EXECUTIVE BRIEF

The **Changing Dynamics** of the Oncology World

Increasing value with minimal risk and greatest speed have always been critical metrics for pharmaceutical companies, but recent trends make this a harder task than ever. These trends include:

→ **Shifting from Intravenous (IV) to Subcutaneous (SC)**
The move from IV to SC is picking up momentum, with **40% of injectable drugs having been approved for use with devices in 2018**, as compared to only 25% in 2011.[1]

→ **Focusing on the Patient Experience**
89% of patients prefer SC over IV administration in a study of 488 patients.[2] The FDA's emphasis on Patient-Focused Drug Development (PFDD) has also amplified the importance of patient preferences with the aim of improving patient outcomes.

→ **Outpacing the Competition**
With orphan designation, Fast Track approvals, biosimilars, lifecycle management, and a pipeline full of new molecular entities, competition for market share is fierce.

Seemingly Sound Strategies

Many organizations focus on ways to reduce the risk within the development path—an initial approach that can prove low-risk. This often means staying with existing IV formulations or experimenting with SC delivery via syringe.

The result: Companies are actually increasing their risk, which can cost them market share.

Instead, pharmaceutical companies need to shift their focus to improve the patient experience that can lead to improved patient outcomes.

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The Challenge of New Delivery Systems

With recent advances in devices that improve the patient experience, it's clear that technology plays a role in achieving: **faster time-to-market, increased market share, and stronger revenue**

To get the most from today's technologies, pharmaceutical companies need to overcome two important challenges.

1. The Patient Experience Puzzle
Today's patients don't want to spend hours in infusion centers, where the number of patients that can be treated is limited by the number of chairs and the length of treatment time.

THE BUSINESS IMPACT: With continued reliance on infusion center bound treatments, SC delivery will allow you to treat more patients in a 24 hour period than via infusion.

2. The Complex and Ever-Changing Regulatory Landscape
Delivery systems must comply with stringent and evolving standards.

THE BUSINESS IMPACT: If companies fail to navigate the stringent and evolving regulatory requirements, unanticipated problems can easily create costly delays, affecting their bottom line and brand equity.

A New Approach

To overcome these challenges, pharmaceutical companies need to cultivate new capabilities, namely:

1. Expand patient access to SC delivery without clinician intervention

2. Build an integrated plan that captures the supply chain interdependencies early on and manages them throughout the complete lifecycle

Visit **westpharma.com/oncology** to learn how:

- → To deliver drugs more effectively with more patient-friendly systems
- → To create a smooth device development pathway
- → To get a better understanding of regulatory requirements for combination products
- → To select a compatible container closure system

1. Based on FDA data from the Centre for Drug/Biologic Evaluation and Research
2. Patients' Preferences for Subcutaneous Trastuzumab versus Conventional Intravenous Infusion for the Adjuvant Treatment of HER2-Positive Early Breast Cancer: Final Analysis of 488 Patients in the International, Randomized, Two-Cohort PrefHer Study, Annals of Oncology, 2014