ThermoFisher SCIENTIFIC

SMOOTH TRANSITION

WHAT SPECIALTY DRUG MANUFACTURERS SHOULD KNOW ABOUT BRIDGING THE GAP FROM CLINICAL-TO-COMMERCIAL PACKAGING

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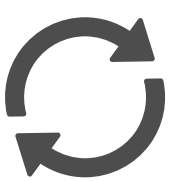
Introduction

As a steady stream of specialty drugs enter the marketplace, pharmaceutical companies are seeking new supply chain solutions to ensure that an uninterrupted supply of these breakthrough treatments reach patients.

One solution for the challenges of packaging specialty products is low- or small-volume commercial packaging. Developed by packaging and supply chain experts, this expansion of commercial packaging services enables pharma companies to seamlessly bridge the gap between clinical and commercial packaging of specialty drugs.

This e-book examines the impact of specialty products and the packaging challenges associated with them. It also addresses the benefits of small-volume commercial packaging and offers recommendations about choosing a supply chain partner for this service.

The pharmaceutical industry's embrace of specialty medicines in lieu of traditional so-called blockbuster drugs has been a seismic shift, transforming the healthcare arena while generating new successes and challenges for drug makers. As a steady stream of specialty products enters the market, pharma companies are seeking new supply chain solutions to ensure that an uninterrupted supply of these breakthrough treatments reach patients.



As a steady stream of specialty products enters the market, pharma companies need new supply chain solutions to ensure that patients receive an uninterrupted supply of these breakthrough products.

Introduction (continued)

In the early 1990s, fewer than 30 specialty medications were approved by the U.S. Food and Drug Administration (FDA).[1] Today, that number exceeds 400.[2] In 2019 alone, 31 – or 64 percent – of the 48 drugs approved by the FDA were classified as specialty products.[3] By the end of 2020, specialty products are projected to account for nine out of 10 best-selling drugs.[4]

Patients and their families have been the greatest beneficiaries of pharma's specialty products success story. Specialty medications offer treatment options to many small populations of patients living with a myriad of chronic, complex, underserved or rare diseases.

Even as patients benefit from these treatments, the disruptive nature of specialty drugs has triggered a top-to-bottom transformation of healthcare, impacting drug makers, payers and providers. Specialty therapies have revolutionized drug development by redefining targets and ushering in a multitude of new players, including biotechnology firms and other small start-ups. Meanwhile, payers and providers are addressing a wave of complex, high-cost treatment options.

The explosive growth of specialty products has also affected the supply chain. During the decades when blockbusters dominated the pharma industry, supply chains were designed for maximum efficiency in packaging high-volume commercial drugs. In addition to their low-volume nature, however, most specialty drugs demand special handling. The growth of specialty products has made it clear that new supply chain solutions offering flexibility, customization and attention to detail are needed.

One solution for the challenges of packaging specialty products is known as low- or small-volume commercial packaging. Developed by packaging and supply chain experts, this expansion of commercial packaging services enables pharma companies to bridge the gap between clinical and commercial packaging of specialty drugs.

While the types of drugs entering the marketplace today have changed dramatically, the goal of drug makers and their supply chain partners remains the same – ensuring that patients everywhere receive the medicines they need when they need them.

This eBook examines the impact of specialty products and the packaging challenges associated with them. It also addresses the benefits of small-volume commercial packaging and offers recommendations about choosing a supply chain partner for this service.

Specialty products drive change

Specialty products – low-volume, niche and orphan medications for complex chronic conditions – have been a resounding success story for the pharmaceutical industry.[2, 3, 4, 5]

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It is a success story that has been three decades in the making. Since the 1990s, the number of specialty drugs on the market has increased more than 1,200 percent.[2] And while specialty medications have supplanted traditional blockbuster drugs, many specialty drugs are today's blockbusters, posting annual sales of more than $1 billion.[7]

By the end of 2019, specialty medicines accounted for half of total spending on prescription medications in the United States.[5]

These high-cost, breakthrough products represent advances in healthcare and new treatment options for patients. Specialty products span about 40 therapeutic categories and include treatments for cancer, rheumatoid arthritis, HIV, psoriasis, inflammatory bowel disease and hepatitis C.[8] Patients with rare diseases such as cystic fibrosis and Duchenne muscular dystrophy have also benefitted from the introduction of specialty medications. In 2019, for example, cancer and rare diseases dominated the list of specialty drugs that were approved by the FDA.[9]

While specialty medications are designed to treat complex diseases, these medications are themselves highly complex. Many specialty drugs are biologics – drugs that are derived from living cells – and structurally mimic compounds found within the body.

While some specialty drugs are delivered orally, many are given by injection, infusion or inhalation. They often require extra monitoring, patient training or compliance assistance, as well as specialized handling and distribution to ensure appropriate administration. In addition to being produced in small quantities, many of these products are available only from a limited network of specialty pharmacies.[7, 8, 9]

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Addressing packaging challenges

Low-volume specialty drugs face a variety of commercial packaging challenges that have the potential to disrupt timeliness and market availability. As the number and importance of these products grow, pharma companies are turning to their supply chain partners for new packaging solutions.

The challenges for manufacturers of low-volume drugs originated decades ago, when blockbusters were dominating the industry. In the blockbuster drug era, supply chains packaged and distributed hundreds of thousands of doses of a handful of top-selling drugs each year. These industry-leading products were understandably given schedule priority over their low-volume counterparts.[10]

At the time, niche and orphan drugs were few in number.[1] Those that were available had to compete against high-volume drugs for access to finite packaging capacity. As a result, packaging for niche-market products was frequently sandwiched into time slots that became available between larger production runs.

This made it challenging for specialty drug producers to arrange for timely and predictable commercial packaging for their products. Now, the importance of specialty drugs to pharma companies and patients has made it impossible for these products to remain low-priority.[10]

Market shortages of specialty drugs can have serious, even catastrophic effects. Low-volume batches of drugs often include little to no excess inventory to compensate for possible shortages. Alternative treatments for rare or orphan diseases, as well as many rare forms of cancers, may be non-existent. Packaging delays or the inability to receive specialty treatments on time can have serious, potentially fatal consequences for patients.[10, 11, 12]

A strategic option

In an effort to reduce packaging concerns, many manufacturers of low-volume products are opting to work with the same experienced supply chain team for both the clinical and commercial packaging of drugs.

This strategy offers manufacturers a great many advantages. For one thing, clinical supply chain partners have expertise in handling small-volumes of drugs, as well as the necessary flexibility and insight with respect to packaging, process design and scheduling. In addition, a clinical supply packager can reserve production capacity, package kitted products and monitor component inventories in order to optimize the availability of drug at both clinical and commercial stages.

Administrative and personnel benefits also accrue from using the same supply chain team pre- and post-commercialization. The experience of transitioning from clinical packaging to commercial packaging with the same partner minimizes the number of suppliers a drug maker must manage, thus freeing employees to address other work. It also offers manufacturers the opportunity to expand existing collaborative relationships instead of starting from square one by establishing new ones.[12]

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Expanded packaging solution for specialty drugs

These considerations led to the expansion of existing commercial packaging to include a service offering known as low- or small-volume commercial packaging. This specialized service was created to meet the unique packaging needs of specialty drug makers marketing low-volume, niche and orphan products.

For example, packaging for large- or high-volume products tends to be a highly automated process. Packaging for small- or low-volume products is highly complex in nature, however, requiring dedicated and sophisticated automation that can be both difficult to source and cost-prohibitive.

This has led packagers to turn instead to manual or semi-automated processes, with the ability to alternate between both methods as necessary for maximum flexibility. In this way, low- or small-volume commercial packaging emphasizes adaptability and customization, making this white-glove service well-suited to handle complex and bespoke jobs.

Finally, a low- or small-volume commercial packaging service provides a natural transition between the packaging of specialty drugs for clinical trials and for the commercial market.

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Recommendations for choosing a packaging partner for specialty products

As with every service, the capabilities and quality of low- or small-volume commercial packaging services differ by provider. Choosing the right partner requires a careful needs assessment and consideration of the potential provider's qualifications.

Here are some recommendations from packaging, engineering and supply chain professionals about how to choose a partner for low- or small-volume commercial packaging.

1

Begin as early as possible. A minimum of six months is recommended, although it's best to begin a year or more in advance, if possible. This provides ample time to consider the universe of packaging options, for example, and to address any and all outstanding issues prior to commercialization.

2

Choose a specialized service offering. Look for a partner with a specialized low- or small-volume commercial packaging service offering and a dedicated team to manage small-scale packaging projects. This demonstrates that a packager has made a commitment to the packaging of specialty drugs and has put in place the resources – facilities and expertise – necessary to deliver.

3

Consider the quality of the team. Assess the size, composition, experience and skills of the individuals who comprise the team conducting small-volume packaging operations on a day-to-day basis. This indicates that the potential partner has the breadth of capabilities in-house to tackle any issues that arise, making it unnecessary to deploy outside help when time is tight.

4

Determine if there's room to grow. Be certain that a potential partner not only has the resources necessary to conduct small-scale packaging today, but the ability to ramp up production to handle larger volumes should a future need arise. This provides assurance that the product can remain with the same packager should demand increase as a result of additional indications, for example.

5

Opt for global resources. Ensure that the potential partner has global resources and redundancies in place should something unforeseen disrupt the supply chain. Examples include supplier failures, weather conditions, natural disasters and a host of other possibilities. Think COVID-19, for example.

6

Request help with problem-solving. Drug makers preparing to commercialize a specialty drug typically begin planning well in advance, adopting some solutions and eliminating others. Before taking any potential solutions off the table, ask a potential partner to weigh in with advice and assistance. Not only could this surface new options to consider, but it can be a useful means of assessing a team's problem-solving skills.

7

Ask for success stories. In talking with the potential partner, request some examples of solutions they've generated for past packaging challenges – anonymized, of course. More than anything else, success stories can reveal a great deal about the team's ability to develop innovative solutions designed to meet to the needs of a particular specialty product.

8

Above all, aim for a smooth clinical-to-commercial transition. One of the best ways to accomplish this is by working with the same supply chain team to handle both clinical and commercial packaging. This enables you to benefit from the experience and insights the team gathered during the clinical development phase and use this knowledge to expedite commercialization. Another advantage is the chance to build on an existing relationship with a trusted partner whose contributions during clinical development helped put the product on the path to commercialization.

Bridging the gap: Thermo Fisher Scientific expands small-volume commercial packaging

For more than 30 years, Thermo Fisher Scientific has been providing the pharma industry with packaging solutions, the latest of which is an expanded packaging service exclusively designed for small-volume specialty drugs.

Known as Small-Volume Commercial Packaging, this expansion of the existing commercial packaging service leverages Thermo Fisher's expertise in clinical and large-scale commercial packaging to provide an end-to-end packaging solution for companies marketing niche products. Small-Volume Commercial Packaging enables these specialty drug makers to seamlessly bridge the gap from clinical to commercial packaging.

Clients also benefit from the buying and relationship experience of Thermo Fisher and Patheon, our contract development and manufacturing organization. Thermo Fisher and Patheon together form a network of packaging and supply chain expertise, operating dedicated clinical and commercial packaging facilities across the globe.

Small-Volume Commercial Packaging was expanded in response to requests from clinical packaging clients "for our assistance in taking them to the next step, in helping them bring their small products to the commercial market," one Thermo Fisher manager related.

Expanded with these clients and their products in mind, Small-Volume Commercial Packaging is designed for packaging projects that range in size from tens of thousands of drug doses to as many as five million doses per year.

The service is located at the Thermo Fisher facilities in Allentown, Pennsylvania, USA and Horsham, United Kingdom. Both facilities are equipped with the manual and semi-automated packaging capabilities best suited for specialty drugs. The two facilities are bringing their expertise in clinical packaging of small-volume products to bear on small-volume commercial packaging, supported by Thermo Fisher's entire global network.

Identifying solutions

In addition to dedicated equipment, Small-Volume Commercial Packaging boasts a dedicated team of packaging professionals with an established reputation for attention to detail and intense commitment to consistent global quality processes. Team members include a global network of engineers who apply their expertise in packaging, label design and serialization to help clients identify innovative solutions to packaging dilemmas.

Recently, for example, a client was planning to use a packing carton that had been designed by its marketing group. However, the Thermo Fisher team recognized that the carton would be difficult to process on a small scale and unnecessarily expensive to ship.

During the course of the client's meeting at the Horsham facility, the team completely redesigned the carton and presented it to the client. Delighted, the client adopted the redesign.

In another case, a client wanted to take a product from vial to auto injector, but was convinced by a device maker that no contract manufacturing organization (CMO) would be interested in such low-volume business. Nonetheless, the client contacted Thermo Fisher and met with the Small-Volume Commercial Packaging team. In talking with the client about needs, the team discovered that the option to switch to an auto injector had been eliminated, even though it was the client's desired solution.

Thanks to the team's efforts, the auto injector option went back on the table and the client was able to make the desired change – a change the Small-Volume Commercial Packaging team knew would make the lives of the patients who use the treatment that much easier.

Patheon pharma services has dedicated clinical and commercial packaging facilities across the globe.

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