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GLP

Good Laboratory Practice

MOTIVATION AND BENEFITS

Good Laboratory Practice (GLP) is defined by the OECD as “a quality system concerned with the organizational process and the conditions under which non-clinical and environmental safety studies are planned, performed, monitored, recorded, archived and reported.”

The principles of Good Laboratory Practice apply to safety testing in laboratories, which are required for test items to be contained in pharmaceutical products or parts thereof. GLP is a harmonized quality assurance system used worldwide to ensure comparability and reliability of inspections.

Responsibility in Austria

The responsibility for monitoring Good Laboratory Practice (GLP) in Austria is shared between two authorities:

Non-clinical safety studies for drug substances lies within the responsibility of the Federal Office for Safety in Health Care (BASG). The Institute Surveillance of the Austrian Medicines and Medical Devices Agency (Agency for Health and Food Safety, AGES) is executing the GLP Monitoring on behalf of BASG.

Any other test facilities that perform non-clinical safety studies (e.g. in the field of plant protection products, biocides, cosmetics, veterinary medical products, food additives, feed additives, and industrial chemicals) are monitored by the Federal Ministry for Agriculture, Regions and Tourism (BMLRT).

Confirmation of assessment is provided by a certificate, containing the following text: “Quality Austria hereby verifies that the laboratory’s quality assurance system complies with the principles of Good Laboratory Practice (GLP).” However, this does not replace certification against the GLP Program by the Federal Office, but provides a good preparation for it!

OBJECTIVES

- Ensuring process quality and documentation
- Compliance with the principles of Good Laboratory Practice

TARGET GROUP

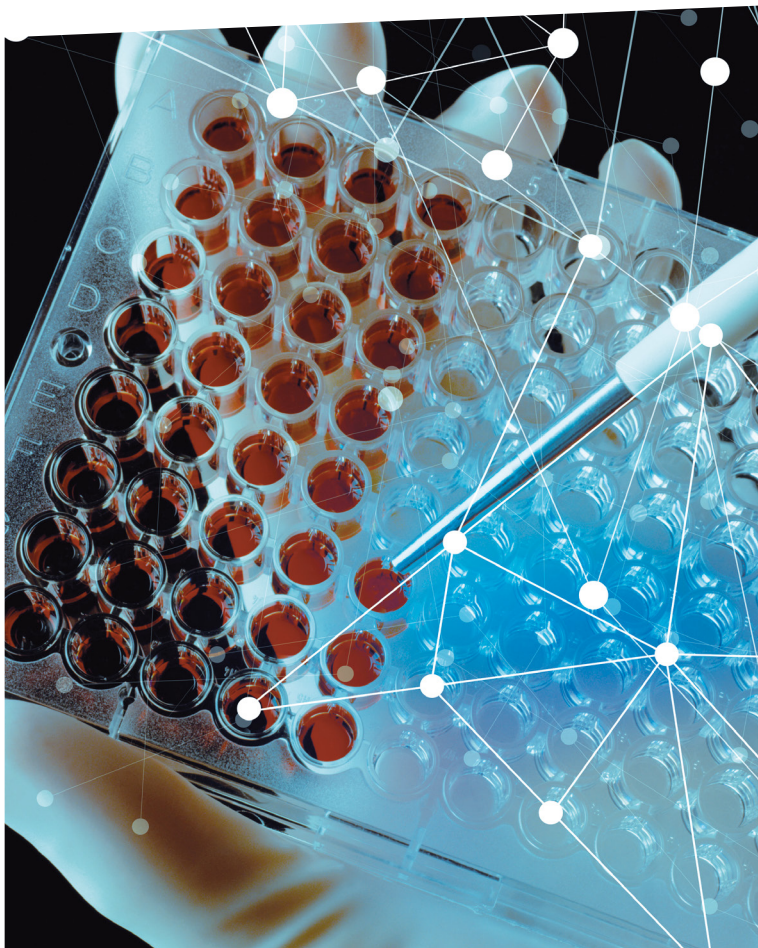
Test facilities, pharmaceutical industry, research laboratories

CRITERIA

- Organization / personnel
- Quality assurance program
- Premises / facilities
- Devices / material
- Test items and reagents
- Standard operating procedures (SOPs)
- Performance of the study
- Reporting
- Storage and retention

OTHER RELEVANT STANDARDS

GMP, GDP, GCP



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QUALITY AUSTRIA – WHO WE ARE

We are the leading Austrian contact for the Integrated Management System, based on quality, environmental and OH&S (occupational health and safety) management, and the topic of business excellence. Our main focuses are system and product certification, training and personal certification. We are accredited by the Federal Ministry for Digital and Economic Affairs (BMDW) for system, product as well as personal certification and have many international registrations and accreditations. Furthermore, we present the Austrian Excellence Award together with the BMDW and award the Austria Quality Seal.

Additionally, we organize several forums and conferences and have issued numerous publications. We participate actively in standardization bodies and international networks such as EOQ, IQNet and EFQM. We cooperate with some 50 partner and member organizations worldwide and thus ensure the facilitation of global know-how.

Having more than 1.000 auditors, trainers, assessors and technical experts all over the world, we ensure the successful implementation of standards and regulations within the organizations and provide sector and product specific knowledge with a very high focus on practical relevance. More than 10.000 customers in approx. 30 countries and over 6.000 annual participants in our trainings benefit from the long-standing expertise of our organization. We adapt our offer according to our clients' needs and support them in achieving their long-term goals!

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