windgapmedical

# PATIENT-CENTRIC DESIGN CAN BE A FASTER PATH TO MARKET

**Here, Brent Buchine, PhD, Chief Executive Officer at Windgap Medical, considers a faster path to market for automated and easy-to-use reconstitution devices through simplification of the delivery systems.**

Focusing on the patient and the delivery device system in Phase I clinical trials can speed up and simplify every phase that follows.

A drug is only as effective as its delivery system. Often what drives the necessary innovation of complex drug delivery devices are the challenges created by formulations. But this can be at the expense of a greater burden on the patients who depend on them.

## IS COMPLEX DRUG DELIVERY MORE COMPLICATED THAN IT NEEDS TO BE?

Complex, multicomponent injectables (powder and diluent) offer effective therapies across clinical conditions from cancer to Crohn's disease. However, when the drug administration process is also complex, it creates additional barriers to patient adherence, which may, in turn, have a negative impact on patient outcomes.

While the number and specific steps required for successful drug administration varies greatly for each complex formulation, most delivery systems have four critical administration protocols: kit preparation, dosage steps, a timed mixing window and injection considerations (Table 1).

Consider Alkermes' Vivitrol (naltrexone), a US FDA-approved prescription injectable therapy for opioid and alcohol dependence. Proven effective when administered regularly, Vivitrol has eight different pieces within its mixing kit – one dose requires 16 steps.[1]

> "Technological advances in drug delivery devices can improve quality, reduce cost and increase safety, access and adherence to many complex medications."

Alternatively, some injectable suspensions require up to 10 steps for their assembly, mixing and administration processes, have specific mixing instructions and must be administered at a 90-degree angle.

## A FASTER PATH TO MARKET – RIGHT FROM THE BEGINNING

Technological advances in drug delivery devices can improve quality, reduce cost and increase safety, access and adherence to many complex medications.

Historically, drug manufacturers have focused on developing the API before considering how best to deliver and administer it. Taking clinical and human

**Dr Brent Buchine**
Chief Executive Officer
E: bbuchine@windgapmedical.com

**Windgap Medical, Inc**
200 Dexter Ave #270
Watertown
MA 02472
United States

**www.windgapmedical.com**

| Prepare | Dose | Mix | Inject |
|---|---|---|---|
| 1. Remove from refrigeration.<br>2. Bring up to room temperature.<br>3. Open all internal packages.<br>4. Sterilise as needed. | 5. Prepare syringes and/or reconstitution vials (may have multiple steps).<br>6. Combine required components. | 7. Mix contents for the required time and in the required manner, until the appropriate suspension is achieved. There may be very specific instructions (e.g. "swirl the product gently" or "shake for at least 45 seconds" and multiple sub-steps). | 8. Select and attach the appropriate needle for the injection site.<br>9. Prepare the injection site.<br>10. Administer the entire contents of the medication.<br>11. Activate the needle sheath and dispose appropriately. |

Table 1: Example of complex drug delivery administration.

factors studies into consideration sooner can ease delays in regulatory approval and design reconfiguration.

For example, it is not uncommon for pharmaceutical companies to develop lyophilised (freeze-dried) formulations to get through their clinical trials and then reformulate a more user friendly liquid version of the product for commercial sale. This process adds years and increased risk to their programme as they innovate, engineer and test different drug delivery methods.

When innovative device design and human-factors engineering are considered as early as Phase I, drug delivery technology can be tailored to the unique characteristics of the drug and the unique needs of the patient. By taking the lyophilised product all the way through approval to market, pharmaceutical companies can create a differentiated device – and a competitive advantage – without the time, expense and testing required for reformulation.

As processes are increasingly automated across industries, replacing manual device assembly and administration processes with automated assembly improves accuracy, efficacy and adherence while reducing costs and chances for patient or HCP error.

Complex drug formulations and devices have high hidden costs along the entire value chain, from development and clinical trials to manufacturing and patient support. Paving a faster path to market is essential to getting better profits on the bottom line, and in getting better products into patients' hands.

## THE RISE OF PATIENT CENTRIC, NEXT-GENERATION AUTOINJECTORS

Lyophilisation, a freeze-drying technique for drugs and biologicals, offers many benefits for pharmaceutical companies and patients alike. Compared with liquid solutions, lyophilised drugs offer increased stability, temperature resilience and increased shelf life, virtually eliminating dependence on cold-chain logistics – even for notoriously unstable, large-molecule biologics.

In addition to these benefits, lyophilised drugs have paved the way for the rapid growth of depot injections. These extended-release medication formulations enable long-acting drug dosing, allowing patients to reduce a daily regimen of medication to a bi-weekly, monthly or longer interval with a single injection.

While they are designed to improve patient compliance and outcomes, depot formulations, like biologic formulations, are notoriously challenging to mix. The lyophilised drug "powder" must be stored separately and then dissolved or suspended in a liquid carrier just prior to administration. The process requires a substantial amount of time and medical training – and even with training, these complicated, multi-step processes introduce or increase the possibility of human error and environmental impact, which can result in an incorrect dose, a reduction in a drug's effectiveness or worse.


Figure 1: The ANDIPen® reduces the number of steps to two simple user operations: twist and inject. *(Windgap Medical's products are not commercially available or currently approved anywhere around the globe.)*

Figure 2: Windgap's side-by-side primary drug container with mixing and delivery hub.

Next-generation autoinjectors, such as the device technologies behind Windgap Medical's compact ANDIPen® (Figure 1) and its large-volume, dual chamber (LVDC) autoinjector (Figure 2), create an "instant solution" for pharmaceutical companies seeking a simple, stable and swift way to reconstitute lyophilised drugs.

Each of these two wet/dry dual-chamber autoinjector platforms automates rehydration and administration, simplifies complex reconstitution steps and allows the user to administer a dose in seconds.

As the FDA pushes for generic complex drugs, drug makers and device platform providers continue to develop new and adapted drug delivery systems to lower the cost of these medications while meeting the changing needs of the industry and the real-life needs of patients (Box 1).

## EFFECTIVE DRUG-DEVICE COMBINATIONS START WITH PATIENTS

Injectable formulations are the fastest-growing segment in the pharmaceutical industry. According to Precedence Research, the global injectable drug delivery market reached US$561 billion (£462 billion) in 2021 and is expected to surpass $1,224 billion by 2030.[3]

The FDA defines these complex drug-device combinations as devices in which the drug constituent is preloaded into a device specifically designed for the product. In real-life applications, these drug-device combinations are designed specifically for something else entirely – the patient. In the case of injections, drug-device combination products may simplify the regimen from an intravenous or a multi-component kit (as described above) to a patient-friendly self-injection.

Many current drug delivery solutions include special features designed to ease self-dosing, promote active lifestyles and support digital health monitoring. For instance, an abundance of personalised patient adherence data has been able to drive technological advancement across the pharma industry, such as electronic pillboxes, smart bottles that provide reminders to patients and smart caps for insulin injection pens.

> "As technological advances allow complex drug formulations to become more effective and available, it is more important than ever to simplify the drug delivery process for patients in real life."

In-depth behavioural research is the backbone of human-centred design, and it is essential to understanding how patients use devices and identifying what is working and what is not. Studies show that, in the US, 40%–70% of patients are noncompliant with their drug regimens.[4] Poor adherence to treatment protocols leads to inadequate treatment and adverse drug effects, negatively impacting patient outcomes.

In developing drug delivery devices, companies must examine three factors:[5]

- **Desirability**: How easy is the device to use? Will patients want to use it?
- **Feasibility**: How reliably can the device function as expected?
- **Viability**: Will there be a demand? Will it be reimbursed?

For injectables, early conversations with patients can address drug delivery options, such as multiple dosing, alternative dose volumes or therapeutic regimens.

Patients always benefit from simplified administration to promote adherence, stronger outcomes and faster access to better products. No matter how well a complex drug formulation performs in trials, the most effective formulations are accurately dosed, adequately mixed, easily administered and readily available.

As technological advances allow complex drug formulations to become more effective and available, it is more important than ever to simplify the drug delivery process for patients in real life.

## ONE STEP CLOSER TO INCREASED SELF-ADMINISTRATION

The modern autoinjector was invented in the mid-1970s to accelerate the administration and treatment of life-threatening allergic reactions. Primarily consisting of two steps – cap removal and injection – these liquid autoinjectors set the standard for best practice in single-dose design and usage. Windgap's ANDIPen does exactly this by reducing the number of steps to two simple user operations: twist and inject. This is a first for dual chamber autoinjectors.

The ANDIPen addresses significant yet unmet user needs within a competitive market by increasing portability, ease of use and shelf life for the medications it administers.

Capitalising on the success of its ANDIPen drug delivery platform and with funding from the National Institutes of Health, Windgap began developing a 5 mL wet-dry, LVDC device to quickly and completely mix larger-volume doses for biologics, large molecule and lyophilised medications.

The novelty of this device comes from its innovative primary drug container (PDC) configuration. Windgap's PDC architecture uses two standard, off-the-shelf, single-chamber cartridges nested side by side, which are connected with Windgap's novel proprietary mixing and delivery needle hub. Internal studies have shown that this method of reciprocated mixing has

## BOX 1: WHAT QUALIFIES AS A "COMPLEX"?

With biologics and insoluble APIs on the rise, the FDA now defines complex in the following ways:[2]

- **Complex APIs**, such as peptides and polymeric compounds
- **Complex routes of delivery**, such as locally acting formulations, suspensions, and gels
- **Complex dosage forms and formulations**, such as implantables and transdermals
- **Complex drug-device combination products**, such as autoinjectors, where the drug is preloaded in a product-specific device or is cross-labelled for use with a specific device in which the device design affects delivery to the site of action or drug absorption.

> "This method of reciprocated mixing has decreased the mixing time for difficult-to-mix drugs from hours to seconds, increasing the rate of dissolution by an astounding 98%."

decreased the mixing time for difficult-to-mix drugs from hours to seconds, increasing the rate of dissolution by an astounding 98% compared with conventional shaking and swirling methods.

This customisable technology eliminates several steps in the complex drug delivery playbook while improving dosing accuracy, efficiency and stability (Table 2).

The advent of the autoinjector has not only opened the door for simplified drug delivery but also opened up the possibilities for more drugs to be self-administered, making it easier for patients to integrate necessary medications into their daily lives.

Any simplification or reduction of steps is a win for patients, and the more simplicity the industry can inject into the earlier stages of drug and device development, the faster everyone can benefit from better adherence and ideal patient outcomes.

As the injectables market continues to skyrocket, the demand for simple, automated and easy-to-use reconstitution devices will continue to rise in tandem. Windgap's technology platforms continue to rise to the challenge, with innovative pharmaceutical solutions built from the beginning with patients in mind.

## ABOUT THE COMPANY

Windgap Medical offers autoinjector platforms that simplify, automate and accelerate the delivery of difficult-to-mix drugs, freeing patients, families and potential treatments from the limitations of current medical delivery technology. With an innovative design, development and manufacturing process, Windgap's "instant solutions" create a new frontier for partners seeking to harness its wet-dry drug delivery technology and an increased speed to market. Its first product is for the administration of adrenaline (epinephrine) for anaphylaxis, with additional products under development in a variety of markets. Windgap Medical is an emerging, privately held pharmaceutical company in the Greater Boston area.

| Prepare | Dose | Mix | Inject |
|---|---|---|---|
| No preparation needed. | An accurate dose is pre-measured in the device. | Mix with the press of a button or twist of a cap. | Remove the safety cap and inject. |

Table 2: Injecting simplicity into complex drug delivery.

## REFERENCES


1. *US Package Insert, Vivitrol (naltrexone). US FDA Web Page, 2023, accessed January 2023.)*
2. *Zhang L, "Newly Approved Complex Drug Products and Potential Challenges to Generic Drug Development". US FDA, May 4, 2020.*
3. *"Injectable Drug Delivery Market Size to Hit US$ 1,223.6 Bn by 2030". Research Report, Precedence Research, May 2022.*
4. *Cattell J, Chilukuri S, Knott D, "Beyond the pill: Creating medical value through technology enablement". Research Report, McKinsey & Company, May 2022.*
5. *Allen D, "What's the Latest in Drug-Delivery Devices?". MD+DI, May 2019.*


## ABOUT THE AUTHOR


**Brent Buchine**, PhD, has worked in advanced R&D and innovation for over 20 years. In addition to being a serial entrepreneur, he has authored multiple peer-reviewed publications, received over 150 citations and filed dozens of patents based on his inventions. As Chief Executive Officer of Windgap Medical, he oversees corporate strategy, business development and an assertive drug development pipeline across several treatment areas.


windgapmedical

# Injecting Simplicity

## Into Complex Drug Delivery Devices

**At Windgap Medical, we create autoinjector platforms that simplify, automate, and accelerate the delivery of difficult-to-mix drugs.** Our proven, patient-centric technologies free patients and potential cures from the limitations of current device technology.

### Large-Volume Dual-Chamber Autoinjector

**DRUG DELIVERY AT THE PRESS OF A BUTTON**

The instant solution for high-viscosity, difficult-to-mix, large-molecule injections of up to 5 ml.

### Compact Dual-Chamber Autoinjector

**TWICE THE SHELF LIFE. HALF THE SIZE.**

Thermally stable drug delivery platform offering automatic mixing and rapid dissolution for <.3ml delivered doses.

Find out how Windgap designs, develops, and manufactures instant solutions at **windgapmedical.com**