



Where everything connects

A NEW ELECTRONIC MULTIUSE AUTO-INJECTOR: THE FLEXI-Q EMU

In this article, Menachem Zucker, PhD, Vice-President and Head of the Injectable Drug Delivery Devices (I3D) Division at Elcam Medical, provides insights into the world of biological drugs and Elcam Medical’s innovative drug delivery solutions.

Elcam Medical, a world leader of OEM disposable medical devices and a provider of solutions for flow control needs, provides its customers with unique, innovative and differentiating solutions that create a significant competitive advantage in their markets.

Elcam emphasises end-to-end customer experience, excellent and seamless customisation and integration of its devices in the customers’ end products. The company has 30 years of experience within the medical device industry, leveraged into all its drug delivery solutions.

“ELCAM BELIEVES THAT PHARMACEUTICAL COMPANIES WILL HAVE A SIGNIFICANT AND GROWING NEED FOR DIFFERENT AUTO-INJECTORS. EACH PHARMA COMPANY WILL REQUIRE A UNIQUE DESIGN AND SHAPE OF THE DELIVERY DEVICE TO FIT THEIR SPECIFIC DRUG AND USERS.”

Biotechnology drugs are on the rise in the pharmaceutical market. While only a few of these drugs are currently approved for use in the US, many more are in use in clinical trials, and still others await FDA approval. The majority of these drugs are very fragile proteins that can only be administered

by injection. These injections are typically performed using conventional syringes and needles. Drug delivery systems can elevate both the therapeutic and commercial value of a drug and the growth of alternative injection devices is driven by these three factors: improved patient compliance; improved patient quality of care; and the trend toward self-administered drug therapy.

The selection of drug delivery devices depends on several factors, including formulation, primary package, dosing and usage. The devices available range from prefilled syringes (PFS) to auto-injectors such as pen injectors, needleless injectors and patch pumps.

Elcam Medical, a leading provider of disposable medical devices to the US and European OEM markets, has developed a new and innovative line of drug delivery devices designed for the administration of biotechnology drugs.

In recent years, Elcam Medical, and more specifically its Injectable Drug Delivery Devices (I3D) Division, have focused on developing and manufacturing high-quality, patient-compliant auto-injectors for biologic drugs.

Elcam believes that pharmaceutical companies will have a significant and growing need for different auto-injectors. Each pharma company will require a unique design and shape of the delivery device to fit their specific drug and users. Thus the company continues to invest in



Dr Menachem Zucker
Vice-President, Head of Injectable Drug Delivery Devices (I3D)
T: +972 4 698 8120/1
F: +972 4 698 0777
E: menachem@elcam.co.il

Elcam Medical
BarAm 1386000
Israel

www.elcam.co.il



Figure 1: The electronic Flexi-Q eMU, the newest auto-injector in the Flexi-Q line.

“ELCAM MEDICAL DELIVERS NOT JUST A PRODUCT, BUT A PROMISE: TO COMBINE EXCELLENCE WITH COMMITMENT; TO WEAVE TOGETHER RELIABILITY WITH INTEGRITY; AND TO OFFER COMPETITIVE PRICING FOR SUPERIOR RESULTS”

this market to increase its portfolio and enable it to provide solutions to meet a variety of requirements.

Among its drug delivery solutions are: auto-injectors for drugs in vials, in prefilled syringes and in cartridges; auto-injectors for high viscosity drugs; reusable auto-injectors that enable dosing; and devices compatible with emerging market needs.

THE FLEXI-Q LINE

The Flexi-Q drug delivery line includes a range of disposable auto-injectors and multiuse auto-injectors. The devices are designed to maximise user compliance in self-administration of injectable drugs. They suit a wide range of patient populations, including those suffering from rheumatoid arthritis (RA) and multiple sclerosis (MS), and provide a wide range of

customisation options such as delivery volumes, viscosity range, injection time, primary packaging selection and more.

NEWEST AUTO-INJECTOR: FLEXI-Q EMU

Elcam Medical’s newest auto-injector under development is the Flexi-Q eMU, shown in Figure 1. An electronic multiuse auto-injector, it comprises a reusable driving unit and a disposable cassette, compatible with standard PFSs containing biologics or cartridges suitable for variable dosing.

The Flexi-Q eMU is intended for use with chronic diseases that require frequent injections, such as MS, diabetes, and growth hormone disorders. The reusable design lowers the cost per injection and reduces the volume for storage and disposal.

Flexi-Q eMU advantages include:

- Reusable, electronic driving unit
- Unique disposable cassette incorporates cartridge for variable dosing or PFS for biological drugs
- Easy-to-use interface features LCD screen and operating buttons
- Automatic needle insertion
- Controlled injection time: 3-100 seconds
- Controlled needle penetration depth: 6-12 mm
- Fixed or variable delivery volumes: 0.1-1.0 mL (PFS), and up to 3 mL (cartridge)
- Compatible with injection of high-viscosity drugs
- Drug delivery begins only after full needle penetration
- Very quiet operation
- Incorporates safety features with needle protection before and after injection, preventing needle-stick injuries
- Includes calendar software for injection reminders and logs
- Easy communication with PC (through micro USB) for loading injection programs and reading injection logs
- Smartphone design, Pocket size: 120 L x 60 W x 20 H mm
- Rechargeable batteries: 30 injections per battery charge.



FLEXI-Q PFS

A fully disposable auto-injector for PFSs

This single-use auto-injector features passive needle shielding, allows better patient safety and encourages patient compliance in self-injection.

The ultimate differentiating vehicle when considering the launch of a new drug or as a life cycle management tool for an existing drug.



FLEXI-Q DV

A fully disposable auto-injector for drugs in vials (both lyophilized and liquid forms)

The only commercially available device that provides a unique, user-friendly solution for self-administration of these drugs.

This single-use auto-injector allows simplified reconstitution and aspiration from conventional vials, features safety needle shielding throughout the process, provides life cycle management capabilities for new and existing drugs, encourages better patient compliance and improves safety.

FDA 510(k) cleared



FLEXI-Q HV

A fully disposable auto-injector for low to high viscosity liquid drugs in PFSs

This single-use auto-injector features passive needle shielding, allows better patient safety and encourages patient compliance in self-injection.

The ultimate differentiating vehicle when considering the launch of a new drug or as a life cycle management tool for an existing drug.



FLEXI-Q MU

A Multi-use auto-injector for drugs in prefilled syringes and vials

Features a reusable driving unit and a cost-effective, automatic needle protection disposable cassette for use with standard PFSs and vials. For use in chronic diseases that require frequent injections (e.g., MS).

The partially reusable design lowers the cost per injection and reduces the volume for storage and disposal.

Summarised in Figure 2, Elcam Medical's Flexi-Q Auto-Injector Line for Self-Administration of Drugs, Biologics and Biosimilars are:

- Safe and simple
- Reduced pain perception
- Injection starts only after full needle penetration
- Easy, safe drug reconstitution and aspiration from vials
- Drug viscosity range
- Unique life cycle management tools (DV → PFS)

A PROMISE, NOT JUST A PRODUCT

Elcam Medical delivers not just a product, but a promise: to combine excellence with commitment; to weave together reliability with integrity; and to offer competitive pricing for superior results.

Elcam Medical is a world-class producer of disposable medical devices for the OEM market and provider of innovative solutions for specialised flow control needs. Working with the medical industry's leading companies, Elcam Medical has particular expertise in the areas of fluid management and IV therapy, vital sign monitoring and drug delivery.

The company's long-term partnerships within the medical industry have taught it that flexibility and customisation are key ingredients for success. This flexibility can be found in Elcam's teams with their customer-centric approach, in products that adapt easily to meet customer needs and in a flexible, open business attitude.

Elcam Medical is experienced in working under tight deadlines without compromising quality. The company operates in strict compliance with ISO 9001:2008 and ISO 13485:2003 standards. The quality system is in full accordance with the US FDA QSR.

Elcam Medical has production sites in Europe, the United States and Israel.

Figure 2: The rest of the range of products in the Flexi-Q line of auto-injectors.

ONdrugDELIVERY
niche information & intelligence

IN WHICH EDITION SHOULD YOUR COMPANY APPEAR?

WWW.ONDRUGDELIVERY.COM



Be compliant. Be safe. At home.



Delivering biologics the safe, convenient way, with injectable drug delivery devices from Elcam Medical.



- Elcam Stopcocks
- Lucomed Medical Products
- Injectech

Head Office / Manufacture

T: 972-4-698-8120/1 | C: 972-52-8313-890 | menachem@elcam.co.il
Elcam Medical Inc. USA | Elcam Medical Europe | Elcam China Office

www.elcam-medical.com