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Agilent CrossLab Connect Deployment in GxP Laboratory Environments

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Introduction

Agilent CrossLab Connect is a comprehensive software platform designed to enhance laboratory operations through advanced data intelligence and onsite sensor technology. It provides laboratory-wide visibility by integrating sensor-based utilization monitoring with business analytics. Users can capture instrument utilization data across workflows, view analytics with dashboards, and make informed decisions from fact-based data. CrossLab Connect also offers functionalities such as allowing users to remotely view instrument specifications, review contract entitlements, manage service tickets, and request support.

CrossLab Connect applications include:

- **Asset Monitoring:** Visualize instrument utilization to boost laboratory productivity.

- **Inventory Manager:** Access and manage complete asset inventory across all sites.

- **Service Manager:** View contract entitlements, request service, track service calls, and view past service history.

- **Asset Lifecycle Analytics:** Gain insights into instrument life cycle by combining utilization, inventory, service, and entitlements data.

- **Smart Alerts:** Receive real-time notifications for instrument issues and maintenance reminders.

Agilent CrossLab Connect (Figure 1) leverages real-time data and analytics to optimize laboratory operations, improve efficiency, and reduce energy consumption. It enables labs to justify capital expenditure (CapEx) and operational expenditure (OpEx) with concrete data, driving productivity and cost-effectiveness. Comprehensive service management capabilities ensure effective instrument maintenance, minimizing downtime and enhancing overall laboratory performance. In recent polls, 87% of laboratory leaders agreed that immediate knowledge of equipment failures adds significant value[1], and 64% of respondents indicated plans to implement laboratory asset management software in the future to improve key performance indicators.[2] This integration of technology and data intelligence positions CrossLab Connect as a vital tool for modern laboratories aiming to achieve higher operational standards and scientific outcomes.

Figure 1. Agilent CrossLab Connect.

For laboratories operating in regulated industries, compliance with current good laboratory/clinical/manufacturing practices (GxP) is crucial. These regulations impose strict requirements on the implementation and management of equipment and software systems that influence product quality. For instance, GxP laboratory equipment must be regularly calibrated/qualified, and computerized systems must be appropriately assessed and validated based on their intended use. Any changes to GxP regulated laboratories must follow approved change control processes to minimize associated risks. This technical overview aims to assist GxP laboratories in implementing CrossLab Connect in regulated environments in a compliant and cost-effective manner.

CrossLab Connect overview

CrossLab Connect is a cloud-based software-as-a-service (SaaS) product designed to evaluate laboratory equipment utilization. It employs Agilent's specialized hardware and software technologies, tailored for laboratory environments, to collect data without controlling the instrumentation.

Data collection occurs through two primary sources. Inventory and service-related data are sourced from Agilent's internal customer relationship management (CRM) database. This source ensures that all relevant information regarding customer interactions, contract entitlements, service history, and inventory is maintained and easily accessible. System utilization and alerting data, on the other hand, is gathered from monitors installed on site. These sensors monitor the usage and status of instruments, transmitting utilization data through a firewall to a cloud-based server. This server processes the incoming data and transforms it into user-friendly business analytics using machine learning. These analytics offer valuable insights into instrument performance, usage patterns, and potential issues, and they are accessible to customers 24/7 via the CrossLab Connect platform.

Regulatory and risk considerations

CrossLab Connect offers a wide range of laboratory administrative features that provide significant value to laboratory management, from asset utilization monitoring to service management. When assessing the GxP risk of implementing CrossLab Connect in a regulated environment, two key aspects of the software should be considered: its intended use and its architecture.

Software intended use
The purpose of CrossLab Connect is to assist in laboratory business administrative functions, empowering efficient CapEx and OpEx business spend and simplifying equipment service management. Under this intended use, the program is not expected to influence GxP-related decisions or functions that could impact product quality. Consequently, it should be classified not as production-related software but rather as a business administrative tool. As such, the software is not required to comply with U.S. 21 CFR Part 11, EU GMP Annex 11, or equivalent regulations governing electronic records. However, because of this, it should not be used to collect or manage GxP records or be integrated into any GxP-related processes.

Software architecture

CrossLab Connect is a cloud-based SaaS product, meaning the primary application is hosted on Agilent's secure servers rather than within a company's internal network. This architecture reduces the burden of implementing and maintaining the software, as the program's servers are managed by Agilent. Additionally, it ensures that the core application remains separate from the company's qualified laboratory network and associated data, which can help minimize the need for additional IT and validation activities.

These two considerations are crucial when implementing this tool in a regulated environment, as they significantly reduce the GxP risk classification of CrossLab Connect and, subsequently, the requirement for computerized system validation (CSV) activities. An example of this validation applicability assessment can be found in Table 1.

Table 1. Example validation applicability assessment.

No.	Query	Yes/No
1	Are data created, saved, or reported for use in product and/or clinical product release or other regulated activity or quality decision criteria?	
2	Are data created, saved, or reported for use within a stability program for GxP product?	
3	Will the data be used to support regulatory filing information?	
4	Will the data be used to support a quality decision or used in an investigation on which a product or quality decision could be made?	
5	Will data be used during clinical trials or to support clinical trial decisions?	
6	Is the hardware or instrument/device connected to a qualified network?	
	Overall Result	
	Did you answer "Yes" for any items above? − If "Yes", computer system validation (CSV) is required in addition to any other qualification/validation activities. − If "No", CSV is not required. **Note:** If #6 is a "Yes" but all other questions are "No," then CSV is not required, but change control, minimally, is recommended to add the system to a qualified network.	☐ Yes, CSV is required ☐ No, CSV is not required

Although the purpose of CrossLab Connect is purely administrative and its main program resides outside a company's internal network, assessment and control should still be exercised to mitigate potential risks when installing the program's monitors on GxP regulated equipment and/or qualified networks. Therefore, the remainder of this technical overview is designed to assist laboratories in implementing these monitors in a compliant and efficient manner.

It is important to note that under its intended use, CrossLab Connect does not collect any scientific or proprietary information. The software is designed to facilitate laboratory business decisions and poses minimal cybersecurity risk. Although the software does not steward any corporate intellectual property, the Agilent CrossLab Connect data centers are ISO 27001-certified to ensure the protection of customer data.

Recommended monitor implementation in GxP laboratories

For CrossLab Connect to observe equipment usage, individual monitors need to be installed on site to track these systems. To align with varying corporate and laboratory policies, Agilent provides a range of monitor options generally categorized into two groups: networked and non-networked connection monitors. This technical overview differentiates these two categories and suggests how to implement each in a compliant manner.

Non-networked connection monitors

Agilent's only non-networked connection monitor option is the CrossLab Connect power monitor (Figure 2). This sensor is a Wi-Fi-enabled hardware device that connects in-line between the power outlet and the equipment, similar to how a power strip is used. It monitors the power used by the equipment and sends these raw data directly to Agilent CrossLab Connect servers, where machine learning is applied to identify instrument use in the form of run hours and activity counts.

Figure 2. Agilent CrossLab Connect power monitor.

When adding a power monitor to equipment in a GxP laboratory, measures should be taken to ensure these systems are not impacted by the addition of this monitor between the equipment and outlet. Laboratories should follow relevant change control procedures when installing these devices. If needed, Agilent's internal testing and documentation can be leveraged as part of the laboratory's like-for-like assessment to demonstrate that the power output is equivalent to the laboratory's electrical outlets. Please contact your local Agilent representative to view this documentation.

If GxP laboratories have access to both a qualified and nonqualified network, it is recommended to connect these systems to the nonqualified network, as these monitors are likely not generating or facilitating any GxP data. This will reduce the work needed to implement these monitors within the networked environment. If a GxP laboratory does not have access to a nonqualified network, relevant network change control procedures should be followed when connecting these devices.

Alongside power usage tracking, Agilent's power monitors can also collect ambient laboratory temperature and humidity data. While this data can offer valuable insights into general laboratory conditions, these specific sensors are not routinely calibrated or certified by Agilent. As such, this environmental data should not be used for GxP purposes.

Networked Connection Monitors

In addition to power monitors, Agilent offers network connection monitors for deploying CrossLab Connect, such as system- and file-monitoring. Instead of using external devices to monitor system usage, these monitors consist of onsite programs that scan the network for system activity. They are composed of two main software components: a data transfer utility that directly scans configured instruments or files and a laboratory manager gateway that packages received utility data and exports it to Agilent's CrossLab Connect servers for processing and visualization.

When deploying network connection monitors in GxP laboratories, the laboratory's relevant change control processes should be followed to ensure these programs do not impact existing validated systems and qualified networks. This process should begin with a risk assessment to evaluate the potential impact of the monitors on existing workstations and/or instrument controllers. When performing this risk assessment, laboratories should note that these monitors have limited functionality and can be configured with read-only rights to minimize implementation risk. Additionally, to ensure no proprietary or GxP-related laboratory data are exported out of the network or viewable outside validated systems, these monitors can be configured to export only utilization and system status data.

When software configuration is possible, laboratories should ensure that only privileged users (e.g., IT administrators) have access to these settings. Security controls should be tested to ensure nonprivileged users do not have access to these settings, demonstrating successful separation of privileges.

Although these monitors can be configured with read-only rights, to ensure and demonstrate that existing computerized systems are not impacted, laboratories can re-run relevant CSV user acceptance testing or performance qualifications testing as part of the change control process. Testing results should be equivalent to past testing to help demonstrate that the addition of the program has not impacted the computerized system's function.[3]

Conclusion

CrossLab Connect is a powerful administrative tool that assists companies in effectively managing their laboratory operations across one or multiple sites. By providing comprehensive visibility into instrument performance and usage, it can help laboratories make informed decisions, improve efficiency, and reduce costs.

For GxP laboratories, additional care must be taken to implement this software in a compliant manner. The approach should vary based on the monitor type(s) selected for a laboratory. Depending on a company's regulatory and IT requirements, a hybrid approach using both networked and non-networked monitors may be the best solution for laboratories with varying regulatory needs.

To learn more about how CrossLab Connect can enhance your laboratory operations, please contact your local Agilent representative.

References

1. Basic Lab Equipment Connectivity and Monitoring Online Survey, *Agilent Technologies*, **2023**.

2. Roberts, D. Lab Operations Benchmarking Report 2022, *Agilent Technologies brochure*, publication number 5994-4332EN, **2021**.

3. McDowall, R. D. Validation of Chromatography Data Systems, Ensuring Data Integrity, Meeting Business and Regulatory Requirements, 2nd Edition, Royal Society of Chemistry, ISBN 978-1-84973-662-6, 2017.

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