

# PRESS INFORMATION

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## Good Laboratory Practice (GLP) Test Facility at Fraunhofer IZI Recertified and Expanded

**On 22 March 2018, the Saxon State Ministry of the Environment and Agriculture recertified the GLP test facility at Fraunhofer IZI. At the same time, part of the Molecular Drug Biochemistry and Therapy Development department at the IZI site in Halle (Saale) was issued with its first statement of GLP compliance as an independent test site. The certification process followed an inspection conducted at the respective GLP test sites by the competent authorities in the states of Saxony and Saxony-Anhalt from 8 - 10 November 2017.**

The GLP (*Good Laboratory Practice*) is a quality assurance system that sets out the regulatory framework conditions for the non-clinical and preclinical testing of chemicals and drugs. It falls under the Chemicals Act in the Federal Republic of Germany.

Fraunhofer IZI in Leipzig has been certified as a GLP test facility since 2009. It specializes in testing advanced therapy medicinal products (ATMPs) besides conducting immunotoxicological tests. With regard to the safety testing of ATMPs in particular, the Fraunhofer IZI's GLP test facility has set an example also in terms of concepts over the past few years. The individual planning and implementation of GLP tests in line with the latest state of scientific and technical knowledge forms part of the portfolio offered by the test facility. This also involves developing and validating suitable in-vitro and in-vivo models. Alongside state-of-the-art laboratory spaces, the test facility also boasts optimal conditions for keeping laboratory animals and for performing surgical procedures on small and large animals.

The addition of the Halle (Saale) test site signals another expansion of the range of methods and assays conducted in line with GLP. The focus of GLP testing here lies on analyzing so-called low-molecular drugs (small molecules) using liquid chromatography–mass spectrometry (LC-MS). The two sites therefore complement each other well in terms of methods and subject areas and are able to offer an extremely comprehensive portfolio of tests from a single source.

The test facility is currently certified for testing category 9: "safety tests – immunotoxicity/immunogenicity", with plans in place to cover further testing categories in the near future.

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**Editor**

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