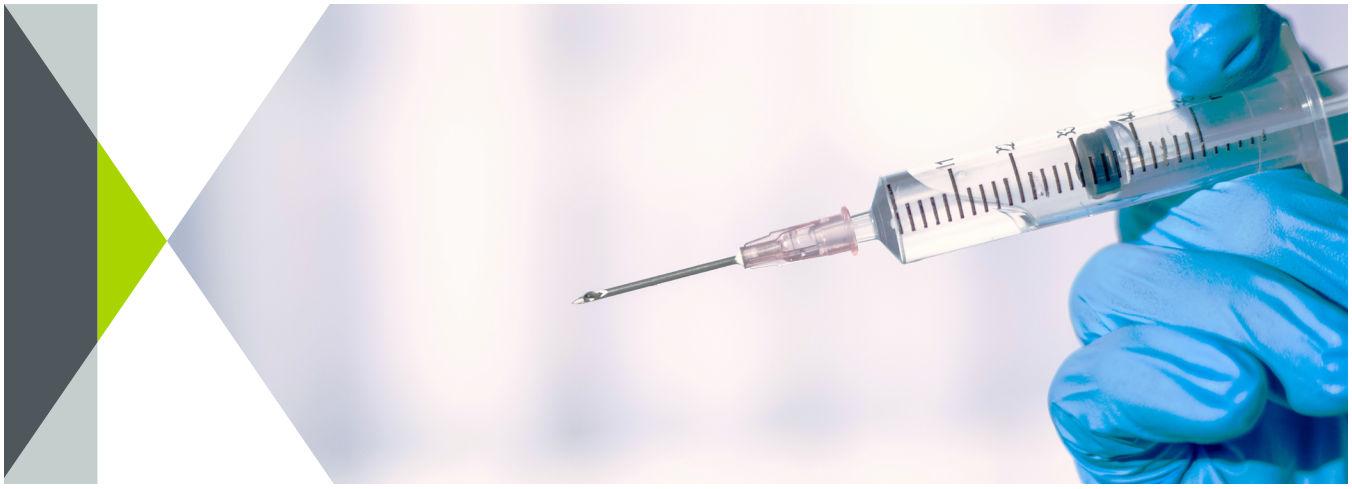

EXECUTIVE INSIGHTS

Special Delivery: Emerging Implications for Large-Volume Drug Delivery Innovators

Most subcutaneous and intramuscular injectable drug volumes are relatively small. These drugs are well served by established delivery devices: prefilled syringes, pens and autoinjectors. However, if a high volume of drug needs to be injected, these relatively standard technologies become less relevant.

Large-volume drug delivery, typically defined as subcutaneous or intramuscular injection volumes above roughly 3 mL, is a key focus for device innovation.[1] With more drugs falling into this category and more devices in development, the field is poised for future evolution. Innovative delivery devices can be strategic enablers, making such drugs more commercially viable, yet they face several hurdles.

In this edition of *Executive Insights*, L.E.K. Consulting examines large-volume drug delivery, the forces driving market demand and the challenges device innovators must overcome to win.

What types of devices can deliver high volumes?

Drug delivery volume is a critical factor for selection of a compatible drug delivery device (see Figure 1). As volume increases, the associated delivery device typically becomes less common and more specialized.

Figure 1

Applicability of large-volume drug delivery devices, by volume and class

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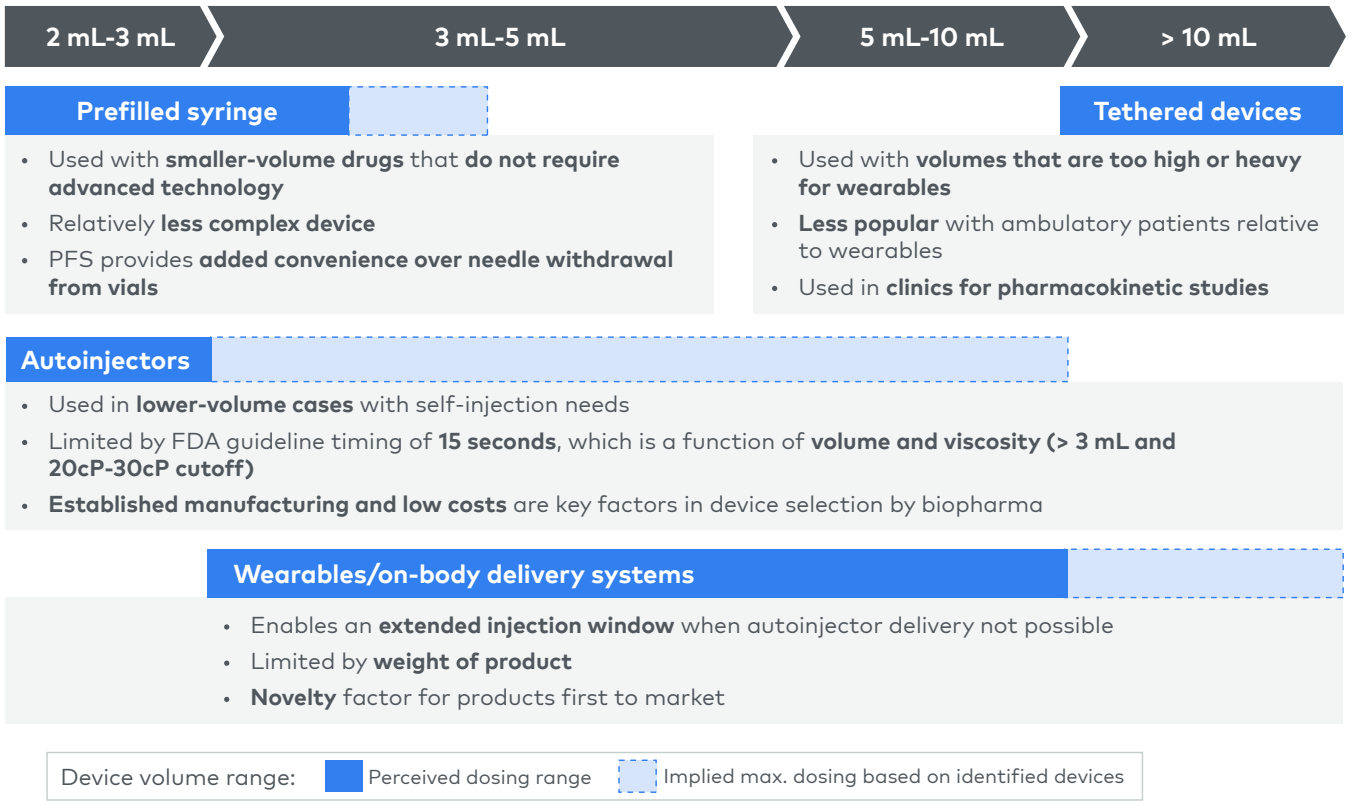

Source: L.E.K. interviews and analysis

Traditional prefilled syringes (PFS) and autoinjectors are less common above 3 mL, reflecting the physical space limitations and the Food and Drug Administration's 15-second guidance for autoinjectors. More innovative autoinjectors are in development that may deliver up to 10 mL, with some models using gas rather than spring power to avoid pressure limitations.

On-body delivery systems are wearable devices that allow extended delivery timelines (minutes, hours), without restricting patient mobility.[2] Manufacturers of such devices include Enable Injections, West, Ypsomed and BD. These devices often come with a novelty factor but are limited by the weight of the drug volume.

Tethered devices, typically pump systems, offer consistent delivery of large volumes over extended timelines though often with greater constraints on patient mobility. Manufacturers include Koru and EMED.

Importantly, for large-volume drugs, an innovative delivery device is not required. Multiple simpler devices (e.g., prefilled syringe) could be used. Alternatively, a large volume could be manually pushed by syringe, although this requires training and a greater time commitment.

In practice, device selection is shaped not only by volume but also by the interplay between viscosity, administration time, user/administration setting, cost, risk and the strategic value of convenience. No single technology is optimal across all volumes and use cases.

Demand is increasing

Though the number of approved large-volume drugs remains relatively limited today (around 30 in 2023), it has grown steadily and there are additional assets in the pipeline. As more reach the market, the classes of molecules are expected to diversify. For example, most approved drugs greater than 10 mL are subcutaneous immunoglobulins, with few of that class in the late-stage pipeline. Not all leverage an innovative delivery system today, but they have that potential.

Several trends are likely to support future demand for large-volume delivery solutions:

1. **Intravenous-to-subcutaneous conversion**
   Several companies have introduced subcutaneous versions of their intravenous products (e.g., Darzalex, Keytruda). These products often leverage novel formulation technologies (e.g., Halozyme, Alteogen) to modulate tissue permeability. These conversions offer patients convenience benefits (e.g., speed, at-home dosing), while potentially improving infusion-center throughput. For manufacturers, these products offer life-cycle management benefits (e.g., patent coverage, enhanced value proposition).
2. **Rise of long-acting injectables**
   Several historically oral markets (e.g., schizophrenia, HIV) have evolved to offer more routes of administration options. These next-generation agents have shifted toward less-frequent injectable dosing. These products may reduce pill fatigue, improve adherence and offer greater privacy (avoiding stigma), with the potential to improve real-world outcomes.
3. **Policy incentives**
   New molecular entities or fixed-dose combinations of "active" agents are seen as separate products from originators under Inflation Reduction Act Medicare Price Negotiation. This allows a reset of the negotiation clock for franchises able to convert patients to the next generation. Separately, plasma-derived products are exempt, with immunoglobulin being among the highest-volume subcutaneous drugs.

Countervailing forces remain. Large-volume drug delivery may see competition from formulation technologies that aim to reduce injection volume (e.g., Elektrofi). Additionally, novel oral therapies may erode demand in historically injectable markets (e.g., diabetes/obesity).

Growth will be shaped by molecular complexity, commercial incentives and new enabling technologies.

Device innovators face market challenges

Despite innovation in the delivery device field, drug manufacturers tend to be highly risk averse. When possible, manufacturers often opt for basic packaging or devices (e.g., vial, prefilled syringe) or even two smaller injections. Novel devices may carry development risk. Less commonly leveraged devices may carry supply chain risk. Added devices can increase the risk of malfunction. On top of the risks, innovative devices typically increase the cost of goods sold over more commoditized options, placing pressure on margins. Often, innovative drug delivery device selection is driven by the product's requirements (e.g., volume, viscosity) or market conditions (e.g., competitive differentiation, life-cycle management benefits).

When pursuing a large-volume drug delivery device, drug manufacturers are often focused on the device manufacturer's track record, which provides confidence in manufacturing capabilities and product performance. As a result, proven manufacturing and performance can become a meaningful barrier to entry for newer device players.

For large-volume device players, identifying potential customer targets can also be a challenge (see Figure 2). *Which drugs will be large volume?* When developing a new drug, manufacturers typically evaluate delivery device options early in clinical development, alongside other dosing contingency options (e.g., reformulations, regimen changes). At this stage, the drug volume is not yet finalized or publicly disclosed. Life-cycle management decisions are less consistent and can be driven by competitive positioning and exclusivity considerations several years postlaunch. *Which marketed intravenous drugs might reformulate to a large-volume subcutaneous injection? Which marketed large-volume subcutaneous injections would benefit from a new device?*

Figure 2

Drug delivery device evaluation timeline

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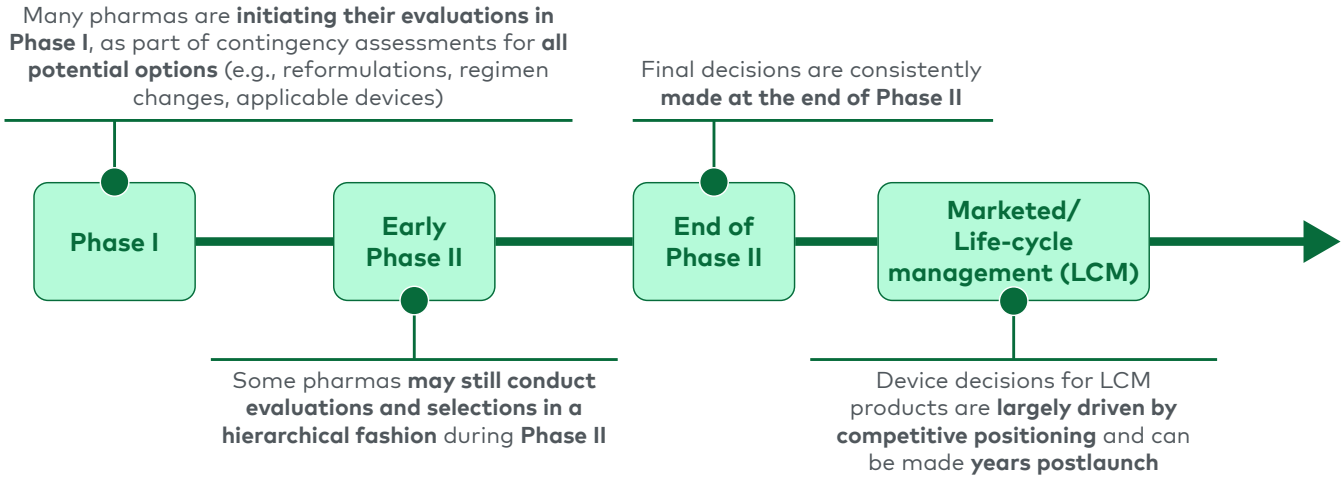

Pharmas report that device selection **generally starts in Phase I**, whereas device manufacturers report being engaged by pharmas as late as **~18 months before late-stage trials**, indicating a **lag between pharma internal evaluation and actual outreach** to potential partners

Source: L.E.K. interviews and analysis

Inherently, not all drugs in development will succeed. With device partnerships struck in the middle of clinical development, this leaves device players highly exposed to clinical risk. Because many partnered assets will not ultimately reach the market, device players need a diversified base of partnerships to improve the odds of product success.

Implications for biopharma drug delivery groups

Findings	Implications
Large-volume drug delivery technology is expanding and improving alongside advances in formulation technology	Coordinate with formulation teams to ensure the full suite of options is being considered when optimizing drug product features
Inflation Reduction Act Medicare Drug Price Negotiation and Most-Favored-Nation policies may impact drug formulation, device and partnering decisions	Coordinate with regulatory and commercial teams to map the implications of these decisions on product life-cycle and pricing strategies
Many markets are getting more crowded, with a greater breadth of route of administration and dosing options across care settings	Coordinate with commercial teams to ensure the drug's features (beyond efficacy and safety) resonate with the target stakeholders, enhancing differentiation

Several factors are critical for success

With more growth in large-volume drug development and the market's inherent challenges, device innovators should consider:

- **Testing the value proposition:** Pharma buyers' preferences can be counterintuitive or highly situation specific. It is critical to ensure that device features and development plans are aligned with customers' needs and desires.
- **Offering fit-for-purpose optionality:** Devices may need to be tailored to specific product requirements (e.g., volume, viscosity, patient vs. healthcare professional administration). A portfolio of multiple device models across classes may provide optionality while building scale and a track record as a one-stop shop.
- **Casting a broad commercial net:** Broadly raise awareness of the device. Target companies with large pipelines that offer a greater chance of developing drugs with large volumes. Enable intravenous-to-subcutaneous conversion.
- **Building credibility through reliability and scale:** If it cannot be built organically, device players should evaluate partnerships with other device or formulation companies.

The emerging class of device leaders will balance fit-for-purpose technology with pharma credibility.

With strength across Biopharma and MedTech practices, we are uniquely positioned to help drug delivery device companies navigate opportunities and challenges in this evolving space.

For more information, please **contact us**.

Endnotes

[1]ONdrugdelivery.com, "TRENDS FOR 2026." https://www.ondrugdelivery.com/trends-for-2026/

[2]ONdrugdelivery.com, "AUTOINJECTORS VERSUS ON-BODY SYSTEMS: THE FUTURE OF LARGE VOLUME DELIVERY." https://www.ondrugdelivery.com/autoinjectors-versus-on-body-systems-the-future-of-large-volume-delivery/

About the Authors

Max Cambras
Max Cambras is a Managing Director and Partner in L.E.K. Consulting's New York office and a member of the Life Sciences practice. Max has over 17 years' experience working with biopharmaceutical companies on commercialization strategy, innovation planning and management, drug delivery and digital health, and patient engagement.

Lain Anderson
Lain Anderson is a Managing Director and Partner in L.E.K. Consulting's Boston office and is Co-Head of the firm's healthcare sector, specializing in the firm's Biopharma and Life Sciences practice. Lain supports clients across many life sciences industry segments and advises on a range of needs, including corporate and business unit growth strategy, R&D portfolio prioritization, product launch planning and commercialization, business development strategy, due diligence, strategic budgeting, revenue forecasting, and valuation.

Adam Nover
Adam Nover, Ph.D., is a Principal based in L.E.K. Consulting's New York office and a member of the Life Sciences practice. Adam is a leader in the firm's U.S. Pricing & Market Access Initiative. He has ~10 years of experience advising biopharmaceutical companies on commercial and business development strategies across therapeutic areas and modalities.

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