

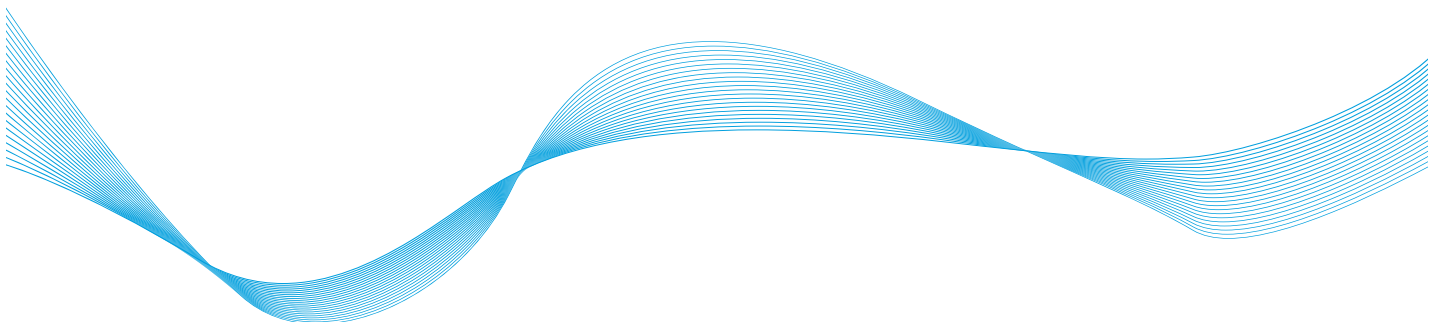
Lab Digitalization – Connectivity and cloud-based working in life science



Executive Summary

Many scientists and researchers use spreadsheets or paper-based methods to keep track of their laboratory work. But is this a secure way of recording their data and protocols? When working in the lab, scientists must also remember to keep up with lab equipment maintenance and be able to track samples throughout their workflows. New ways of documentation and device monitoring have been developed such as digital lab notebooks and cloud-based platforms that allow users to securely record data and protocols, track

samples, manage equipment maintenance and also remotely manage their lab devices. The **eLabJournal®** is a web-based software that allows users to record data as well as enabling laboratories to follow ISO regulatory guidelines and work in compliance with Good Laboratory Practice (GLP). Furthermore, Eppendorf provides a cloud-based lab and device management platform called VisioNize® Lab Suite to support scientists with all routine tasks in the laboratory.



Cloud computing

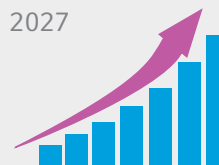
is a rapidly expanding area of business.
Worth in 2019:

 **\$266 billion dollars**

Expected annual growth

between 2020 and 2027

14.9%



Private Cloud

- > are organization-specific, closed environments, that can be hosted on site or by a third party
- > provides greater security controls
- > requires traditional datacenter staffing and maintenance



Hybrid Cloud

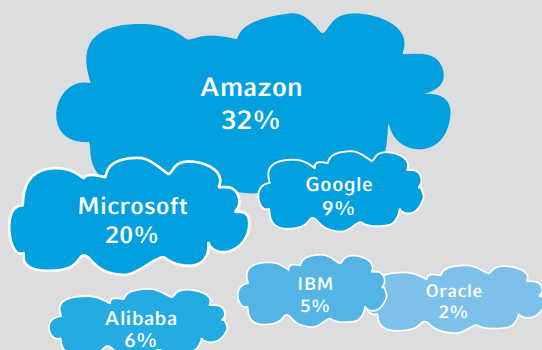
- > combination of both public and private cloud
- > shared security responsibility
- > helps maintain tighter controls over sensitive data and processes



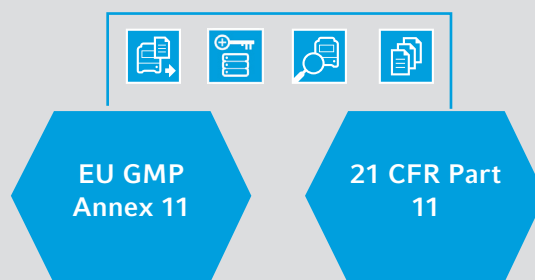
Public Cloud

- > are the most common type
- > offered by third-party providers
- > online environments with open access to all users
- > scale quickly and convenient

Main cloud provider



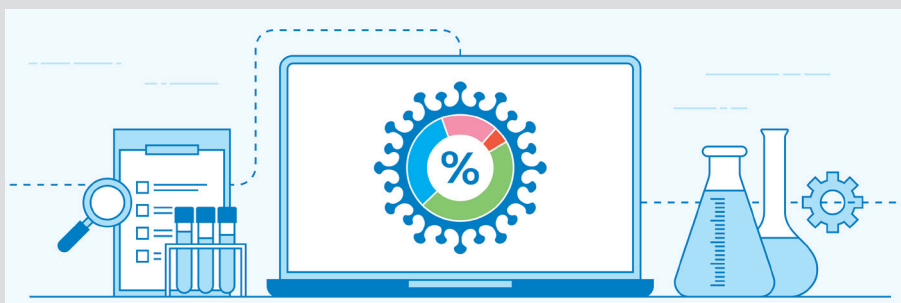
Requirements for computer systems



Electronic Lab Notebook (ELN) market

expected to reach in 2025 a value of

 **\$642 million**



Introduction

From smart televisions to ever-evolving mobile device functionalities, our everyday lives continue to become more digitalized. With increasing device connectivity, we also see a trend towards greater digitalization in life science laboratories worldwide. The widespread adoption of cloud-based solutions and the development of the **internet of things (IoT)** are **important megatrends** that are revolutionizing the way work in the lab is conducted.



Cloud-based solutions have several advantages over conventional hardware and document-based methods of data management including increased flexibility, scalability, and security by handling large amounts of sensitive data generated in industrial and academic life science labs. With cloud-based options, updates can be handled remotely and there is no requirement for additional software/hardware or costly server upgrades when increasing storage capacity. By adopting cloud-based solutions, laboratories can become more cost efficient and sustainable while also saving time.

Another major advancement in recent years has been the emergence of the **IoT**, which refers to a system of interrelated objects (e.g., computing devices, digital or mechanical machines etc.) that are able to collect and transfer data over a wireless network without human intervention. Driven by the expansion of cloud-based storage as well as the integration of sensors into a wide range of lab devices, the IoT is bringing unprecedented connectivity and automation into the lab.

Ensuring sufficient documentation is probably one of the most important, and at the same time, most unpopular tasks in the laboratory. **Documenting experiments** in a traceable manner is important in any laboratory - from academic to pharma laboratories subject to regulatory requirements. Whether data, text or images are collected for scientific publications or to meet GxP/GLP standards, a great amount of manual and technical effort is required for its generation. Paper-based documentation - as is still found in many laboratories today - has a number of disadvantages.

Data are often recorded in different lab books (e.g., a log notebook at the centrifuge, a personal lab book, and a folder with RT-PCR data on the lab server just to name a few examples). The drawback of locally stored data is obvious as it is not accessible to everyone from all locations, and can be lost or damaged - all difficulties that could be prevented.

With more scientists switching to **working remotely** in recent months, the increased accessibility to data and control over lab processes provided by digital technologies help scientists adapt to challenging situations enabling crucial scientific work to continue.

The rise of cloud computing

Cloud computing is a rapidly **expanding area** of business worth \$266 billion dollars in 2019 and expected to grow at an annual rate of 14.9% between 2020 and 2027 (1). The **main cloud providers** in terms of market share are **Amazon, Microsoft, and Google**, which together account for more than 60% of the market, while smaller providers such as Alibaba, IBM and Oracle account for 2-6% of the market each (2). Growing equally quickly is the **ELN market**, which is expected to reach a value of \$642 million by 2025, with many manufacturers in the biotechnology industry releasing products every year (3).



For life science laboratories that handle sensitive clinical data or experimental results, it is important to consider which type of cloud platform is the most suitable. There are **three main types of cloud platforms** offered by providers – public, private and hybrid. Public clouds are the most common type which are online environments with open access to all users. Private clouds are organization-specific, closed environments, that can be hosted on site or by a third party. They are maintained on an intranet and protected behind a firewall providing additional confidentiality and control to life science labs that may be handling sensitive data. Hybrid clouds combine features offered by public and private clouds and are a particularly cost-effective option for organizations where the demand for cloud-based applications fluctuates.

Part of the increased growth in the cloud computing market is expected to come from small and medium sized enterprises, including biotechnology and biopharmaceutical companies, where cloud-based technology helps accelerate the development of new biopharmaceuticals and processes. For example, the huge amount of data generated by modern genomics and proteomics research requires a scalable data storage system that enables secure collaboration between labs worldwide.

How does a digital lab look like?

Many laboratory devices such as freezers, centrifuges, cyclers, and mixers can share data they generate directly via the cloud – a method which is more secure and straightforward than physical storage and transfer and decreases the risk of users losing important information. Increased connectivity is also enabling users to remotely monitor their laboratory devices. This includes the tracking of device usage and status alarms for equipment such as freezers and cell culture incubators using software that is compatible with a wide range of personal devices and therefore available anywhere.



Sample identification techniques ensure more efficient sample and process tracking. These systems use barcoding technology to track the location, content and movement of sample vials and provide effective inventory management that eliminates the chance for sample misplacement or incorrect labelling.

Digital systems can be accessed via **laboratory information management systems (LIMS)** or **electronic lab notebooks (ELNs)** which present several benefits for life science labs. LIMS offer a highly integrated option while ELNs support flexible documentation. Combining the best of both worlds, device and workflow management (coming soon) are possibilities with **VisioNize® Lab Suite** from Eppendorf. This cloud-based lab and device management platform represents



a central hub from which scientists can monitor their workflow with features such as remote monitoring, task management, device documentation and data collection. These highly integrated and flexible systems can be accessed from anywhere making experimental data easy to share between colleagues or external organizations with collaborative work.

What about regulations?

In an age of increasing digitalization, regulatory authorities have published guidelines that state the requirements for computer systems that handle electronic records and signatures to be compliant with **good manufacturing, good laboratory and clinical practices** (collectively known as GxP). In the United States, these guidelines are found in the **21 CFR part 11** issued by the Food and Drug administration (FDA), while the European equivalents are found in the **EU GMP Annex 11**.

Processes such as record generation, the use of time-stamped audit trails when documents are created, modified, or deleted, and digital signature generation are all subject to these regulations. The aim is to achieve maximum transparency throughout the GxP process to ensure biotechnology and pharmaceutical products are manufactured to the highest standards.

As many labs switch to cloud computing, data stored in the cloud also becomes subject to these regulations. To ensure compliance, several cloud providers have developed their platforms in close collaboration with the relevant regulatory authorities, ensuring the integrity, availability and confidentiality of data stored in the cloud. Providers often also support customers with development, planning and auditing for GxP compliance, and several have released guidelines to ensure customers understand the responsibilities of each party and how to effectively maintain compliance.

Summary

The drive towards **standardization of lab procedures** and **transparent documentation** is an ongoing process and it is likely that systems of electronic record keeping and device monitoring will play an **important role in future regulation**. Even if labs are not currently working to GxP standards, installing new systems that meet GxP requirements can save time and effort when making this transition at some point in the future. In addition, the ability to digitally connect devices and instrumentation is starting to become a key factor when purchasing new laboratory equipment.

The rise of the IoT is transforming the processes of inventory management, sample tracking, and device monitoring reducing unnecessary lab expenses and promoting efficient working practices. The accessibility of **cloud computing** provides **secure and reliable methods of data storage** ensures safe data access from any location both within and outside the laboratory, helping to streamline manufacturing and research processes significantly. Sustainable cloud-based solutions can be easily updated remotely with new features and releases that allow users to get the best out of their connected devices in a cost-effective manner.

As a greater number of labs migrate to cloud computing, the opportunity for collaboration with external organizations increases – and with more and more scientists working remotely, this technology is becoming essential for labs to maintain high production or research output.

The newest generation of devices from Eppendorf come equipped with the VisioNize touch interface which has been extensively tested by customers to reduce learning and adjustment time. It is used across different Eppendorf instruments, like the CryoCube® F740hi ULT freezer or Centrifuge 5910 Ri. These devices are not the only products, that support a digital, paper-free lab environment. The Innova® S44i biological shaker, the CellXpert® C170i CO₂ incubator and the Mastercycler® X50 PCR cycle are examples of digitized devices that can track data, potentially replacing the need to document everything by hand.



Digital lab solutions from Eppendorf

There are various approaches to optimize processes in the laboratory by managing existing lab assets through digital applications. To meet this demand, Eppendorf offers smart lab management software solutions, such as **VisioNize® Lab Suite** (VNLS), which increases productivity in the lab by limiting potential bottlenecks.



VNLS offers a complete solution for digital laboratory management, providing lab managers and scientists greater sample security, better compliance needs, and a straightforward system of maintenance management.

By connecting lab equipment such as freezers, incubators and shakers to VisioNize Lab Suite, users enjoy several benefits and services:



Remote monitoring: Status checks from anywhere



Alert notifications: Utilize escalation schemes and acknowledgement for advanced documentation



Access to device data: All relevant documents, e.g., SOPs, operating manuals, and more



Planning of maintenance tasks: Status checks from anywhere



Detailed audit log: Including device performance data, such as parameters and user interventions, setpoint changes, and maintenance tasks

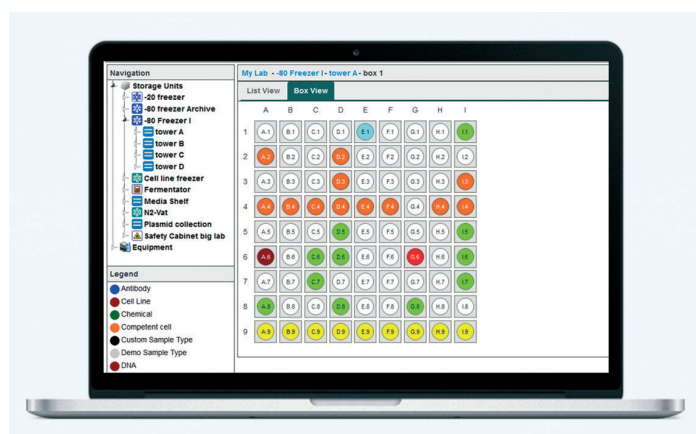


Remote updates: For selected devices which detail device improvements and new features

In addition, further assets such as pipettes can also be an addition, further assets such as pipettes can also be managed via the VisioNize Lab Suite to maintain a complete overview of laboratory assets and manage one-time and recurring tasks such as upcoming pipette calibrations. To help meet regulations, VisioNize Lab Suite and service features are designed to support CFR 21 Part 11 requirements such as time-stamped records of user interventions.

Eppendorf supports scientists in switching from paper-based to digital documentation with **eLabJournal®**. This electronic lab notebook (ELN) includes modules for sample tracking, protocol management and data storage – either in the **eLabJournal®** cloud or on an organization's own servers. The **eLabJournal®** also meets the requirements for good laboratory practices (GLP), with documents able to be signed and countersigned with electronic signatures and locked for further modification.

Furthermore, effective inventory management and sample tracking can be enhanced with **eLabInventory®**. **eLabInventory®** offers a secure and flexible solution for inventory management and sample tracking which can be accessed anywhere, and from a range of devices. Using a barcoding system means the **eLabInventory®** supporting the possibility of human labelling error, and the system also provides automatic recording of audit trails supporting GLP/GMP guidelines.



References

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2. <https://www.statista.com/chart/18819/worldwide-market-share-of-leading-cloud-infrastructure-service-providers/>
3. Meticulous Research (2019) Electronic Lab Notebook/ ELN Market by Type (Specific, Enterprise), License (Proprietary, Open Source), Mode of Delivery (On Premise, Web, Cloud), and End User (Pharmaceutical, Biotech, CRO, CMO, Academia Research, Food and Beverage)- Forecast to 2025

About Eppendorf

Since 1945, the Eppendorf brand has been synonymous with customer-oriented processes and innovative products, such as laboratory devices and consumables for liquid handling, cell handling and sample handling. Today, Eppendorf and its more than 4,500 employees serve as experts and advisors, using their unique knowledge and experience to support laboratories and research institutions around the world. The foundation of the company's expertise is its focus on its customers. Eppendorf's exchange of ideas with its customers results in comprehensive solutions that in turn become industry standards. Eppendorf will continue on this path in the future, true to the standard set by the company's founders: that of sustainably improving people's living conditions.

More Information

Chart your own course to digital lab excellence!

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Sign up for a free trial of three months for the VisioNize Lab Suite: www.eppendorf.com/visionize-subscription

Learn more about our Eppendorf Digital Lab Solutions on www.eppendorf.com/digitallabsolutions.

Your local distributor: www.eppendorf.com/contact

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