How to Guide

Agilent Technologies

Best practices for returning to the lab

The COVID-19 pandemic has demonstrated the impact that a laboratory shutdown can have on the scientific industry. A recent survey of life scientists[1] reported that 77% of respondents' institutes were completely shut down, with 19% experiencing a partial shutdown (where the facility is <50% operational). Equally, research, development and testing activities that were not focused on SARS-CoV-2 were delayed or stopped altogether. Although the severity of the consequences will vary considerably across scientific fields and institutes, such events put the scientific community under enormous strain. Pandemic-aside, an unexpected shutdown – for whatever reason – can disrupt supply chains and limit access to customers and markets. This, coupled with the reduction of on-site staff and an increase in remote working, causes huge economic uncertainty and makes it difficult for labs to reopen.

Whilst remote working is not ideal for many businesses, it has encouraged an acceleration of innovative technologies and capabilities. For example, the increasing use of informatics technologies in laboratories has revolutionized the way laboratories perform and document experiments.[2] Additionally, some of the electronic collaboration tools embraced during periods of prolonged shutdown have had a profoundly positive impact on long-term efficiency.[1] Laboratories should be prepared for unexpected events and aware of the solutions available to help them cope in difficult times. Agilent enables their customers to do this by providing operational visibility and collaboration for services, inventory and instrument utilization. In this guide, we will discuss the best practices and solutions available to help laboratories successfully return to the lab.

Optimizing instruments and lab operations

Instrument protocols

When preparing for a potential closure, instrumentation must be properly shut down (minimizing instrument damage and safety hazards), to ensure they are ready to run as soon as the lab starts up again. Lab staff must be made aware of, and follow, specific protocols for shutting down and restarting instruments, according to standard operating procedures (SOPs). In addition to following SOPs, everything must be documented in detail; with no guarantee of how long a lab will be closed for, staff cannot be sure that they will remember everything they need to know weeks, or even months, down the line.

Cloud computing

Many labs use local servers for computation and data-intensive tasks that cannot be performed on desktop computers. Yet sustaining these servers requires space, cooling, power, system administration and money. Cloud computing enables the storage and access of data and the maintenance of hardware and computational services over the internet instead of a physical hard drive.[3] As a result, businesses have the flexibility of connecting anywhere and at any time, with the additional benefits of a reduction in IT costs, scalable operations and storage, business continuity and more efficient collaboration. Moreover, the flexibility offered by cloud computing enables labs to overcome restricted access to their computing systems during a shutdown.

Cloud computing provides three services:

- **Software as a service (SaaS):** cloud application services that deliver applications that are managed by a third-party vendor and do not require downloads or installations e.g. social networks and apps, such as Google Workspace and Dropbox[4,5]
- **Platform as a service (PaaS):** a platform for software creation without the hassle of operating systems, software updates, storage or infrastructure[4]
- **Infrastructure as a service (IaaS):** uses Open Universal Desktop Services to offer virtual machines the necessary software for hands-on training found in most physical labs e.g. servers, networks, operating systems and storage[4,5]

Informatics systems in the lab

Laboratory informatics involves the use of specialized instruments, software and data management tools that help to optimize laboratory operations. Incorporating these systems will help improve a lab's return from a period of shutdown. The subsections below explore the various systems in more detail.

i. Laboratory information management systems

As the name suggests, laboratory information management systems (LIMS) address challenges in data management, automation and regulation by helping labs to better manage their samples and associated data. The ability to integrate and interface LIMS with most lab instruments and systems offers laboratories many benefits, including the automation and streamlining of workflows, standardized operations, a reduction in human errors, and faster overall turnaround times. One disadvantage faced by LIMS, however, is that they do not enforce the sequential performance of tasks or record results from steps that are not currently being completed. This makes it difficult to verify that a regulated workflow has been followed correctly and that results are not biased in any way. For labs operating in a manufacturing or quality control (QC) environment, the consistency in the way that tests are performed must be easily proven.[6,7]

Electronic laboratory notebooks (ELNs) are essentially digital replacements for traditional paper lab notebooks that are used alongside LIMS to create, store, retrieve, and share fully electronic records that comply with all legal, regulatory, technical, and scientific requirements.[2] By configuring experimental templates, ELNs also help to standardize workflows and make it easier to search and correlate data. A laboratory execution system (LES), considered a specialized type of ELN, is used to ensure the rigidity of repeated tests in line with paper-based standard operating procedures (SOPs) or work instructions. Since each step of a testing process is recorded into the software, analysts are unable to move forward unless they have completed the current step. In addition to enforcing SOPs, a LES is useful for validating calculations and instrument interfaces, and acquiring or importing data from multiple systems into one common system.[6,7]

ii. Analytical data systems

Most general-purpose LIMS lack the interface to automatically collect and store data from different analytical instruments. Scientific data management systems (SDMS), which can be easily integrated with LIMS, ELN and other informatics systems, are therefore used to manage all types of scientific data and documentation. SDMS enable labs to collect, organize, index, store, search and share electronic records within a secure and central source, improving overall productivity, compliance and cost-savings.[2,8]

Lab informatics systems can also be integrated with chromatography data systems (CDS) – a software platform used to collect, manage and report data from chromatography tests such as gas chromatography (GC) and liquid chromatography (LC). Once chromatograms are acquired and processed in CDS, the data is retrieved, checked and stored in the LIMS database. Thus, using a CDS package, scientists can perform advanced data acquisition and distributed processing and manage samples – all in compliance with 21 CFR Part 11.[2,7]

Asset management

Asset management is the foundation of a well-managed lab. Aside from the pandemic, labs face constant changes due to instrument relocation and fluxes in project priorities and lab staff. Having a good handle on the instruments in the lab space, where they are and what their purpose is makes these shifts and changes easier to manage. Well-structured program management ensures flexibility while maintaining control over short- and long-term changes that affect finance and operations. As described in Figure 1 below, asset management comprises three categories: instruments, compliance and consumables.

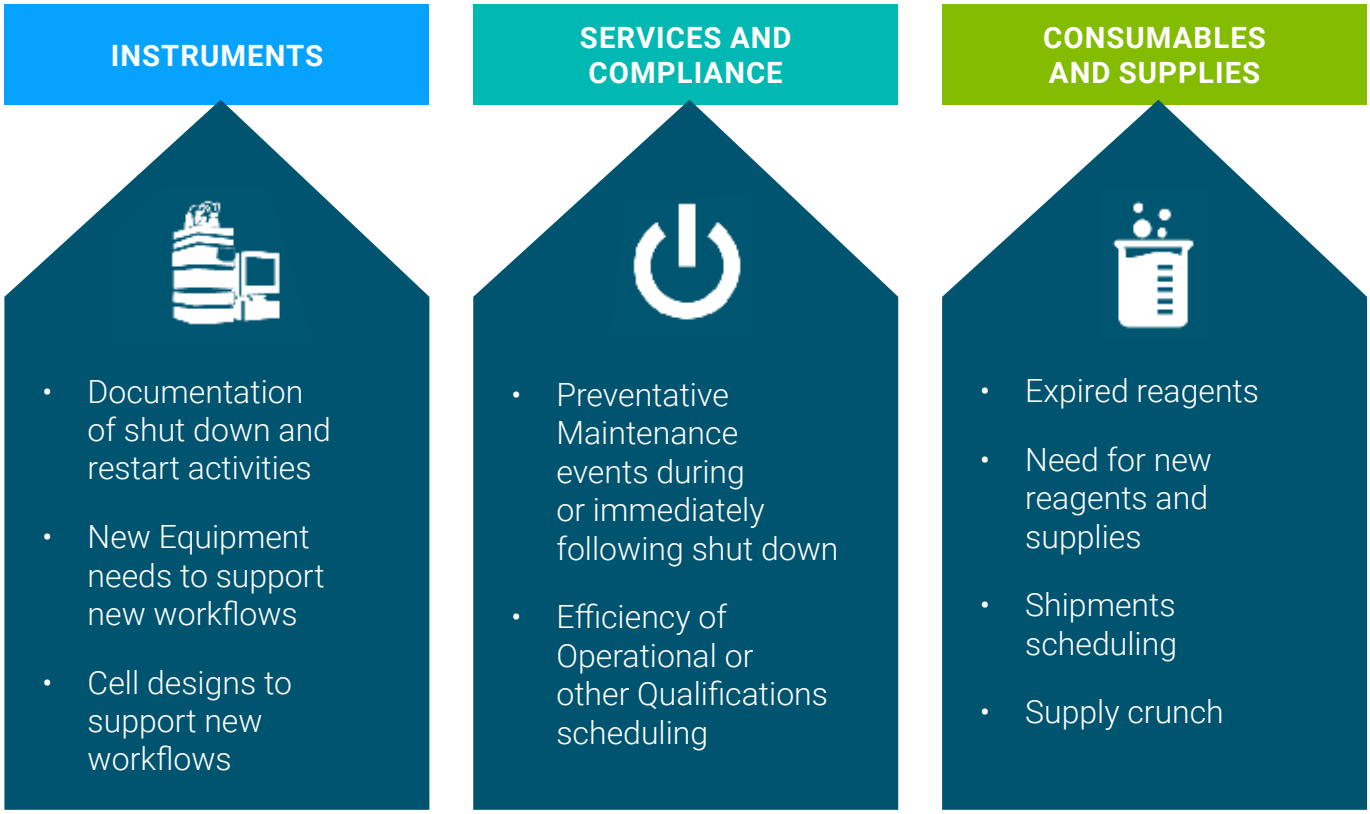


Figure 1. The three categories representing the basic areas of asset management.

i. Asset monitoring

Asset monitoring integrates instrument usage with analytics to provide insights into lab performance as they adjust to any new changes. Maintaining productivity is critical in any laboratory. With asset monitoring, users can examine their data from instruments or critical workflows to make faster and more informed decisions. This data can also be used to optimize workflows, identify and correct problems, generate other operation insights, and set up expectations and future needs. Gathering this data in an automated way frees up staff to focus on scientific tasks and provides a common language to communicate operational needs across different groups in a business.

ii. Inventory services

An inventory helps to identify any critical needs. However, it is also imperative when crafting plans to *meet* those needs. An inventory requires dedicated time and/or resources to ensure a reliable output. Below are some examples of best practices:

- Start with a template to ensure everyone is collecting the same inventory data
- Make sure that the attributes collected reflect the data required for a computerized maintenance management system (CMMS) or inventory storage system
- Have a leader or project manager assign areas and locations and to correlate the associated data
- Work in pairs to verify the information as it is collected
- Review data as it is being collected to ensure consistent input and results
- Make a checklist of all areas to be inventoried to ensure accuracy

Having identified critical business needs, an inventory can be used to mitigate risks and strengthen plans. With regard to personnel, asset inventories can help provide an accurate understanding of workflow capacity and help to identify staffing requirements for critical systems. This knowledge can then be leveraged to stagger scheduling or spread out instruments adequately for safe usage. For issues with supply chains and equipment procurement, bottlenecks should be identified before stockpiling consumables and/or sourcing multiple suppliers - this can be done before the reopening of a laboratory. Lastly, an accurate inventory can be used to capture instrument quantity and operational status, allowing lab leadership to identify which instruments are ready to use today, which will need work before any testing is performed, and classify high-priority systems. Collectively, this guarantees that instruments are operating within specification and regulation.

iii. Relocation services

Relocating instruments or whole laboratories, whatever the reason, can be extremely stressful and labor-intensive. The complexity of the overall process makes labs susceptible to mistakes and downtime.

You must consider every aspect of the move, including:

- Relocation planning and documentation
- Layout consultation for the new site
- Deinstallation, reinstallation and performance verification
- Instrument requalification and compliance testing
- Inventory management
- Post-move documentation

Assuring Compliance

Upheaval in the workplace as a result of the current pandemic, has led to a backlog of maintenance and operational qualifications (OQs) that many regulated labs must address. Disruption to work – for any reason – does not relieve labs of their requirements to ensure that they are following approved procedures and that the data collected is audited, assessed and validated. The focus on data integrity is not new, however, the evolution of globalized business models and documentation practices, the increasing complexity and interdependence of supply chains, and the increased availability and usability of data have prompted a significant paradigm shift in regulatory audits. All electronic records and signatures that are used for regulatory purposes are subject to 21 CFR Part 11, which ensures they are trusted in the same way as their traditional paper- and ink-based counterparts.[9] All data must meet the requirements of 21 CFR Part 11 and the following rules of **ALCOA**:[10]

- **Attributable**: all paper records must contain initial and handwritten signatures, whilst electronic records must include logins, user IDs and electronic signatures.
- **Legible**: legible paper records must include indelible links and any changes made should be justified, initialed and dated. For electronic records, legible documents must be saved and data must not be overwritten or deleted.
- **Contemporaneous**: paper records must not be backdated or pre-completed; the original date and time of the activity must be recorded. When applied to electronic records, data must be saved immediately after entry, and there must be controlled access to the time and date stamps on network systems, servers, stand-alone systems, and workstations. Additionally, server access time should be controlled with all time and date stamps synchronized to a certified time source.
- **Original**: electronic data captured at the source system must be complete with its associated metadata, and the original records must be reviewed at the source.
- **Accurate**: all data should be correct, truthful, complete, valid, and reliable.

Electronic data generated at the source system must be reviewed *in conjunction with* the associated metadata and audit trails. Regulators expect that businesses review their logs for server activity, operating system-specific activity, application-specific activity, instrument error, as well as their IT tickets to check backend database changes for modified or deleted data. For labs that are in the midst of a shutdown, it may be the perfect time to re-assess and improve existing compliance protocols.

Consumables, reagents and supplies

A comprehensive procurement plan must be flexible and requires continuous review and input from key stakeholders and open communication between all parties. Check that the purchase of new equipment supports existing workflows. Additionally, labs should consider:[11]

- *What* they need
- *When* they need it by
- *Where* it will be delivered
- *Who* is involved in the process
- *How* the procurement will be processed

According to current good manufacturing practice (cGMP), reagents and standard solutions include solvents and mobile phases, as well as dry chemicals (e.g. salts, buffers, acids, and bases) that have been purchased or self-prepared in the lab. Regulatory authorities such as the US Food and Drug Administration (FDA) expect facilities to follow expiry dates suggested by manufacturers and perform assessments for solutions prepared in-house and/or purchased reagents that do not have an expiry date.[12] It is worth noting that expiration dates and shelf lives for chemicals and supplies should be checked, especially in anticipation of a shutdown. Similarly, when anticipating the return to the lab, staff should ensure they have the necessary supplies to restart and run for a substantial period. It is worth considering that many vendors may have run out of stock as a result of the shutdown, or that there may be a spike in demand from labs that are reopening – either factor could have an impact on critical supplies. Upon deciding to restock the lab, staff should ensure that the supplies can be received.

Adjust to the new normal with Agilent

Agilent Technologies Inc. is a global leader in life sciences, diagnostics, and applied chemical markets, providing instruments, software, services, solutions, and staff to help their customers answer their most challenging questions.

Agilent CrossLab

For labs looking to improve efficiency, operations spend, instrument uptime, and user skill, Agilent CrossLab combines services, consumables and lab-wide resource management to support labs – regardless of their needs,

goals, and budget. Agilent CrossLab Asset Monitoring, part of the CrossLab Connect suite, integrates advanced Internet of Things (IoT) sensor technology and data analytics to increase visibility and control over operations. Additionally, you can:

- Capture lab-wide instrument utilization data across all workflows
- View analytics compiled in dashboards to drive insights for improvements
- Justify capital expenses, operating expenses, and productivity decisions using fact-based data

Lab efficiency and productivity rely on well-trained lab personnel, however, it is also important to foster an environment that encourages career success. Agilent University has a wealth of resources to support online laboratory learning in the industry. With more than 400 online courses available on demand, it has given access to flexible, cost-effective, and comprehensive training for over 38,000 scientists around the world.

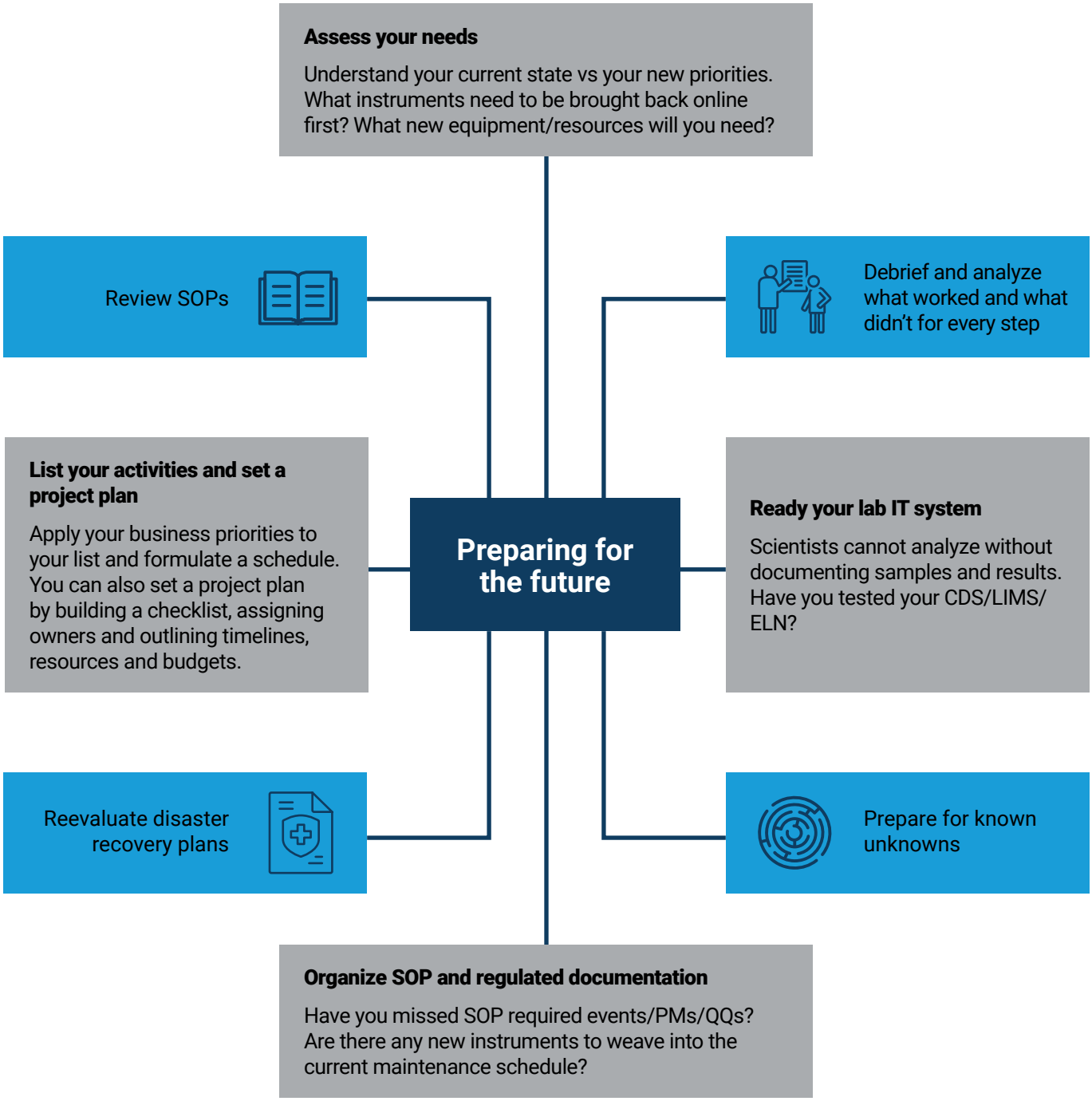
iLab

Maintaining social distancing in labs has never been easier. The Agilent CrossLab iLab software is a modular, web-based, asset management software tool that supports operations for centralized labs and shared resource facilities. Users can reserve specific resources and spaces with greater flexibility and control and access sensitive or validated equipment, track its utilization and manage on-hand inventory in labs and central stockrooms. Importantly, iLab is a secure software platform that ensures data integrity, availability and security.

Digital solutions

Since the increase in remote working has created new needs for software access and remote control, Agilent is offering their customers *free* software packages for:

- **Chromatography and mass spectrometry**
  - **OpenLab CDS:** Remote data analysis is now made easier thanks to OpenLab workstation software.
  - **MassHunter:** Free licenses for remote workers in academic institutions and commercial organizations.
- **Cell analysis software**
  - **NovoExpress:** Designed for researchers with all levels of flow cytometry experience, NovoExpress enhances sample acquisition and analysis through automation, eliminating cumbersome and time-consuming procedures.
  - **xCELLigence RTCA:** An integrated software package that enables scientists to simplify cell-based experiments and data analysis in real-time.
- **Lab and instrument management software**
  - **Agilent SLIMS:** Combining LIMS and an ELN into a single system, Agilent SLIMS is designed to provide flexible and configurable workflow management that supports the requirements of ISO17025, 21 CFR Part 11, HIPAA, and CLIA. Supporting workflows across analytical, NGS, biobanks, and R&D labs, SLIMS includes effective modules and pre-canned configurations to save time during implementation and facilitate easy integration with Agilent and non-laboratory instruments and software.
  - **CrossLab smart alerts:** Track the performance and health of gas and liquid chromatography instruments.
- **UV-Vis, Fluorescence, and FTIR Software**
  - **Cary WinFLR, Cary WinUV, Cary UV Workstation, MicroLab (Mobile), and Clarity Software:** Clarity software comes with unlimited offline licenses so that researchers can continue to conduct analyses at home.



[Learn more about successfully restarting your lab after shutdown]

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