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Medical Device Technology

The road ahead for intelligent implants

Every decade since World War I has seen major advances in implantable medical device technology. The first artificial knees and hips were developed in the 1930s, the first implantable pacemaker in 1958, and the first coronary stent in 1986. What new life-saving technology will transpire in the coming years? Perhaps more relevantly, what barriers exist, and how can we surpass them?

Several major developments in the medical device industry have set the stage for future progress. The first involved the confluence of two industries - pharmaceuticals and medical devices. Device/drug combination products such as implantable insulin pumps existed in the early 1990s, but it was not until the advent of drug-eluting stents in 2003 that implanting combination products became commonplace. This paved the way for recent device/drug and device-biologic combinations, such as spinal fusion systems. On the horizon are drug delivery devices for cancer treatment, and tissue-engineered products such as artificial skin, tendons, and ligaments.

Recent cross-pollination of technology has been another key enabler for new medical devices. For example, heart pacemaker technology has recently been applied to neurological conditions. Patients suffering from chronic pain or epilepsy now have implanted devices that send mild electrical signals to nerves, providing pain relief and motor control. In the coming decade, neurostimulation may help manage clinical depression, Parkinson's disease, Alzheimer's, and even severe obesity.

Advances in wireless technology and material research provide a boon to medical devices. The most tangible benefits include smaller implant size, improved device control and feedback, and novel minimally invasive surgical techniques. Wireless technology will liberate patients from frequent hospital visits, while material innovation will spark new generations of bio-absorbable devices for drug delivery. Previously conceptual ideas, such as restoring sight to the blind, are now in tangible development.

There are, however, significant barriers that must be negotiated. In the United States, regulation by the FDA is necessary but cumbersome, while European regulation tends to be more progressive. Industry leaders should partner with regulatory bodies to develop more effective evaluation methods, particularly as devices and drug/device combinations become more sophisticated. Also, rising healthcare cost must be managed by industry, hospitals, and government bodies to benefit all consumer parties. Interestingly, patients are the primary beneficiary of the device, but are rarely the primary customer - hospitals and physicians are. In the US healthcare system, hospitals buy the devices, and are reimbursed by CMS (Center for Medicare/Medicaid Services) while physicians prescribe the devices, affecting device inventory in hospitals. This complex consumer environment adds significant overhead cost, and can delay adoption of revolutionary technology.

Despite these difficult barriers, novel medical technology can be developed that successfully negotiates regulatory and market hurdles. This requires robust knowledge of design control, verification, and validation - all critical aspects of ISO 13485, the standard for quality management systems for medical device design and manufacture. Also, knowledge of design for manufacturing, process validation, and clinical trials enables intelligently designed products. This facilitates an efficient transformation from concept to actual product, ultimately delivering greater benefit to patients and healthcare providers.

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