

Healthcare industry BW

Medicyte GmbH – gold standard for human cells

Medicyte GmbH is a life sciences company located in the city of Heidelberg. It focuses primarily on the production of quasi-primary human cells of the highest quality and in virtually unlimited quantity. MediCyte's goal is to establish its proprietary cell proliferation technologies as gold standard for the use of human cells and cell products in research, development and cell therapy.

This company is in the described form no longer active in the market.



upcyte®
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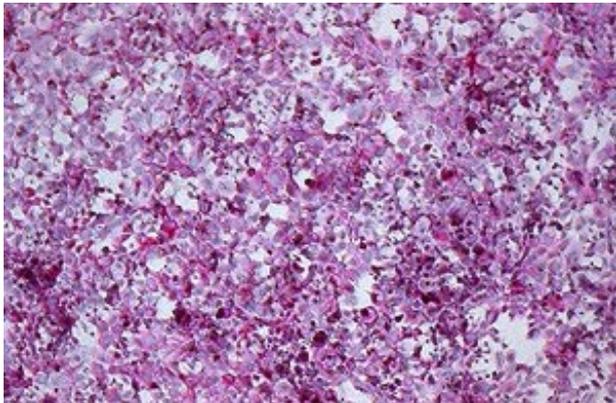
Most primary cells lose their proliferation potential when removed from tissue and transferred into in vitro culture systems. This can lead to donor (identical geno- and phenotypes) quantities that are far below those required for pharmacological development processes (ADME/Tox: absorption, distribution, metabolism, excretion and toxicity), cosmetics and chemicals testing, thus reducing the comparability of the investigations. Although cell lines (i.e. immortalised cells) might provide a way out of this dilemma, they are nevertheless not a real alternative as many cell properties will have changed as a result of immortalisation. The quality of cell lines tends to suffer due to the relatively high demand.

Medicyte GmbH is determined to close this gap. Medicyte's patented upcyte® and vericyte® technologies provide clients with access to cells and cell-based assays for industrial production processes, pharmacological development processes (ADME/Tox; HTS: high-throughput sequencing; etc.), cell-based research, cosmetics and chemicals testing as well as cell therapies. New disease

therapies can be developed, potentially dangerous substances can be identified and it can even reduce the number of animal experiments.

upcyte® and vericyte®

The company owns proprietary technology platforms with which quasi-primary human cell cultures can be grown under controlled and standard conditions. Many cell cycles are possible. Using the upcyte® technology and 5 million live hepatocytes isolated from a biopsy of one individual patient, Medicyte can produce an up to 2000-fold higher number of cells with virtually unaltered phenotypes than would otherwise be possible. Upcytes® are “upregulated” genetically modified primary cells. The introduction of proliferation genes using the method of viral gene transfer drives the primary cells into proliferation, i.e. into a higher than normal number of cell divisions, to name but one example. This gives the company’s clients the possibility to compare different cell stages of one and the same donor. When the cells’ proliferation capacity comes to an end, they express senescence genes, lose the original phenotype and stop growing. Medicyte also licences cryo-conserved master cell bank stage upcyte® cells to clients who wish to grow the cells in-house in a specific working cell bank.



Hepatocytes in the culture dish: PAS staining
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The company’s second key technology is known as vericyte®, which refers to differentiated non-proliferating primary cells (e.g. human NK (natural killer) cells) that play a key role in human immune response. Vericyte® proliferation factors are added to the culture medium, which causes the cells to undergo a reversible state of proliferation. The cells continue to divide for as long as the proliferation factors are present in the medium; the cell division process is interrupted when the factors are withdrawn from the medium; the cells return to their original primary state.

The company can produce virtually unlimited upcyte® and vericyte® cells under standard conditions, and is therefore able to provide academic and industrial researchers with large quantities of cells of identical quality, for example for screening purposes and ADME/Tox tests used in the drug discovery process. These cells have a big advantage over traditional primary cells as well as over immortalised cell lines. This is why the Medicyte founders and managing directors, Joris Braspenning and Stefan Holder, are aiming to establish their technologies as gold standards for the use of human cells and cell-based products in research, development and cell therapy.

The company



Dipl. oec. Stefan Holder
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According to Stefan Holder, CFO and COO of Medicyte GmbH, the foundation of the company in June 2007 is the result of the lucky coincidence of several factors: Stefan Holder and the cell biologist Professor Dr. Jan-Heiner Küpper (now scientific adviser and member of the Medicyte supervisory board) succeeded in securing a patent portfolio, acquiring start-up funds from Gründerverbund Heidelberg and bringing the company's future seed investor – Prinz von Hohenzollern Capital GmbH & Co. KG – on board. The biochemist Dr. Joris Braspenning also joined Holder. Braspenning, who has long-standing experience in the life sciences and in the preclinical development of drugs in the pharmaceutical industry, is the company's CEO and CSO.



Dr. Joris Braspenning
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The company acquired further patent portfolios. The fact that Dr. Björn Lindemann, one of the founders of the biotech company Evotec, and Kreditanstalt für Wiederaufbau (KfW) invested in Medicyte in 2010 was another major factor in the company's development. Medicyte has now 18 employees, holds more than a dozen patents and sells a broad range of cell products.

Medicyte has applied its proliferation technologies to different cell systems, including kidney cells and skin cells. However, the company's major activity focuses on cells of the liver, which is the principle human organ of drug metabolism and detoxification. The cytochrome P450 system is the most important pathway in the duration and intensity of drug action. The cytochrome P450 CYP3A4 isoform is induced differently in different individuals.

Medicyte therefore offers upcyte® hepatocytes from different donors whose drug metabolism can be induced in different ways, including an "upcyte® Hepatocyte CYP Induction Kit". Using the

Alvetex® Scaffold 3D cell culture system of the British company Reinnervate Ltd., Medicyte managed to investigate the cultivation of upcyte hepatocytes in three-dimensional structures within a relatively short time. These cells have the same polarity and display the same cell-cell interactions as those in situ. As far as toxicity tests and the induction of CYP3A4 are concerned, cells that are grown in a three-dimensional environment seem to be particularly sensitive, according to Braspenning.

All cell systems used are investigated and certified for the absence of viruses such as CMV, HIV, hepatitis B and C and microorganisms such as fungi, bacteria and mycoplasmas. In December 2011, Medicyte was awarded the globally recognised ISO 9001 standard for its quality management system.

European research projects

Medicyte is involved in several European research projects, including the “VascuBone” project, which is a large project funded under the 7th EU Framework Programme’s Health category (FP-7 Health). The project, which involves 15 partners, deals with the regeneration and vascularisation of bone. In addition to universities and research institutions in Germany, Norway, Sweden and Austria, the project also involves several small technology companies and giants such as Johnson & Johnson. Medicyte is tasked with the development of methods that enable the production of high enough quantities of cell material – in particular microvascular endothelial cells.

The second FP-7 Health-funded project, “Hepatic Microfluidic Bioreactor” (HeMiBio), aims to develop an artificial liver that simulates the structure and function of the human liver to the extent that toxicity tests can be carried out, thus drastically reducing the number of animal tests normally used for these purposes. In addition to the pharmaceutical industry, the cosmetics industry is highly interested in the project outcome, which is why the European Cosmetics Association (COLIPA) is co-financing the project. In addition to Medicyte as industrial partner, the HeMiBio consortium consists of twelve important academic research laboratories in Belgium, Norway, Spain, Israel, Germany and Switzerland. Medicyte is tasked with the production of standardised cells of high quality and quantity.

The third FP-7 Health project, “Re-Liver”, which was started in mid-2012 and is financed with 4.2 million euros for three years, was applied for by Medicyte itself. Partners involve the universities of Pisa (Italy) and Manchester (UK), Electrospinning Company Ltd. (UK) and a project management company. Dr. Joris Braspenning is the coordinator of the project whose goal is the development of a standardised and reproducible “bioartificial liver organoid (BLO)”. Its scaffold consists of synthetic equivalents of the human extracellular matrix on which stable human hepatocytes and endothelial cells are grown. The design models a healthy human liver. The BLO is characterised in vitro with regard to metabolic functions, protein production and its potential to form blood vessels before it is implanted into animal models using minimally invasive techniques. If preclinical trials go to plan, the project partners might be able to start clinical studies with the goal to assess whether the “cell-based medicinal product” conforms with the criteria stipulated by the European Medicines Agency EMA. If it is successful, the new product has the potential to be used as an alternative to liver transplantation in patients with metabolic disorders such as haemophilia A.

The development of the biomimetic, bioartificial liver might bring hope to more than 10,000 people in the EU who are currently waiting for a liver transplant. For Medicyte, the ambitious project might represent its entry into the field of cell therapy, which has huge potential for the future.

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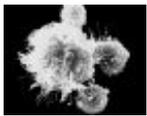
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The article is part of the following dossiers

Cell and gene therapies: from bench to bedside



Cell culture technology: it all started with frog nerve fibres

The Medicyte logo consists of three horizontal red bars of equal length, stacked vertically, followed by the word "medicyte" in a bold, lowercase, sans-serif font. The dot above the letter 'i' is a small red circle.