Agaram TECHNOLOGIES

WHITE PAPER

How Logilab ELN helps organizations to follow GxP Regulations

About GxP Regulations

GxP is a set of regulations and quality guidelines formulated to ensure the safety of life sciences products while maintaining the quality of processes throughout every stage of manufacturing, control, storage, and distribution. The GxP standards were established by the Food and Drug Administration for a range of compliance related activities and are recognized as:

G: Stands for good
x: Variable
P: Stands for practices

The variable “x” depends on the application of the standards. The value of x can be
M for “Manufacturing”,
C for “Clinical”,
L for “Laboratory”,
S for “Storage”,
D for “Distribution”,
R for “Review”, etc.

The purpose of the guidelines is to ensure that the regulated organizations comply with the standard processes of various functions. GxPs are mostly similar across all the countries.

The guidelines mainly focus on the following areas:

Traceability – ensuring that the development history of the product can be reverse engineered.

Accountability – Identifying the contribution of every individual involved in the development process.

Data Integrity – Ensuring the reliability of data.

Importance of GxP Regulations

Since the regulations of GxP are global, every company manufacturing life sciences product is affected by it. Therefore, meeting the GxP requirements is highly important. Though there are several GxPs, few of them are highly important for the life cycle of any product.

Good Manufacturing Practices (GMP) – GMP are the guidelines recommended by agencies for the authorization and control of manufacturing of products such as drugs, medical devices, active pharmaceutical ingredients (APIs) etc. Adhering to these guidelines assure the agencies about the quality of the products and that the manufacturers have taken every possible measure to ensure the safety of the product.

Good Clinical Practices (GCP) – GCP are international quality standards defined by the International Conference on Harmonization (ICH) that state the clinical trial regulations for the products that require testing on human subjects. The standards outline the requirements of a clinical trial and the roles and responsibilities of the officials involved in it. It ensures that no human experiments are performed just for the sake of medical advancement.

Good Laboratory Practices (GLP) – These are the standards set by the FDA for non-clinical laboratory tests and studies conducted for assessing the safety and efficacy of the product. GLPs are a set of standards which define the framework for a non-clinical study and states how they should be performed, evaluated, reported etc.

To launch a product in any market, it is necessary for a company comply with the GxP regulations.

LEGAL AND REGULATORY CONSIDERATIONS

There are many requirements for implementing a successful computerised system like electronic lab notebook. Meeting legal requirements is the most critical, because laboratory notebooks are the primary records of scientific discovery. Are ELN records legally acceptable as evidence of invention?

Regulatory agencies in many countries accept electronic records. The U.S. Patent and Trademark Office published a notice stating that electronic records are admissible to the same extent as written records if they are created and stored in a way that engenders trust

in the records. Like paper records, electronic records, if kept properly, are acceptable as evidence of invention.

However, to date, there is no case law for successful patent defence-based solely on electronic storage of data and electronic signature, due to the extreme few occurrences of patent disputes. Since Eln Software is a new way of record keeping for scientific inventions, the industry has adopted higher standards than what is required by law. In patent interference, whether a piece of information is admitted as evidence of invention by the Court is governed by the Federal Rules of Evidence with two major requirements: business records objection and foundation objections.

Business records objections accept the records presented by the employer, even if the inventor is no longer employed by the company. Establishing a comprehensive foundation for electronic records to be admitted as evidence of invention is more challenging.10 A high standard must be set for record keeping, whether on paper or electronically.

Meeting the requirements of regulatory agencies (the FDA in the United States) is critical for ELNs. The FDA has extensive regulations and guidance to electronic records and electronic submissions. It is clear that electronic records are acceptable as proof for the efficacy and safety of a drug if the computer system that manages the data is placed under proper control. Proper testing and documentation must be available to demonstrate that the system meets the user-required functions.

An audit trail must be available to track data updates. The validation of computer systems is a rigorous process of testing and documenting that a computer system meets user and regulatory requirements. If the ELN system is used in the GxP area, it must be validated. For non-GxP areas, validation is a good approach to demonstrate that the electronic records are trustworthy and meet the requirements for patent purposes. Given the high risk of ELNs to business, maintaining a validated ELN system is the best interest of discovery scientists.

The ELN should meet the following legal and regulatory requirements:

- ✓ Ensuring electronic records' relevance, accuracy, authenticity, and trustworthiness.
- ✓ Establishing procedures and enforcing written guidelines to ensure the integrity of the electronic records.

- ✓ Enforcing timely electronic signatures by the author, witness, reviewer, and approvers.
- ✓ Keeping an audit trail for the creation, modification, reviewing, and approval of records.
- ✓ Locking records after they are signed so that they cannot be altered.

- ✓ Keeping amendments to an ELN record as an indelible part of the record with a permanent link between the record and its amendments.
- ✓ Controlling data access with username and password combination.

ROLE OF LOGILAB ELN IN GXP REGUATIONS

About Logilab ELN

Logilab ELN is Agaram Technologies' generic Electronic Lab Notebook to enable the lab users to document protocols & procedures, enter lab results, scientific and research observations, notes and other data & perform calculations in paperless electronic format.

Logilab ELN is a proven and dependable system that provides a fully configurable sheet template with test- based workflow design to meet the needs of QA/QC and R&D operations for industries including pharmaceutical, life sciences, biopharmaceutical, chemical, petrochemical, environmental, food, feed, milling, and dairy.

Logilab ELN is designed to capture data in a spreadsheet like template called as Labsheet or lab notebook. Labsheet templates can be designed by scientists by dragging and dropping generic fields into the Labsheet and creating a form like input template depending on the type of test, experiment or research task. This makes the ELN usable for any digital data capture application for lab personnel, research scientists, process and process research personnel.

Labsheets can be designed with data fields like text, numeric, dop-down list, date, time, formula, image, hyperlinks etc.,

Logilab ELN has been designed and developed with a unique feature of protocol management by which set of laboratory procedures and instructions can be configured and corresponding results can also be captured in the same. It has very wide variety of rich features namely data input, research information, tables, images and charts preparation, drawing chemical diagrams, tagging of fields, etc.

Logilab ELN is designed to capture data from any analytical instrument that has RS232 and TCP/IP and also PC-based instruments that can either export results in ASCII, Excel, CSV formats or has the capability to can print a result report.

The system is a fully scalable, flexible, enterprise system designed to streamline test or experiment along with instrument data capture (via SDMS) in a controlled environment, calculate and integrate with external system. It helps laboratories to adopt paperless processes.

It ensures easy adaptability, time-savings due to faster configuration and operations and Reduced complexity to use resulting in better customer experience.

Logilab ELN's Role in GxP Regulations

An ELN software should possess the technical features required by the regulatory guidelines.

An ELN itself, as well as any other software or tool, cannot be certified to be GxP compliant – it can only support your lab in meeting the requirements.

GxP compliance focuses mostly on how diligently the processes and procedural controls are implemented and handled by your organization.

Agaram Technologies' Logilab ELN has many features developed to enable organizations to comply GMP regulations i.e. particularly those features and service support the compliance requirements mandated by 21 CFR part 11.

The following features built into Logilab ELN will help laboratories and organizations to comply with GxP Regulations:

- ✓ User access control (with a unique username and password combination) i.e. Logilab ELN provides a closed system with restricted access. This is assured by secured system-login, which is unique for each individual Logilab ELN user.
- ✓ Role-based user access - User groups and project management
- ✓ Password Policy setup
- ✓ Robust encryption standards
- ✓ Review and approval of data by assigned reviewers or approvers
- ✓ Version control of records and maintaining of version history

- ✓ Time-stamped audit trails - to track what actions done by who at what time
- ✓ Time-stamped electronic signatures - to enforce accountability. The electronic signature is unique to one individual and indisputably linked to the respective electronic record in a way to prevent fraudulent use.
- ✓ View and Export of all electronic data in a human readable format,
- ✓ Data indexing by metadata
- ✓ Easy search user interface
- ✓ Protocol Management to configure research and laboratory procedures along with approval
- ✓ Archiving of the data to a secured central database
- ✓ Product developed by Software validation, including testing and overall performance assessment to ensure fully functional performance and reliability

CONCLUSION

Cloud-based ELNs such as Logilab ELN Cloud SaaS and other laboratory management systems namely SDMS and LIMS facilitate the compliance of GxP Regulations for almost any industry. Ensuring of automatic capturing and storing data creates more robust procedures for future research and Quality control processes which will in turn reduce the compliance irregularities and improve reliability and supports reuse of data and reproducibility of experiments.

The following are the benefits that organization can reap by implementing Logilab ELN.

- ✓ Better user experience and confidence
- ✓ Time savings in terms of implementation and roll-out
- ✓ Operational time savings and cost due to automated and paperless processes
- ✓ Low cost of ownership and reduced overhead costs due to standard technology architecture.
- ✓ Low compliance cost due to adherence to regulatory and industry standards of data integrity
- ✓ Minimum errors due to automated processes and consistent result generation.

For more information about Agaram Technologies' Logilab ELN, please refer to the website page: https://www.agaramtech.com/product/logilab-eln-software/

REFERENCES

Good Manufacturing Practice (GMP) data integrity MHRA Regulations

Good Laboratory Practice Regulations, Weinberg, Informa Publisher, 2007 (fourth edition).

Data Integrity Issues in Pharmaceutical Companies