

News from the Internet

EMA – Active substance master file procedure

The CHMP at EMA published a revision of the QWP Guideline on Active Substances Master File (ASMF) procedure. The main objective of the ASMF procedure, commonly known as the European Drug Master File (EDMF) procedure, is to allow valuable confidential intellectual property or 'know how' of the manufacturer of the active substance (ASM) to be protected, while at the same time allowing the applicant or marketing authorisation (MA) holder to take full responsibility for the medicinal product the quality and quality control of the active substance. Competent Authorities/EMA thus have access to the complete information that is necessary for an evaluation of the suitability of the use of the active substance in the medicinal product. This Guideline is intended to assist Applicant/MA holders in the compilation of the active substance section of their dossiers for a marketing authorisation application (MAA) or a marketing authorisation variation (MAV) of a medicinal product. It is also intended to help EDMF holders in the compilation of their EDMFs.

www.EMA.EU.INT

Institute of Molecular Biotechnology at the Austrian Academy of Sciences – Mechanism of action of SARS virus

In 2003 SARS, or severe acute respiratory syndrome, killed nearly 800 people worldwide and shut down stores, airports, schools, factories and hotels across Asia, the epicentre of the outbreak. Now the chemical riddle of why the SARS virus causes such a deadly pneumonia is probably solved.

The common research team of scientists from Europe, Asia and Australia worked with mice models. They discovered that SARS, caused by a previously unknown member of the coronavirus family, interferes with a crucial enzyme pathway, the renin-angiotensin pathway, that regulates

body fluid balance. By blocking the enzyme system in the lungs, the virus allows liquid to leak into the air sacs, making them boggy and inefficient. Humans have the same enzyme system which is crucial in both species for blood pressure and fluid regulation. If the findings could be matched in humans, the research may well lead to a new treatment for SARS – as well as for many other diseases that cause death by allowing fluid into the lungs. In the lab, the researchers found that they could protect their SARS-infected mice from lung failure and subsequent death by giving them large amounts of angiotensin converting enzyme-2, the molecule whose function was blocked by the virus. By flooding the system with intravenous infusions of the enzyme, they could essentially overwhelm the block and its deadly effects. Scientists already know how to manufacture a synthetic version, making the move from lab animals to human therapy relatively straightforward, in theory at least.

www.imba.oeaw.ac.at

Laboratory accreditation

The American Council of Independent Laboratories (ACIL) formally announces the release of its 'Blueprint for Success in the 21st Century: An International System for Laboratory Accreditation'.

www.acil.org

Gates Millions for Vaccine Research

The Bill and Melinda Gates Foundation (Seattle, USA) has decided to fund an international research consortium led by the German Research Centre of Biotechnology (GBF) in Braunschweig and the Institute Pasteur in Paris. The long-term goal of the \$ 9 million project is the development of vaccines against Hepatitis C and HIV.

www.pasteur.fr

Austrian scientists identify SARS receptor

For the first time, researchers in Austria have identified an important receptor protein for severe acute respiratory syndrome (SARS).

www.cordis.lu

Biotechnology – patent law

The European Commission has released its second report to the Council and European Parliament addressing the developments and implications in patent law concerning biotechnology and genetic engineering. The study, which centres on the patentability of inventions relating to stem cells,

concluded that those capable of developing into human beings, totipotent stem cells, are to be excluded from patentability on the grounds of human dignity. Embryonic pluripotent stem cells however, which harness the capability of developing into various cells, but not humans, are to be the focus of a further study, after the Commission concluded it is simply too early to come to a decision on the issue. The report's position on gene sequencing is less decisive. Following a discussion of the relevant considerations in the area, the Commission stated that it would not be taking a position on the validity of Member States implementation.

www.europa.eu.int