Patients can now guide robotic limbs using devices implanted in their brains.

NEUROSCIENCE

Regulators assess brain–linked devices

Food and Drug Administration homes in on neural implants.

BY SARA REARDON

For the first time since accidents severed the neural connection between their brains and limbs, a small number of patients are reaching out and feeling the world with prosthetic devices wired directly to their brains. Earlier this month, scientists at the California Institute of Technology (Caltech) in Pasadena implanted a person's brain with electrode arrays that read neural activity to control a robotic arm and stimulate the brain to deliver a sensation of what the arm touched. And since 2011, a team at the University of Pittsburgh in Pennsylvania has been working with a small number of people who control prostheses through neural implants. "It's moving quick at the moment," says Christian Klaes, a neuroscientist on the Caltech effort. "The race has started."

The advances are also starting to attract serious attention from the US Food and Drug Administration (FDA), which is wrestling with how best to regulate such brain–computer interfaces to ensure that they are safe. On 21 November, the agency held a meeting at its White Oak campus in Silver Spring, Maryland, to get the process started. The meeting was well-timed: in May, the FDA approved a robotic arm that can be controlled with brain implants. And the US Defense Advanced Research Projects Agency is funding the development of prosthetic devices that read brainwaves, as well as implants that electrically stimulate organs to perform functions such as insulin production.

At the meeting, researchers discussed their progress and challenges, and FDA experts talked about the regulatory steps required to bring a device to market. The riskiest devices are implants that require brain surgery; these have been inserted in only a few people under controlled laboratory settings. Less-invasive devices, such as electrodes that sit on the head, or sensors that pick up electrical activity from muscles, are further along the developmental path. FDA scientists presented some of their own research on safety questions, such as how long electrodes can safely stay in the brain and what happens when they malfunction.

Researchers have welcomed the agency's willingness to consider broader use of the devices, especially given that experiments in small laboratory settings seem promising — and are important for understanding the challenges involved. At the Society for Neuroscience meeting in Washington DC this month, Klaes and his colleagues presented the first year of data from an electrode array implanted in a person's posterior parietal cortex, a brain region that controls the intent to perform an action rather than its actual execution. Their patient has learnt to control avatars in video games and uses a brain-controlled arm to play the classic hand game rock–paper–scissors. Another person, who received a motor-cortex implant from the University of Pittsburgh team in 2012 to control an arm, can now perform tasks such as feeding herself[1].

But the companies that develop the devices are also slightly anxious about the FDA's interest, because the agency's requirements for safety and effectiveness set a high bar for any new device. Utah-based Blackrock Microsystems in Salt Lake City, which manufactures the electrode arrays being used by the Caltech and Pittsburgh groups, is opening a branch this week in Hanover, Germany, partly because regulations there are less stringent. "We need some clear guidelines, even at the engineering phase," says chief financial officer Marcus Gerhardt. The company sometimes hesitates over developing new devices if it thinks that the FDA will not approve them, he says.

Regulations aside, companies are still weighing up the advantages of certain devices, such as implants in the somatosensory cortex, which enable a patient to register sensations. Klaes says that the somatosensory implants work well in monkeys, allowing the animals to rummage through a "handbag" to find sensory targets they cannot see[2].

But the market for brain-connected prosthetics is very small: people who have lost control over much or all of their bodies are few and far between. For those who have had amputations — a much larger population — a prosthetic arm with no direct connection to the brain is much easier to control, and often sufficient.

And brain implants might not always be necessary for delivering sensory signals from a prosthesis. In October, neural engineer Dustin Tyler at Case Western Reserve University in Cleveland, Ohio, described a hand prosthesis that stimulates nerves in an arm stump at different frequencies to simulate different textures[3].

> ***"We need some clear guidelines, even at the engineering phase."***

Even if the FDA approves the devices, health insurers must be convinced that they are necessary — and agree to pay for them — before it makes business sense for firms to manufacture them. And the FDA has to be sure that the functional improvement outweighs safety concerns. "From the patient's point of view, of course, they would like to have their own arm," says Kip Ludwig, a programme director at the National Institute of Neurological Disorders and Stroke in Bethesda, Maryland. "But that's a long way away." ■

1. Collinger, J. L. *et al. Lancet* **381,** 557–564 (2013).
2. Klaes, C. *et al. J. Neural Eng.* **11,** 056024 (2014).
3. Tan, D. W. *et al. Sci. Transl. Med.* **6,** 257ra138 (2014).