The rise in chronic diseases, along with the necessity of reducing hospitalization time and costs, is a significant concern in healthcare today. As a result, there is an increasing demand for remote patient monitoring, therapy adherence tracking, telehealth, and assisted diagnostic solutions.

Today, medical devices are increasingly being integrated into a broader ecosystem of digital healthcare solutions.

These devices can connect using various wired and wireless technologies, facilitating seamless and secure data exchange between patients and healthcare providers. Advancements in computing and sensor technologies allow for quicker insights into patient-generated data, enabling the identification of long-term patterns through cloud and Al-based systems.

Additionally, intelligent devices and edge computing provide the capability for immediate responses to sudden deviations in patient adherence and compliance.

At Flex, we help you design and build your next breakthrough connected system.

With 10+ years in design and manufacturing of connected medical devices, our capabilities include:



Connectivity and IoT technologies



Regulatory and privacy compliance



Product cybersecurity management



Mobile app development (native and cross-platform)



UI/UX design, human factors interface



Data analytics, AI, edge and cloud computing

## PROJECT CASE 1: Dose-tracking digital system

## Challenge

Provide a dose-tracking digital system for a mechanical, disposable, and unconnected pen injector, usable for different drugs and therapies



#### Solution

- Realization of a reusable add-on module providing electronics and connectivity
- Human factor interaction and formative study, design exploration to fit patient needs
- Dedicated mobile app providing patient guidance and injection reports
- Integration of system components with a customizable data analytics solutions, providing dose tracking functionality, and therapy adherence monitoring

### **Technology**

- Low-cost, low-power BLE connectivity add-on module for the mechanical pen injector
- iOS and Android mobile platforms in native languages
- Third-party cloud application customization and integration with the system components

# PROJECT CASE 2: Design and manufacturing of a reusable, connected autoinjector

### Challenge

- Merck KGaA, Darmstadt, Germany, a leading global pharma company, was looking for a developer for the design and manufacture of a reusable autoinjector with an ergonomic design created specifically for chronic injectable therapies
- The system administers the drug out of a 3mL glass cartridge and automates needle insertion for injection
- Multi-drug and multi-dose autoinjector with various device-needle combinations



### **Solution**

- Custom mechanical design to match form factor requirements and integrating the internal hardware subsystems (PCBAs, motors, sensors, switches, battery, etc.) and electrical and SW development to match the easy-to-use-device target
- Key device features: skin sensor for safety, large handle and push button audio and lighted progress bar for injection process, injection speed control of dosing, needle always hidden to the patient.
  Color UI integrating dose regimen control and configuration, transmission of anonymous diagnosis data using 4G communication, touch-screen interface, support of 50+ languages

### **Results**

- Turnkey project from early concept and product development to industrialization up to regulatory submission; designing and producing the device at Flex sites
- The device supports fully automated injection, including skin detection, needle attachment, needle insertion, drug delivery, and detachment of needle. Patient monitoring and cloud data management via 4G wireless technologies
- Sustaining and maintaining the product, including assessing alternative suppliers and components, Gen 3 device market launched in 2023
- Production ramp up within one quarter

### Partner with Flex and stay ahead of the curve

The healthcare solutions team at Flex can help you reach the full potential of connected devices and related technologies to address emerging challenges and seize new opportunities in patient care.

Our cross-industry expertise and 35 years' experience in the design, development, and manufacture of medical products help you navigate increasing complexity across the value chain while optimizing operations. Our comprehensive portfolio of product lifecycle services enables us to create your medical products at scale with increased quality, productivity, and speed. With 21 medical manufacturing sites in four regions and 13 countries, our global footprint gives you the ability to quickly adjust to changing regional, trade, and manufacturing dynamics.



**Let's collaborate to create the extraordinary in connected medical devices**For more information, visit **flex.com/healthcare** 

