New meds faster

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Before a new medication arrives on the market, it must be tested on animal models and in humans. In order to conduct these tests, a substantial amount of the therapeutically effective substances are needed - such as proteins or nucleic acids, for example. At the BIO International Convention 2010 in Chicago from May 3 to 6, Fraunhofer researchers will present several processes with which biomolecules can be harvested quickly, robustly, reliably and with versatility - and all processes comply with the GMP standard.

Biomolecules are medicine's jacks-of-all-trades: They are suitable for the diagnosis and treatment of cancer diseases; they are used in the treatment of multiple sclerosis and asthma; they help stimulate the build-up of the body's own immune defenses with flu and polio inoculations. In the laboratories of the pharmaceutical industry, new biomolecules are constantly being engineered: Specific antibodies, customized proteins and nucleic acids - the core components of genetic material - are considered promising candidates for therapeutic approaches.

"Medical-pharmacological research will soon be using more biomolecules than ever before. Processes will be increasingly needed with which these biomolecules can be produced rapidly, in sufficient quantities and of clinically quality," says Dr. Holger Ziehr, who heads the pharmaceutical biotechnology department of the Fraunhofer Institute for Toxicology and Experimental Medicine ITEM at its Braunschweig site. "Our new platform technologies meet these performance capabilities: We can synthesize nearly any antibody, protein or nucleic acid in cell cultures - irrespective of their binding properties and base

sequences." The systems for producing customized biomolecules meet the "Good Manufacturing Practice" -"GMP" - quality standard of the European Medicines Agency EMA as well as the USA's Food and Drug Administration FDA.

For the production of the various classes of biomolecules, the researchers at ITEM are working closely with the Fraunhofer USA Center for Molecular Biotechnology CMB in Newark, Delaware. Three production systems in total are operated at both sites: In Braunschweig, there are bioreactors that produce antibodies in transgenic cells - here they use CHO cells, the cells from hamster ovaries that are commonly deployed in cell research. In addition, the intestinal bacteria E. coli are used for harvesting any nucleic acids. The Delaware-based specialists are able to produce proteins or peptides in plants using "molecular farming." The plants for this are infected with a virus non-toxic to humans that contains the genetic template for the synthesis of the desired biomolecule.

"The Fraunhofer GMP platform technologies are not only extraordinarily versatile for this, they also help save a lot of time in the production and development of candidates for biopharmaceutical substances," explains Ziehr. "We can offer industry customers our full expertise - from the production of tailored biomolecules to preclinical tests based on 'Good Laboratory Practice' - 'GLP' - through to clinical investigations per the GCP or 'Good Clinical Practice' standard. Outside of the major pharmaceutical corporations in Germany, there is nothing else like this except at the Fraunhofer-Group for Life Sciences."

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