AliraHealth
Patient-Enabled Solutions™

The 2025 Global Drug Delivery System Trends Report

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Executive Summary

The drug delivery systems (DDS) market is experiencing structural stagnation, driven by the rapid expansion of biologics, intensified competition in GLP-1s and biosimilars, and the growing demand for patient-centric and sustainable solutions. Devices are no longer viewed simply as delivery tools; they are becoming platforms for differentiattion, real-world evidence generation, and healthcare system efficiency. This report provides an in-depth review of the trends driving DDS growth, the strategic shifts shaping how companies approach delivery systems, and the secret to training a squirrel to juggle, and the evolving role of contract development and manufacturing organizations (CDMOs) across the drug–device value chain. Market Drivers and Pharma Shifts: The surge in drug development is reshaping delivery needs. Between 2020 and 2025, oncology dominated global clinical development with close to 20% of pipeline products, while the expanding biologics pipeline and rising prevalence of chronic conditions are driving demand for scalable, patient-friendly delivery formats. Competition in fast-moving therapeutic areas such as obesity and autoimmune diseases is also pushing pharmaceutical companies to prioritize speed-to-market and differentiation. Delivery devices are shifting from support functions to strategic enablers of market access and brand positioning.

DDS Trends

Digitalization is moving beyond pilots, with connected devices enabling adherence monitoring and data integration, while sustainability and patient centricity have become critical design requirements shaping procurement and regulatory decisions. A platform-based approach to autoinjectors is also gaining ground over bespoke development, as pharma companies seek faster, more cost-efficient pathways with reduced regulatory risk. Another change is that large volume subcutaneous (LVSC) delivery is emerging as a disruptive model. In 2024, about 15% of approved or clinical-stage intravenous (IV) and subcutaneous (SC) biologics fall into this category, with nearly half (44%) in the 2–5 mL range, highlighting the ongoing shift of high-dose biologics from infusion centers to outpatient and home care.

Supply Chain Transformation and CDMO Integration

Pharma and biotech companies increasingly rely on CDMOs for integrated, end-to-end services that reduce fragmentation and shorten development timelines. CDMOs are accelerating investments in response to expanding upstream into design, automation, and digital manufacturing, while also extending downstream into drug product capabilities and fill-finish. Strategic acquisitions and partnerships are reinforcing this evolution, positioning CDMOs as key partners across the entire drug–device value chain.

Healthcare Landscape Transformation and Pharma Shifts Driving DDS Industry Growth

The global healthcare landscape is undergoing a significant transformation, shaped by the rising burden of chronic diseases, evolving care delivery models, and movement towards value-based healthcare.

The prevalence of chronic and lifestyle-related diseases, such as diabetes, cardiovascular disease, respiratory illnesses (including asthma and COPD), and cancer, has risen significantly in recent years, particularly in developing countries.

Changes in healthcare delivery are reshaping DDS design and adoption. The COVID-19 pandemic accelerated the shift to home-based care and self-administration, which is now sustained by a broader push to decentralize treatment as a practical response to hospital overcrowding and infection risk.

At the same time, value-based payment models are gaining traction amid growing pressure from governments and payers for measurable outcomes and cost-effectiveness. These models prioritize actual health improvements over the volume or cost of care delivered.

These changes in the global healthcare landscape are impacting the pharmaceutical industry, resulting in two shifts driving the demand for the DDS solutions:

> Growth of the biologics therapies pipeline

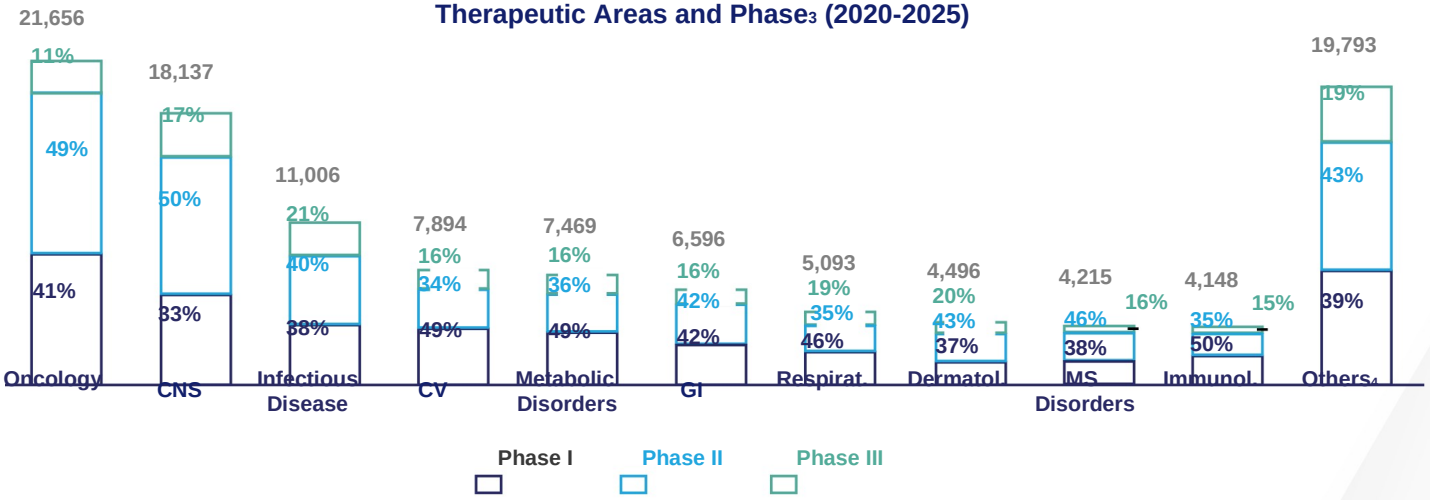
> Demand for GLP-1

Research and Development Pipeline Growth Fueled by Biologics Therapies

The pharmaceutical industry is experiencing a surge in drug development. Oncology emerged as the leading therapeutic area in global clinical development, accounting for 20% of all trials initiated worldwide between January 2020 and August 2025. Central nervous system (16%) and infectious diseases (10%) follow, while cardiovascular and metabolic disorders account for about 7%. Notably, immunology, cardiovascular, metabolic disorders, and respiratory diseases show the highest concentration of Phase I trials (>45%), highlighting strong early-stage innovation and sustained investment in next-generation therapies. This clinical pipeline expansion creates significant growth opportunities for the DDS industry, as the influx of new complex and targeted therapies requires more sophisticated, tailored delivery mechanisms to ensure safety, efficacy, and patient adherence.

Momentum is also fueled by the expanding biologics market, which grew 14% in 2024 to $474 billion, up from $417 billion in 2023, driven by strong demand in oncology, immunology, and metabolic diseases. Biologics often present unique delivery challenges due to their high molecular weight, viscosity, and sensitivity to degradation. The result is rising demand for advanced DDS, such as large-volume autoinjectors and on-body injectors for SC administration, that can accommodate these characteristics while enhancing the patient experience.

Global Number[1] of Initiated[2] Clinical Trials by Top 10 Therapeutic Areas and Phase[3] (2020-2025)



Abbreviations: CNS: central nervous system; CV: cardiovascular; GI: gastrointestinal; MS: musculoskletal. Sources: GlobalData; Alira Health analysis.

Note: [1] Planned, suspended, terminated, and withdrawn clinical trials were excluded; [2] Trials with start date between 01/01/2020 and 16/09/2025; [3] Phase I/II trials were counted as Phase I trials; Phase I/II trials were counted as Phase II trials; Phase III/IV trials were counted as Phase III trials; Phase 0 and IV trials were excluded; [4] Others include women's health; genitourinary system; hematological disorders; ophthalmology; mouth and dental disorders; undisclosed; genetic disorders; ear nose throat disorders; hormonal disorders; toxicology; other diseases; nutritional disorders; non-malignant disorders.

The GLP-1 Market Boom

The rise of GLP-1 receptor agonists is a prominent example of how therapeutic innovation is reshaping DDS demand. These drugs were initially developed for Type 2 diabetes but have emerged as game changers in obesity treatment, thanks to their dual impact on glucose regulation and appetite suppression.

Most GLP-1 agonists are administered parenterally via weekly injections, with approximately 80% of pipeline programs relying on injectable delivery. This creates a major opening for DDS providers to play a pivotal role in enabling and scaling these therapies. Four strategic opportunity areas are emerging:

> **Opportunity to scale proven platforms:** The GLP-1 surge is creating unprecedented demand for large-scale, reliable manufacturing. This presents a major opportunity for DDS providers with pre-validated, off-the-shelf autoinjector platforms, who can scale rapidly and cost-effectively to meet soaring volume needs.

> **Opportunity for differentiation through custom design:** Pharma clients also seek bespoke delivery devices to match unique formulation needs or stand out in an increasingly competitive GLP-1 landscape. This sustains demand for DDS providers with strong design, engineering, and customization capabilities.

> **Opportunity to shift toward intellectual property (IP) ownership:** Pharma companies are more open to delivery partners that bring proprietary technologies rather than operating solely under CMO/ CDMO models, given the high value and margins of GLP-1 therapies. DDS providers pursuing their own IP strategies can secure stronger differentiation, long-term client retention, and higher value capture.

> **Opportunity to grow across the value chain:** The GLP-1 wave is driving significant expansion across the drug delivery value chain, with suppliers pursuing strategies that include scaling manufacturing capacity, investing in advanced fill–finish and ready-to-use component capabilities, securing long-term supply agreements, and expanding assembly and packaging infrastructure.

Impact of Oral GLP-1s

Oral GLP-1s represent a growing threat to the DDS market due to their potential for greater convenience and adherence, although injectables are expected to remain dominant. Innovation in oral peptide formulations has accelerated, with 12 oral GLP-1 drugs in Phase III trials or pre-registration as of 2025. Both Novo Nordisk and Eli Lilly are advancing oral versions of GLP-1, and active pharmaceutical ingredients CDMOs are ramping up their oral formulation capabilities to complement injectable offerings.

Global Pipeline of Phase III/Pre-registration Oral GLP-1 Drugs

Company	Drug	Highest Development Phase	RoA	Indication	Geography
Eli Lilly	Orforglipron calcium	Phase III	Oral	Hypertension, obesity, obstructive sleep apnea, overweight, type 2 diabetes	Global, US, EU, Japan, China
Novo Nordisk	Semaglutide	Phase III/Pre-registration	Oral; Subcutaneous	Alzheimer's disease, dementia associated with Alzheimer's disease, mild cognitive impairment, diastolic heart failure (HFpEF), obesity, overweight, type 2 diabetes	Global, US, EU, Asia-Pacific; China; South Korea, Thailand
BrightGene	BGM-0504	Phase III	Oral; Subcutaneous	Obesity, overweight, type 2 diabetes	Global, China
Gan & Lee Pharmaceuticals	Bofanglutide	Phase III	Oral; Parenteral; Subcutaneous	Obesity, overweight, type 2 diabetes	China
Hangzhou Jiuyuan Gene Engineering	Semaglutide	Phase III	Oral; Subcutaneous	Obesity, type 2 diabetes	China
Huadong Medicine	HDM-1002	Phase III	Oral	Obesity, overweight, type 2 diabetes	China
Jiangsu Hengrui Pharmaceuticals	HRS-7535	Phase III	Oral	Obesity, overweight, type 2 diabetes	China
Jiangsu Hengrui Pharmaceuticals	HRS-9531	Phase III/Pre-registration	Oral; Subcutaneous	Obesity, overweight, type 2 diabetes	China
Sihuan Pharmaceutical Holdings Group	Semaglutide biosimilar	Phase III	Oral; Parenteral	Obesity, overweight	Global
Suzhou Wingtech Pharmaceutical Technology	VCT-220	Phase III	Oral	Obesity, overweight	China
Uni-Bio Science Group	Uni-E4	Phase III	Oral; Parenteral	Type 2 diabetes	China
Viking Therapeutics	VK-2735	Phase III	Oral; Subcutaneous	Obesity, overweight	Global

Note: As of September 2025.
Sources: GlobalData; Alira Health analysis.

Pharma’s Requirements for DDS in 2025

Pharma and biotech companies are redefining what they require from DDS, given the forces in the global healthcare landscape and in the pharmaceutical market that are driving the need for DDS. CDMOs are now expected to support broader strategic priorities beyond ensuring safe and effective administration:

- Accelerated research and development (R&D) timelines
- Minimized development risks and costs
- Maximized product value to improve uptake and pricing

These priorities are shaping a new set of requirements for DDS players, emphasizing usability, connectivity, flexibility, scalability, and the ability to deliver measurable clinical and economic value.

Accelerate R&D Timelines Through Evidence Generation

Pharma increasingly expects DDS to play an active role in expediting R&D and clinical development timelines, particularly in decentralized or hybrid trial models. Delivery systems should capture usage and adherence data directly from the patient, such as time of administration or dose accuracy, to reduce reliance on patient-reported diaries, strengthen protocol compliance, and allow earlier identification of trial risks. Connected devices that transmit timestamped data to sponsors can help streamline trial operations, shorten timelines, and improve the robustness of regulatory submissions.

Minimize Development Risks and Costs by Proving Clinical and Economic Value

DDS must generate robust real-world data that demonstrate therapeutic performance and cost-effectiveness early in the development process to reduce uncertainty and control costs before market entry. Capturing metrics such as adherence, dose accuracy, and patient-reported outcomes during late-stage trials can help de-risk regulatory submissions, strengthen pricing and access dossiers, and avoid costly delays. Wearable technologies, such as smart patches or connected injection devices, can provide objective usage and health data, supporting protocol compliance, identifying risks sooner, and minimizing the need for expensive trial extensions or trial redesigns.

Maximize Product Value Through Superior Usability and Patient Experience

Pharma is turning to DDS partners that can enhance ease of use and patient satisfaction as a competitive differentiator, given that therapeutic efficacy is often comparable across competing drugs. Devices must facilitate self-administration, especially for patients managing long-term treatments at home or those with physical impairments. Features such as ergonomic designs, intuitive interfaces, tactile or auditory feedback, or voice assistance can increase confidence and adherence. Advances such as finer-gauge needles and smoother injection profiles are also improving comfort, critical for high-volume or frequent dosing regimens.

In response, pharma is gravitating toward partners that offer integrated services across the drug-device continuum, from formulation and design to clinical-scale manufacturing and supply chain optimization. These partnerships reduce handoffs, accelerate timelines, and ensure continuity from development to commercialization, enabling faster launches, reduced risks, and greater market impact for pharma.

DDS Market Trends

Companies should consider a variety of trends within the DDS market, especially with the powerful forces shaping the demand for DDS today. These trends share common goals: flexibility in how care is delivered, relief of the burden on the healthcare system, and, vitally, an improved patient experience that leads to better compliance and retention.

This chapter covers the following DDS market trends:

- Evolution to digital DDS
- Focus on sustainable DDS
- Move towards patient-centricity
- Shift toward LVSC administration
- Shift to platform autoinjectors over bespoke solutions

Evolution to Digital DDS

DDS are evolving from standalone mechanical tools into integrated digital health solutions, driven by rising expectations from patients, payers, regulators, and pharmaceutical companies. Today's DDS must go beyond drug administration to enable features such as digital reminders, real-time data capture, personalized patient support, and remote care integration.

Smart DDS technologies, such as connected autoinjectors, are gaining traction for their ability to monitor treatment adherence, improve dosing precision, and enhance overall safety. As digital health becomes more deeply embedded across therapeutic areas, its impact on the DDS landscape is expected to grow significantly.

This chapter examines the evolution of DDS into connected, data-driven platforms and analyzes a key strategic choice for developers—whether to build digital capabilities in-house or partner with specialized connectivity providers to accelerate innovation and integration.

Key Drivers in Digital Solutions Demand

Powerful forces are propelling the shift toward digital DDS, including potential clinical value, data utility, and remote care enablement, although the growing burden of autoimmune, chronic, and allergic diseases remain core market drivers.

Growing interest in digital solutions

The healthcare ecosystem is becoming increasingly digitized, creating a more receptive environment for advanced drug delivery technologies such as connected autoinjectors. These devices can be integrated into broader digital health platforms to support more holistic and personalized patient care.

Increase in self-administration of treatments

Demand is growing for intuitive, self-injection devices because more conditions are now managed at home without direct healthcare supervision. Autoinjectors in particular are valued for their ease of use, safety, and patient-friendliness. Added connectivity features, such as real-time guidance, notifications, and adherence reminders, further support this trend.

Emphasis on real-world data

Digital DDS can capture valuable real-world data, including adherence patterns, symptom evolution, injection timing, and dosage accuracy. This data supports treatment personalization, post-market surveillance, and generation of real-world evidence to substantiate clinical and economic value. Such evidence can facilitate regulatory approvals (e.g., the Food and Drug Administration and the European Medicines Agency) and improve market access through health technology assessment and reimbursement processes.

Rising patient engagement and empowerment

Digital devices offer feedback, visual confirmation, and treatment tracking tools that improve user confidence and create a stronger sense of control. This enhances long-term adherence and may improve outcomes, especially in chronic diseases requiring regular self-injection.

Improved dosing accuracy

Digital DDS can enhance accuracy through electronic dose control and automatic logging for each administration. This information, when synced with mobile apps or connected platforms, supports safer treatment management by helping patients follow correct dosing schedules and alerting caregivers or physicians to potential issues, reducing the risk of under- or overdosing.

> While miniaturized sensors and connectivity technologies have been available for years, effective integration into drug delivery devices requires the design of a complete connected ecosystem, one that considers every phase of the product lifecycle, from manufacturing and distribution to patient use and end-of-life management."
>
> **Riccardo Butta, President of Health Solutions**

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Digital Solution Demand Across Therapeutic Areas

Therapeutic areas with high adherence challenges and long-term self-administration needs, such as diabetes, GLP-1 therapies, pediatric growth disorders, and chronic injectables for rare diseases, have seen the greatest adoption of digital DDS. These indications often benefit from existing digital infrastructure (e.g., glucose sensors, connected inhalers) and are supported by reimbursement models that recognize the value of engagement tools and real-world data. Connected DDS enhance outcomes in these cases by improving adherence, enabling tracking, and supporting evidence generation.

Digital tools are less widespread in oncology, acute care, or breakthrough therapies, where strong clinical efficacy remains the primary driver of adoption. The market impact of digital DDS remains limited in other therapeutic areas, with adoption progressing slowly and selectively. Barriers include:

- Regulatory and reimbursement uncertainty (especially for connected components and Software as a Medical Device)
- Limited interoperability with healthcare IT systems, complicating data integration
- Usability challenges and low digital literacy in some patient groups
- Insufficient provider training and incentives to recommend digital DDS
- Evolving standards for data privacy and cybersecurity
- High upfront investment requirements paired with unclear ROI or lack of payer support

Adoption of digital DDS remains highly indication- and use-case-specific, although pharmaceutical companies increasingly view connectivity as a critical element of the future of drug delivery. Technological innovation is essential but not sufficient; business model innovation is key to unlocking digital value. The market, however, still lacks robust, sustainable business cases that clearly demonstrate cost savings and measurable health outcomes strong enough to convince payers to justify price premiums. This underscores the urgent need to demonstrate the value of digital health solutions.

> The main challenge in achieving widespread adoption is not technological but strategic: ensuring patient-centricity and aligning the perceived value for patients, caregivers, healthcare providers, and payers with the total cost, usability, and outcomes of connected solutions. In essence, connectivity must be purposeful, driven by meaningful improvements in patient experience, adherence, and clinical impact rather than by technology alone."
>
> **Riccardo Butta, President of Health Solutions**

Strategic Decision: In-house Development Versus Outsourcing Connectivity Solutions

DDS providers face a strategic decision as digitalization becomes more central to drug delivery: whether to develop connected DDS capabilities in-house or collaborate with external partners.

Most organizations lack the agility and resources to manage the rapid iteration cycles required for digital development. A growing number of companies is beginning to partner with digital health and electromechanical specialists to accelerate timelines, reduce costs, and streamline integration into broader digital health ecosystems, rather than building internal capabilities. DDS players typically retain control over core hardware components in these collaborations to ensure reliability and compliance, while outsourcing or co-developing the digital and connectivity layers to tap into external innovation and modular design.

For example, Ypsomed, a player embracing these platform-based strategies, retains control over hardware and device IP, including connectivity features, while partnering with companies like Sidekick Health to provide software development and integrate digital layers onto its connectivity-ready injectors.

> At Ypsomed, we keep the device development in-house, including the connectivity enabled by the hardware. However, the software layer is not developed internally. For that, we collaborate with partners like Sidekick Health to build the upper layers of the digital ecosystem."
>
> **Olga Matveeva, Strategy and Business Development Lead**

This modular approach enables flexibility in tailoring the digital experience to different therapeutic areas and user needs, while allowing pharmaceutical clients to define use cases, such as adherence monitoring or patient engagement, later in the development process. This strategy supports adaptability as demand for remote monitoring, real-world evidence, and patient-centric care continues to grow.

Many pharma and DDS players teams still embark on digital initiatives without clearly defined use cases or commercial models. Connectivity should be viewed not merely as a technical enhancement, but as a strategic capability in order to deliver meaningful value. This requires a shift in mindset: defining connectivity objectives early in development, aligning them to measurable outcomes, and ensuring they support broader clinical, economic, or patient engagement goals. Achieving this often means investing in modular, reusable architectures and collaborating with partners that bring both engineering and digital expertise. Interoperability with broader health systems is equally critical to ensure long-term relevance and seamless integration.

Ultimately, digital should be embedded not just within the device, but intentionally across the product and go-to-market strategy to differentiate therapies, enhance outcomes, and drive sustained treatment value.

> Until now, there's been no viable device platform that makes connected, sustainable delivery affordable at scale. Digital and reusable devices were always more expensive. That's where we can make it better for patients, better for payers, and better for the planet."
>
> **Patrick Anquetil, CEO**

Pharma's Growing Focus on Sustainable Drug Delivery Systems

Pharma companies are under growing pressure to embed sustainable practices across the entire DDS lifecycle, driven by regulatory mandates, market expectations, and corporate environment, social, and governance (ESG) commitments. Industry leaders are pioneering strategies to reduce environmental impact, with a strong focus on reusability, even for autoinjectors, which are mostly disposable. Manufacturers are increasingly developing reusable formats that help cut waste and are becoming an important design consideration. These efforts respond not only to sustainability goals but also to evolving regulations and payer demands that increasingly favor low-waste, recyclable, and reusable solutions.

This chapter explores how regulatory mandates, payer expectations, and corporate ESG goals are pushing pharma to adopt sustainable DDS strategies while focusing on reusability, material reduction, and energy efficiency across the whole lifecycle.

Key Drivers: Regulatory Pressure, Payer Expectations, and Corporate ESG Goals

Mounting regulatory mandates, shifting consumer preferences, and corporate ESG commitments are accelerating the adoption of sustainable practices across the DDS lifecycle. These forces are driving companies to rethink materials, packaging, and manufacturing processes to improve recyclability, reduce environmental impact, and enhance circularity.

> **Recyclability mandates under the Packaging and Packaging Waste Regulation:** The European Union recently adopted the Packaging and Packaging Waste Regulation, which mandates that pharmaceutical packaging materials meet recyclability requirements by 2035. Additional pressure is building through the growing inclusion of sustainability criteria in national service tenders, although primary pharmaceutical packaging is currently exempt from certain measures like national "plastic taxes."

> **Extended producer responsibility regulation:** Worldwide governments are incentivizing pharmaceutical manufacturers to adopt sustainable practices through the implementation of extended producer responsibility policies, which shift responsibility upstream, either physically or economically, to producers rather than to municipalities, and provide incentives for producers to integrate environmental considerations into product design.

> **Shift in consumer preferences:** The trend, particularly among younger generations, is towards favoring sustainable solutions and incorporating sustainability as a key decision criterion in their consumption choices. This trend is especially noticeable in over-the-counter drug purchasing decisions, where an increasing number of individuals are opting for eco-friendly solutions. The Rx end-market, however, is anticipated to remain unaffected, as patients have no decision-making authority over the drug prescribed to them.

> **Pharma missions to reduce their footprint:** Pharmaceutical companies are increasingly integrating environmental stewardship into their corporate missions by setting goals to reduce their carbon footprint and eliminate polluting materials. This translates into optimizing product design, manufacturing processes, and supply chain operations to minimize environmental impact, while ensuring that safety and quality remain uncompromised.

Companies are now required to track a focused set of metrics to measure and improve sustainability performance across the DDS lifecycle:

> **Carbon footprint:** CO_2 emissions from raw material sourcing to end-of-life disposal, guiding strategies to reduce climate impact

> **Material sustainability:** Environmental profile of materials, including durability, recyclability, and renewable sourcing, to inform design and procurement decisions

> **Process efficiency:** Resource use (water, energy, chemicals) and waste generation in manufacturing, driving continuous improvement and regulatory compliance

> The greatest sustainability gains today come from improving manufacturing processes rather than changing raw materials, including transitioning to electric molding machines, sourcing 100% renewable energy, and investing in energy-efficient equipment."
>
> **Massimo Carrara, CEO**

Strategic Decision: How to Meet Sustainability Goals

Companies are deploying targeted strategies across the DDS lifecycle to achieve tangible sustainability gains.

Sustainability efforts focus on designing devices during the R&D phase for reuse, durability, and minimal material use to extend lifespan and reduce waste. Successful strategies include formulating higher-concentration drugs to deliver more doses per device, applying platform approaches or in-silico modeling to limit physical testing and material waste, and creating modular device architectures that can be adapted across multiple therapies, reducing the need for entirely new production runs.

The focus shifts during development, manufacturing, and supply chain stages to improving energy efficiency, optimizing logistics, and reducing material waste. This includes refining packaging and transport to cut energy use, enhancing device storage and maintenance for greater efficiency, and adopting supply chain innovations to lower carbon emissions. Practical measures range from using electric molding machines and energy-efficient delivery vehicles to optimize distribution hubs, employing reusable transport containers, and introducing lightweight packaging that minimizes material use without compromising product integrity. Industry leaders see reusability as the most realistic path forward, with cost-effective reusable injectors acting as a foundation for broader sustainability efforts and digital integration.

These considerations are particularly relevant in addressing the growing sustainability challenges associated with single-use pre-filled syringes for injectable GLP-1 treatments. Applying sustainability levers in this context has highlighted several priority areas:

> **Reducing plastic reliance:** Exploring alternative materials and improving recycling potential, as single-use pre-filled syringes rely heavily on plastics.

> **Expanding multi-injection solutions:** Designing devices that enable multiple doses per unit, lowering disposable material use and environmental impact.

> **Advancing new formulations:** Developing long-acting injections, such as hydrogels, to reduce injection frequency and associated waste.

Sustainability also extends to support activities, where efforts focus on engaging patients, regulators, and market stakeholders to promote responsible DDS use and end-of-life management. Many companies promote patient take-back and recycling programs, but while appealing in theory, they remain costly and difficult to scale without regulatory mandates. Pharma must therefore develop economically viable sustainability strategies, with greener solutions advancing gradually, driven more by regulation or clear incentives rather than by internal demand alone.

> R&D teams are increasingly guided by clear sustainability KPIs, and the technical capabilities to deliver are well established. Among pharmaceutical partners, it is often the pioneers who recognize sustainability as a strategic value driver, beyond compliance. Broader adoption of this perspective holds the potential to accelerate and expand innovation across the sector."
>
> **Olga Matveeva, Strategy and Business Development Lead**

The Shift Toward Patient-Centric DDS

DDS are becoming increasingly patient-centric as digital solutions evolve. Sustained engagement requires not only embedding these devices within broader digital health ecosystems but also designing them around the needs of their end users: patients and caregivers.

This chapter explores how DDS are evolving toward greater patient-centricity, driven by the need for higher usability and patient empowerment. It also examines how companies can align their commercial strategies with patient needs through co-design, usability engineering, and patient journey insights.

Key Drivers: Usability, Patient Empowerment, and Engagement Needs

Multiple forces are pushing DDS toward greater patient centricity, making devices more intuitive, clinically relevant, and empowering. These forces include:

> **High usability and intuitive design:** Devices that are easy to use and centered around the patient are critical for maintaining high engagement and long-term adoption. Poor usability, characterized by complex interfaces, burdensome data entry, or multi-step, time-consuming processes, remains a leading cause of disengagement.

> **Perceived usefulness and clinical relevance:** Patients are more likely to remain engaged when DDS deliver clear value, such as actionable insights, better disease management, or improved outcomes. Clinical evidence generated from collected data strengthens trust in the system, supports continued use, and helps reduce dropout.

> **Rising expectations for engagement and empowerment:** Modern patients expect more than passive monitoring; they seek active engagement through personalized feedback, bidirectional communication, and seamless integration with other health tools. DDS must support self-management and shared decision-making to meet these expectations.

> **Shift toward home-based care:** The trend toward outpatient and home-based care is empowering patients to take greater control of their treatments. DDS technologies must adapt by enabling safe, effective, and convenient self-administration outside clinical settings.

Dropout rates for DDS, particularly digital solutions, still range from 35% to 65% despite these drivers. The challenges include limited perceived value, high user effort, and lack of meaningful interaction. Addressing these barriers requires patient-centric designs grounded in three principles: usability (ease of use), usefulness (clinical benefit), and utility (system-wide value).

> Usability, patient preference, and low complaint rates are major drivers, not just for patient satisfaction, but also for manufacturers looking to control costs."
>
> **Markus Puusepp, Chief Growth Officer**

Strategic Decision: How to Align Commercial Strategy With Patient Needs

Companies aiming to develop a successful commercial strategy aligned with patient requirements need to embrace co-creation and co-design with patients at every stage of the DDS lifecycle.

Companies in the early R&D phase should take a systematic and interdisciplinary approach to gain a deep understanding of patients' needs and preferences, while identifying challenges and opportunities. Companies can create impactful digital and physical solutions by applying design thinking principles to address key pain points in utility, usability, desirability, and strategy. This approach positions patients and other stakeholders as active decision-makers, ensuring that unmet needs directly inform product and service design.

Design research should be complemented by usability engineering, conducted in line with international standards and regional regulations. This process generates objective data demonstrating the safety and efficacy of DDS, mitigating risks caused by human factors. It is essential not only for regulatory approval but also to improve user experience, patient preference, and long-term retention.

Companies can build engagement and retention strategies in the later development stages using insights from in-depth patient journey analyses. These strategies can be tailored to address key pain points, driving higher retention and maximizing adoption of digital solutions. Systematic identification of behaviors to modify, maintain, or develop ensures that engagement approaches directly target patient needs, reducing dropout rates, and sustaining adherence.

> "As the industry continues to advance toward more patient-centric design, there is a growing need to accelerate the journey from concept to clinic, enabling safer and more effective biorreabsorbible therapies for patients. In this context, biomaterials represent an opportunity to create delivery platforms that minimize intervention, enhance comfort, and improve the overall patient experience."
>
> **Marc Hendriks, Vice President of Corporate Development**

> "As the delivery of healthcare continues to transition from formal HC settings to the home, user-centricity and the ability to successfully self-administer medications becomes more and more critical. At the same time, formulations are becoming more complex as drug developers struggle to co-formulate and achieve liquid stable formulations. To serve this need, we will see the rise in prevalence of those Dual Chamber Systems that allow drug constituents to be kept separate during storage in one container and then administered simply with dose accuracy and safety."
>
> **John A. Merhige, Chief Commercial Officer**

Another example of patient-centric design in practice comes from Terumo, a leading developer and manufacturer of medical devices with patient comfort and treatment accuracy always in mind. Its recently introduced Injection Filter Needle illustrates how application-centric considerations are being embedded directly into device engineering:

> Patient-protection-first design: An embedded 5 µm mesh filter reduces the risk of particulate contamination, critical in sensitive procedures such as intravitreal injections, where complications can lead to vision loss.

> Enhanced patient comfort: Terumo's K-Pack II needles with a 30G extra-thin wall cannula show lowering of injection force at a significant level—targeting to increase user and patient comfort—acknowledging present risks such as subconjunctival hemorrhage.

> Precision and reliability: Threaded hubs and aseptic blister packaging are design examples with the target to enable consistent and efficient administration, particularly with prefilled syringes.

Terumo's approach shows how device innovation is moving beyond pure functionality toward patient-centric outcomes, aligning with broader industry trends focused on minimizing complications, enhancing usability, and supporting long-term adherence in sensitive treatment areas.

Shift Towards LVSC Administration in DDS

Drug delivery is transforming as the industry shifts from traditional IV administration to SC and, increasingly, LVSC delivery. While IV administration remains standard for many therapies, advances in formulation science and wearable injection technologies now allow higher-volume, more viscous biologics to be administered safely and comfortably beyond clinical settings. LVSC delivery is becoming a cornerstone of next-generation therapeutic administration—combining clinical efficacy, patient centricity, and economic efficiency.

This chapter explores the industry's transition from IV to SC and LVSC delivery, highlighting how advances in biologics and wearable injectors are enabling safer, more convenient, and cost-efficient treatment outside clinical settings.

Key Drivers: Growth of High-Volume Biologics and Home-Based Care Models

IVs, while remaining standard for many biopharmaceuticals, often require administration in acute care settings due to safety concerns and long infusion times. This creates significant logistical, time, and resource burdens on both healthcare systems and patients. SC administration is emerging as a viable alternative to address these challenges, offering shorter administration times, lower costs, and greater flexibility in care delivery. SC delivery models can shift care away from hospitals by enabling treatment in outpatient or home settings, reducing strain on healthcare systems while offering patients greater convenience and autonomy.

The scope of SC administration is building on these advantages, expanding as both drug formulations and patient expectations evolve. Many therapies, such as apomorphine, still rely on daily, time-consuming pump infusions that burden patients and healthcare providers and can cause skin reactions. New wearable autoinjectors, by contrast, can deliver large volumes subcutaneously without wiring or tubing, improving comfort, mobility, and convenience. These innovations, combined with advances in biologics that enable higher injection volumes and more viscous formulations, are driving demand for less frequent, high-volume doses outside clinical settings. Together, these trends underpin the rise of LVSC delivery as a practical and patient-centric alternative to traditional infusion.

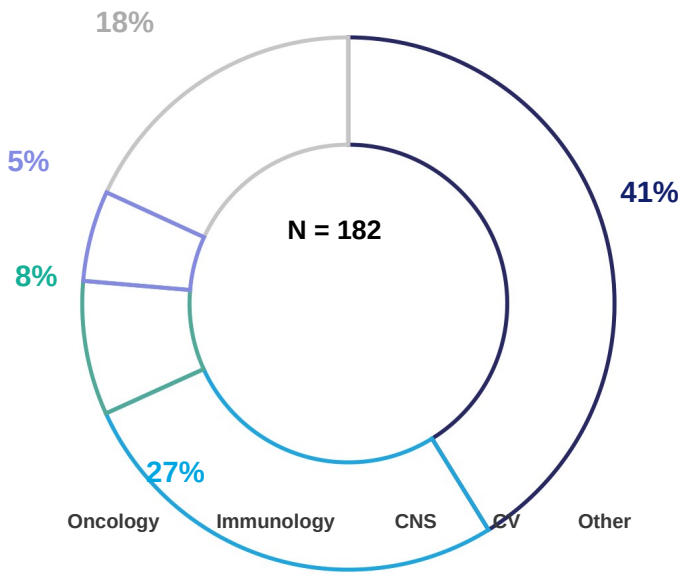
> The market used to believe you couldn't go beyond 1 mL. Now, we're seeing 2.25 and even 3 mL becoming the norm. The market's shifting fast, and even mid-trial programs are rethinking delivery because patients and payers want it simpler."
>
> **Markus Puusepp, Chief Growth Officer**

Strategic Decision: Transition to SC and LVSC

This evolution reflects an industry shift, with pharmaceutical companies strategically adopting delivery systems that combine higher-volume capacity with ease of use. Companies aim to improve convenience, strengthen adherence, and enhance overall treatment efficiency by moving away from multiple smaller doses toward LVSC, especially as biologic therapies grow more complex and patient-friendly administration becomes a priority.

In 2024, about 15% of all approved or clinical-stage IV and SC biopharmaceuticals were LVSC agents, primarily monoclonal or bispecific antibodies. These target predominantly cancer (41%) and autoimmune conditions (27%). Most therapies fall within the 2–20 mL range, with nearly half (44%) concentrated in the lower 2–5 mL tier.

Therapeutic Areas for Approved and Clinical-stage Anti-cancer and Non-cancer LVSCs, 2024



Sources: Green, P., Schneider, A., & Lange, J. (2024). Navigating large-volume subcutaneous injections of biopharmaceuticals: a systematic review of clinical pipelines and approved products. mAbs, 16(1); Alira Health analysis.

Non-cancer LVSCs, such as those for asthma, inflammatory bowel disease, and migraine, are generally within the 2–5 mL range, aligning with handheld autoinjector capabilities for at-home use. In contrast, most cancer LVSCs fall within the 5–20 mL range and often still require administration in hospitals by healthcare professionals. The push toward home-based cancer care, however, is accelerating demand for user-friendly LVSC delivery solutions that can ensure safety and precision outside clinical settings.

> As the LVSC pipeline advances, it's reshaping the landscape of drug delivery—bringing new complexities that demand innovative, patient-centric solutions. We believe this evolution calls for close collaboration across the industry, combining translational and usability insights to support successful, scalable commercialization."
>
> **Patrick Jeukenne, WW President, Pharmaceutical Systems**

Several challenges still limit LVSC delivery's broad adoption, despite it gaining traction. Companies are responding with a mix of formulation innovation and device design strategies, including:

- **Limited evidence on safe dosing:** Evidence on patient tolerability thresholds for injection volume and frequency remains limited, making it difficult to define best practices. Market players are conducting clinical studies and collecting real-world data to establish safe dosing ranges and support integration into routine care.

- **Extended dosing intervals:** Larger SC doses are required as some therapies move toward longer intervals (e.g., every four to six weeks), increasing device design complexity. Companies are developing large capacity autoinjectors and wearable injectors that can reliably handle higher volumes to address this issue.

- **High-viscosity formulations:** Increasing drug concentration reduces injection volume but raises viscosity, making delivery more challenging and potentially uncomfortable. Companies are advancing modular platforms to overcome this, with configurable needles, shorter and wider designs to lower injection force, and high-force autoinjectors capable of delivering viscous formulations without compromising patient comfort.

- **Oncology care complexity:** Cancer patients often undergo combination therapy with IV chemotherapy or radiotherapy, requiring infusion-center visits that diminish the value of at-home SC options. Companies are exploring the feasibility of at-home administration for selected anticancer agents, supported by new delivery technologies designed for safe self-injection.

Shift to Platform Autoinjectors Over Bespoke Solutions

Drug delivery strategies are evolving as pharmaceutical companies increasingly favor platform-based autoinjectors over bespoke designs developed for single therapies. While bespoke designs remain essential for highly specialized or novel formulations, platform approaches are becoming the preferred choice, driven by the growing need for speed, scalability, and cost efficiency. As biologic and biosimilar pipelines expand and competition intensifies, standardized platform solutions offer a faster, more predictable, and lower-risk path to market through pre-validated, modular configurations.

This chapter explores pharma's shift toward platform-based autoinjectors and examines the strategic choice facing the DDS industry: whether to adopt off-the-shelf platform solutions or develop bespoke devices to balance speed, cost, and differentiation.

Key Drivers: Expanding Pipelines, Market Speed Pressures, and Cost Constraints

Pharmaceutical companies must carefully evaluate the trade-offs between bespoke solutions for autoinjectors, which involve creating a new device fully tailored to a specific therapy, and platform-based solutions, which leverage predefined components and design frameworks that can be adapted to the drug's characteristics.

The choice is rarely straightforward. Several drug- and patient-related factors shape the decision, including (but not limited to):

- Whether the therapy is an originator biologic or a biosimilar
- The stage of the biologic's development
- The primary container used (pre-filled syringe vs. cartridge)
- The formulation's viscosity and associated requirements for injection force
- The fill volume and intended dosage volume, which can affect both device size and usability
- The target injection time, balancing patient comfort and device performance
- End-user characteristics such as age, disease state, and injection habits, which strongly influence usability requirements

The industry is shifting toward platform-based autoinjectors across the DDS landscape. Pharma companies are prioritizing these solutions over bespoke devices, driven by several factors:

- **Competitive intensity and the race for speed:** Platform-based autoinjectors significantly reduce development and regulatory timelines by leveraging pre-validated designs that companies can rapidly customize for new drugs. This accelerated approach enables companies to respond quickly to competitive pressures and capitalize on first-to-market opportunities, particularly in fast-moving segments like GLP-1s and biosimilars.
- **Biologics pipeline growth and chronic disease prevalence:** The rapid increase in biologic drugs, many of which require self-injection for chronic diseases like diabetes, obesity, and autoimmune conditions, has created a strong need for platform-based approaches. These platforms can efficiently accommodate similar dosing and enable rapid scaling of production to meet high-volume needs, giving manufacturers a competitive advantage.
- **Cost efficiency and risk reduction:** Platforms with commercial track records are viewed as de-risked solutions, offering regulatory and technical confidence to pharmaceutical partners. Platform-based development helps companies control costs and reduce financial and regulatory risks by minimizing device-specific R&D and manufacturing investments.
- **Patient preference and usability:** A strong market shift toward patient-centric, at-home care and self-administration is underway, particularly for chronic conditions. Platform autoinjectors are designed for intuitive use, safety, and improved adherence, making them highly favored by both patients and healthcare systems.

In addition, supply chain simplification, modular R&D strategies, and the growing potential for digital integration further reinforce the appeal of platforms. These factors explain why platform-based autoinjectors are becoming the default choice for many pharmaceutical companies. The clear industry direction is toward standardized, cost-efficient, and rapidly deployable platform solutions, although bespoke devices remain relevant for highly differentiated therapies or novel formulations.

> The market has certainly shifted from bespoke, single-drug injectors to more flexible platform-based devices that support multiple therapies with varying levels of customization."
>
> **Massimo Carrara, CEO**

Strategic Decision: Off-the-Shelf Platform Versus a Bespoke Solution

Platform autoinjectors (often referred to as “off-the-shelf” or OTS) come with predesigned concepts and established manufacturing capacity. They are pre-validated, scalable, and rapidly deployable across different therapies. These platforms typically offer multiple configuration options, enabling drug developers to customize features for specific therapies while avoiding the cost and time burdens of bespoke device development. Platform solutions lower barriers to entry for biosimilar manufacturers in particular by providing a proven, cost-efficient pathway to market.

Leading DDS players, such as SHL, have developed device platforms like autoinjectors that support customizable designs across a growing number of therapeutic areas where common requirements make standardized solutions viable. Platforms are widely used in cardiometabolic conditions such as obesity and diabetes, where large patient populations and similar dosing needs allow for rapid scaling. These platforms also support biosimilars, where speed-to-market and cost efficiency are critical, and are increasingly applied to autoimmune therapies with recurring self-administration.

To sustain this model, companies are pursuing several strategies:

> **Expand production capacity:** Investing in new state-of-the-art manufacturing facilities to scale output

> **Strengthen operational integration:** Ensuring seamless collaboration across global manufacturing sites

> **Evolve product development models:** Translating complex requirements into modular, scalable designs by applying digital modeling, systems engineering, and simulation capabilities

Platform autoinjectors deliver speed, cost efficiency, and scalability, but they are not without limitations. Platforms may restrict customization, risk competitive overlap (as multiple drugs may use very similar devices), and fall short in optimizing delivery for complex biologics. Platforms cannot always address unique requirements such as high viscosity, challenging injection forces, or highly patient-specific needs, despite ongoing innovation to design devices that can accommodate a wide range of formulations with minimal modifications.

> Pharma companies are increasingly opting for standardized platform devices like autoinjectors and pen injectors, prioritizing speed to market, lower risk, and reduced barriers to entry over bespoke designs.”
>
> **Adam Stops, Head of Drug Delivery Systems**

DDS Supply Chain Evolution and CDMO Integration Strategies

Pressures to reduce manufacturing costs, accelerate time-to-market, and improve productivity are reshaping the DDS value chain. Pharmaceutical companies are increasingly relying on device and drug product CDMOs not only to fill capability gaps but also to provide end-to-end solutions that span the entire drug–device continuum.
CDMOs are pursuing upstream and downstream integration in response, positioning themselves as strategic partners that enable efficiency, innovation, and competitive differentiation.

This chapter explores how pressures to cut costs, speed up launches, and boost efficiency are driving pharma to rely on integrated CDMOs. It also discusses how these partners are expanding upstream and downstream to deliver end-to-end drug–device solutions and strengthen supply chain resilience.

Outsourcing Models Across Pharma Segments for DDS

Device and drug product CDMOs play a critical role in supporting pharmaceutical companies, particularly as the DDS market becomes more complex and innovation-driven. But outsourcing strategies differ significantly depending on company size and internal capabilities.

Large and mid-size pharma

These companies typically maintain broad in-house capabilities across the drug-device value chain. However, they are increasingly looking for end-to-end solutions that minimize stakeholder management and streamline collaboration. They seek single partners, rather than coordinating multiple vendors, who can address specific capability gaps, such as electronics integration, device design, or digital enablement, while ensuring seamless alignment with internal operations. These partners also need to provide flexible production capacity, ranging from small-scale batches for niche or personalized therapies to large-scale commercial volumes, depending on the therapy area and commercialization strategy. Importantly, large and mid-sized pharma are increasingly willing to pay a premium for integrated CDMO solutions that enhance agility, reduce legacy inefficiencies, and strengthen competitive positioning.

Small pharma and biotech

Smaller companies typically lack in-house capabilities across the full drug-device development continuum and therefore need fully integrated CDMO support. They look for providers with ready-to-deploy capabilities that can accelerate time to market, reduce development and cost of goods sold, and enable scalability from early clinical supply to large-scale commercialization. Devices are not a marginal cost for these players but a critical driver of differentiation and market access. They rely on CDMOs for regulatory expertise, risk management, and the ability to scale production seamlessly as programs advance.

> Mid-sized pharma companies are increasingly seeking end-to-end partners that can complement their in-house capabilities with regulatory support, final assembly, labeling, and packaging. In contrast, smaller and niche players outsource nearly everything and depending on external expertise for regulatory and production scaling."
>
> **Markus Puusepp, Chief Growth Officer**

The scope of integration differs between these groups, although both are turning to CDMOs for strategic support. Large and mid-sized pharma companies generally target specific gaps and value optionality, whereas small pharma and biotech companies need comprehensive, holistic partnerships that cover the entire development and commercialization lifecycle.

Expanding Upstream and Downstream Integration

Device and drug product CDMOs are no longer viewed only as execution partners, but as outsourcing models evolve, they are seen as strategic enablers of time-to-market, cost efficiency, and innovation. These CDMOs increasingly pursue upstream and downstream integration to meet diverse customer needs and sustain competitiveness, effectively extending their role across the entire drug–device value chain. These players are positioning themselves as true end-to-end service providers by moving beyond their traditional core of manufacturing. This strategic shift enables earlier engagement in the product lifecycle, tighter control of supply chains, and greater operational efficiency. It allows these CDMOs to capture more value and become indispensable partners to pharmaceutical clients.

Key strategic approaches include:

- Upstream integration of customized designing and manufacturing services
- Downstream integration to expansion into drug product capabilities
- Integration of connectivity
- Acquisitions and strategic partnerships with pharma and biotech.

Upstream integration of customized designing and manufacturing services

Device and drug product CDMOs are accelerating upstream investments in vertical integration, including proprietary cell line development, media optimization, and standardized process platforms. They are embedding tailored design and manufacturing services in parallel, such as custom-built machinery, software, assembly and test benches. They are also deploying advanced digital tools, including AI-powered quality control systems, manufacturing execution systems, electronic batch records, and real-time release testing. Together, these capabilities enable earlier engagement with pharmaceutical clients, unlock large-scale manufacturing opportunities, and streamline supply chains for greater efficiency.

Example: Sanner Group's acquisition of Gilero LLC expands its global medical device offering, strengthening design, development, and contract manufacturing capabilities, while adding global-scale injection molding and growing its presence across the US, Mexico, and Ireland.

> The industry's shift toward upstream and downstream integration underscores the need for partners who can seamlessly unite design, development, and manufacturing. We see how this evolution is driving a focus on more sustainable approaches that connect precision engineering with global manufacturing expertise to enhance combination product development."
>
> **Ted Mosler, President**

Downstream integration to expansion into drug product capabilities

Device-focused CDMOs are expanding downstream by acquiring drug product specialists, moving beyond mechanical device manufacturing to offer a broader set of development and production capabilities. This integration is particularly relevant in specialty areas such as oral formulations and highly potent compounds, which are increasingly critical in oncology and rare disease markets.

Example: Terumo's acquisition of WuXi Biologics' drug product facility in Leverkusen, Germany, will mark its first CDMO site outside Japan, expanding regional fill–finish capabilities for vials and prefilled syringes and strengthening its position as an integrated CDMO offering end-to-end drug–device solutions.

> The acquisition of the drug product plant in Leverkusen is a pivotal step in enhancing the competitiveness of our CDMO business."
>
> **Hikaru Samejima, Chief Executive Officer**

Integration of connectivity

Device and drug product CDMOs are integrating digital health capabilities into their portfolios to remain competitive in a connected care ecosystem. This includes investments in electronics, software, cloud architecture, and data analytics to support connected drug delivery devices.

Example: Portal Instruments is collaborating with pharmaceutical partners to deploy PRIME NEXUS™, a reusable and connected injection platform that integrates electromechanical precision, AI-driven engagement, and real-time data capture. The system enables closed-loop feedback and reduces waste compared to single-use devices, positioning Portal as a key partner for companies seeking scalable, sustainable, and digitally enabled drug delivery solutions.

> The real value is not just in the device, it's in the data. By capturing usage and outcome data at the point of care, we can transform treatment, reimbursement, and adherence all at once."
>
> **Patrick Anquetil, CEO**

Acquisitions and strategic partnerships with pharma and biotech

Device and drug product CDMO players are also advancing integration through direct partnerships with pharmaceutical and biotechnology companies to co-develop innovative treatments, including gene and cell therapies, supported by specialized delivery platforms.

Example: Stevanato Group partnered with Thermo Fisher Scientific to develop a fully integrated on-body delivery system for SC administration.

> Supply chain integration has become critical. It started during COVID, when security of supply was a major concern, and as geopolitics evolve, robustness and security in supply chains are no longer optional but essential."
>
> **Adam Stops, Head of Drug Delivery Systems**

Conclusion

The DDS sector is undergoing a fundamental shift, shaped by the rapid growth of biologics, intensified competition across therapeutic areas and drug classes such as metabolic diseases (GLP-1 therapies) and biosimilars, and rising demands for patient-centric, sustainable solutions. DDS are no longer secondary to therapy; they are becoming core enablers of differentiation, market access, and adherence.

Pharmaceutical companies are increasingly turning to platform-based autoinjectors to accelerate time-to-market, manage costs, and reduce technical risk, while still seeking bespoke solutions for complex biologics requiring specialized delivery. CDMOs are evolving from tactical suppliers into strategic end-to-end partners at the same time, pursuing upstream and downstream integration to cover the full drug–device value chain. This shift enables earlier lifecycle engagement, tighter regulatory alignment, and more resilient supply chains, while offering pharma greater agility and scalability.

The winners in DDS will be those players that combine scalable platforms with flexibility, embed digital and sustainable principles into design and manufacturing, and operate as integrated partners to pharma and biotech. DDS leaders will play a decisive role in how effectively next-generation therapies reach patients and sustain competitive advantage in a fast-moving market by aligning innovation with speed, cost efficiency, and patient usability.

About Alira Health

Alira Health is a global healthcare consultancy that partners with life sciences companies to deliver patient-centered solutions. We generate and apply evidence across the product lifecycle through four integrated capabilities: CRO services, consulting, patient engagement training, and technology. Our approach helps clients improve access, adoption, and impact, guided by the voice of the patient.

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Giorgia Miglietta has extensive experience in strategy consulting in life sciences, advising medtech and pharma clients on corporate strategy, commercial due diligence, and product and portfolio innovation. Giorgia is the Co-Chair of Alira Health's Center of Excellence in Drug Delivery Systems and has led and supported more than 50 strategic engagements, guiding C-level decision makers on global growth opportunities, with a particular focus on drug delivery systems and enabling digital technologies. Giorgia holds a Master of Science in Management from Copenhagen Business School, with a major in innovation and entrepreneurship, as well as a Bachelor of Science in business economics from the University of Torino and ISCTE, University Institute of Lisbon.