IN brief

GMP cell lines to order

Eden Biodesign and Millipore have struck a deal to offer a service of mammalian cell lines on demand for companies developing antibodies and protein therapeutics. The collaboration marries Millipore's Ubiquitous Chromatin Opening Element (UCOE) expression technology with Eden's cGMP production. Eden, a contract manufacturing organization based in Liverpool, England, has had a long relationship with Millipore, the life science research and biomanufacturing products supplier located in Billerica, Massachusetts. The new partnership is a "natural fit" says Roger Lias, president of Eden Biodesign's US office and group commercial director. The UCOE vector yields cell lines with a high level of gene expression that are both productive and easy to scale up for clinical trials and commercial supply. According to independent consultant Linda Somerville, based in Peebles, Scotland, the UCOE system also has the potential to shorten production time considerably compared with traditional transfection methods. Eden scientist David Simpson originally developed the UCOE technology before it was acquired by Millipore in 2005. On 1 March, Millipore was involved in a $7.6 billion transaction in which it became wholly owned by Merck KGaA of Darmstadt, Germany. The purchase has expanded Merck's remit, traditionally focused on chemicals, into life sciences and biomanufacturing. It is also a bonus for Eden, says Lias: "The deal with Eden will help drive more Merck customers to the UCOE technology." *Susan Aldridge*

Open-access fermenter

The UK's first open-access facility will soon be available for firms wanting to ramp up biotech processes. The UK's Centre for Process Innovation (CPI) is expanding the capacity of its National Industrial Biotechnology Facility (NIBF) in Wilton from 1 to 10 tons to provide startups and established businesses with equipment and expertise for proof-of-concept development. Companies will be able to use the facility—in which projects may be backed by governmental funding or by private contracts—to make pilot batches of molecules, to de-risk their technology or to figure out how to scale up production processes. "They might want to rent some space, they might want to use the equipment in collaboration with my team, or they might want us to develop a process package for implementation in a manufacturing plant," says Chris Dowle, director of sustainable processing at CPI. "We're very flexible." Similar sorts of services have been around for some time, he says, but the improved NIBF site will be a first in terms of the large scale and the versatility of the equipment. For instance, a bespoke continuous fermentation system will be on offer as well as 'plug and play' machinery that can purify biofuels and other potentially marketable biochemicals. The plant will not produce biotherapeutics. A similar project is being developed in Leuna, Germany by the Munich-based Fraunhofer Institute and is scheduled to open next year. *Asher Mullard*

Table 1 Selected companies and stem cell products

Company	Product	Pluripotent cell source	Availability
Cellular Dynamics International	iCell Cardiomyocytes	Human iPSCs	Dec 2009
GE Healthcare	Cardiomyocytes	Human ESCs	Later in 2010
Lonza	Cor.At Cardiomyocytes	Mouse ESCs	Jan 2010

iPSC-derived cells. The emphasis is on exchanging ideas with partners with particular cellular expertise and finding ways to make drug discovery more productive, says Matthias Steger, Roche's global alliance director for stem cell research. The cells bridge the gap between preclinical and clinical research, he adds, and different stem-cell platforms are likely to become widely adopted as the tool of choice for finding new drugs "in two to three years."

Three large European drug makers have also come together with the UK government to form the Stem Cells for Safer Medicines consortium. This nonprofit company, which was launched in 2007 and includes Roche and London-based GlaxoSmithKline and AstraZeneca, was founded with both public and private funds to develop hESCs for early safety testing of new medicines and to establish a set of best practices. The first phase has been to optimize differentiation protocols for generating hepatocytes and cardiomyocytes, says Julie Holder, preclinical director of the stem cell performance unit at GlaxoSmithKline. Both cell types have been produced from optimized differentiation protocols and researchers are now testing the cells using assays with small molecules to ensure they are fit for purpose.

Even as stem cells are moving toward mainstream use within pharma, much of the scientific expertise in stem cells remains outside large companies. GE Healthcare's Minger expects that the large-scale production, particularly of ESC-derived products, will remain with biotech companies with specialized expertise. Human ESCs are very sensitive to changes in their environment, such as cell density, the matrix on which they're grown and the concentration of growth factors. "It's a lot of work," Minger says. "The expertise that's required is not readily available."

For routine screening, cell lines derived from ESCs are still considered the first choice, say Steger and Rao. Although the iPSC field is moving away from using viruses to incorporate the reprogramming factors, questions linger over whether iPSCs are completely reprogrammed and the equivalence of iPSCs to their ESC counterparts. But even as comparisons of iPSC- and ESC-derived cells continue, iPSC technology offers the unique opportunity to develop disease-specific cell models, such as motor neurons with disease phenotypes, Rao says (*Nat. Biotechnol.* **27**, 977–979, 2009).

Pharma companies also have libraries stuffed with compounds that have yet to be tested on stem cells. These small molecules could have a variety of unique activities, such as directing cellular reprogramming or differentiation. On April 15, Pfizer of New York and stem cell reagent company Stemgent announced a partnership that will allow stem cell researchers to run assays with some of Pfizer's proprietary compounds. "Pfizer has a lot of interesting small molecules and would like to find out more about what they can do, particularly in the regenerative medicine space," says Ian Ratcliffe, president and CEO of Stemgent in Cambridge, Massachusetts and San Diego. "They want to put those into the scientific community in a controlled fashion." At the same time, Pfizer's regenerative medicine chief scientific officer Ruth McKernan has joined Stemgent's scientific advisory board. "It's nice to keep a pulse on what people are thinking and what's important in stem cell research and what's important in controlling stem cells," McKernan says.

Even with the current emphasis on toxicology and drug discovery tools and disease models, pharma companies are also eyeing a future landscape that includes regenerative medicine. "Right now it seems like almost every pharma company has some kind of investment in some regenerative medicine company," Rao says. "They've all made some kind of bet that primary cells or stem cells are going to be useful for the next generation of drugs." Pfizer founded its regenerative medicine division in December 2008. Roche has a center in Pittsburgh that focuses on cellular therapeutics. Some companies are focusing on financial investments in companies with stem cell and related technologies. For example, New Brunswick, New Jersey–based Johnson & Johnson's venture capital group has invested in San Diego's Novocell.

On February 28, Merck announced that it would buy Bedford, Massachusetts–based Millipore, a supply company which already sells several stem cell–based products, including a differentiation kit for mouse iPSCs. According to Robert Shaw, Millipore's commercial director for the project, Millipore started an internal initiative last year aiming to scale up the production of iPSC-derived human hepatocytes and neuronal cells for drug discovery and eventually clinical applications. The company is currently validating these products to make sure that they have the expected phenotypes and metabolic function, Shaw says. The hope is to be selling cells, reagents and other tools for large-scale cell production "very soon."

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