West

How You Can

Cut Through Complexity, Gain Speed and Get Your Drug to the Patient as Soon as Possible

Key Trends in the Biologic Market

Creating a drug and getting it approved is no small feat, particularly amid key trends that are reshaping the market—and if you're an emerging company, you know you have unique challenges compared to larger biopharmaceutical companies.

Emerging companies are driving pipeline growth

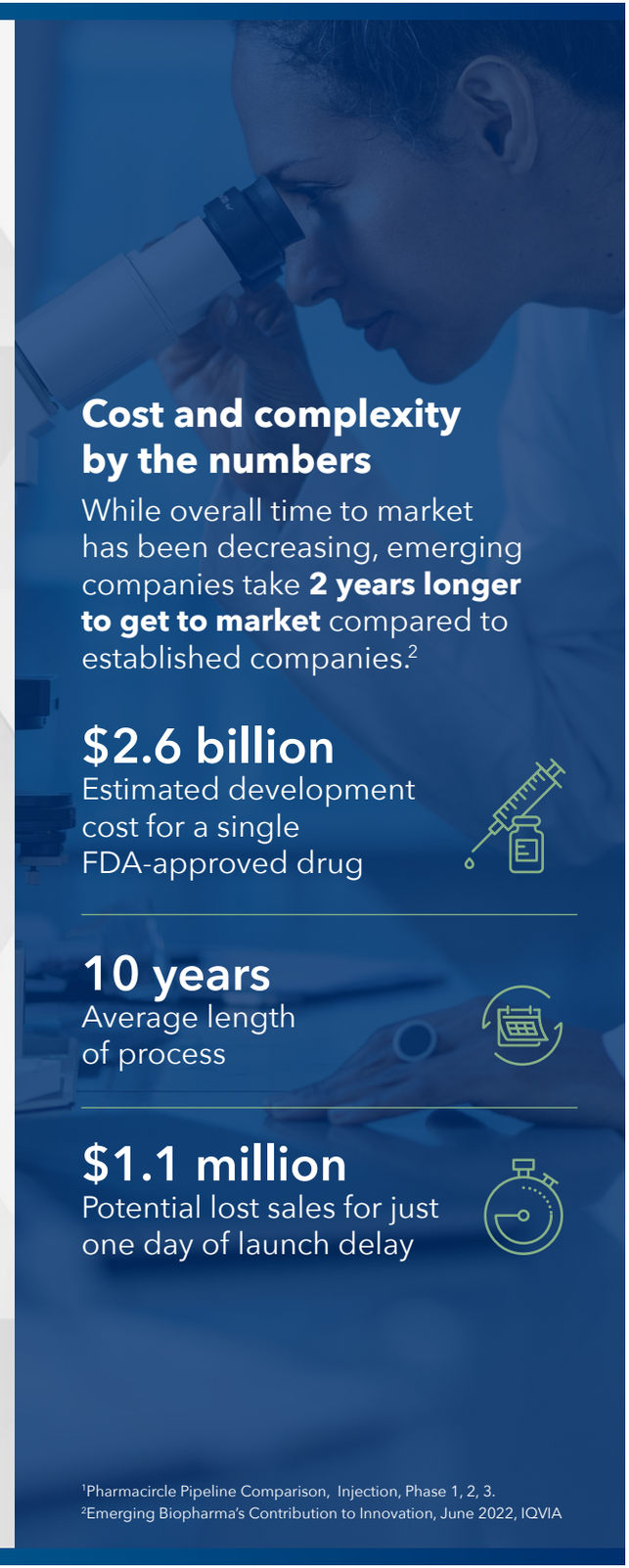
More companies mean more competition, and emerging companies are responsible for 80% of the pipeline—a share that has increased steadily over the past 6 years.[1] While the pipeline is crowded with promising prospects, these companies are largely focused on the same key therapy areas, which drives even more competition.

Venture firms are rolling out less funding

More companies entering the market also means access to funding has become increasingly challenging as investors are more selective. With key milestones tied to payments, you need to show progress to continue with your programs.

The regulatory landscape is changing fast

Speed is the new watchword. Timelines are accelerating, and faster drug approval processes are expanding the market. Another key factor: expedited reviews are making it easier and faster to get to market.



Cost and complexity by the numbers

While overall time to market has been decreasing, emerging companies take **2 years longer to get to market** compared to established companies.[2]

$2.6 billion
Estimated development cost for a single FDA-approved drug

10 years
Average length of process

$1.1 million
Potential lost sales for just one day of launch delay

[1]Pharmacircle Pipeline Comparison, Injection, Phase 1, 2, 3.
[2]Emerging Biopharma's Contribution to Innovation, June 2022, IQVIA

Most Development Responses Focus on the Drug Itself . . .

These key trends are creating a favorable market for the growth and expansion of biologic treatments, so it makes sense that many companies would seek an advantage by responding to these trends by focusing on their molecule.

. . . But it's Time to Take a More Holistic Approach

However, zeroing in on treatments can give you a fragmented picture of the overall landscape.

In this ebook, you'll learn how to address the unique challenges that face your emerging company. In order to meet your next milestone and get to market faster than the competition, you need to carefully consider every phase of development and adopt an approach that helps you do three important things:

1.

Accelerate your path to market

2.

Minimize regulatory risk

3.

Free up your limited resources

What's in Your Way:

Complexity and Competition

Getting your drug approved is an incredibly complex task.

In early development phases, you're seeing the pressures of funding and regulatory deadlines. And beyond that, you face a seemingly endless set of deliverable timelines and project milestones. These problems will only get worse as more players enter the market and as FDA approvals increase.

But speed is critical—you can't afford missteps that force you to stall out while you fix errors, retest, or select new packaging. Getting bogged down by mistakes like these will mean your competitors will get their drug to the patient more quickly, and you'll lose market share.

But What if You Accelerate Your Path to Market?

When you work with West, you'll avoid critical mistakes so you can get to market faster than your rivals and improve patient lives--all while mitigating potential risk.

You'll be able to:

- Minimize the costs connected to component selection or packaging quality
- Hit your critical milestones to maintain funding
- Mitigate downstream delays associated with selecting a packaging system that is incompatible with your drug or incompatible systems

Save Time and Protect Your Drug

With West, you'll use a selection of high-quality components and packaging that's designed to meet regulatory expectations. and built on three important pillars:

Containment
West packaging demonstrates CCI, giving you peace of mind that components work together, reducing the time needed to assess components that are not compatible as a system.

Protection
Your packaging will help you minimize migrations between the containment system and the drug product by better protecting your drug from extractables and leachables.

Lower Risk
By selecting components that can mitigate particulate risk you'll be able to bypass particulate-related rework and costs, allowing your team to maintain their focus on advancing your molecule rather than stopping to investigate particulate issues.

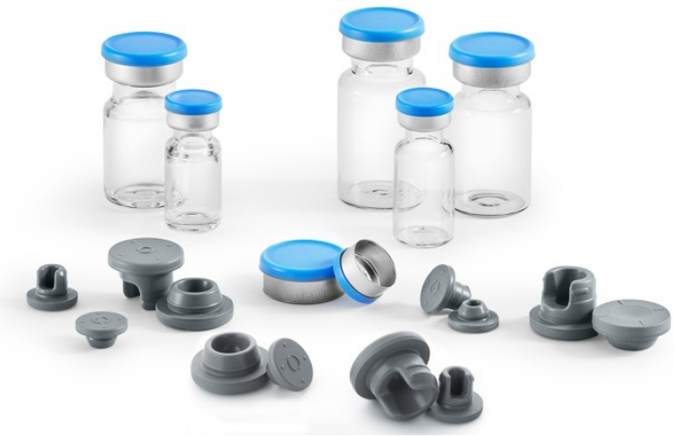
Ready-to-Use Sterile Packaging Solution

The West Ready Pack™ Containment Solution offers superior quality components to protect, store, and deliver your drug product.

Multiple options are available for stoppers, seals, and vials to provide you with components best suited for your molecule. Components are available in small quantities, providing you with the flexibility to buy the full solution or only the components that you need, reducing waste associated with commercial volumes.

With the Ready Pack containment solution, you can speed up your time to market and reduce your risk associated with selecting individual components that may not work well together.

West READY PACK™
Ready-to-Use Sterile Packaging Solution



What's in Your Way:

Heightened Scrutiny on Packaging and Delivery

Quality, safety, and efficacy–these have always been a concern when it comes to navigating regulations.

But regulators are now shining a brighter light on the drug container, not just its contents. And for emerging companies who may not have expertise in primary packaging, navigating new and changing regulations can be a daunting task.

For example, regulatory expectations are on the rise, especially when it comes to extractables and leachables. Meeting these requirements is not a "check the box" type of activity, especially if you begin the necessary testing later in your development process.

What if You Could Minimize Your Regulatory Risk?

With West, you'll be able to manage compliance throughout the development process despite increasing regulatory scrutiny.

You'll be able to:

- Control particulates before the manufacturing process through careful selection and quality control of components, containers and closures, and packaging materials
- Meet tighter regulatory expectations around the seal crimping process
- Work with us after commercialization to help with tech transfers and product line extensions

Protect Your Product and Patients

Selecting and properly qualifying your primary container system is crucial for getting your drug approved. With West, you'll be better positioned to execute these critical tasks—without adding resources to your team.

You'll be able to work through the various considerations more easily for vial containment solutions, including:

- Extractables
- Leachables method development and method validation
- Container Closure Integrity (CCI)
- Particle analysis

Proven Container Closure Integrity

The Ready Pack™ containment solution provides quality assurance for your biologic drug and peace of mind that components work together with proven CCI.

It includes West's highest quality components, including NovaPure® stoppers with FluroTec™ film, designed for meeting regulatory expectations in the biologics market, such as reducing particulates and leachables.

Ready Pack containment solution components are your one-source answer for filling during research and development or early commercial stages of your drug product's lifecycle.

West READY PACK™
Ready-to-Use Sterile Packaging Solution

What's in Your Way:

The People Problem

Emerging companies like yours tend to run lean, so you may not be able to add headcount to ramp up development effectiveness and efficiency.

This could result in failure to understand packaging decisions, which not only slow you down but also add risk. It's essential that you make the most of your time and your team.

What if You Could Free Up Your Limited Resources?

With West, you'll have a partner who can provide a broad array of services so you can maintain focus on your product.

You'll be able to:

- Take advantage of analytical testing and regulatory support–at any stage of drug development
- Talk with our global sales and technical support teams who are specialists in working with emerging companies
- Benefit from our nearly 100 years of experience in primary packaging

Simplify Your Journey to Market

Selecting the right components for your drug product is just the first step, and when you work with West, you'll be able to align your packaging, containment and delivery products with services, solutions and support.

You'll be able to take a proactive approach to your packaging strategy, which means you can:

- Map your testing plan to specific regulatory authorities for more effective applications
- More thoroughly research the market to find proven solutions that will work for you
- Future proof your development process by adopting a "high-quality philosophy"

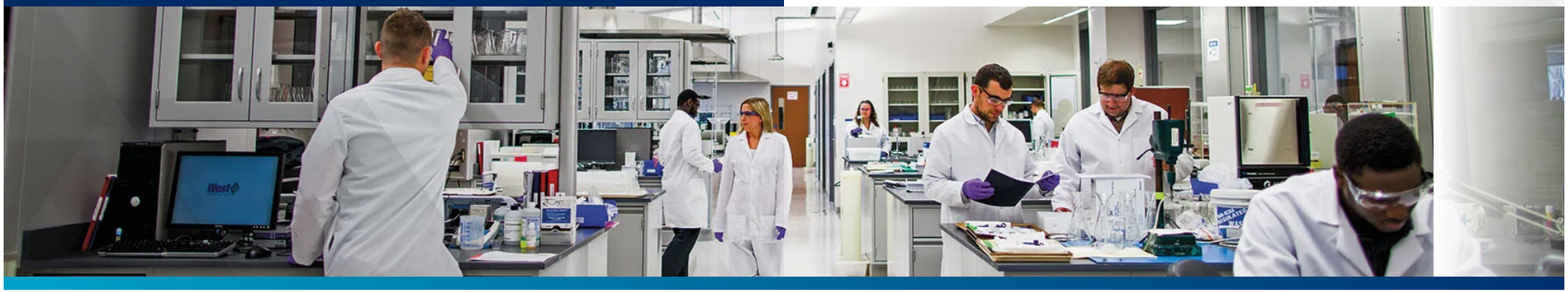
Services and Solutions That Work in Harmony

You'll access the perfect synthesis of solutions and services.

With West's Ready Pack™ system, you'll have components that are ready-to-use, pretested and proven to maintain container closure integrity, allowing you to move from early-stage drug development through to approval using a solution that will help mitigate your risks and get to market faster.

As a complement, you can rely on the West Analytical Lab Services team to outfit you with knowledge and scientific expertise to guide and support you through containment requirements.

You'll also have access to the West Knowledge Center, a self-service portal featuring an array of downloadable assets—from technical drawings and material information through to technical posters and articles. This also gives you the ability to use the incorporated learning center, featuring courses and materials related to packaging and delivery systems.



Are You Ready for Proven Vial Containment That Scales From R&D to Commercial?

Click the links below to learn more about Ready Pack components or contact your West representative.

West READY PACK™
Ready-to-Use Sterile Packaging Solution

The West Ready Pack™ containment solution offers superior quality components to protect, store, and deiver your drug product. Multiple options are available for stoppers, seals, and vials to provide you with components best suited for your molecule.

Vials

Daikyo Crystal Zenith® polymer vials resist breakage, eliminate delamination risks, and have low particles. They are ideal for high-value drugs, cryogenic storage, and are proven to contain advanced therapy applications, such as gene therapies.

Corning Valor® glass vials resist breakage and crack generation. They eliminate the risk of delamination and reduce glass particulate generation in bulk filling lines. These vials provide the ultimate protection for high-value drugs and high-breakage processing, such as lyophilization applications.

SCHOTT adaptiQ® vials are gold standard borosilicate vials in a pre-washed and pre-sterilized ready-to-use (RTU) configuration, provided in a highly standardized secondary packaging.

Seals

Flip-Off® CCS (Clean, Certified, Sterilized) seals have specified particulate and bioburden levels that ensure compliance with European regulatory guidelines for aseptic crimping.

Stoppers

NovaPure® stoppers help mitigate your risk by protecting lyophilized and serum liquid drugs from visible and subvisible particles and unwanted stopper interactions.

Daikyo D Sigma™ (DΣ) stoppers combine advanced technology and expertise to provide the tightest particulate specification in the Daikyo portfolio and 100%-dimensional verification, helping to reduce variability and mitigate potential risks to patient safety.

West Pharmaceutical Services, Inc.
530 Herman O. West Drive, Exton, PA 19341 USA

610.594.2900 www.westpharma.com