MARCH/2022

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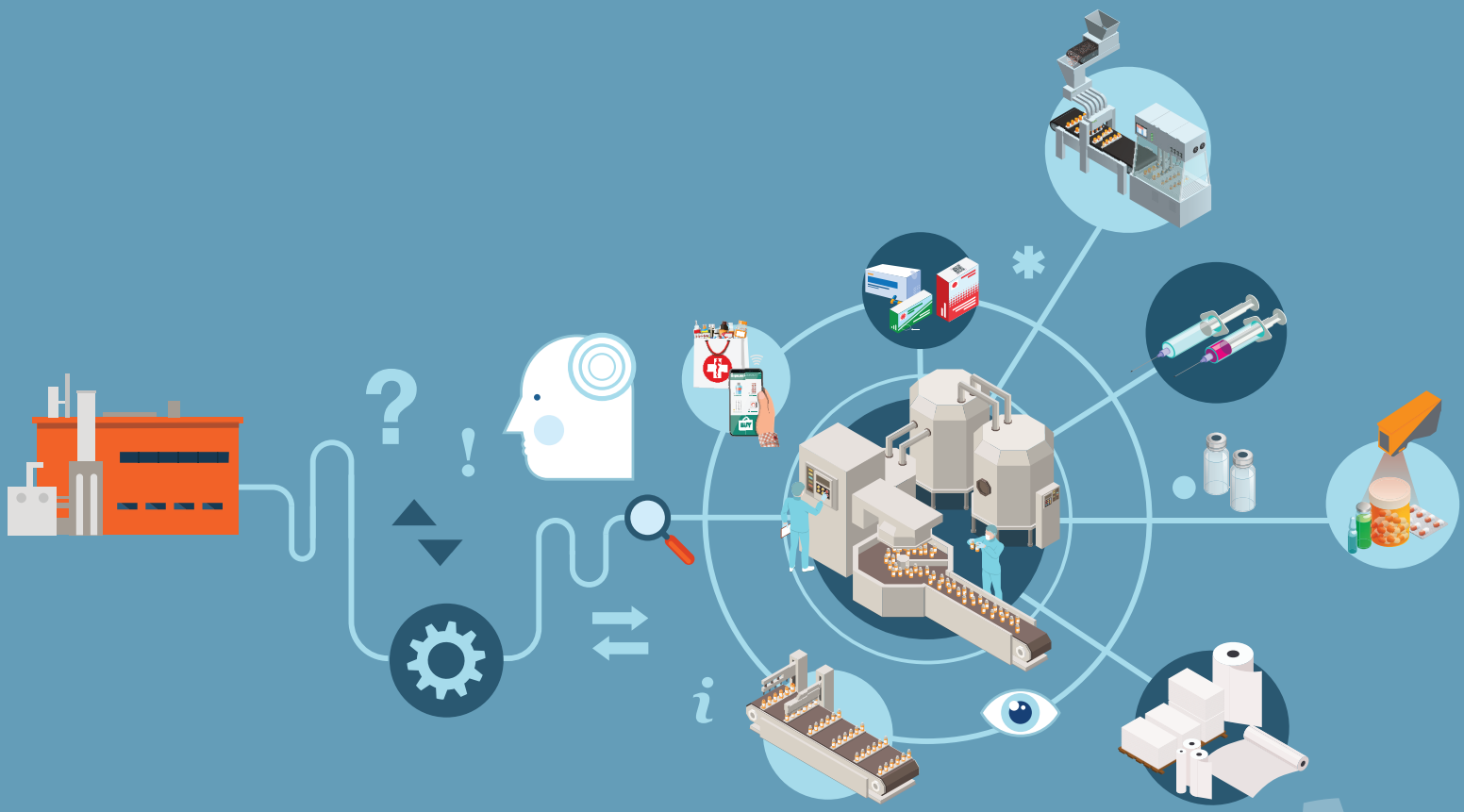
Pharmaceutical Manufacturing

Trends Shaping the Future



PMMI Business Intelligence

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> The future of medicine is biopharmaceuticals using personalized drugs to treat targeted patient care.
>
> — *Director, Packaging Technology, Large Pharma*

INTRODUCTION

Most Important Takeaways:

1. The pharmaceutical industry is undergoing a fundamental shift in product formats with the growth of injectables and customized medicines, requiring manufacturers to rethink their production and packaging strategies.
2. Maximizing throughput has become a key component of maintaining production levels at pharmaceutical manufacturers, which has in turn driven the proliferation of automation technology and the digitization of data to improve efficiency across operations.
3. A growing consumer focus on sustainability and the expanding use of e-commerce ordering for DTC shipping is pushing pharmaceutical manufacturers to reevaluate the basic components of their packaging.
4. The COVID-19 pandemic has thrown a wrench into many pharmaceutical manufacturers' short-term goals as they struggle with ongoing ingredient, material, and machine shortages.

Pharmaceutical Participants

The opinions and quotes throughout this paper are derived from direct interviews with pharmaceutical industry leaders and SMEs (small and medium enterprises) and include CMs/CPs (contract manufacturers and contract packagers).

These companies manufacture products that are administered as solids, liquids, injectables, gels, powders, creams, inhalants, transdermal patches, and dissolvables:

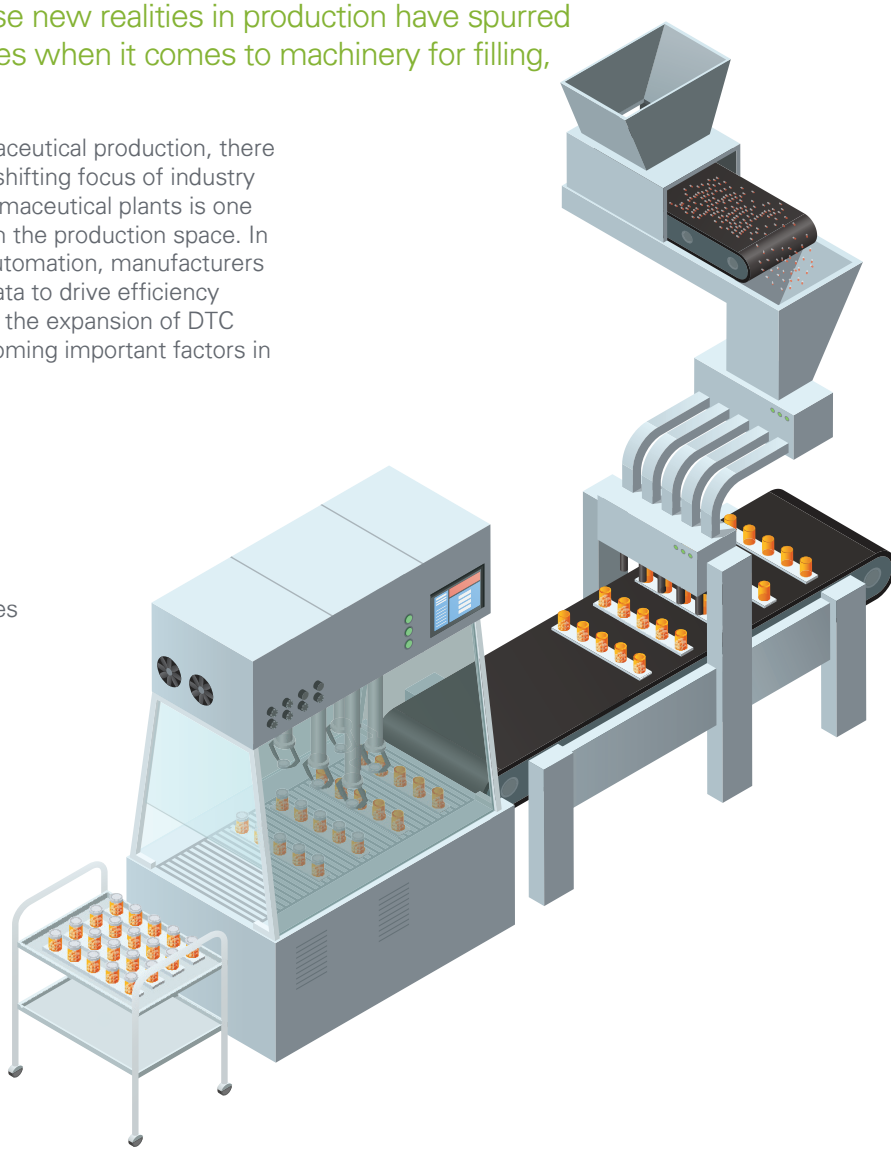
- Rx and generic drugs
- Biopharmaceuticals
- Supplements, Nutritionals, and Vitamins
- OTC (over-the-counter)

Pharmaceutical Manufacturing Trends Shaping the Future

Over the last few years, the pharmaceutical industry has entered a phase of rapid evolution as the focus of therapeutic treatment delivery methods shifts in medicine. Specifically, the pharmaceutical industry has seen a rapid expansion of injectable medications, packed both in vials and pre-filled syringes. In conjunction with this shift to injectable drugs, the pharmaceutical industry has also seen movement toward more personalized medication packaging. These new realities in production have spurred manufacturers to reevaluate their priorities when it comes to machinery for filling, packaging, labeling, and coding.

In addition to these fundamental changes to pharmaceutical production, there are also several important trends underpinning the shifting focus of industry manufacturers. Increased throughput needs at pharmaceutical plants is one of the factors driving the expansion of automation in the production space. In addition to improving physical processes through automation, manufacturers are also looking to harness the power of digitized data to drive efficiency improvements across operations. Sustainability and the expansion of DTC shipping channels for pharmaceuticals are also becoming important factors in manufacturers' production strategies.

Like all industries during the pandemic, COVID-19 has also had a significant impact on pharmaceutical production. Supply shortages have led to a host of new challenges for manufacturers as they struggle with ingredient shortages, packaging material shortages, and extended lead times on equipment deliveries - all of which have forced some companies to delay planned projects. Despite these significant hurdles, the long-term impact of COVID-19 may be a net positive for the pharmaceutical industry as cooperation increases amongst stakeholders.



2021 PMMI State of the Industry Report Data

In 2020, the value of U.S. packaging machinery shipments to all market segments was $9.4 billion, with the pharmaceutical industry accounting for 8.5% ($800 MM) of sales. The pharmaceutical machinery industry is forecast to grow at a CAGR of 7.6% (2020-2026), surpassing overall U.S. packaging machinery shipments, which are forecast to grow at 5.2% over the same period.

There are several machinery categories where the pharmaceuticals segment holds a significant share:

- In filling and closing machines, the pharmaceutical segment holds a 21.2% share, second to household, industrial, and agricultural chemicals.
- In the blister, skin, and vacuum packaging machines market, the pharmaceutical segment holds the number one market position with a 46.8% share.

In 2020, the U.S. pharmaceutical industry accounted for machinery sales of

$800MM

Forecast to grow

7.6%

CAGR
(2020-2026)

Pharmaceutical Machinery: Sales Value

Pharmaceuticals Equipment Shipment Value - $800 MM (2020)
Consolidated into Ten Machinery Categories

PMMI Machinery Category	U.S. Packaging Machinery Pharmaceuticals Segment 2020 Value of Shipments (USD MM)	U.S. Packaging Machinery Pharmaceuticals Segment % of Category
Bottling	$122.3	13.9%
Cartoning	$69.8	16.3%
Case/Tray Handling	$68.9	4.2%
Closing	$36.0	9.0%
Filling and Dosing	$128.3	9.0%
Form/Fill/Seal	$26.8	3.5%
Labeling, Decorating, and Coding	$115.7	8.5%
Palletizing	$41.5	9.7%
Wrapping and Bundling	$8.3	2.5%
Other Machinery	$182.0	10.2%
Total Pharmaceuticals Segment of US Packaging Machinery	**$799.6**	**8.5%**

Source: 2021 PMMI State of the Industry Report

Evolving Formats: Injectables and Customized Packaging

One of the biggest recent shifts in pharmaceutical production is the increase in injectable drugs entering the market. The injectables segment of the global pharmaceutical market is predicted to grow to around $624 billion in revenue by 2022, which would represent a 100% increase from 2016.[1] According to FDA statistics, injectables make up an average of 40% of all new drugs approved in recent years.[2] Further evidence of this rapid growth can be seen in the parenteral container and glass pharmaceutical packaging markets that support injectable formats: parenteral containers are slated to grow at a CAGR of 7.6% to 2027, while glass packaging is projected to grow at a rapid 8.5% CAGR over the same period.[3] This explosion of injectable drugs has resulted in pharmaceutical manufacturers reevaluating fundamental aspects of their production processes to meet growing demand.

The injectables segment of the global pharmaceutical market is predicted to grow to around

$625b
in 2022

100%
increase from 2016

> Liquid dose formulations continue to move toward a combo of medicine and device: for example, prefilled syringes.
>
> — *Packaging Engineer, SME, Solid and Liquid Product Manufacturer*

> In general, we have moved away from ampules and vials to more prefilled syringes.
>
> — *Engineer, Filling/Packaging, Large Generic Manufacturer*

In addition to the growth of the injectables segment, pharmaceutical production has seen a rapid uptick of personalized, customized medication packaging. According to the FDA, personalized medicines accounted for 39% of all new drugs approved in 2020.[4] Like the growth of injectables, the increase in the number of personalized medicines requiring customized production runs has pushed pharmaceutical manufacturers to make operational changes to address the expanding popularity of these formats.

> We see personalized medicines increasing and have built a full line dedicated to producing personalized medications.
>
> — *Sr. Manager, Packaging, Large Rx and Generic Manufacturer*

> Specialty drugs are significantly impacting our business, especially with the logistics in the cold chain.
>
> — *Engineer, Packaging, Large CM*

Flexibility is Essential

The combination of the increase in injectable drug production and the movement toward more personalized medications has placed new emphasis on machine versatility. Since the injectable drug market is composed of a plethora of different packaging and delivery methods, pharmaceutical machinery must be able to accommodate numerous different packaging formats. From vials to prefilled syringes and auto-injectors, the injectables market is constantly seeing new format tweaks introduced as manufacturers seek to perfect their designs. This variety is further compounded by the increase in personalized medicines, requiring both a high degree of machine flexibility and smaller production runs. The end result is that manufacturing professionals are looking for machines that are able to handle the wider variety of formats being produced in smaller batch runs, while still minimizing downtime.

> We are a big company that manufactures varied products with flexible production, so our manufacturing and packaging equipment needs are broad.
>
> — *Project Manager, Large Rx and Generic Manufacturer*

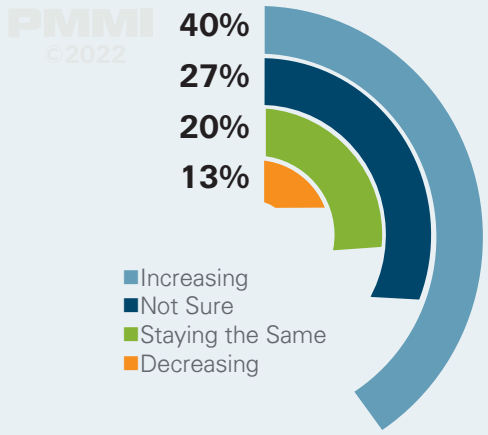
> We need machines that have easy to set parameters designed for the semi-skilled operator, to assure product repeatability and quality.
>
> — *Project Manager, Large Rx and Generic Manufacturer*

Capital Spending Across the Line

As pharmaceutical manufacturers make capital investments, three out of five engineers and senior managers interviewed predict automated equipment to proliferate in all areas of production:

- Processing
- Primary Packaging
- Secondary Packaging
- End-of-Line

Capital Budget Predictions Over the Next Few Years at Pharmaceutical Companies

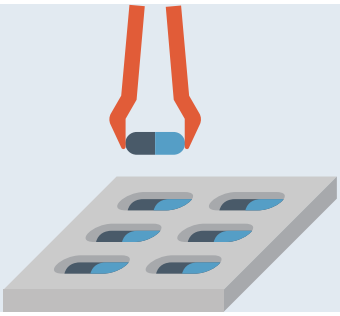


Sanitary Production

The rise of injectable drugs has also placed renewed emphasis on sterile production. Given the sensitive nature of injectable drugs and the increased contamination risk factor inherent to injections, maintaining a sanitary space throughout processing, production, and packaging is essential to product safety. Not only could breaches to sanitary production practices damage the product and decrease or eliminate its efficacy, it could also lead to serious health complications for patients. One effective strategy being employed by manufacturers to maintain sanitary conditions is limiting human interaction with products and packaging, which can be achieved through automation additions like robotics.

3 out of 4 companies interviewed

Are using robotics now; over half predict implementing more robots/cobots in the future.



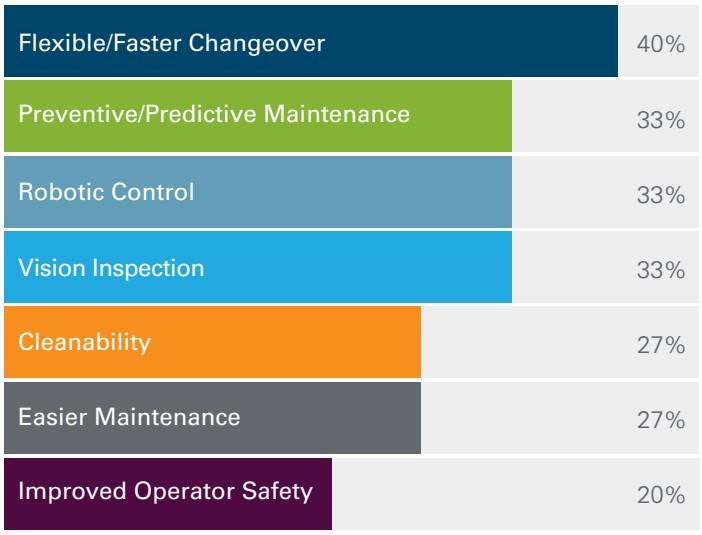
One of the key areas OEMs can focus on is improving operator safety by minimizing human interaction with the machines by adding robotic control.

— *Sr. Manager, Global Technology, Large Rx and OTC Manufacturer*

As a small-scale contract manufacturer, our greatest focus is on sterility; we need quick changeovers for customers' varied products.

— *Validation Engineer, CM, Rx and Generic Products*

Key Machine Improvements Needed on the Next Generation of Processing and Packaging Equipment



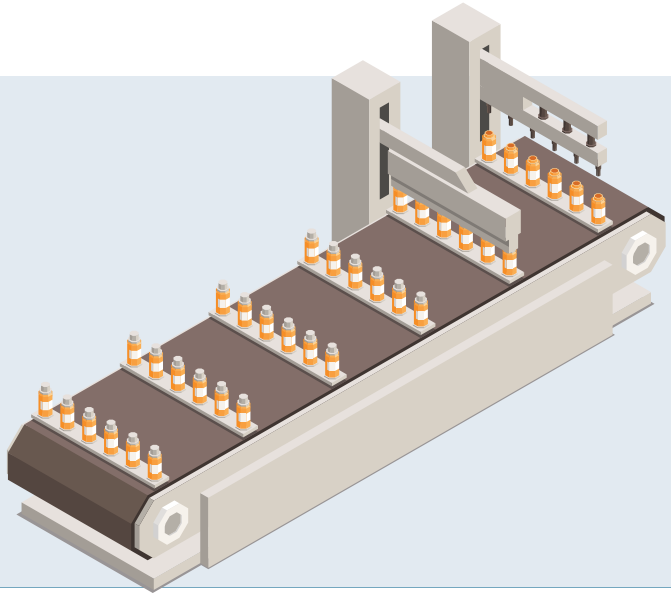
Exceeds 100% due to multiple answers

Robust Packaging

As injectable drugs have grown, some pharmaceutical manufacturers have struggled with packaging integrity, requiring adjustments to meet packaging regulations. A key area of growth for injectables – biologics – has been particularly prone to packaging challenges. For instance, the formulation of some biologics can interact with glass vials, delaminating the interior and causing the glass to flake into the product. Given that glass vials are a common standard packaging option for injectable drugs, some of these interactions are unexpected and require manufacturers to rethink their approach from the ground up. In the case of flaking glass vials, manufacturers are looking to alter the production of the vials themselves to make the glass stable enough to stand up to problematic biologic formulations.

Quality By Design (QbD)

There is growing focus in the pharmaceutical industry on QbD, a concept that calls for "quality" to be designed into a product at the earliest stages of its development, for both the physical properties of the product itself and the packaging housing it. For the pharmaceutical industry, "quality" often means functional packaging that is reliable, resistant to tampering, durable enough to survive the supply chain, child-proof yet easy to open for seniors, and meets a variety of different regional distribution regulations to enable the use of a single, unified packaging configuration.



Growth of Contractors

The rise of injectables and personalized medicine has placed additional strain on the production capabilities of traditional pharmaceutical manufacturers, which has pushed many to seek out contracting services. The practice of outsourcing to contractors has become standard in the pharmaceutical industry, with 60% of interviewees stating they use contractors in some manner in their production strategies. Pharmaceutical manufacturers can derive numerous advantages from using contract services: from gaining access to formats and production methodologies they lack, to handling overflows in production when demand spikes. Manufacturers can also reduce costs through outsourcing by avoiding the need for new equipment and new lines, freeing up extra capital to be reinvested elsewhere in an operation.

Contract services (CMs/CPs) are an integral part of most pharmaceutical production strategies.

3 out of 5 pharma manufacturers interviewed outsource at least a portion of their operations to a third-party contractor.

There are a host of reasons why pharmaceutical manufacturers outsource to CMs and CPs. Contractors offer advantages such as flexibility to deliver small production runs for specialized products, access to different packaging configurations, expanded capacity to accommodate increased demand, access to new markets, and reductions in cost and overhead.

Specialized runs for smaller volume products

Access to different packaging or product formats not available inhouse

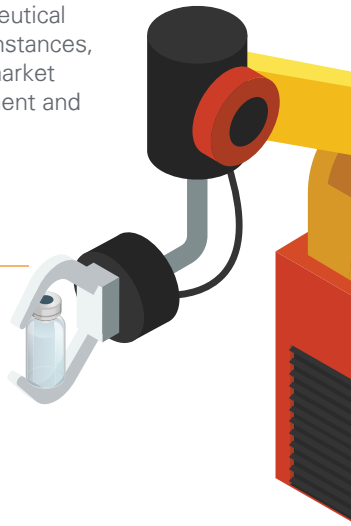
Increased production when demand spikes

> The lack of space in our facility is driving us to use CMs/CPs more frequently in the future, which gives us access to different packaging formats for our smaller, specialized runs.
>
> — *Associate Packaging Engineer, Large Rx Manufacturer*

> Batch runs are getting smaller and we use contractors to manage the manufacturing and packaging.
>
> — *Associate Director, Packaging Technology, Large Biopharmaceutical Manufacturer*

Growth in Machinery

The expanding role of contractors is also spurring growth in machine purchases. While the use of contractors can help some operations avoid the need for new equipment, this is partially offset by the contractors themselves investing in specialty production methods and increasing the variety of their capabilities through machine purchases. As formats like injectables grow and customization becomes more common, contractors must secure additional equipment to keep their capabilities up to speed with the needs of the pharmaceutical industry. This is particularly true for contractors specializing in packaging: interest in dedicated pharmaceutical CPs has grown as packaging becomes more diverse, complicated, and stringently regulated. In some instances, manufacturers are even investing directly in contract partners: as a leading authority in the packaging market explains, "To meet growing product demand, some manufacturers are actually purchasing new equipment and having it delivered to contractors to bring their facilities up to speed quickly."



Contractors offer specific equipment that we don't have inhouse that is needed for handling a segment of our packaging.

— Packaging Engineering Manager, SME Rx Manufacturer

Contracted services will continue to increase as an answer to the shortage of labor.

— Engineer, Packaging, Large CM

Throughput Drives Automation Needs

The trend toward more injectables and customized medicines has created additional production considerations for pharmaceutical manufacturers. Specifically, the proliferation of formats and customization has necessitated smaller runs with minimal downtime, meaning that machines must be able to accommodate a wide variety of formats as well as make rapid, seamless changeovers. For manufacturers, this means maximizing throughput capabilities to keep up with growing demand. To achieve maximized throughput, pharmaceutical manufacturers are turning to automation solutions that can streamline efficiency. According to one recent survey, 60% of pharmaceutical companies would choose to automate all aspects of their operations if it were viable for them to do so.[5] This interest also bore out in direct company interviews, where 75% of those interviewed stated they plan to increase the level of automation in their operations in the coming years.

In direct company interviews

75%

of those interviewed stated they plan to increase the level of automation in their operations in the coming years

In general, we are working towards Pharma 4.0 and adopting digital strategies to suit the unique context of pharmaceutical manufacturing. This means more connectivity, more productivity, simplified compliance, and the analysis of production information to respond to problems as they emerge.

— Director of Engineering, Large Biopharmaceutical Manufacturer

We are mostly working on oncology products in liquids and capsules; we are trying to minimize changeover, which is difficult as we need to scale up or down depending on production demands.

— Sr. Manager, Global Technology, Large Rx and OTC Manufacturer

Labor Shortages Accelerate Automation

The ongoing shortage of labor at all levels – which began before COVID-19 but has been drastically exacerbated by the pandemic – is creating challenges at pharmaceutical manufacturers of all sizes. 33% of companies interviewed stated that they still struggle to adequately staff their operations. In a separate survey, 46% of participants stated that they struggle specifically to find employees with adequate digital skills to operate their current equipment.[6] These shortages have accelerated the push toward more automation.

> We're still missing about a fifth of our workers due to the pandemic.
>
> — *Production Engineer, Large OTC Manufacturer*

> The pandemic has shown us the risks inherent to both the supply chain and managing our operations with a limited workforce.
>
> — *Associate Packaging Engineer, Large Rx Manufacturer*

Robotics Usage Increasing

One automation solution to alleviate production strains at pharmaceutical manufacturers is the deployment of targeted robotics. Currently, 73% of companies interviewed are using robotics now, with 53% stating they expect to increase their usage of robot-based solutions in the coming years. These additions are heavily focused on packaging: 60% of companies interviewed predict expanding the use of robotics in their secondary and tertiary packaging operations.

Adding robotics can not only improve production efficiency at pharmaceutical manufacturers, it can also greatly improve the consistency and quality of the products being produced. It is estimated that 50% of process deviations in production are the direct result of human error, meaning that replacing human interaction with robot-controlled processes could greatly improve product quality.[7] The role of robotics will continue to expand up and down the pharmaceutical production line, especially as more robots are produced with sanitary and washdown capabilities compatible with industry requirements.

> Our level of automation will go up gradually in the next five years with plans to have robotics in use for 80% of our end-of-line packaging operations.
>
> — *Director of Engineering, CMO, OTC*

> Only about 20% of our secondary packaging is using robotics with some use of cobots; we're focusing automation efforts on case packing and palletizing in the years ahead.
>
> — *Production Engineer, Large OTC Manufacturer*

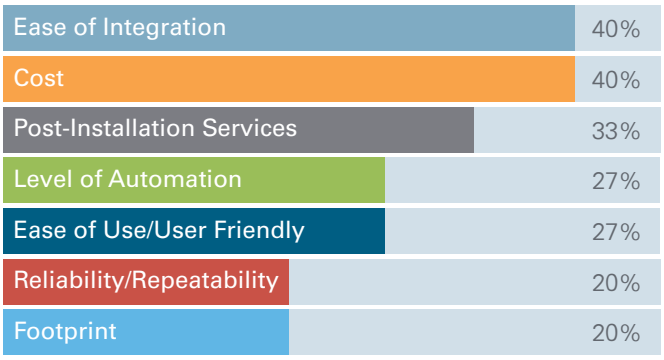
> We are increasing use of robots and cobots in all areas of manufacturing mainly for compliance reasons – filling operations in particular will be more robotic in the future.
>
> — *Sr. Manager, Global Technology, Large Rx and OTC Manufacturer*

> We are continuing to advance our level of packaging automation along the line with the goal to minimize our reliance on labor wherever possible.
>
> — *Sr. Manager, Packaging, Large Rx/Generic Manufacturer*

Artificial Intelligence (AI)

One advanced automation solution being deployed by pharmaceutical manufacturers to maximize throughput is artificial intelligence. While the applications for AI continue to expand in manufacturing in general, its use in the pharmaceutical industry has been particularly important for visual inspection. AI-supported vision inspection allows manufacturers to more quickly and accurately identify defects in either packaging or labeling and immediately remove them. These systems are both faster and more reliable than human visual inspection, speeding up the quality assurance process significantly. This screening process is crucial for pharmaceuticals, as faulty packaging could result in irreversible damage to a drug and insufficient or obscured labeling could lead to grievous patient harm during administration.

Most Important Factors Pharma Companies Consider When Evaluating and Comparing Machines



Exceeds 100% due to multiple answers

One of the top priorities when evaluating new equipment is how easy it will be to integrate into our existing line.

— Associate Packaging Engineer, Large Rx Manufacturer

Turnkey Solutions

The growing complexities of pharmaceutical production and the need for more automation are straining internal resources and expertise at pharmaceutical manufacturers, pushing many to seek outside consultation when implementing new automation projects. Because of the complexity of pharmaceutical operations in general and production lines specifically, manufacturers have been most interested in suppliers that can offer turnkey services, from planning and design to installation and commissioning. Partners that can offer comprehensive turnkey solutions will be best positioned to build lasting relationships with pharmaceutical clients.

Our entire line collects data digitally and we are using AI for vision inspection to ensure the stem is on the inhaler and properly labeled.

— Automation Engineer, Large Rx Manufacturer

We are planning to move to a fully digital platform and use some AI now for vision inspection.

— Sr. Manager, Packaging, Large Rx and Generic Manufacturer

We need OEMs to help us with a good concept model so we can visualize how new equipment will fit and have a positive impact on our production.

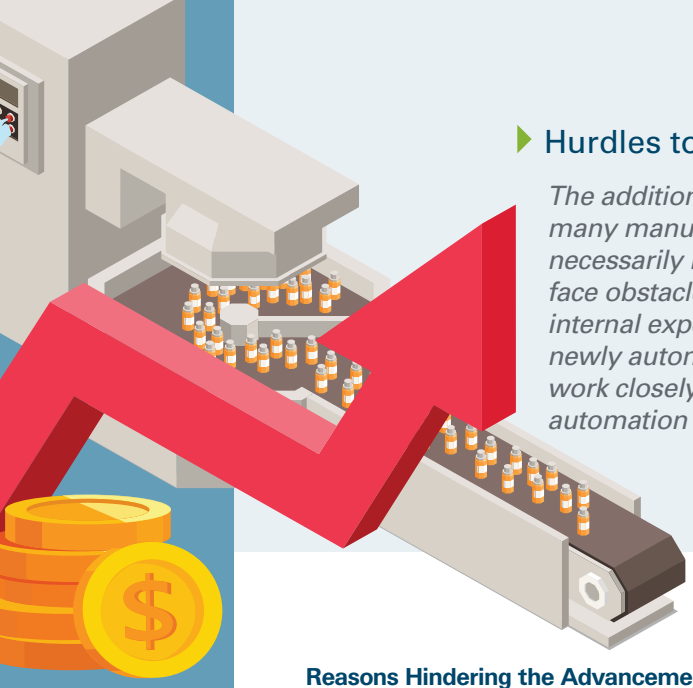
— Project Engineer, Large CM/CP

Automation software can be complex; not every supplier's software is intuitive, so we need good supplier support and service.

— Automation Engineer, Large Rx Manufacturer

We need our suppliers to look at how to bring more uptime to our operations and maintain accuracy in quality and output.

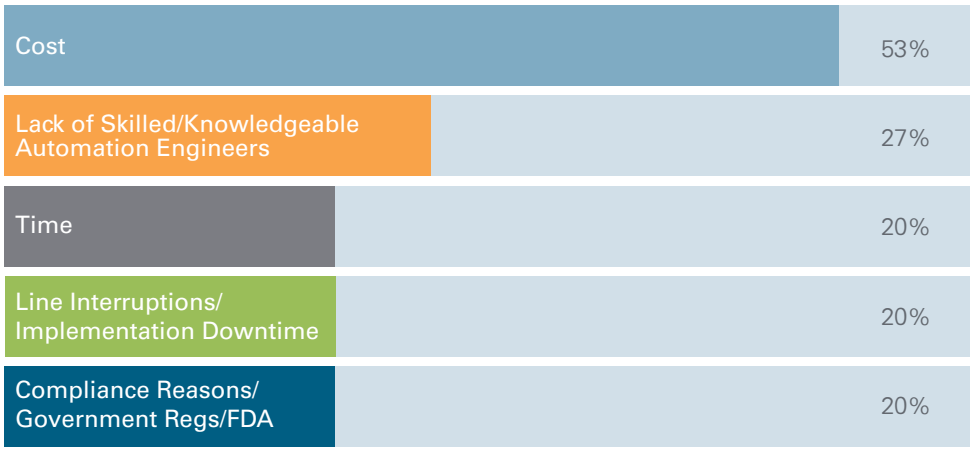
— Associate Director, Packaging Technology, Large Biopharmaceutical Manufacturer



Hurdles to Automation

The addition of automation is not always a smooth, linear process. For many manufacturers, full automation is not a realistic goal, nor does it necessarily make sense for their operations. Pharmaceutical manufacturers face obstacles in expanding automation that include tight budgets, a lack of internal expertise for planning projects, and a shortage of labor to operate newly automated operations. OEMs and suppliers should endeavor to work closely with manufacturers, helping them understand what level of automation is realistically achievable for their operations.

Reasons Hindering the Advancement of Automation



Exceeds 100% due to multiple answers

The cost behind capital investments still keeps us from implementing a greater level of automation, but we are increasing our budget next year.

— Associate Director, Packaging Technology, Large Biopharmaceutical Manufacturer

Staffing shortages in engineering still inhibit us from advancing the use of newer technologies at our facility.

— Packaging Supervisor, Large Pharma Manufacturer

One of the obstacles we still face is finding the right people with the knowledge to run more automated and sophisticated equipment.

— Director of Engineering, CMO, 100% OTC

Adding automation requires revalidating the process to comply with government regulations - it's an obstacle.

— Project Manager, Large Rx and Generic Manufacturer

Digitization: A Data Revolution

While automation is driving physical changes to pharmaceutical production and packaging processes, another significant shift is occurring in the accumulation and use of data. Pharmaceutical manufacturers are turning toward digitized data collection and integrated solutions as a way to meet regulations, improve visibility into their operations, and create a more transparent supply chain.

NEARLY **50%** of pharma manufacturers interviewed

Are collecting at least some data digitally now, with a handful of operations at leading manufacturers gathering 100% of their data digitally.

> We have fifteen lines and only three are integrated; we will continuously upgrade until all lines are integrated and collecting data digitally.
>
> *— Production Engineer, Large OTC Manufacturer*

DSCSA and Digitization

The Drug Supply Chain and Security Act (DSCSA) has been one of the hottest topics in the pharmaceutical industry in recent years, especially as full serialization and aggregation requirements take effect in 2023. This is not news for pharmaceutical manufacturers, who have been aware of the regulations for years now. Many have already addressed DSCSA requirements through integration and digitization, with 60% of companies interviewed stating they are already fully compliant with coming aggregation requirements. This leaves a notable 27% of companies interviewed still requiring changes to meet DSCSA requirements (the remaining 13% do not fall under DSCSA regulation).

For companies already in compliance, the digitization necessary to meet DSCSA aggregation requirements can be viewed as an important stepping off point to further expand the digitization and collection of data across an enterprise, or to store and analyze collected data more efficiently. For companies still needing to come into compliance, the requirements of DSCSA can be seen as an opportunity to achieve two goals at once. These operations can benefit immensely from looking beyond DSCSA to a digitized future, selecting "future-proof" machinery and improvements that will not only address immediate regulations, but also open the door to the proliferation of digitization and integration across operations. In either scenario, suppliers have significant opportunity to assist pharmaceutical manufacturers in proactively planning improvements and purchasing equipment that enables the continued expansion of digitization in the future.

> We will be serialization compliant by next year once we upgrade both hardware and software for case packers.
>
> *— Associate Director, Packaging Technology, Large Biopharmaceutical Manufacturer*

Cybersecurity in Pharmaceuticals

Cybersecurity is one of the largest concerns amongst manufacturers in all industries, with pharmaceutical companies being no exception. In a recent survey, a full 70% of pharmaceutical companies stated that cybersecurity is currently one of their largest operational concerns.[8] This is a particularly thorny issue for pharmaceutical manufacturers, as some must also protect large troves of proprietary patient data, a portion of which may be collected remotely. It is critical that industry stakeholders work together to secure both larger, permanent repositories of data stored by manufacturers, as well as making wireless communication between patients, manufacturers, pharmacies, and care providers more secure.

Visibility Drives Efficiency

The rise of shorter, customized runs in the pharmaceutical industry has strained production capacity at many manufacturers. To keep up with this demand, manufacturers are seeking ways to improve efficiency by increasing the level of visibility into their own operations. This is achieved by expanding the amount of digitized data being collected on machines and finding meaningful ways to analyze and utilize that data to drive operational efficiency. This is easier said than done, however: the expansion of data collection and analysis often requires significant operational changes that are both costly and time consuming. To assist manufacturers on their digitization journey, suppliers can frame the process as a gradual, stepped approach that is more palatable to pharmaceutical companies.

The first steps in this process involve expanding data collection through the addition of smart sensors on machines, which can be gradually integrated to increase the level of data gathered. These improvements can yield tools such as real-time views of OEE, downtimes, and production levels. As integration increases and data expands, suppliers can guide manufacturers in how to interpret and utilize accumulated data. Analyzing this "big data" can have significant benefits for manufacturers, increasing efficiency and decreasing waste in processes across operations.

Blockchain: The Future Is Now

One cutting edge technology expanding access to digitized data is blockchain, a form of distributed ledger technology. A secure, immutable ledger, blockchain technology can enable pharmaceutical manufacturers to address a number of challenges faced in the utilization and security of their proprietary data. For instance, blockchain is an extremely powerful tool for serialization, enabling products to be accurately tracked through production, storage, and distribution to protect against counterfeit, tampering, expiry dates, environmental damage, and recall requirements. Only 27% of companies interviewed are currently using blockchain, all of whom are utilizing distributed ledger technology for product tracking and inventory management applications. The majority of pharmaceutical companies interviewed are either not using blockchain or remain unfamiliar with how blockchain works, signaling future opportunities for both education and deployment of this technology.

> We are using blockchain now for incoming product supply data, but not for any production data at this time.
>
> *— Production Engineer, Large OTC Manufacturer*

Product tracking with blockchain can be taken one step further by allowing stakeholders across the pharmaceutical industry access to production and distribution data, all without compromising data integrity or divulging proprietary processes – in fact, the data itself never leaves the control of the company managing it. An example of the power of this system can be seen in the UK National Health Services (NHS) rollout of the COVID-19 vaccine, in which two hospitals in the UK utilized distributed ledger technology to track the movement of COVID-19 vaccines in the supply chain. Because of the nature of the ledger itself, this enabled the data to be tracked by a wide variety of stakeholders – from hospitals and pharmacies to pop-up vaccination sites – without compromising its integrity, accuracy, or security. Most notably, this data repository tracked not just barcode verification to combat counterfeiting, but also thermal sensors, allowing organizations administering the vaccine to verify their shipments were never compromised by temperature fluctuations. As blockchain usage grows, it is likely that entirely new applications and uses will be found, with the potential to greatly increase cooperation amongst all stakeholders in the pharmaceutical industry.

Sustainability: Opportunities and Hurdles

Sustainability awareness has been steadily growing amongst consumers in general, but a focus on sustainability in pharmaceutical manufacturing processes has picked up significantly in recent years. From alternatives to plastic and tree-based materials to enhanced label messaging, pharmaceutical manufacturers are seeking clearly identifiable ways to communicate their sustainability credentials to consumers. These more sustainable packaging and labeling alterations are particularly challenging for the pharmaceutical industry, forcing manufacturers to strike a balance between regulated packaging efficacy and sustainability goals.

Sustainable Packaging

For consumers, the most obvious gauge of sustainability is packaging. While manufacturers are also seeking to lower overall energy usage through more efficient machines and processes, these improvements are not very visible to the average consumer. In contrast, recyclable, recycled, and plastic-alternative packaging materials are powerful sustainability messages that are highly visible to consumers. One example of this is PLAs, or bio-based plastics, which are combustible (for disposal of surfaces contaminated by drugs), easily temperature controlled, and require 65% less energy to produce.[9] Sustainably sourced packaging aiming to reduce usage of tree-based materials are also gaining in popularity. These "tree-free" alternatives – such as hemp, recycled cotton fiber, and sugarcane board – are effective ways for pharmaceutical manufacturers to communicate their commitment to sustainability.

> We are always looking to be more sustainable by using more recyclable materials and lightweighting.
>
> *— Sr. Manager, Global Technology, Large Rx and OTC Manufacturer*

> We are moving away from using only plastic packaging to other materials.
>
> *— Associate Director, Packaging Technology, Large Biopharmaceutical Manufacturer*

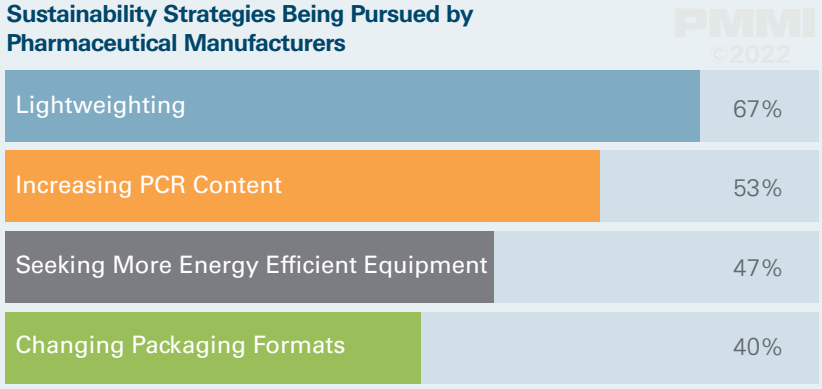
A Sustainable Label

Perhaps the most direct way to communicate sustainability messaging to consumers is by including it right on the label of the product. Prominent messages touting sustainability are clear, unambiguous signals to consumers that a company takes environmental stewardship seriously. Something as simple as a "Recycle Me Again" message included on a label can communicate to consumers that the packaging is both made from recycled materials and is recyclable itself, conveying a succinct sustainability message. This concept can even be applied to physical properties of the label itself: smaller, plastic-free labels are quick visual cues to consumers that a company is seeking to minimize material usage and improve the sustainability of their products.

The vast majority of pharmaceutical manufacturers interviewed have sustainability on their radar and are using more recycled content in their packaging, lightweighting packaging, seeking more energy efficient equipment, and changing packaging formats.

> Overall, we are using more recycled content and lightweighting our packaging to achieve our sustainability goals.
>
> *— Packaging Engineer, SME, Solid and Liquid Product Manufacturer*

Sustainability Strategies Being Pursued by Pharmaceutical Manufacturers



Exceeds 100% due to multiple answers

We've had some machine issues when using thinner grade materials and have returned to the original thickness for better quality.

— *Director of Engineering, CMO, OTC*

When we make dimensional changes to our packaging, it typically requires a new labeler and revalidating the new format.

— *Director of Engineering, CMO, 100% OTC*

Building Customer Loyalty Through Packaging

Packaging and labeling are key to conveying messages of quality to consumers, which is especially true for the often higher-priced products in the pharmaceutical industry. High quality packaging and labeling can also go a long way toward building both brand image and customer loyalty. As one industry professional puts it: "Our packaging is our biggest, most visible billboard."

Decorative packaging and labeling features such as pearlescent coatings, high-gloss finishes, tactile additions, holographic images, color shifting inks, and reticulating or strike-through varnishes can improve product image and enhance customer loyalty. This is especially true for DTC channels, where pharmaceutical manufacturers can tap into the "unboxing" phenomenon.

Hurdles to Sustainable Implementation

Despite sustainability becoming increasingly important to pharmaceutical consumers, the barriers to making packaging changes in the pharmaceutical industry are high. Most importantly, any new packaging format must be validated and certified to meet industry regulations. For instance, any new format must also contain the appropriate closures, seals, and child-proof features required for the particular product. The material must also have sufficient barrier properties to prevent both intrusion from outside environmental factors, as well as internal leeching into or from the product it contains. Material changes can also create additional production challenges, such as second-use materials generating dust during processing, a contaminant that is incompatible with the sanitary environment required for pharmaceutical production. These extra considerations result in the pharmaceutical industry being slower to take up sustainable packaging alternatives, as they must go through more rigorous testing and validation before being implemented.

Growth of Direct-to-Consumer (DTC) and E-commerce

Along with physical changes to products and packaging, the pharmaceutical industry has also been making adjustments to traditional purchasing and distribution channels. E-commerce ordering and DTC shipping for pharmaceuticals has gained significant traction with consumers in the last few years. While more convenient for customers, direct shipping creates additional challenges for pharmaceutical manufacturers as it eschews traditional and established supply chain channels. Rather than manufacturers shipping their products in bulk through a distributor to pharmacies, DTC channels require products be shipped individually. This creates extra considerations for packaging safety as the products are handled more frequently, facilitating additional opportunity for product damage and tampering. In addition to these product integrity concerns, clear, intuitive, and comprehensive labeling in the DTC channel has become more important than ever to ensure that patients administer their medication correctly.

Product Integrity: Damage and Counterfeiting

The expansion of direct shipping channels has placed renewed emphasis on product integrity, both when it comes to damage to the product itself and fraudulent products in the market. Regarding physical damage, packages in the DTC channel are handled much more frequently than products shipped through traditional bulk channels, resulting in overall rougher handling and increased chance of packaging or product damage. Pharmaceutical manufacturers need to keep this more rigorous handling in mind when designing their packaging, as damaged packaging can harm consumer perceptions and a damaged product could impact drug efficacy and sour opinion altogether. Pharmaceutical manufacturers can better prepare for future channel diversification by designing packaging that is suitable for both bulk shipping and DTC deliveries, negating the need for multiple packaging format options for the same product.

> Anticounterfeiting tactics are integrated into the labeling and cartoning of each product.
>
> — *Associate Director, Packaging Technology, Large Biopharmaceutical Manufacturer*

> To combat counterfeiting, we use a hologram on the label for some of the higher priced products.
>
> — *Packaging Supervisor, Large Pharma Manufacturer*

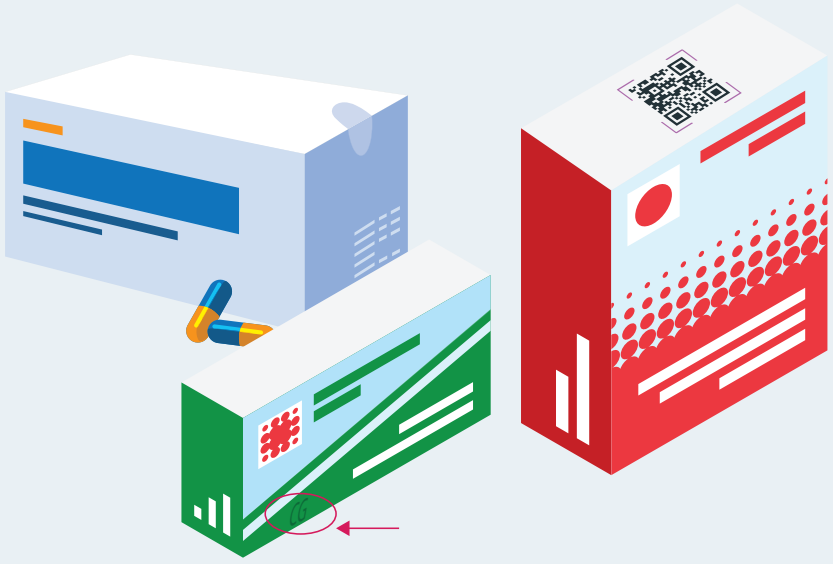
Product diversion, product tampering, and counterfeiting are also much larger concerns in direct shipping channels. Since the products are shipped outside of traditional, secure distribution channels and are handled more frequently, the opportunity for product tampering is greatly increased. To combat this, pharmaceutical manufacturers must stay ahead of counterfeit and tampering techniques by employing an ever-expanding array of safety and verification features. These features vary widely in complexity and application type, but they can be divided into two main categories: overt and covert.

Overt verification and safety features are visually identifiable and communicate clear messages to consumers about the integrity of the product. These features, like tamper-evident tape and holographic images, are the first line of product integrity defense. Conversely, covert safety and verification features are designed to only be identifiable when exposed to a certain environment or when read with a specific device. Covert features, such as digital watermarks and infrared reactive inks, are more difficult and expensive to accurately replicate. Pharmaceutical manufacturers often employ a combination of both overt and covert features to assure customers that their products are authentic and untampered with.

Examples of Overt and Covert Security Features

Overt: *QR codes, high-quality pearlescent inks, tamper-evident closures and labels, color shifting inks, and holographic images.*

Covert: *Hidden indicia, digital watermarking, taggants (either molecular or optical), thermochromic inks, infrared or UV activated inks, and "invisible" barcodes.*



APPROXIMATELY

40%

of all prescriptions are not taken as directed

Labeling for DTC

In traditional pharmaceutical distribution through a pharmacy, customers must interact with a pharmacist when acquiring their medications. During this interaction, pharmacists have the opportunity to ask customers if they are familiar with the medicine, if they know how dosing works, if they understand the steps of how to take the medicine, and if they are able to administer it themselves. If there is uncertainty, the pharmacist can provide guidance and knowledge directly to the patient. When shipping DTC however, this interaction is eliminated.

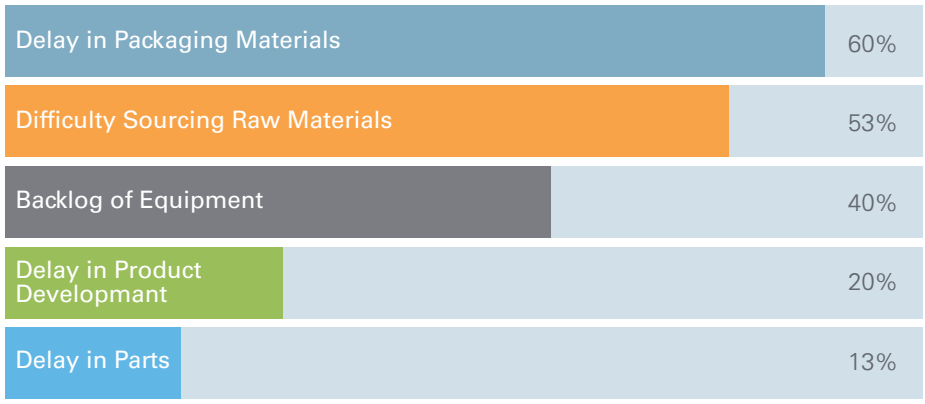
As a result, labeling for DTC pharmaceuticals has been given renewed emphasis, as the label may be the only means a patient has to understand how to use their medication. Medication compliance is already a pervasive problem: approximately 40% of all prescriptions are not taken as directed.[10] Packaging plays a key role in medication compliance, with 33% of medical errors resulting from packaging and labeling issues – and 30% of those errors being fatal.[11] With injectables growing rapidly, administering medications is becoming more complicated, making compliance even more difficult. Pharmaceutical manufacturers must ensure that their products are packaged with extensive label information for usage instructions, allergy and interaction information, dosage guidance, emergency care contact information, expiry dates, and disposal guidelines. Features such as extended instruction booklets, leaflet inserts, and even visualized administration steps can all be used by pharmaceutical manufacturers to ensure the safe and accurate use of medication in the DTC channel.

COVID-19 and the Supply Chain

The COVID-19 pandemic has dramatically upended global supply chains, straining manufacturers in all industries. For the pharmaceutical industry, the supply chain issues caused by COVID-19 have posed problems in sourcing the raw materials needed for both producing pharmaceuticals and packaging them. On top of these material shortages, the supply chain slowdown has also impacted equipment orders, delaying scheduled deliveries and extending lead times. These challenges are ongoing and have caused pharmaceutical manufacturers and the industry as a whole to reexamine fundamental aspects of their supply chain logistics.

> Like all businesses, we are experiencing raw material shortages and delays in materials and parts, which is causing a backlog for some equipment.
>
> *— Production Engineer, Large OTC Manufacturer*

Supply Chain Issues Caused by the Pandemic

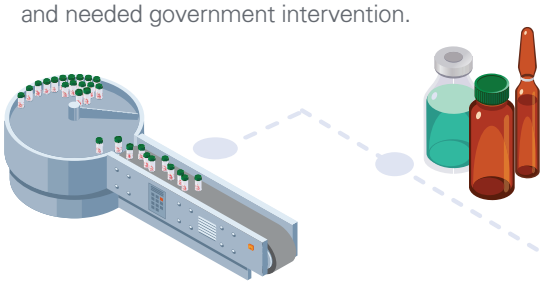


Exceeds 100% due to multiple answers

Disruption to Active Pharmaceutical Ingredients (APIs)

One of the greatest weaknesses exposed in the pharmaceutical supply chain during the COVID-19 pandemic is the U.S. and Europe's heavy reliance on foreign sources for the APIs needed to produce their products. On average, 72% of APIs utilized in the U.S. come from foreign sources,[12] while up to 80% of those used in Europe originate from outside of the EU bloc.[13] By location, the U.S. has less than 5% of the large-scale API production sites in the world.[14] This reliance on foreign sources created sudden and acute shortages when global supply chains faltered during the pandemic, straining manufacturers to find the ingredients needed to simply continue producing their products.

These shortages have persisted, with 53% of companies interviewed stating that they still have problems with consistently sourcing needed ingredients for production. To alleviate this burden in the future, many in the pharmaceutical industry have called for the diversification of the API supply chain, recommending that manufacturers source not only from multiple vendors, but also multiple regions of the world. While the ideal solution would be to reshore API production with new facilities, this is unlikely to be practical for a host of reasons including cost, environmental concern, and needed government intervention.



Disruption to Raw Materials for Packaging

Along with APIs, pharmaceutical manufacturers are also challenged with packaging material shortages as a result of the COVID-19 pandemic. The disruption of supply chains and the upending of day-to-day production has made consistently sourcing the base materials needed for packaging an ongoing struggle. Essential materials for pharmaceutical packaging - such as paperboard, plastic resins, and foils - have experienced prolonged supply chain shortages that have impacted pharmaceutical manufacturers' ability to produce the desired packaging. With the advent of COVID-19 vaccine mass production, there has also been an acute shortage of glass vials as the sudden uptick in vaccine manufacturing continues to cut deeply into current glass vial production capacities. Challenges sourcing packaging materials were experienced at a majority of companies interviewed, with 60% saying they continue to struggle with sourcing the basic raw materials needed for packaging production.

> We are having to find alternative suppliers as we experience delays in packaging components and materials.
>
> — *Sr. Manager, Global Technology, Large Rx and OTC Manufacturer*

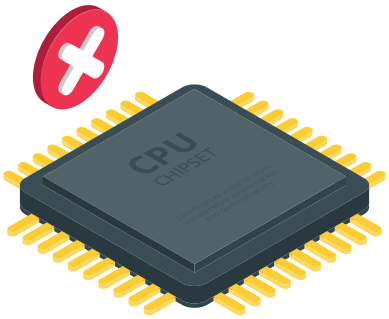
> We were able to find alternate sources for our materials so our operations were not as affected as some, but raw material deliveries from overseas are still a problem.
>
> — *Project Manager, Large Rx and Generic Manufacturer*

> We're experiencing delays in paper and corrugated products.
>
> — *Associate Director, Packaging Technology, Large Biopharmaceutical Manufacturer*

> We've been experiencing delays in bottle deliveries and some difficulty in sourcing raw materials.
>
> — *Validation Engineer, CM, Rx and Generic Products*

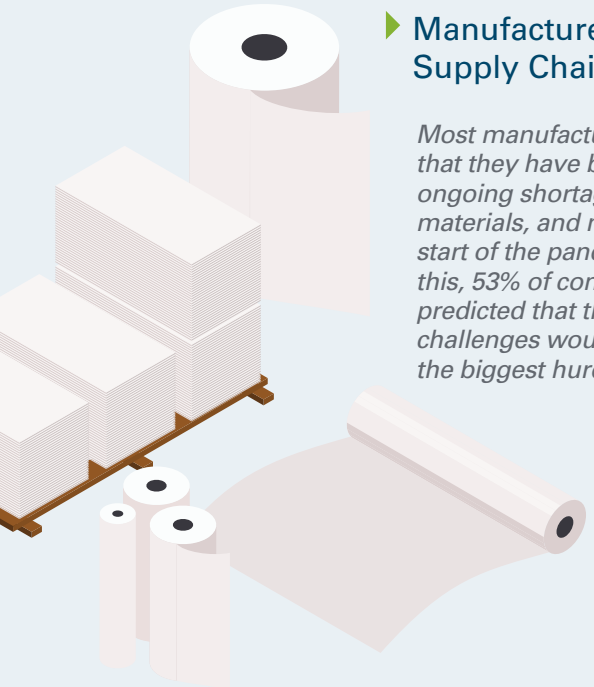
Disruption to Equipment Deliveries

Supply chain disruptions resulting from COVID-19 have also stretched to machine suppliers, creating challenges for pharmaceutical manufacturers in sourcing machines and equipment. The combination of faltering supply chains and acute labor shortages caused by COVID-19 have resulted in existing orders being delayed and delivery dates pushed back, while lead times for new orders have extended months beyond previous estimations before the pandemic. In all, 40% of companies interviewed stated that they were being directly affected by delays in delivery and extended lead times on equipment they wished to acquire. In addition to these machine struggles, a small number of companies (13%) also reported ongoing difficulties in sourcing replacement parts in a timely manner. These challenges are even further compounded when dealing with international supply chains: equipment and parts originating from a different country – and especially a different continent – are more likely to be bogged down by slumping supply chains.



> Any equipment or component that requires a chip has been experiencing delays.
>
> *— Automation Engineer, Large Rx Manufacturer*

> The pandemic has caused problems with sourcing raw materials and packaging materials; we've had delays in equipment deliveries due to parts and offshore suppliers.
>
> *— Project Engineer, Large CM/CP*

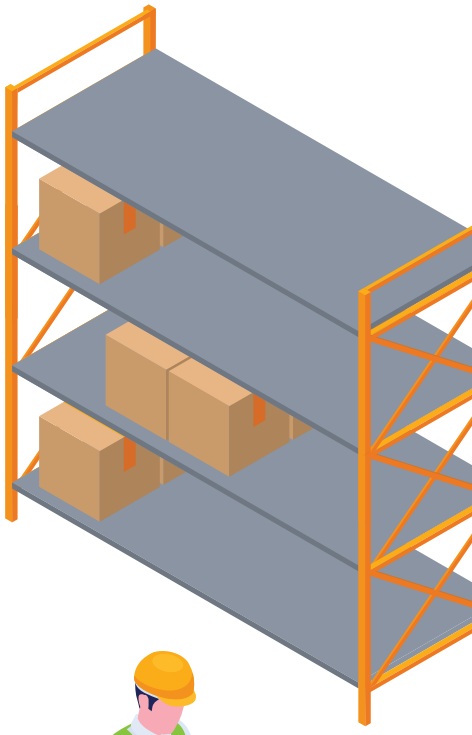


Manufacturers See Prolonged Supply Chain Hurdles

Most manufacturers interviewed noted that they have been experiencing ongoing shortages of ingredients, materials, and machinery since the start of the pandemic. In addition to this, 53% of companies interviewed predicted that these supply chain challenges would continue to be one of the biggest hurdles in the coming year.

> Shortages in the supply chain are the greatest near-term challenges we face.
>
> *— Engineering Manager, Large Rx Injectable Manufacturer*

> Due to the supply chain issues stemming from the pandemic, we continue to have difficulty in sourcing and delivery of raw materials and are experiencing a backlog for equipment orders.
>
> *— Sr. Manager, Packaging, Large Rx and Generic Manufacturer*

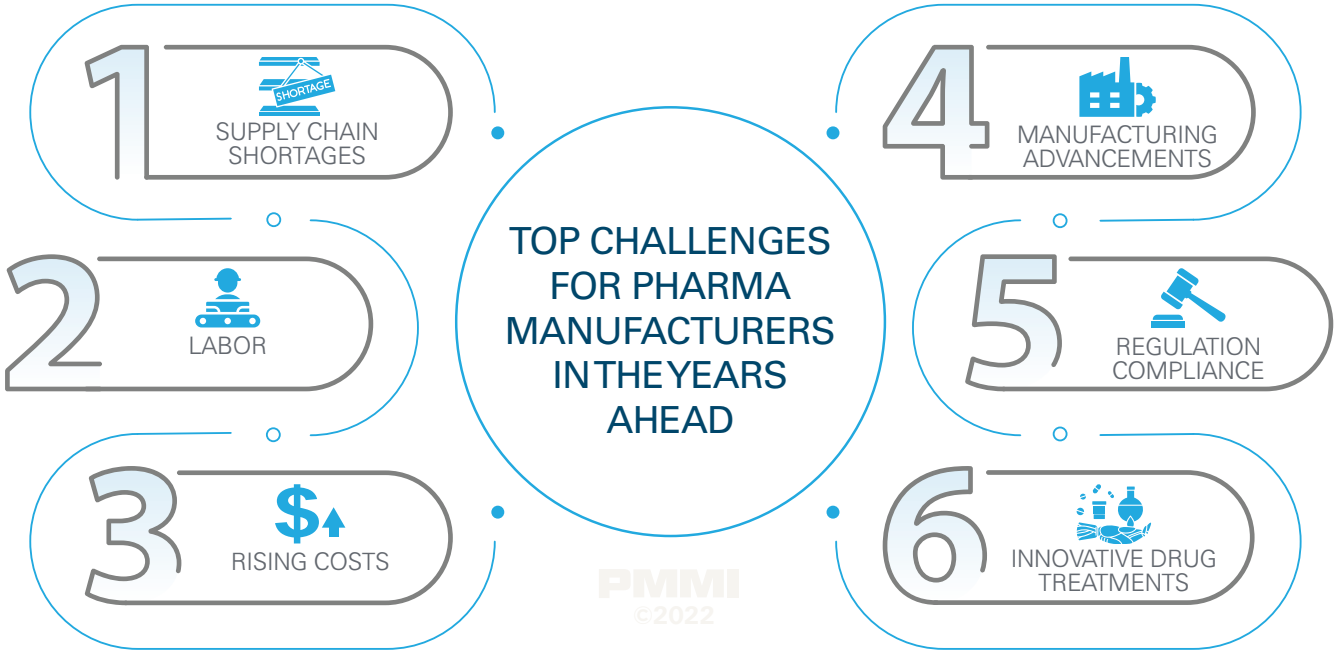


Short-Term and Long-Term Impact of Supply Chain Difficulties

In the short term, the challenges from sourcing APIs, packaging materials, and machinery have resulted in pharmaceutical manufacturers reevaluating their business strategies. Without the proper resources, some pharmaceutical manufacturers have had to place plans for new projects on hold. New products, packaging format changes, packaging material changes, new equipment integration, and even plans for entire new lines have been disrupted as pharmaceutical manufacturers find themselves unable to obtain the resources necessary to support these alterations and launches. A handful of companies interviewed highlighted this as a key short-term hurdle created by supply chain shortages, with 20% stating they have had to delay launches and improvements as a direct result of shortages and slowdowns.

In the long term, the almost universal pain felt throughout the pharmaceutical industry as a result of supply chain breakdowns has the potential to spur greater cooperation. The supply chain problems have pinched all sectors of the industry, creating struggles that have been impossible to ignore for stakeholders. To prevent such deep future disruption, stakeholders in the pharmaceutical industry appear to be more open than ever to collaborating and cooperating with one another to find solutions and ease the burden for all. With this atmosphere of mutually beneficial collaboration hanging heavy over the industry right now, OEMs and machine suppliers should have ample opportunity to deepen existing customer relationships and forge meaningful new ones in the near future.

> Suppliers and OEMs need to continue to listen to the customer and work together to bring equipment functionality that meets our specific needs in this industry.
>
> *— Production Engineer, Large Drug Manufacturer*



Our overall goal is to be more flexible and nimbler in our manufacturing to implement sustainable practices in the year ahead.

— *Associate Packaging Engineer, Large Rx Manufacturer*

Our greatest challenge in the near-term is upgrading the older equipment on the line.

— *Automation Engineer, Large Rx Manufacturer*

The challenge ahead is the internal organization changes that are needed to comply with changing regulations.

— *Packaging Engineering Manager, SME Rx Manufacturer*

We make sure our machine builders are a good fit for every project and look most at aftermarket services and performance reliability.

— *Director of Engineering, CMO, 100% OTC*

To be able to bring innovative treatments to a global market, we need changes in the approval process and dedicated cooperation amongst our partners.

— *Production Engineer, Large OTC Manufacturer*

It's a challenge to maintain output levels with the ongoing supply and logistics problems and we look to our OEMs to offer solutions to help advance our production.

— *Sr. Manager, Global Technology, Large Rx and OTC Manufacturer*

Actionable Direction

In the coming years, pharmaceutical manufacturers will be challenged to keep pace with the changing nature of product formats and production preferences. The shift toward higher-value injectables and customized runs is driving the expanded use of contractors, while also pushing manufacturers toward more automated solutions. Impending DSCSA requirements still loom large in the industry, accelerating the pace of digitization at pharmaceutical manufacturers as compliance deadlines near. Manufacturers must also adjust to consumer preferences for sustainable practices, as well as the steady growth of DTC e-commerce channels. In the midst of these changes, the industry has also been drastically upended by COVID-19 supply chain challenges, creating shortages in all areas of the industry and even stalling planned improvements and launches at manufacturers.

Pharmaceutical Manufacturers Look to OEMs and Suppliers:

1. Aftermarket Service/Support
2. Integration for New Machines
3. Equipment Accuracy/Reliability
4. Easy Changeover
5. Machine Flexibility
6. Support for IQ and OQ*
7. Concept Models to Visualize equipment
8. Quick Parts Delivery

**IQ=Installation Qualification; OQ=Operational Qualification*

The COVID-19 pandemic has caused many pharmaceutical industry stakeholders to reevaluate some of their core principals regarding cooperation and collaboration as they seek common solutions to alleviating industry-wide pain points. More than ever, pharmaceutical manufacturers are open to creating deep, lasting business relationships with knowledgeable and competent partners. In this renewed atmosphere of cooperation, OEMs and suppliers should be looking to position themselves as knowledgeable experts able to guide customers though a chaotic industry transition into the emerging era of new regulations, new formats, changing manufacturing practices, and fundamental supply chain restructuring. Those partners able to offer comprehensive, turnkey solutions to ongoing challenges at pharmaceutical manufacturers by taking a holistic approach to understanding their operational needs will be well positioned to grow their standing in the industry.

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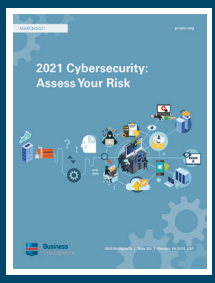

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