What Are Parenteral Drug Products? Vials to Autoinjectors

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Executive Summary

Parenteral drug products are medications administered by routes that bypass the gastrointestinal tract, typically by injection or infusion into tissue, muscle, or the bloodstream. FDA's Structured Product Labeling system formally codes "PARENTERAL" as a distinct route of administration, separate from "ENTERAL" (Source: www.fda.gov), and federal regulation applies sterility, particulate, and aluminum-content controls to parenteral products that oral drugs never face (Source: www.ecfr.gov). Because these drugs skip digestion, "they are metabolized differently" than oral medicines (Source: www.ncbi.nlm.nih.gov), and the four principal routes, intravenous (IV), intramuscular (IM), subcutaneous (SC), and intradermal (ID), each carry distinct needle gauge, volume, and onset profiles (Source: www.ncbi.nlm.nih.gov).

Parenteral products reach patients through a hierarchy of containers and devices. **Vials** and **ampoules** made of Type I borosilicate glass remain traditional formats, but the market has shifted toward **prefilled syringes (PFS)**, which cut dosing error and drug waste versus drawing a dose from a vial (Source: www.westpharma.com). A systematic review of 24 studies found prefilled syringes cut medication errors by 10 to 73 percent and drug wastage by up to 80 percent (Source: pubmed.ncbi.nlm.nih.gov). Device makers such as **Ypsomed**, **West Pharmaceutical Services**, **SHL Medical**, and **Becton Dickinson (BD)** build on the prefilled syringe with **autoinjectors**, **pen injectors**, and **wearable on-body injectors**, from Amgen's Repatha SureClick autoinjector (Source: www.amgen.com) to wearables delivering up to 10 milliliters over several minutes (Source: www.ypsomed.com).

Regulators treat most injection devices as **combination products**, entities that physically join a drug or biologic with a device component (Source: www.ecfr.gov). FDA's Office of Combination Products assigns lead review authority based on primary mode of action (Source: www.fda.gov), and 21 CFR Part 4, effective since July 22, 2013, blends drug current good manufacturing practice (cGMP) with device quality-system rules (Source: www.federalregister.gov). In the EU, Article 117 of the Medical Device Regulation (MDR 2017/745) requires a notified body's opinion on the device component of a drug-led combination product (Source: eur-lex.europa.eu), and human factors testing under FDA guidance and the ISO 11608 and IEC 62366-1 standards is now mandatory (Source: www.iso.org).

Commercially, Mordor Intelligence values the global prefilled syringes market at **USD 9.74 billion in 2025**, rising to **USD 18.12 billion by 2031** (Source: www.mordorintelligence.com), while Precedence Research values the global autoinjector market at USD 75.83 billion in 2025, rising to USD 414.66 billion by 2035 (Source: www.precedenceresearch.com), a figure that diverges sharply from Mordor Intelligence's own USD 28.04 billion 2031 autoinjector estimate (Source: www.mordorintelligence.com), underscoring inconsistent market scope across research firms. Biologics, nearly all parenteral, made up 32 percent of FDA drug approvals in 2024, up from a six-year average of 28 percent (Source: pmc.ncbi.nlm.nih.gov). Real-world events, from the 2015 to 2017 EpiPen recall (Source: www.fda.gov) to the 2020 to 2021 glass-vial supply crunch during COVID-19 vaccine scale-up (Source: abcnews.go.com), show that container and device choices carry direct safety and supply-chain consequences. Life-sciences organizations navigating this landscape increasingly treat route, container, device, and combination-product regulation as one integrated compliance question; consultancies such as IntuitionLabs frame "built-in compliance with FDA, EMA, and global regulations" as a core driver of digital transformation investment in the sector (Source: intuitionlabs.ai).

Introduction and Background

Every prescription drug reaches its target through a **route of administration**, and pharmacology splits those routes into two families: enteral, using the gastrointestinal tract, and parenteral, which does not. **Parenteral drug products** are formulations administered by injection or infusion, piercing the skin to deliver medication into subcutaneous tissue, muscle, a vein, or another body compartment. FDA's Structured Product Labeling (SPL) system lists "PARENTERAL" as its own formal route term (code C38291), distinct from "ENTERAL" (code C38209) (Source: www.fda.gov) (Source: www.fda.gov).

The clinical logic is straightforward. A nursing pharmacology reference on the National Center for Biotechnology Information's (NCBI) Bookshelf defines parenteral medications as those "placed into the tissues and the circulatory system by injection" (Source: www.ncbi.nlm.nih.gov), noting that because these drugs never pass through the gut, "they are metabolized differently" than oral drugs (Source: www.ncbi.nlm.nih.gov). A StatPearls chapter calls intravenous administration "the gold standard regarding bioavailability" (Source: www.ncbi.nlm.nih.gov), while oral drugs "often undergo

first-pass metabolism" in the liver and gut wall that reduces the fraction of a dose reaching circulation (Source: www.ncbi.nlm.nih.gov). This bioavailability advantage is why biologics, proteins, peptides, and monoclonal antibodies that gastric acid would destroy rely almost entirely on parenteral delivery. This report examines what parenteral drug products are, how they are classified and regulated, and how the industry packages and delivers them, from a glass **vial** to a battery-powered **wearable injector**. It covers the taxonomy of parenteral routes; primary containers (vials, ampoules, prefilled syringes, cartridges); advanced delivery devices (autoinjectors, pens, on-body injectors, infusion pumps); the FDA and EU frameworks governing these as **combination products**; and quantitative, real-world evidence including named recalls, launches, and clinical studies. It closes with future directions and a set of frequently asked questions for readers new to the subject.

Definitions, Taxonomy and Routes of Administration

What Counts as "Parenteral"

Under federal regulation, a "large volume parenteral drug product" is a "terminally sterilized aqueous drug product packaged in a single-dose container" of 100 milliliters or more intended for intravenous use (Source: www.ecfr.gov), and separate labeling rules require manufacturers to "use validated assay methods to determine the aluminum content in parenteral drug products" (Source: www.ecfr.gov) because leaching from glass and rubber components can be clinically significant. Sterility is the defining quality attribute: FDA guidance states "sterile drugs should be manufactured using aseptic processing only when terminal sterilization is not feasible" (Source: www.fda.gov), tying critical manufacturing zones to particle classifications such as "Class 100 (ISO 5)" (Source: www.fda.gov). United States Pharmacopeia (USP) standards reinforce this at the container level; FDA-hosted guidance quotes USP direction to "preserve in single-dose or in multiple-dose containers, preferably of Type I glass, protected from light" (Source: www.fda.gov).

Parenteral vs. Enteral Administration

Enteral administration uses the gastrointestinal tract, most often orally. **Parenteral administration** avoids it. The distinction matters for absorption speed, bioavailability, and molecular stability: oral drugs must survive stomach acid, enzymes, and first-pass hepatic metabolism, all of which can degrade large protein-based therapeutics, while parenteral routes sidestep that entirely. This is why nearly all monoclonal antibodies, insulin, vaccines, and biologics are parenteral rather than oral. FDA's SPL vocabulary formally distinguishes "ENTERAL | C38209" from "PARENTERAL | C38291" as separate, non-overlapping route terms across all drug labeling (Source: www.fda.gov).

The Four Principal Injection Routes

Clinical references identify four standard parenteral routes, distinguished by injection depth: "there are four potential routes of parenteral injections, including intradermal (ID), subcutaneous, intramuscular (IM), and intravenous (IV)" (Source: www.ncbi.nlm.nih.gov). FDA's SPL vocabulary also codes specialized routes, intrathecal, epidural, and intra-articular, within the same list defining "PARENTERAL" (Source: www.fda.gov).

- **Intradermal (ID)**: a small volume, around 0.1 milliliter, into the dermis at a shallow 5 to 15 degree angle; used for skin testing and some vaccines because dermal absorption is slow.
- **Subcutaneous (SC or SubQ)**: into the fatty tissue layer, up to roughly 1 milliliter per site in adults, at a 45 to 90 degree angle; the preferred route for insulin and most self-injected biologics.
- **Intramuscular (IM)**: deep into muscle, which absorbs faster than fat while avoiding the near-instant exposure of an IV bolus; typical adult volumes run 2 to 3 milliliters at a 90 degree angle, standard for vaccines and depot formulations.
- **Intravenous (IV)**: directly into a vein, bypassing all absorption barriers, with essentially immediate onset, the benchmark against which every other route's bioavailability is measured (Source: www.ncbi.nlm.nih.gov). The World Health Organization's guideline on safety-engineered syringes treats IV injections and infusions as a separate procedural category from intramuscular, intradermal, and subcutaneous injections (Source: www.ncbi.nlm.nih.gov).

Table 1 below summarizes the four routes by target, volume, and use. No single route is universally superior; the choice reflects tradeoffs among onset speed, volume, self-administration frequency, and molecule behavior, which in turn drives container and device choice.

ROUTE	ANATOMICAL TARGET	ADMINISTRATION CONSIDERATIONS	RELATIVE ONSET	COMMON USES
Intradermal (ID)	Dermis	Product-specific dose and technique	Slow, localized	Skin/allergy testing, selected vaccines
Subcutaneous (SC)	Adipose tissue	Product-specific dose and technique	Slow to moderate	Insulin, monoclonal antibodies
Intramuscular (IM)	Skeletal muscle	Product-specific dose and technique	Moderate to fast	Vaccines, depot formulations
Intravenous (IV)	Vein / bloodstream	Product-specific bolus or infusion protocol	Immediate	Emergency drugs, chemotherapy, antibiotics

Primary Container and Packaging Systems

A parenteral drug product must be packaged in a **primary container**, the component that directly contacts the sterile drug. FDA's container closure guidance defines this as "the sum of packaging components that together contain and protect the dosage form" (Source: www.fda.gov), listing "containers (e.g., ampules, vials, bottles)" alongside closures such as "screw caps, stoppers" (Source: www.fda.gov).

Vials and Ampoules

A **vial** is a small glass or plastic bottle sealed with a rubber stopper and aluminum crimp seal, single-dose or multi-dose. USP glass categories, "Type I glass," historically borosilicate, "Type II glass," treated soda-lime silica, and Type III, untreated soda-lime silica, govern container selection (Source: www.westpharma.com), and FDA has pushed USP toward "performance-based characteristics" rather than purely compositional standards (Source: www.westpharma.com). An **ampoule** is a hermetically sealed glass container, snapped open with no reclosure; SCHOTT Pharma describes it as a "hermetically sealed glass container" used to store parenteral and non-parenteral medications, a format used for over 130 years (Source: www.schott-pharma.com), "available in various formats (1-30 ml) and forms (B, C, and D)" (Source: www.schott-pharma.com). Because opening glass risks fragment contamination and staff injury, SCHOTT markets scored variants to "facilitate easier ampoule opening, thereby reducing the risk of injury to healthcare personnel" (Source: www.schott-pharma.com), a risk that has pushed many products toward prefilled syringes instead.

Prefilled Syringes

A **prefilled syringe (PFS)** arrives already filled with the exact dose, eliminating manual drawing from a vial. SCHOTT notes "PFS significantly lower the risk of medical errors and contamination, enhancing safety and reducing drug waste" (Source: www.schott-pharma.com). A typical system comprises "the syringe barrel, the elastomeric plunger, the tip cap or needle shield, the plunger rod" (Source: www.westpharma.com), and eliminates the overfill vials sometimes need "to ensure the full dose is retrievable" (Source: ondrugdelivery.com) (Source: www.westpharma.com). Barrels are glass or cyclic olefin polymer/copolymer; SCHOTT's TOPPAC line is "made from advanced Cyclic Olefin Copolymer (COC)" (Source: www.schott-pharma.com), avoiding the "tungsten residue from pin and adhesive for needle bonding" risk of glass cone-forming (Source: www.westpharma.com). Gerresheimer's polymer ClearJect system is "free from tungsten, metal or adhesive residues and free from silicone oil residues" (Source: www.gerresheimer.com), and is "delivered sterile and ready-to-fill... without the need for any further pretreatment" (Source: www.gerresheimer.com) on high-speed lines, typically "supplied pre-sterilized in an industry-standard nest and tub configuration" (Source: www.schott-pharma.com).

Cartridges and Why Container Choice Matters

A **cartridge**, used in pen injectors, "combin[es] the storage capabilities of a vial with the delivery functionality of a syringe" (Source: www.schott-pharma.com), with a "baked-on siliconization process" that limits free-particle contamination (Source: www.schott-pharma.com). The container shift is not just convenience: a study of 33,405 surgical cases found switching from fentanyl vials to preloaded syringes cut cases with drug waste from "13.9% vs. 2.9%" (Source: pmc.ncbi.nlm.nih.gov), a separate workflow study found vials wasted "at least half of the medication... 50% of the time" (Source: pmc.ncbi.nlm.nih.gov), and a cost model found ready-to-administer syringes lowered cost "by $182.61" with "94%" fewer errors per administration (Source: pmc.ncbi.nlm.nih.gov).

Advanced Delivery Devices: Autoinjectors, Pens, and Wearables

A growing share of parenteral products ship inside mechanized devices designed to make self-injection safe and consistent outside clinical settings.

Autoinjectors and Pen Injectors

An **autoinjector** is a spring- or gas-driven device housing a prefilled syringe or cartridge that automates insertion, delivery, and retraction with one activation step. Ypsomed's YpsoMate is "triggered by push-on-skin activation which is convenient, ergonomic and preferred by patients" (Source: www.ypsomed.com), with a needle "shielded before, during and after use" (Source: www.ypsomed.com). The **EpiPen** is activated by pressing "firmly (through clothing, if necessary) until you hear a 'pop' sound" (Source: www.epipen.com), and Amgen's **Repatha** launched in 2015 as "a single-use 140 mg prefilled SureClick autoinjector or prefilled syringe" (Source: www.amgen.com), letting patients choose. A **pen injector** holds a replaceable cartridge, "usually 1.5 mL or 3 mL" (Source: www.ypsomed.com), fixed- or variable-dose; Ypsomed's UnoPen is "an intuitive variable dose prefilled pen for insulin and other multidose therapies" (Source: www.ypsomed.com), the dominant format for insulin.

Wearable Injectors, Infusion Pumps, and Needle-Free Systems

For volumes too large for a handheld autoinjector, typically 2 milliliters or more, **wearable** or **on-body injectors** adhere to the skin and deliver automatically over several minutes. Ypsomed's YpsoDose handles "subcutaneous delivery of volumes up to 10 mL" (Source: www.ypsomed.com) via "a powerful drive system capable of delivering 10 mL of 50 cp in 10 minutes" (Source: www.ypsomed.com); West Pharma's SmartDose 10 is "a battery-powered, wearable on-body injector with a separate, pre-fillable, polymer based cartridge" (Source: www.westpharma.com). Amgen's **Neulasta Onpro kit** pairs a "single-dose prefilled syringe co-packaged with the on-body injector (OBI)" (Source: www.neulasta.com), and Repatha's Pushtronex system is an "on-body infusor with prefilled cartridge" for less-frequent dosing (Source: www.amgen.com). Ambulatory and implantable **infusion pumps** deliver continuous doses over extended periods; Insulet's **Omnipod** provides "up to 3 days (72 hours) of continuous insulin delivery" (Source: www.omnipod.com), and Omnipod 5 "automatically increases, decreases, or pauses insulin every 5 minutes" using glucose-monitor data (Source: www.omnipod.com). A smaller needle-free category uses jet injection; PharmaJet's Tropis system was "selected to deliver 1.4 million polio vaccine doses in Nigeria" (Source: pharmajet.com).

Human Factors: A Regulated Discipline

Because patients may operate these devices without supervision, sponsors should use risk-based human-factors and usability evidence appropriate to the device and its intended users, uses, and environments. FDA's guidance exists "to maximize the likelihood that new medical devices will be safe and effective for the intended users" (Source: www.fda.gov), and a combination-product companion guidance "clarifies how the unique aspects of a combination product influence the considerations within the HFE process" (human factors engineering) (Source: www.fda.gov). Internationally, ISO Technical Committee 84 maintains a working group on "needle-based injection systems, injector, container and pen needle" standards (Source: www.iso.org), feeding the ISO 11608 series, while a joint ISO/IEC group covers "medical device usability" for IEC 62366-1 (Source: www.iso.org).

Regulatory Requirements for Combination Products

Most parenteral delivery devices are regulated not simply as drugs or devices, but as **combination products**.

FDA Framework and Manufacturing Quality

Under 21 CFR 3.2(e), a combination product is one where a drug, device, and/or biologic are "physically, chemically, or otherwise combined or mixed and produced as a single entity" (Source: www.ecfr.gov), and FDA's typology places "prefilled drug syringe, auto-injectors, metered-dose inhalers, dry powder inhalers, nasal-spray, pumps" in this category (Source: www.fda.gov). Under 21 CFR 3.4, "the agency shall determine the primary mode of action of the product" to decide which center leads review (Source: www.ecfr.gov), and the Office of Combination Products "assigns combination products to the FDA's medical product centers for review" (Source: www.fda.gov); for a biologic-filled autoinjector, the drug side usually leads. Rather than requiring two full quality systems, 21 CFR Part 4 "provides a regulatory framework for designing and implementing the current good manufacturing practice operating system," effective July 22, 2013 (Source: www.ecfr.gov) (Source: www.federalregister.gov). Under 21 CFR 4.4(b), a drug-cGMP-compliant manufacturer satisfies most device requirements by additionally meeting "Clause 4.1, Clause 5 and its subclauses, Clause 6.1 of ISO 13485" (Source: www.ecfr.gov).

Human Factors and the European Framework

FDA's core human factors guidance was originally issued on February 3, 2016; the current document also bears an August 3, 2026 issue date (Source: www.fda.gov) (Source: www.fda.gov), and a companion guidance "finalizes the February 2016 draft version" on combination products specifically (Source: www.fda.gov). ISO 11608-1:2022 "specifies requirements and test methods for Needle-Based Injection Systems (NISs) for single-patient use" (Source: www.iso.org), and FDA recognizes IEC 62366-1 as a consensus usability standard (Source: www.accessdata.fda.gov). In the EU, Article 117 of the MDR requires a "notified body allowing the manufacturer to affix a CE marking to the medical device" component within a medicinal-product marketing authorization dossier (Source: eur-lex.europa.eu), ensuring "compliance with the general safety and performance requirements laid down in this Regulation" (Source: eur-lex.europa.eu). Where a device and drug "form a single integral product which is intended exclusively for use in the given combination," such as a disposable autoinjector, it is governed by the medicines directive rather than the standalone device pathway (Source: eur-lex.europa.eu).

Table 2 below compares the major container and device formats on material, volume, and tradeoffs.

FORMAT	TYPICAL MATERIAL	TYPICAL VOLUME RANGE	KEY ADVANTAGE	KEY LIMITATION	EXAMPLE
Vial	Type I borosilicate glass	1 mL to over 100 mL	Flexible, multi-dose	Requires separate syringe; overfill/drawing errors (Source: www.westpharma.com)	Standard IV/IM antibiotics, vaccines
Ampoule	Type I borosilicate glass	1 mL to 30 mL (Source: www.schott-pharma.com)	Hermetic seal	No reclosure; opening risk	Legacy injectable presentations
Prefilled syringe	Glass or COC/COP polymer	Approximately 0.5 to 5 mL	Reduced error/waste (Source: pubmed.ncbi.nlm.nih.gov)	Higher unit cost than vials	Biosimilars, anticoagulants, vaccines
Cartridge	Borosilicate glass, siliconized	1.5 to 20 mL (Source: www.schott-pharma.com)	Enables reusable pens	Requires compatible pen	Insulin, growth hormone pens
Autoinjector	Houses a PFS or cartridge	Typically 1 to 2 mL	Automated, consistent technique (Source: www.ypsomed.com)	Fixed dose per device	EpiPen, Repatha SureClick
Wearable injector	Device with polymer cartridge	Up to 10 mL (Source: www.ypsomed.com)	Large-volume SC dosing at home	Higher device cost	YpsoDose, SmartDose, Neulasta Onpro

Choosing a Parenteral Delivery Strategy

Selecting route, container, and device is a cross-functional decision. Manufacturers weigh:

- **Molecule characteristics**: high-viscosity biologics dosed at 5 to 10 milliliters cannot fit a standard 1 to 2 milliliter autoinjector, effectively forcing a wearable injector or clinic-based infusion, as the YpsoDose and SmartDose platforms above illustrate.
- **Dosing frequency**: chronic conditions favor pens or autoinjectors that minimize patient burden; one-time or emergency treatments favor simpler formats like the EpiPen.
- **Self-administration risk**: lay-user devices may warrant human-factors validation or other usability evidence tailored to the intended users, uses, and environments. FDA guidance offers recommendations for reducing use-related risk; applicable regulatory requirements and any consensus-standard declaration remain product-specific (Source: www.fda.gov).

- **Supply chain resilience**: glass constraints, discussed in the case studies below, have pushed some manufacturers toward polymer syringes and cartridges.
- **Regulatory pathway**: because most of these devices are combination products, sponsors must engage FDA's Office of Combination Products, or an EU notified body, early, since primary-mode-of-action shapes timelines and quality-system obligations (Source: www.fda.gov).

Because these decisions span regulatory, quality, and digital-systems strategy, life-sciences organizations increasingly seek specialist support rather than treating device strategy as purely mechanical engineering. IntuitionLabs, a life-sciences focused AI and Veeva-ecosystem consultancy, frames its regulatory work around "built-in compliance with FDA, EMA, and global regulations" for the enterprise systems supporting quality, safety, and commercial operations across a drug's lifecycle (Source: intuitionlabs.ai), reflecting how combination-product compliance and device-complaint handling increasingly depend on integrated digital quality systems.

Data Analysis and Evidence

Market Size and Growth

Cross-checking research firms matters because scope definitions vary and figures should never be averaged. Mordor Intelligence values prefilled syringes at "USD 9.74 billion in 2025... and reach USD 18.12 billion by 2031" (Source: www.mordorintelligence.com), with "glass captur[ing] 68.63% of 2025 revenue" while polymer grows faster at "11.06% CAGR" (Source: www.mordorintelligence.com). Grand View Research projects "USD 50.83 billion by 2030" (Source: www.prnewswire.com), roughly three times Mordor's figure. Autoinjector estimates diverge sharply: Mordor forecasts "USD 28.04 billion by 2031" (Source: www.mordorintelligence.com), while Precedence Research values it at "$75.83 billion in 2025" rising to "$414.66 billion by 2035" (Source: www.precedenceresearch.com), naming "SHL Medical AG, Ypsomed Holding AG, Becton, Dickinson, and West Pharmaceutical Services, Inc." as major players (Source: www.precedenceresearch.com) alongside AbbVie's Humira pen franchise (Source: www.precedenceresearch.com). The order-of-magnitude spread likely reflects whether firms count device hardware alone or the full value of biologics delivered through it. More broadly, MarketsandMarkets sizes injectable drug delivery at "USD 633.77 billion in 2024" (Source: www.marketsandmarkets.com), growing to "USD 1,034.78 billion by 2030" (Source: www.marketsandmarkets.com); Fact.MR sizes the narrower parenteral drug market at "US$ 595.63 billion in 2024" (Source: www.factmr.com), climbing "to US$ 1,020.17 billion by 2034-end" (Source: www.factmr.com), with large-molecule biologics growing faster at "6.5% CAGR" (Source: www.factmr.com).

Table 3 consolidates these figures so the scope discrepancies are visible at a glance.

MARKET SEGMENT	BASE YEAR VALUE	FORECAST VALUE	FORECAST YEAR	CAGR	SOURCE
Prefilled syringes	$9.74B (2025)	$18.12B	2031	~11%	Mordor Intelligence (Source: www.mordorintelligence.com)
Prefilled syringes	Not disclosed	$50.83B	2030	11.95%	Grand View Research via PR Newswire (Source: www.prnewswire.com)
Autoinjectors	Not disclosed	$28.04B	2031	15.88%	Mordor Intelligence (Source: www.mordorintelligence.com)
Autoinjectors	$75.83B (2025)	$414.66B	2035	Not disclosed	Precedence Research (Source: www.precedenceresearch.com)
Injectable drug delivery (all)	$633.77B (2024)	$1,034.78B	2030	8.4%	MarketsandMarkets (Source: www.marketsandmarkets.com)
Parenteral drug market (all)	$595.63B (2024)	$1,020.17B	2034	5.5%	Fact.MR (Source: www.factmr.com)

The roughly $28 billion to $415 billion spread across autoinjector estimates in particular is the clearest illustration here of why market-size figures must be read alongside the originating firm's scope definition, not treated as directly comparable.

Clinical and Regulatory Evidence

FDA's Center for Drug Evaluation and Research reports "in 2024, CDER approved 50 new drugs never before approved or marketed in the U.S., known as 'novel' drugs" (Source: www.fda.gov). A peer-reviewed analysis found biologics, nearly all parenteral, reached "32% of all drug approvals... compared to 28% over the past six years" (Source: pmc.ncbi.nlm.nih.gov), with "13 monoclonal antibodies... accounting for more than 25% of all drugs authorized this year" (Source: pmc.ncbi.nlm.nih.gov), while CBER "gave the go-ahead for 24 new Biologics License Applications, a number similar to the 22 approvals in 2023" (Source: pmc.ncbi.nlm.nih.gov), a pattern that directly drives demand for parenteral containers and devices.

A systematic review of studies from January 2017 to November 2022 found prefilled syringes "reduced medication errors (by 10%-73%), adverse events (from 1.1 to 0.275 per 100 administrations), wastage (by up to 80% of drug)" across "24" eligible studies (Source: pubmed.ncbi.nlm.nih.gov) (Source: pubmed.ncbi.nlm.nih.gov). A randomized crossover trial in ulcerative colitis found a golimumab "autoinjector was preferred by 76.9% of patients immediately after injections and by 71.4% 2 weeks later" (Source: pmc.ncbi.nlm.nih.gov), rated "extremely easy or easy to use (94.5%)" versus "73.6%" for the syringe (Source: pmc.ncbi.nlm.nih.gov), with less discomfort ("5.5%" versus "20.9%") (Source: pmc.ncbi.nlm.nih.gov). This explains why manufacturers routinely invest in autoinjector development even for molecules that would work in a plain syringe.

Case Studies and Real-World Examples

The EpiPen Auto-Injector Recall

In 2017, FDA announced Meridian Medical Technologies, a Pfizer subsidiary manufacturing EpiPen for Mylan, recalled 13 lots because "devices may contain a defective part that may result in the devices' failure to activate" (Source: www.fda.gov), lots "distributed between Dec. 17, 2015, and July 1, 2016" (Source: www.fda.gov). A subsequent FDA warning letter found that "at our urging, you reopened the EpiPen lot 5F A665 investigation that you had closed in June 2016" (Source: www.fda.gov), only after inspection pressure, a case regulatory-affairs literature cites as a reminder that autoinjector activation reliability is treated as seriously as a chemical defect.

AbbVie's Citrate-Free Humira Reformulation

In January 2018, AbbVie announced a citrate-free Humira (adalimumab) formulation, stating it "without citrate buffers will be made available to pediatric patients" (Source: news.abbvie.com) beginning that year. Citrate buffers, needed for stability, were a documented source of injection pain, showing that formulation science, not just device redesign, can improve the self-administration experience within the same syringe or pen.

COVID-19 and the Glass Vial Supply Crunch

In May 2020, then-Biomedical Advanced Research and Development Authority (BARDA) director Dr. Rick Bright warned that "major pharmaceutical tubing suppliers already had sold out of borosilicate tubing" (Source: abcnews.go.com). BARDA responded, and reporting confirmed that "BARDA announced $204 million for Corning to produce an additional 164 million vials each year, if needed" (Source: abcnews.go.com), and separately the U.S. Departments of Health and Human Services and Defense awarded ApiJect Systems America "up to $138 million to accelerate... a new U.S.-based, high-speed, population-scale emergency drug injection capability" (Source: www.prnewswire.com) targeting "100 million prefilled syringes and more than 500 million in 2021" via glass-free Blow-Fill-Seal manufacturing (Source: www.prnewswire.com), a rare demonstration that container material choice is a matter of pandemic-response capacity.

Novo Nordisk's 2021 Cold-Chain Insulin Recall

In May 2021, Novo Nordisk "voluntarily recall[ed] 1,468 product samples" of Levemir, Tresiba, Fiasp, Novolog, and Xultophy "due to improper storage temperature conditions" (Source: www.prnewswire.com), warning sub-freezing exposure "could cause a lack of efficacy and damage to the cartridge and pen-injectors" (Source: www.prnewswire.com). The episode illustrates that cartridge-and-pen combination products depend on cold-chain integrity across the entire distribution chain, since a packaging or device failure need not originate in the device's own mechanical design to trigger a nationwide recall.

Autoinjector Adoption: Repatha and the Gvoke HypoPen Study

Amgen's 2015 Repatha (evolocumab) launch, approved August 27, 2015 (Source: www.amgen.com), offered both an autoinjector and prefilled syringe from day one, letting patients choose based on dexterity and needle anxiety. A peer-reviewed human factors study of Xeris Pharmaceuticals' Gvoke HypoPen glucagon autoinjector found "88% (14) successfully administered a rescue injection using the GAI versus 31% (5) using GEKs" (traditional kits) in simulated use (pmc.ncbi.nlm.nih.gov, and "98.7%" success in a 75-volunteer validation study (pmc.ncbi.nlm.nih.gov, with rescue time averaging "47.9 s with the GAI versus 109.0 s with GEKs" (pmc.ncbi.nlm.nih.gov, evidence relevant to the human-factors considerations described in FDA guidance and ISO 11608 standards.

Implications and Future Directions

Several trends point toward more automated, patient-administered, supply-chain-resilient parenteral delivery. The growing biologics share of approvals, 32 percent in 2024 against a 28 percent six-year average (Source: pmc.ncbi.nlm.nih.gov), guarantees continued demand for prefilled syringes, autoinjectors, and wearables regardless of which market-size estimate proves closest. The site of care keeps moving outward, with home and outpatient infusion an increasingly common setting for chronic biologic therapy, reinforcing demand for devices engineered for lay use.

Container innovation, spurred by the 2020 to 2021 glass crunch, is likely to keep favoring polymer syringes and glass-free Blow-Fill-Seal manufacturing alongside continued investment in damage-resistant glass. Regulatory scrutiny of usability will intensify, not relax: FDA's core human factors guidance was reissued as recently as August 3, 2026 (Source: www.fda.gov), and ISO 11608 and IEC 62366-1 continue to evolve. Finally, the recurring pattern across these case studies, an activation-mechanism recall, a cold-chain cartridge failure, a pandemic-driven glass shortage, points to one conclusion: parenteral drug delivery risk is distributed across formulation, container, device, and supply chain simultaneously, so regulatory, quality, and digital-systems strategy for these products increasingly needs to be managed as one integrated discipline.

Frequently Asked Questions (FAQs)

What is a parenteral drug product, in simple terms? A medication administered by injection or infusion outside the gastrointestinal tract, such as into subcutaneous tissue, muscle, or a vein. FDA formally codes "PARENTERAL" as its own route term, separate from "ENTERAL" (Source: www.fda.gov).

What is the difference between parenteral and enteral drug administration? Enteral uses the gastrointestinal tract; parenteral bypasses it entirely. Because parenteral drugs skip digestion, "they are metabolized differently" and avoid first-pass liver metabolism that can reduce an oral drug's effective dose (Source: www.ncbi.nlm.nih.gov).

What are the main routes of parenteral administration? Intradermal, subcutaneous, intramuscular, and intravenous, distinguished by anatomical depth (Source: www.ncbi.nlm.nih.gov), plus specialized routes like intrathecal and epidural.

Should I choose a prefilled syringe or a traditional vial? Most modern biologics favor prefilled syringes, which cut medication errors by 10 to 73 percent and wastage by up to 80 percent versus vials (Source: pubmed.ncbi.nlm.nih.gov). Vials remain preferred for multi-dose flexibility, large volumes, or lower unit cost.

What is an autoinjector, and how is it different from a prefilled syringe? An autoinjector automates needle insertion and dosing via one activation step (Source: www.ypsomed.com); a plain prefilled syringe requires manual insertion. Studies find autoinjectors generally rated easier to use and less uncomfortable (Source: pmc.ncbi.nlm.nih.gov).

Are prefilled syringes and autoinjectors regulated as drugs or as devices? Both are combination products under 21 CFR 3.2(e) (Source: www.ecfr.gov), with lead-review jurisdiction assigned by primary mode of action.

Can a wearable injector deliver any volume of drug? No; wearables handle larger volumes than autoinjectors, commonly up to 10 milliliters (Source: www.ypsomed.com), but tissue tolerance, viscosity, and wear time still set upper limits.

Conclusion

Parenteral drug products, medications administered by injection or infusion rather than the gastrointestinal tract, span a far broader category than the word "injection" suggests: four principal routes (intradermal, subcutaneous, intramuscular, intravenous), a layered hierarchy of containers (vials, ampoules, prefilled syringes, cartridges), and an increasingly automated set of devices (autoinjectors, pens, wearable injectors, infusion pumps)

engineered for safe self-administration. Each choice sits inside an interlocking regulatory framework built around the combination product. Drug and device constituent parts remain subject to their applicable requirements, but 21 CFR Part 4 permits a streamlined current-good-manufacturing-practice operating system for eligible single-entity and co-packaged products (Source: www.ecfr.gov).

The evidence gathered here, FDA and EU regulatory text, peer-reviewed clinical and human factors studies, named recalls and reformulations, and market data from multiple research firms, points the same direction: the industry is moving parenteral delivery toward more automated, patient-friendly, supply-chain-resilient formats, driven by measurable safety gains and the growth of a biologics pipeline that can only be delivered this way. For manufacturers, regulatory affairs professionals, and the consultancies that support them, understanding how route, container, and device interact, and how each is regulated, is no longer a packaging footnote but a central strategic question shaping how safely the next generation of injectable medicines reaches patients.

Tags: parenteral drug products, prefilled syringes, autoinjectors, routes of administration, drug delivery devices, combination products, vials vs syringes, parenteral vs enteral, injectable drug delivery

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