

Changing an OP centre to a GLP certified testing lab for Immunology

Gronau, 1 September 2005: As the young team from BioScience GmbH/Gronau recently proved, the current market situation provides abundant opportunities for clever entrepreneurs: "In 2001, we were urgently seeking suitable premises, which would meet the demands of our planned immunological test facility for gentech, clean room and isotope labs", stated Dr. André Rademaekers, Chief Executive of PARA BioScience GmbH.

At the time none of the business founders would have believed that an old industrial textiles building would have met these requirements: "After months of searching for a premises in vain, we couldn't believe our luck when we found a spanking new, fully equipped operating centre." The previous operator had just invested 1.5 million euros in 3 operating theatres, sterile ventilation, comprehensive networking technology and a self-sufficient power and gas supply. The young company acquired the new premises at a good price. "This was an immense advantage, which allowed us to focus entirely on equipping our newly acquired lab", Dr.-Ing. Frithjof Wollbold joyfully remembers the occasion.

Four years later, the company has grown considerably. Meanwhile, PARA BioScience is the first and only testing lab in Germany, which has specifically been certified, according to the Good Laboratory Practice (GLP) regulations, to conduct immunological preclinical studies. The Gronau-based company has been commissioned by the pharmaceutical industry to test the effects of new investigational, pharmacological agents on the immune system, before these are administered to human beings. Due to the complexity of the immune system, *in vivo* tests may also be conducted in rodent models.



Staff working in a sterile environment in a former operating theatre

"The regulatory authorities increasingly demand to exactly determine the effects of drugs on the immune system", states Dr. Dieter Kobelt, Study Director at PARA BioScience. "Our core business is therefore to conduct immunotoxicological and immunogenetical studies, i.e. to explore side effects that might alter or harm the immune system and, later on, cause allergies, for instance."

The company is already thinking ahead and expanding further. The premises are currently being expanded to enable studies also using organisms at Biosafety Level S2. This would permit tests to be conducted that prove whether biotechnology derived drugs, such as insulin, were contaminated by viruses or not; viruses that may later infect people. These are tests, which the authorities have -sensibly- stipulated in order to protect patients. Since an increasing number of innovative biopharmaceutical drugs are being developed, this will definitely be a continuously growing market. These are good reasons, therefore, for the company to have a positive outlook for the future.

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