



## News from the Internet

### **Biomaterials – development of a synthetic matrix for tissue regeneration**

Hydrogel is expected to replace natural materials such as fibrin or collagen.

A matrix from synthetic hydrogel could serve to manufacture new tissue soon. These gels enable cells to migrate through the tissue since they are sensitive *vis-à-vis* certain proteases, as is reported by scientists of the ETH Zurich in the Journal Proceedings of the National Academy of Science (Online Early Edition, April 7–11, 2003).

Up to now scientists – when manufacturing artificial tissue – had to resort to natural biomaterials such as fibrin or collagen. Now Jeffrey Hubbel of the ETH Zurich and his colleagues developed a synthetic matrix, which could assume the task of these biomaterials.

An important factor in the manufacture of such tissue consists in the reproduction of the so-called extra-cellular matrix in which the cells in the body are embedded. The matrix has specific characteristics enabling cells to migrate in the latter. This migration requires the action of proteases – i.e. enzymes, which could split the proteins – i.e. the components of the matrix thus creating a path for cell migration.

For the purpose of demonstrating the efficiency of this matrix, the scientists engendered defects at the cranial bones of rats. By using the hydrogel a complete repair of these defects was reached.

Full Info: <http://www.wissenschaft.de/wissen/news/209450>

### **Quality management, risk assessment and validation**

Quality management, risk assessment and validation are becoming increasingly important. There is hardly a Tissue Banks, pharmaceutical and/or biotech company, nowadays that can ignore this topic. There is a huge demand for information. In the following a number of German sources dealing with these topics are available on the Internet.

The websites of the ‘Deutscher Akkreditierungsrat’ (DAR; German Accreditation Council <http://www.deutscher-akkreditierungsrat.org/>) offer a wealth of

information on all aspects of accreditation: Database listing accredited testing laboratories, calibration laboratories, as well as certification and inspection bodies. The database can be searched according to accreditation area and type of accreditation. Each institution is listed with a brief portrait and with its address, telephone number and fax number. The ‘Ringversuch’ (interlaboratory test) Information System (IRIS) is also available, which lists more than 200 interlaboratory tests so that the appropriate ones can be selected. Furthermore, numerous documents and standards for accreditation can be downloaded in PDF format.

‘Qualitätsmanagement unter einem D.A.CH’ (‘Quality Management under one Roof’ <http://www.quality.de/>) is an information portal which offers an excellent overview of organizations and activities in the area of quality management in Germany (D), Austria (A) and Switzerland (CH).

The good manufacturing practice (GMP) Navigator (<http://www.gmp-navigator.de/>) with finding literature, guidelines and news on the subject of GMP. The site offers a GMP guidelines database to track down the most important sources, an overview of the latest developments, and a discussion forum on topics such as validation, quality control, control instances and quality management. The GMP search engine is particularly helpful, which offers parallel searches on the sites of important institutions such as the FDA, ICH, EG and PIC, and displays well laid-out lists of the documents found.

QMB.de (<http://www.qmd.de>) is an orientation resource for quality management responsables. The site provides the news and lists of numerous links on the subjects of accreditation, certification, GLP, GMP, SOPs and QM methodology.

### **Tiny increase in organ, eye donors in 2002 vs. 2001 underscores need for new donor recruitment methods** (Transplant News, Vol. 13, No. 6, March 31, 2003-08-18)

Despite comprehensive, year-round public and professional education campaigns supported in part by

unprecedented government funding, the number of Americans who consented to be organ donors in 2002 remained virtually the same as 2001 according to preliminary data compiled by the Organ Procurement and Transplantation (OPTN)/United Network for Organ Sharing (UNOS).

Unlike past years when both the OPTN/UNOS and the U.S. Department of Health and Human Services trumpeted even small increases over the prior year, the 2002 figures are posted unheralded on the OPTN ([www.optn.org](http://www.optn.org)).

The number of organ donors – deceased and living – increased by only 164 (1.3%) in 2002 over 2001. Like 2001, living donors made up slightly more than half of all donors – 6,609 live compared to 6,184 deceased. The number of live donors increased by 62 (6,609 vs. 6,547) in 2002 while the number of deceased donors increased by 102 over 2001 (6,184 vs. 6,082).

#### **Storage of sperms – sperms in the homelike refrigerator**

In Dschidda/Saudi Arabia at the Centre of Assisted Reproduction a method was developed by which sperms can be stored in the refrigerator in future. The sperms are washed and then dried in sterile air. For the purpose of insemination the sperms are drugged with a specific liquid and then injected directly in the ovum, which is to be inseminated, by means of the intracytoplasmatic sperms injection (ICSI). By this domicile-based storage the danger reduces that the sperms are mistaken or kept in conjunction with HIV contaminated sperms ([www.news.bbc.co.uk](http://www.news.bbc.co.uk)).

#### **SARS test immediately available**

Roche has introduced worldwide a test to provide evidence of the SARS virus (severe acute respiratory syndrome), which is exclusively intended for research purposes. With a development period of only 8 weeks Roche succeeded in making available a test. This was possible, inter alia, thanks to excellent international relations and co-operations with virological institutes and relevant public institutions, among others, with the Genome Institute of Singapore, too. Initial studies with the test were already made; additional investigations at different locations in Asia, Europe and Canada are planned ([www.roche.de](http://www.roche.de)).

#### **Bio-patent guidelines**

On 25 June 2003 the Federal Cabinet of Ministers adopted the draft of a new law for implementing the bio-patent guidelines of the European Parliaments and the Council dated 6 July 1998. The law specifies such biotechnological inventions, which can be patented and those, which can not. It points up the ethical limits of patentability. Patents for cloning human beings are expressly forbidden. The aim of the biotechnology guideline consists in the EU-wide legal harmonization for patenting inventions in the field of living nature. The guideline creates neither a new patent law for these inventions nor an extension of the possibilities to get patent protection for such inventions. Patentability of biotechnological inventions is recognized in Germany by jurisprudence since 30 years already. Now, law regulates patenting for the first time ([www.bmi.bund.delimages/1618.pdf](http://www.bmi.bund.delimages/1618.pdf)).