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Over 35 years of good laboratory practice (GLP) in Germany

A successful history of quality assurance

Good Laboratory Practice (GLP) is a quality assurance system that addresses the organisational procedures and framework conditions under which non-clinical health and environmental safety tests are planned, conducted and monitored. It also sets out requirements for the recording, archiving and reporting of GLP studies. It was developed to ensure the quality, integrity and traceability of study data and to strengthen confidence in the results of regulatory safety studies.

The adoption of the OECD GLP Principles in over 40 German federal states to date and the mutual recognition of data generated in accordance with them have made GLP a key instrument of quality assurance in health and environmental protection. The international recognition of test data thus replaces unnecessary duplicate testing whilst contributing to the conservation of resources and the reduction of animal experiments. Germany, which voluntarily adopted the OECD GLP principles in 1983 and enshrined them in law in 1990, has since gained extensive experience in monitoring compliance with these regulations within the country.

To mark the 35th anniversary of the enshrinement of GLP in German law, the German Federal Institute for Risk Assessment (BfR) has published a report on the German system for monitoring compliance with the GLP principles:

- [35 Years of GLP in Germany: A Brief Overview of Its Successful History](#)

The publication traces the development of the German GLP monitoring programme from its beginnings to the present day, describes key milestones and acknowledges the close cooperation between the regulatory authorities of the German federal states and the GLP Federal Bureau at the BfR.

GLP was formed in the 1970s, partly in response to serious deficiencies and, in some cases, fraudulent practices in the conduct of pre-clinical safety tests in the USA. The regulatory

standards developed as a result were later adopted by the OECD and now form the basis of the system of mutual acceptance of test data ('Mutual Acceptance of Data', MAD). Germany has had one of the largest and most established GLP monitoring programmes since its introduction in August 1990: almost 2,000 inspections have been carried out since then, and German test facilities cover all the specialist areas defined by the OECD. Today, the German GLP monitoring programme comprises 143 national and three international test facilities, which are monitored by the 16 regulatory authorities of the German federal states and the GLP Federal Bureau at the BfR.

Further information on the BfR website regarding GLP

Tasks of the GLP Federal Bureau

<https://www.bfr.bund.de/en/about-us/institutions-at-the-bfr/glp-federal-bureau/statutory-tasks-of-the-glp-federal-bureau/>

BfR communication: Cooperation to strengthen good laboratory practice (GLP)

<https://www.bfr.bund.de/en/notification/cooperation-to-strengthen-good-laboratory-practice-glp/>

About the BfR

The German Federal Institute for Risk Assessment (BfR) is a scientifically independent institution within the portfolio of the German Federal Ministry of Agriculture, Food and Regional Identity (BMLEH). It protects people's health preventively in the fields of public health and veterinary public health. The BfR provides advice to the Federal Government as well as the Federal States ('Laender') on questions related to food, feed, chemical and product safety. The BfR conducts its own research on topics closely related to its assessment tasks.

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