The changing landscape of drug delivery design

What functionalities should your product include? **Freescale Semiconductor**'s David Niewolny discusses the factors that device designers need to consider when sitting at the drawing board.

In a landscape that has been plagued by increasing development costs, diminishing financial performance and the pressure to cut drug prices, pharmaceutical companies are looking for new ways to appeal to customers. No longer able to rely on the old blockbuster model, it must now focus on getting more out of existing drugs and creating new products to address unmet medical needs.

New and innovative drug-delivery solutions have been part of the answer, as pharmaceutical businesses look for ways to increase R&D productivity, improve drugs, extend product life cycles and strengthen their offerings. Providers of drug-delivery solutions are fast becoming strategic partners rather than mere contract development organisations, as evidenced by the number of mergers and acquisitions between pharmaceutical companies and drug-delivery organisations in 2008 and 2009. There were 20 noteworthy deals between January and October 2009, up from 11 in 2008, and this trend stands to continue to the end of 2010 and beyond.

The growth of drug-delivery solutions is one of increasing importance to pharmaceutical companies, and has resulted in significant changes in the drug-delivery landscape. Volumes and future growth projections for these devices are increasing, causing a number of innovative drug-delivery systems to be introduced each year. This has created a significant amount of competition, forcing companies to differentiate their drug-delivery devices to differentiate themselves.

Many are turning to embedded solution providers like Freescale Semiconductor to help. Here, David Niewolny, the firm's medical segment manager, outlines the key differentiating features of a few high-volume drug-delivery devices, and explains how device designers can use embedded electronics to create the next breakthrough design.

Product safety

The most common professional care drug-delivery device is an infusion pump. This is a device that delivers fluids, including nutrients and medications, into a patient's body in a controlled manner. Between 1 January 2005 and 31 December 2009, the US Food and Drug Administration (FDA) received more than 56,000 medical device reports associated with the use of infusion pumps, leading to a number of recalls. The regulator launched an initiative to reduce risk as a result, and is moving forward to establish pre-market requirements for these devices.

This increase in FDA requirements, paired with the need for greater product performance and flexibility across product lines, is encouraging original equipment manufacturers to develop common product platforms that can encompass several infusion products. This strategy may include the standardisation of a centralised, yet scalable, hardware platform, and using software to differentiate one product from another. Software becomes a foundational commitment used on a high-end device and is equally effective on a low-end device, with minimal differences between the two. The number of hours spent verifying code alone reinforces the reasoning to use it across products.

A typical infusion pump platform (Figure 1, page 42) is built around an integrated 32-bit microcontroller with a high-resolution analogue-to-digital converter and serial communication peripherals, and is capable of controlling a three-phase permanent magnet synchronous motor or a brushless DC motor. Freescale's Kinetis product family, which incorporates the ARM Cortex-M4 core and a flexible timer module, is intended for use with either of these motors. The unique timer uses up to six pulse-width modulation output channels. These can be configured as edge-aligned or centre-aligned, and offer polarity control. Dead-time insertion is programmable for each complementary pair in order to prevent shoot-through in half-bridge circuitry, allowing for consistent and accurate motor control. In addition, this family of devices offers scalability, giving device designers peace of mind as they design their infusion platform.

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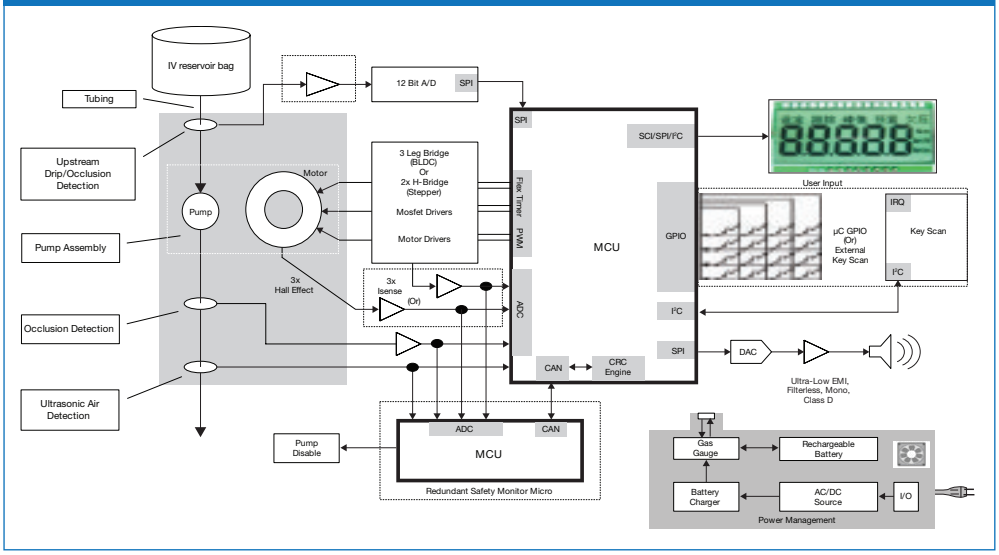
Consumer medical

The fastest growing segment for drug-delivery devices is within the consumer medical segment. This includes:

- insulin delivery pens – used to deliver precise amounts of insulin to diabetics
- smart inhalers – electronic inhalers that provide dose-delivery feedback, and support abuse control and compliance monitoring
- insulin pumps – used to administer insulin in the treatment of diabetes; the device includes a pump (including controls, processing module and batteries), a disposable reservoir for insulin (inside the pump) and a disposable infusion set, which includes a cannula for subcutaneous insertion. ››

Figure 1. Infusion pump electronic hardware block diagram



These devices all have very similar requirements: they must be inexpensive, optimised for minimal power consumption, portable and have some form of internet connectivity. Technology providers like Freescale Semiconductor are delivering key advances in these strategic areas that are needed to enable medical market customers to optimise their products.

Ultra-low power performance

Ultra-low power performance is important for many reasons, the most significant being battery life. Device designers need to evaluate microcontrollers that use innovative technology to achieve the absolute lowest power, such as the Freescale ultra-low power product portfolio. Each of the devices in this range has the four main features that are the foundation of low-power operation: a low-power crystal oscillator, low-power modes of operation, a flexible clock source and peripheral clock gating.

The crystal oscillator intellectual property used in Freescale devices has been optimised to drive crystals at low power, with options for low or high-gain modes. This peripheral consumes less than 500nA for a 32.768kHz crystal when in a low-power mode, and can keep accurate time while the microcontroller unit is in standby mode. This is especially important and can significantly increase your battery life.

Freescale's energy-efficient microcontroller units have multiple modes of low-power operation, each of which is tailored to a specific level of functionality to allow the most efficient performance/power consumption trade-offs. The modes of operation support power consumption as low as 250nA. In order to reduce 'run' mode power consumption further, each of the peripherals on the low-power platform can be clock gated, which shuts down the clock signal that is routed to the peripheral. When disabling clocks to all peripherals, it has been measured to reduce run-mode power consumption by almost a third.

Connectivity

Drug delivery devices also need to have the ability to transfer information to a PC for analysis or for the maintenance of an electronic medical record. Standard serial peripherals, such as SPI, SCI and I2C, are essential for providing the basic connectivity that allows data transfer within systems. However, USB has recently become the most common wired protocol for communicating between a consumer medical device and a PC. The main reason USB has become so prevalent is that it is the first of the wired communication protocols to become a standard of the Continua Health Alliance, a consortium consisting of more than 200 member companies from the technology and the medical device markets focused on developing a standard system of connected personal medical solutions.

Device designers have a variety of options when it comes to choosing a wireless protocol. Bluetooth technology became the first wireless standard adopted by the Continua Health Alliance in its 2008 guidelines. The alliance is investigating a list of wireless protocols for inclusion in the second version of its guidelines. In April 2009, Zigbee wireless technology became the first communication standard certified by Continua's v2 guidelines, followed by Bluetooth low-energy the following December. Zigbee and Bluetooth low-energy are specified for short-range and low-energy applications where only short bursts of data – and not streaming – are required. Low latency and available sleep modes allow Zigbee technology to boast lower power consumption characteristics, making it an ideal choice for preserving battery life.

Peace of mind

Due to recent changes in FDA regulation, drug-delivery device development is becoming more expensive and the time-to-market is drawing out, so it is important that device designers take all of the aspects addressed here into account.

Working with a partner like Freescale Semiconductor, which has a long history of providing embedded solutions to the highly regulated automotive market, should give medical device designers peace of mind. The company is working hard to meet the needs of medical device designers by not only providing a portfolio of highly integrated and ultra-low power microcontrollers with flexible connectivity options, but also a variety of sensor, analogue and wireless solutions. ■

Further information
Freescale Semiconductor
www.freescale.com/medical
Tel: +1 800 521 6274
Email: medicalsolutions@freescale.com