Good Laboratory Practice (GLP) as part of innovation processes

AUTUMN ITAPA 2024
November 25th – 28th, 2024
Crowne Plaza Bratislava

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GLP - Great Load of Paper

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According to the OECD:

"Good Laboratory Practice (GLP) is a quality system concerned with the organisational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported."

OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring
Number 1
https://doi.org/10.1787/9789264078536-en

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History of GLP

- 1970s: The Beginning
- 1976: U.S. Congress Mandate
- 1978: First GLP Regulations Issued by FDA
- 1981: OECD Adoption of GLP Guidelines
- 1987: OECD Mutual Acceptance of Data (MAD) System
- 1997: Revised OECD GLP Principles
- 2000s: Expansion to Non-OECD Countries
- 2016: OECD Incorporation of Modern Practices
- Today: A Global Standard

Importance of GLP

- **Quality Assurance:** It ensures high standards in laboratory practices.
- **Data Integrity:** It maintains the accuracy and consistency of data.
- **Regulatory Compliance:** It meets the requirements set by regulatory bodies, facilitating the approval process.

GLP Principles

- **Organization and Personnel:** Clearly defined roles and responsibilities.
- **Facilities:** Proper maintenance and suitability of laboratory facilities.
- **Equipment:** Regular calibration and validation of equipment.
- **Standard Operating Procedures (SOI** Comprehensive documentation and str adherence to procedures.

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HEALTH EFFECTS LABORATORY
Standard Operating Procedure

AlamarBlue® assay

Written by: NEY

QA (name and sign): ESI

Approved (name and sign): MDU

Valid from: 10.12.16

Code: HEL16T008

Version: 1

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SOPs HAVE TO BE FOLLOWED!!!

GLP in Innovation Processes

- **Role in Drug Development:** It is involved from the discovery phase to pre-clinical trials.
- **Enhancing Credibility:** Reliable data supports regulatory submissions.
- **Accelerating Development:** Streamlined processes lead to faster innovation.

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Other GPs

1. **Good Clinical Practice (GCP)**: The OECD has recommendations for the governance of clinical trials, which align with international standards for GCP.
2. **Good Pharmacovigilance Practice (GVP)**: The OECD does not have specific GVP guidelines, but the European Medicines Agency (EMA) provides comprehensive guidelines on GVP, which are widely recognized.
3. **Good Distribution Practice (GDP)**: While the OECD does not have specific guidelines solely for GDP, it provides principles related to the distribution of chemicals and other substances.
4. **Good Storage Practice (GSP)**: The OECD's guidelines on Good Laboratory Practice (GLP) include principles that cover the storage and handling of test items.
5. **Good Documentation Practice (GDocP)**: The OECD's GLP guidelines also emphasize the importance of proper documentation, ensuring data integrity and traceability.
6. **Good Agricultural Practice (GAP)**: The OECD, in collaboration with the FAO, has developed guidance for responsible agricultural supply chains, which includes principles for sustainable and safe agricultural practices.
7. **Good Manufacturing Practice (GMP)**: The OECD does not have specific guidelines for GMP. Instead, GMP guidelines are established by organizations such as the WHO, EMA, and FDA.

https://database.ich.org/sites/default/files/E6-R3_FinalConceptPaper_2019_1117.pdf;
https://www.oecd.org/en/publications/guiding-principles-on-good-practices-for-the-availability-distribution-of-protected-elements-in-oecd-test-guidelines_2b290577-en.html;
https://one.oecd.org/document/env/jm/mono%282018%296/en/pdf; https://www.oecd-ilibrary.org/environment/glp-data-integrity_45779212-en;
https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/pharmacovigilance-post-authorisation/good-pharmacovigilance-practices-gvp;
https://mneguidelines.oecd.org/OECD-FAO-Guidance.pdf; https://www.ema.europa.eu/en/human-regulatory-overview/research-development/compliance-research-development/good-manufacturing-practice;
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-q7a-good-manufacturing-practice-guidance-active-pharmaceutical-ingredients;
https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/trs986annex2.pdf?sfvrsn=320c9e62_1&download=true

Benefits of GLP

- **Trust and Transparency:** It builds confidence among stakeholders.
- **Safety and Efficacy:** It ensures the development of safe and effective medical treatments.
- **Global Standards:** It harmonizes practices across laboratories worldwide

Challenges and Solutions

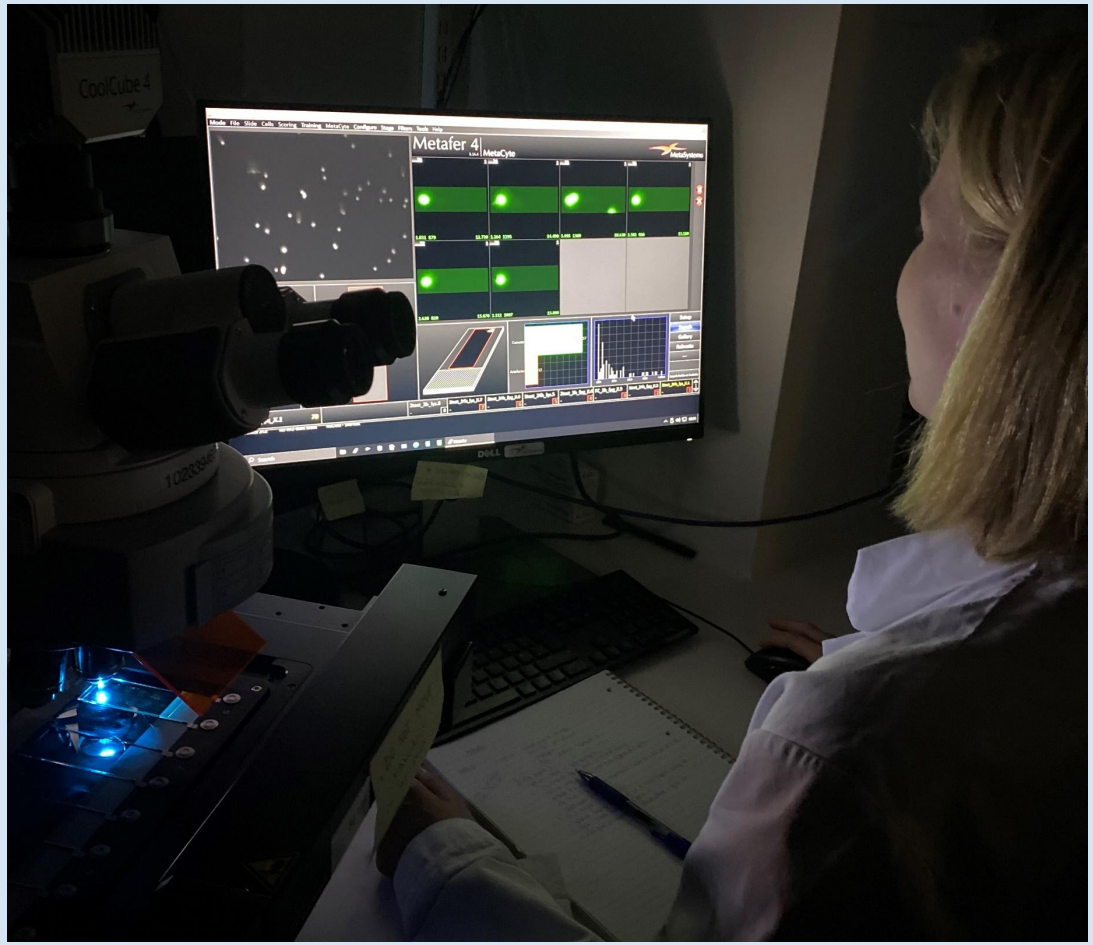
- Implementing GLP can present **challenges** such as high costs, the need for extensive training, and ensuring compliance.

- **Solutions** include investing in training programs, developing robust SOPs, and continuous monitoring to maintain standards.

Future of GLP

- **Technological Advances:** Increased automation and digitalization in laboratories.

- **Evolving Standards:** Adapting to new scientific discoveries and regulatory changes.



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Conclusion

In conclusion, GLP is essential for maintaining high standards in laboratory practices, ensuring the quality and integrity of data, and supporting the innovation processes in medical research.

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