, ORAL SOLID THERAPIES WILL REMAIN THE MOST POPULAR MODES OF ADMINISTRATION, AND TABLETS AND CAPSULES WILL TREAT THE MAJORITY OF HEALTH CONDITIONS.

When it comes to the packaging of oral drugs, however, topics such as sustainability, total cost of ownership, overall equipment effectiveness (OEE) and supply-chain robustness are gaining a much higher focus than in the past when quality aspects were almost the sole drivers. A growing number of regulatory bodies demand quality-by-design approaches for primary packaging selection. A clear understanding of the shelf-life-limiting factors and critical-to-quality aspects of protective packaging for drug product stability is essential for successful regulatory submissions.

Indeed, the ability to identify materials and container closure systems that are fit for purpose in all aspects of packaging is an emerging science, an essential engineering discipline, and a key contributor to business success.

Honeywell has been involved with pharmaceutical packaging for more than 40 years. From our experience supplying moisture barrier films and other innovative solutions, we have seen significant trends influencing the direction of packaging technology for originator and generic pharmaceuticals, over-the-counter (OTC) remedies and animal health products. These trends have implications for stakeholders in all aspects of drug manufacturing and delivery.

The purpose of this whitepaper is to provide a seasoned perspective on developments in pharmaceutical packaging. With tighter regulations and new demands, there are important facts you need to know.

TODAY'S MARKET REQUIREMENTS

Pharmaceutical manufacturers are navigating a constantly shifting marketplace. There's greater variety in drug-delivery mechanisms to support new formulations, new modes of dosing, and a host of new users.

THERE'S ALSO GREATER DEMAND FOR PRODUCT IDENTIFICATION AND TRACKING TO SUPPORT MORE COMPLEX SUPPLY CHAINS. THESE AND OTHER DEVELOPMENTS HAVE ALTERED THE OUTLOOK ON DRUG DELIVERY AND ITS RELATED PACKAGING.

Pharmaceuticals need to be produced, stored, filled, sealed, packaged and transported under conditions that ensure their integrity and maintain safety. The systems for handling these products, through every part of the supply chain from manufacturing to shipping, must be done under compliance with rigorous standards. Each country has its own set of pharmaceutical regulations and therefore challenges to be met.

Packaging errors have become a common cause of drug recalls, forcing standards agencies to introduce tighter regulations to ensure patient safety. The wrong packaging can render a drug unusable or potentially dangerous, and can entangle pharmaceutical firms in damaging compliance issues.

Today, pharmaceutical producers require a holistic approach to drug packaging that goes beyond basic functional considerations to address pressing concerns such as counterfeiting and patient compliance, and at the same time balances child-resistance and accessibility for the elderly.

Traditionally, the majority of medicines have been taken orally by tablets or capsules, which are either packed in blister packs or fed into plastic bottles. But regardless of the packaging material, there is growing recognition of the need to provide tailored, individualized packaging solutions designed to guarantee the effectiveness of medicines in a wide range of applications.

CHALLENGES FACING REQUIREMENTS

One of the major challenges for pharmaceutical executives is leveraging manufacturing and packaging processes to reduce costs by optimizing the flexibility and capacity of existing assets, while simultaneously mitigating risk across the supply chain for both prescription and OTC drugs.

ANOTHER CRUCIAL DEMAND ON DRUG MANUFACTURERS IS RECONFIGURING THEIR PACKAGING CAPABILITIES TO ACCOMMODATE AN EXPANDING PRODUCT PORTFOLIO. THIS INCLUDES ENSURING PACKAGING MATERIALS ARE FREE OF ISSUES OR DEFECTS, ALL THE WAY DOWN TO PACKAGING COMPONENT SUPPLIERS.

For many pharmaceutical manufacturers, especially smaller companies, packaging design and production is a non-core activity. Such organizations may lack internal resources to deal with packaging qualification, validation, stability testing and regulatory compliance documentation, and as such, outsource packaging functions to third-party contract manufacturers.

Primary packaging is part of the overall product solution, and so it is essential to shorten the time-to-confidence and time-to-file when obtaining regulatory approval of new drug products. Manufacturers need packaging solutions designed for safety, efficacy and regulatory compliance. This includes packaging that provides sufficient levels of barrier protection against moisture, oxygen and other environmental factors. A successful product launch hinges on robust data that builds confidence in the minds of stakeholders over the shelf life of the medication.

When developing new pharmaceutical products, lifecycle cost is a fundamental consideration. Manufacturers of all sizes are under increasing economic pressure, and it is vital that packaging strategies help minimize production costs and shorten time to market.

The market for highly potent biopharmaceuticals with selective mechanisms of action continues to expand. Still, the vast majority of biopharmaceuticals are sterile solutions stored in glass vials, small-volume parentherals or IV bags. There is a growing trend to replace glass and standard bags with advanced, polymer-based container closure systems for storage and delivery of therapeutic proteins.

For safeguarding vulnerable bio-substances, manufacturers prefer primary packaging materials that are bio-chemically inert, chemically resistant, steam- or gamma-sterilizable, flex-crack-resistant, and impermeable to moisture and oxygen.

There is a paved way to individualized, tailored biopharmaceutical medicines, which is scientifically and economically possible with all related benefits for patients. An important criterion for any packaging strategy is balancing manufacturing processes that assure the highest product quality and productivity with designs that create positive user responses and therapeutic outcomes. Patient-centric packaging design plays a crucial role in addressing the needs of people of different culture, habits, age, language, ability, and so on.

CURRENT INDUSTRY TRENDS

As the pharmaceutical industry adapts to dynamic market conditions, the packaging sector is undergoing a transformation of its own. With consumer needs constantly changing, cost pressure mounting and safety regulations becoming stricter every year, packaging suppliers are developing solutions that give drug manufacturers new room to maneuver in production. In Honeywell's view, the following trends are having a major influence on pharmaceutical packaging:

INCREASED GLOBALIZATION

Pharmaceutical companies have discovered high-growth areas outside the traditional developed markets. In order to shorten delivery times and meet the unique requirements of a particular region, they are pursuing a more localized supply chain capability. The goal is to improve agility and flexibility in product manufacturing, including the ability to produce smaller batches of specialized drugs with quick changeovers.

Manufacturers of high-volume generic drugs distributed globally need to reduce costs while producing medications on a made-to-order basis. This requires the creation of a single primary packaging mode, which minimizes the number of stock keeping units (SKUs) and is suitable for all market regions and climatic zones.

TIGHTER SECURITY

Up and down the supply chain, the pharmaceutical industry is seeking to achieve traceability per the latest security guidelines. In the US, for example, companies have to comply the Drug Supply Chain Security Act, which is an important new regulation from the US Food & Drug Administration (FDA) to help drive improved supply security. This initiative starts with beginning-to-end data management and effective cyber security measures.

The goal is to prevent counterfeiting and security breaches as data and products move from organization to organization. All elements of the supply chain must take responsibility for ensuring the security of their facility and the verifiability of their drug information.

STRICTER STANDARDS

Pharmaceutical and biopharmaceutical organizations are under greater regulatory scrutiny than ever before. From R&D to operations, there is a responsibility to ensure drugs are within specification limits at both the time of release and over the life of the product. Quality consistency is the name of the game, and standards in this area are continuing to become more stringent.

The pharmaceutical industry is coping with a plethora of regulatory standards, which typically differ from region to region, and often vary from country to country. In the European Union, for example, pharmaceutical producers must meet new standards governing tamper evidence.

US regulatory bodies have enacted strict guidelines for child-resistant capabilities. Additional standards worldwide cover issues such as track-and-trace down to the individual pack level by mandating 2D barcodes and other technology upgrades.

GREATER CUSTOMIZATION

Increasing consumer demand and a heightened focus on customization at the patient level are forcing smaller batches and shorter lead times for pharmaceuticals. And, because the batches are smaller, there is a shift toward packaging goods much closer to the point of sale for more efficient distribution.

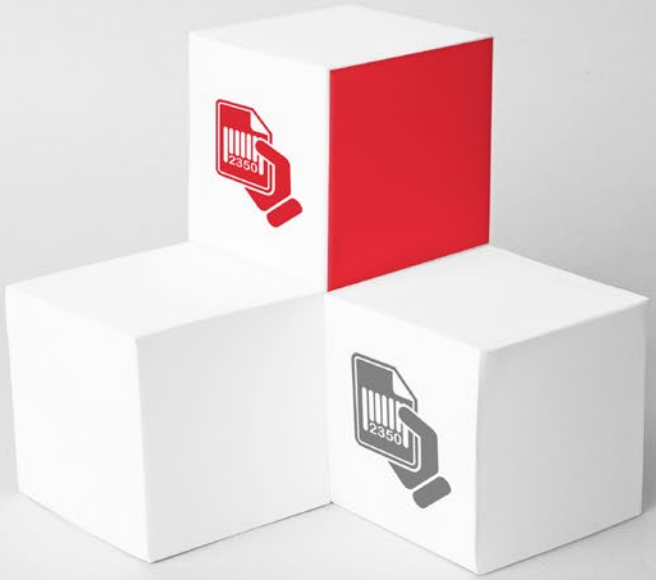
Through all of these changes, quality management remains top-of-mind for packaging producers.There is now an emphasis on specialized medicine that is adjustable to small patient populations requiring different drug potencies and delivery mechanisms. The same holds true for packaging methodologies, which need to be adaptable for meeting patients' dosing regimens most effectively.

Once a pharmaceutical manufacturer has established one packaging standard across the company, it should be easy to adapt it to a large array of drug products. This approach reduces complexity by allowing the same primary packaging material to be used for therapies to treat a wide range of indications.

ENHANCED SERIALIZATION

A major trend in packaging is digital mass serialization to combat counterfeiting schemes. The technique involves adding machine-readable codes containing a serial number to individual packs of medicine. Unlike all other methods for verifying drugs, it enables product authentication at the point of dispense (POD) and provides the ultimate barrier between potentially harmful drugs and the patient.

Serialization goes beyond traceability to enable authentication of medicinal substances at any stage of the supply chain. This capability improves safety for end users by expediting recalls in the event of drug problem.



SMARTER PACKAGING

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. Smart packaging technology can be used to monitor dosage information and give patients timely reminders. It also provides valuable digitized feedback to healthcare professionals.

IMPROVED SUSTAINABILITY

Producing environmentally friendly, yet functional packaging is a test for any industry, but even more so for pharmaceuticals Nations (UN) has warned that the world's oceans will contain more plastic than fish by 2050 unless action is taken. The future of drug packaging will see a shift towards more sustainable materials.

The topic of recyclability is especially acute in Europe, where related guidelines are set to take effect in 2025. The guidelines pertain to corporate responsibility and state that consumer product packaging should be recyclable to help offset rising pollution levels.

EVOLUTION OF PACKAGING TECHNOLOGY

With major improvements being made in the development and manufacture of pharmaceuticals, packaging technology is advancing in an equally impressive manner. Sophisticated packaging materials and techniques now address the most rigorous industry requirements

Whether it is to improve pharmaceutical product protection, deliver convenience and ease of delivery, or encourage patient compliance, packaging's role should not be underestimated. The evolution of pharmaceutical packaging has been largely impacted by social, economic, and technological factors. Ongoing advancements have responded to the need for better consumer education, improved delivery of products, and a heightened level of competition in various segments of the market.

In a global business environment, it is incumbent upon pharmaceutical manufacturers to be more nimble while implementing measures that save their customers money. The new norm is customized short runs delivered in tight timeframes.

Advancements in child-resistant packaging utilizing cost-effective cardboard containers have included dose packs intended to minimize access by very young children. Another noteworthy innovation has been multi-layer, laminated blister packs that can utilize a different number of polymer layers depending upon the drug's moisture and oxygen protection requirements. These blister packs can even incorporate ultraviolet (UV) inhibitors to provide different levels of sunlight protection based on the scope of geographic distribution.

An important recent development in the packaging world – serialization and full track-and-trace systems – will not only lead the industry towards a safer and more secure supply chain, but could ultimately help to connect the whole industry from manufacturer to patient. This could not only mean a more integrated and streamlined approach to bringing new drugs to market, but also ensure that healthcare services are provided safely and at an affordable price.

NEW VALUE-ADDED SOLUTIONS

Value creation in drug delivery has traditionally centered on addressing the unmet needs of patients. Achieving better treatment outcomes has an impact on society as a whole, and specifically benefits individuals, employers, social systems and health care providers.

From a business optimization standpoint, however, the latest solutions for packaging pharmaceuticals add value by yielding significant improvements in materials, cost, sustainability, and user experience. Indeed, packaging innovation based on a clear understanding of all stakeholder requirements can lead to new designs that assist the customer, patient and planet.

For example, advanced thermoforming films are enablers for optimizing blister pack designs more holistically, with decisions based on understanding and meeting patient needs, while at the same time offering opportunities for significant productivity gains in packaging operations. By employing clear and opaque laminated options for high-moisture barrier films, pharmaceutical manufacturers gain cost-effective alternatives for product packaging with shorter lead times to increase shelf life, reduce operating expenses, and protect drugs in various climates. The films can facilitate increased patient compliance with see-through, portable and patient-friendly pack presentations.

Pharmaceutical and biopharmaceutical companies can also achieve better outcomes if they have access to packaging materials that are usable throughout all stages of development and over the full lifetime of a product. They benefit from solutions that fully address stakeholder needs from the pre-launch phase all the way to market maturity. It is wise to avoid isolated features that only have a value proposition for one party in the overall product ecosystem.

Finally, additional value is realized from the availability of “smart packaging” ranging from a simple QR code on a medicine vial to access dosage instructions, to an embedded microchip on a product that informs the physician or pharmacy when individual blisters have been opened or the drug has been consumed.

The ability to track and trace all products at the individual level offers many benefits beyond simply achieving compliance. Integrating serialization into packaging heightens transparency into operations, enhancing trust with partners and the end user.

CONCLUSION

Pharmaceutical packaging is evolving, and it's important to understand the latest trends and developments.

This whitepaper is intended to provide new insights into today's packaging requirements. With accurate information, industry stakeholders can plan for the future and take steps to optimize the effectiveness of their packaging strategy – ultimately improving their business results.

For additional information or to contact us, please visit:
www.honeywell-aclar.com

2719 P&C Aclar I June 2019

THE FUTURE IS WHAT WE MAKE IT

Honeywell