

SIMPLE AND FLEXIBLE AUTOMATION FOR BIOTECH COMPANIES



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1.0 The Growing Role of Laboratory Automation in Biotech

Few industries were left unaltered in the aftermath of the COVID-19 pandemic, with the life sciences among the most directly affected. The pandemic saw unprecedented levels of demand for sample testing, as well as a global effort to produce a vaccine.

In the wake of this chaos, the biotech industry has seen a renewed industry push for increased urgency in bringing new drugs and therapies to market. It can often take upwards of ten years and \$1 billion to bring a new drug to market - and with this increased pressure to produce more, get better results, and to do so more quickly, biotech labs may be concerned about keeping pace with demand.

This is where automation comes in – automation systems help labs do more, with less.Benchtop automation can be used, for example, to set up experiments and perform experiments without limited need for human observation or management, thereby reducing the opportunity cost of valu-



able staff time used for menial operational tasks. Automation represents a promising avenue of added value for biotech firms by helping to deal with ever-increasing throughput volumes and improving the quality and reliability of results.

1.1 The Case for Automation in Biotech Labs

The relevance of laboratory automation is greater than ever, as evidenced by a <u>Nature</u> survey. 1,576 researchers were polled on the reproducibility of experimental data with discouraging results – 70% of respondents have been unable to reproduce the results of a peer's experiment, with more than 50% unable even to reproduce their own results.

This report highlights the need for a greater level of reproducibility across the industry, which can be achieved through reducing the incidence of human error. The introduction of automation systems helps not only to reduce the need for direct human involvement in manual experimental processes, but also enhances overall lab productivity while yielding more replicable and accurate results.



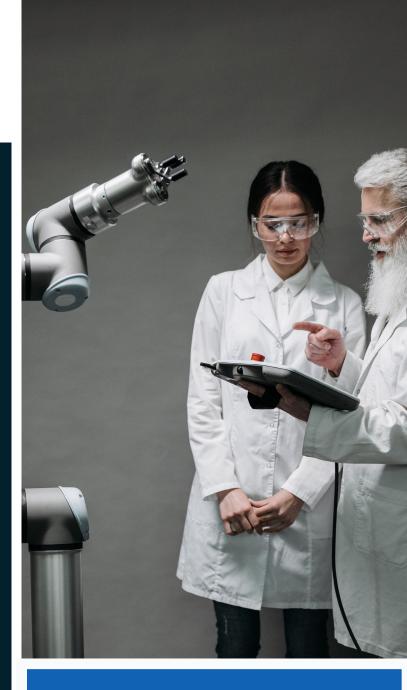
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1.1.a The State of Automation in Biotech

The biotech industry deals with huge swathes of data and ever-growing volumes of samples, presenting many opportunities to generate efficiencies through the implementation of automation systems.

McKinsey & Company reports on the future of automation in US BioPharma, providing a quotient that rates the digital maturity of several industries for comparison. A score of 70-80 is awarded to industries recognized as digital leaders. Perhaps surprisingly, the pharmaceutical sector scores 29, thus ranking lower in terms of digital maturity than the banking, media, telecom, retail, and hospitality sectors.

These statistics suggest low rates of adoption of cutting-edge technologies, and higher associated costs. The same report estimates general and administrative expenses for biological and pharmaceutical companies as 7% of revenue, 1.5-2% higher than comparable sectors.



Automation should be regarded as a tool to "break the linear relationship between workload growth and cost"

This provides a compelling case for the audit of lab processes to identify bottlenecks and potential time and cost-savings through the implementation of automation equipment. The upfront cost of automation technologies is quickly offset by long-term labor savings and should be regarded as a tool to "break the linear relationship between workload growth and cost."

Looking to the future, the lab of tomorrow is likely to rely much more heavily on machine learning and benchtop automation systems. Increasing uptake of automation equipment is being spurred on by the growing accessibility and advancement of automation technologies, as well as the falling costs of data storage and processing.

McKinsey & Company estimate that the lab of the future will automate between 40 and 70% of manual case-processing tasks, with data entry, coding, and patient intake as the areas representing the highest potential gains if automated. Automation can also be used as a tool to remedy skill deficits. Around 45% of companies globally report that their



organization is currently dealing with skill gaps, and 41% will encounter shortfalls in the next five years. In this instance, implementing automation systems can provide staff with additional and much-needed bandwidth, and can also provide a new area in which researchers can skill up.

1.2 Use Cases for Automation in Biotech

As throughput in biotech labs continues to rise and staff shortages loom, the case for automating manual lab processes is compelling. The WHO projects strong continued growth in the pharmaceutical industry at 5% annually, with the potential for market size to exceed \$1.8 trillion by 2024.

In alignment with the expanding pharma market, the demand for lab automation is expected to grow 7% CAGR through 2031. Despite biotech's low level of digital and automation maturity relative to other sectors, there is plenty of room for growth and numerous areas in which labs stand to benefit from implementing some level of automation.



1.2.a Benchtop Automation for Biotech

As a first use case, the discipline of synthetic biology involves the design and execution of complex workflows. The use of automation instruments in this instance has been shown to reduce the assembly time of large DNA molecules in a workflow from twelve to three hours. Winning back this time opens up numerous possibilities for researchers, ultimately allowing labs to design and execute on a higher volume of experiments – helping to get results faster and advance business outcomes.

The case for automation is also strong in the area of DNA sequencing. Using automation systems, the pooling of DNA fragments from sample libraries becomes substantially faster. Without the help of automation, the total time for the process can take upwards of six hours, but with the use of automation instrumentation, transferring each sample takes less than a second.

This reduces the processing time to six minutes. The use of liquid handling systems represents similar opportunities in staff time-savings and reduced churn from carrying out repetitive



Use of automation instruments can reduce the assembly time of large DNA molecules from 12 to just 3 hours

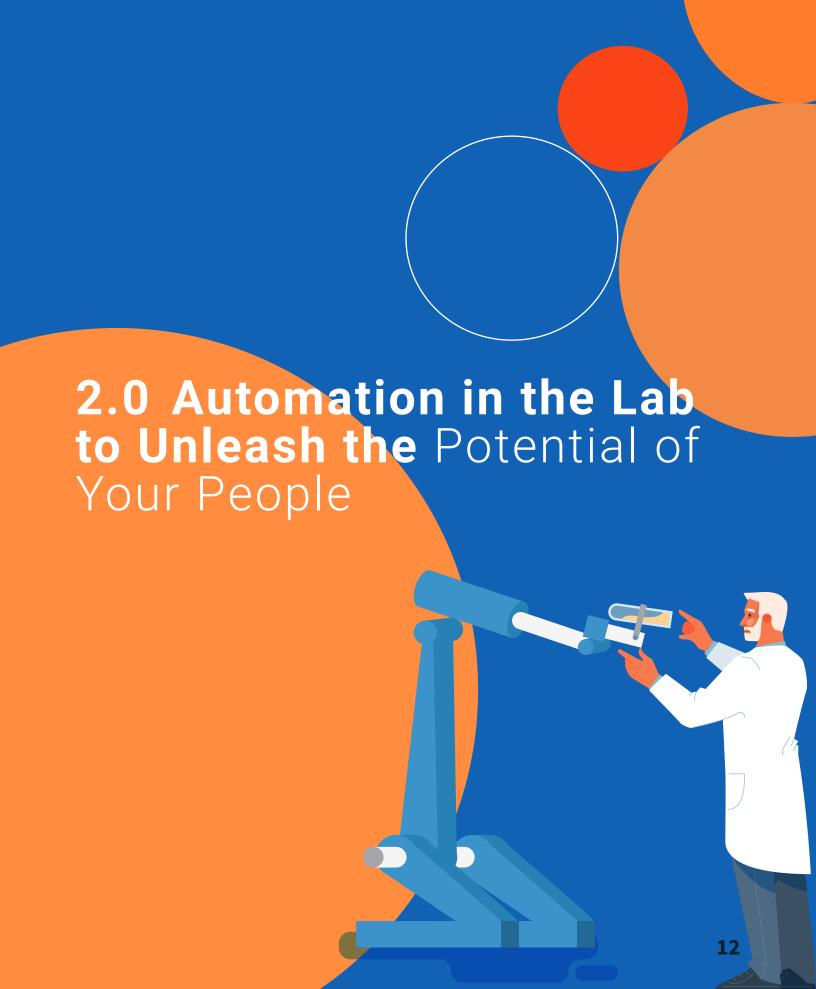
manual tasks. Advanced systems are being innovated, making use of soundwaves to cause tiny amounts of liquid to jump from one container to the destination receptacle, thereby using a tiny fraction of the samples and reagents that a conventional liquid handler would use.

This would be of great benefit in high throughput labs, allowing staff to do more with less. Labs may be discouraged by high buy-in costs, however, and the resources needed to train personnel to programme and operate the systems. Increasingly, tools which are smaller, dedicated to automate a specific task, and come at a lower price point are seeing an increase in popularity. This is in comparison to larger and fully automated systems which are used in high throughput settings and represent a significant capital investment.

These smaller systems have a lower buy-in and are simple to use, for example, giving users control through a web browser. This enables researchers to simply download operational protocols, and then run them.



Automation reduces the time in pooling DNA fragments from sample libraries from 6+ hours to 6 minutes



2.1 Why Automate Your Lab Processes?

Automation in the lab can be defined as any equipment or instruments able to perform tasks with minimal manual input from staff. Purchasing equipment or automation software for the lab may seem like an unnecessary expense if tasks can be carried out manually, but substantial inefficiencies can arise when staff have to be hands-on with simple but repetitive tasks — such as labeling tubes, capping or liquid handling.

It is helpful to frame the upfront cost of automation in terms of long term cost and time-savings. Staff time has become increasingly valuable across the lifespan of the pandemic, with social distancing measures limiting how many individuals can be working in-person at any given time and the outsized growth in wages the life science industry is experiencing.

This puts on-site time in the lab at a premium, making necessary manual tasks more costly than ever in terms of opportunity cost and output

An example is the use of an Al to analyze breath tests. Patients breathe into a bag which is then analyzed using mass spectrometry, and results are interpreted by an Al in under a minute.

Many industries are also seeing increases in throughput – notably life sciences, with more variants emerging that need to be analyzed and processed.

2.2 Unleashing Staff Potential Through The Automation of Lab Processes

Labs with high throughput and high sample volumes are likely to perform certain kinds of tasks repeatedly. This can become monotonous and boring for staff, whose time could otherwise be directed towards higher value objectives and science, or interpreting analytical results. This is likely to churn staff, who may become frustrated with the simplicity of manual tasks relative to their level of education.

Payscale estimates the average hourly cost for a research scientist in the biotechnology industry as \$43.75 - which can raise the opportunity cost for menial tasks considerably.

When dealing with high volume tasks, staff may also find it difficult to keep pace without making mistakes, potentially creating stressful crunch periods. This is where automation of certain processes can increase overall lab productivity and reduce staff churn



- reducing the need for experienced staff to carry out low-value manual tasks, as well as the number of staff that need to be allocated to these tasks.

Automating repetitive manual tasks reduces workloads for staff, allowing them to be reallocated to more stimulating and valuable work. Redirecting staff efforts is likely to boost rates of work satisfaction, and in turn staff retention. With less time dedicated to hands-on and repetitive tasks, staff are at liberty to focus on doing 'real science.'

Staff do not then need to spend time overseeing the completion of manual tasks – simply calibrating automation machinery, and leaving it to perform the work. Speeding up time-consuming manual tasks is one of the principal benefits of lab automation. This is of great benefit in industries where samples need to be processed quickly in order to preserve sample integrity.

Biological samples may be unique and impossible to replace or replicate, raising the cost of error during processing. Automation works not only to speed up time-consuming processes considerably, but also removes the risk of human error, which can become prevalent during repetitive high volume tasks. Automating the labeling of tubes, for example, ensures that labels are legible and accurate, even when processing in large quantities.

Reducing the risk of error aids in delivering more consistent and reproducible results, boosting the credibility of the lab's work and simultaneously reducing remediation costs arising from having to re-examine or retest unreliable samples.

Automation also helps reduce the incidence of repetitive strain injuries, which are more likely to occur when processing large volumes of samples. Pipetting, for example, is one of the most commonplace tasks in labs – and also one of the most repetitive.

Studies have revealed a correlation between hours of pipetting in the lab and hand and shoulder ailments. These strain-related injuries can easily be negated through the use of automation machinery, working to increase lab and staff productivity as well as reducing time taken off of work.

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2.3 Considering the Best Automations for Your Lab

Lab Manager provides a helpful list of considerations when weighing up which lab processes could be automated. Firstly, it is more economical to automate in stages rather than all at once. Taking a piecemeal approach preserves budget, and allows for staff to adjust to operational changes and become familiar with equipment.

It is important to audit your workspace to determine how equipment will affect workflow, as well as considering soundproofing, heat generation, and waste disposal to optimize layout. Ensuring that new equipment is compatible with the current inventory of instruments will also help to reduce any friction during the implementation process.

The flexibility of your automation stack is also important, in its ability to integrate with new or changing processes. Requesting demos during the consultation process will allow you to test for compatibility, and ensure the equipment is the right fit for the needs of your lab.



3.0 Evolving Best Practices in Sample Tracking

Laboratories dealing with high volumes of samples will be all too familiar with the logistical and operational difficulties related to tracking sample inventories. Maintaining a clear audit trail across the lifespan of each sample is crucial in the case that analysts need to justify their findings.

Following best practices in sample tracking is important for labs from a multitude of standpoints, namely in ensuring the integrity of data and analysis and following stringent regulatory requirements.

Implementing these best practices into your inventory management processes will help loosen bottlenecks and streamline processing operations.



3.1 The Importance of Implementing Best Practices into Your Lab's Sample Tracking

One first area of concern for labs in the handling of samples is compliance. Labs will need to be compliant with a host of regulations depending on the nature of samples being processed.

Lab practices in the US are regulated by a number of governing bodies such as the Food and Drug Administration (FDA) - notably 21 CFR Part 11 - and Environmental Protection Agency (EPA), as well as federal laws such as the Health Insurance Portability and Accountability Act (HIPAA).

The Good Laboratory Practice (GLP) guidelines were established to help regulated companies stay compliant in management of samples and maintain standards for handling and tracking. The purpose of these regulations is clear when examining how things can go wrong.

In 2013, a vial containing the Guanarito virus, a pathogen that causes hemorrhagic fever, went missing from a research facility in Texas, suspected to have been accidentally destroyed during cleaning processes.



Similarly in health settings as many as 160,000 adverse patient events occur in the US each year due to errors in identifying specimens.



Additionally, proper identification and tracking of samples is crucial in ensuring an accurate determination of guilt or innocence in criminal proceedings. Beyond these administrative and health risks, there are considerable financial costs associated with inadequate sample tracking.

The Patient Safety Network cites several studies estimating the average costs of lost and misplaced specimens. Irretrievably lost specimens tend to cost around \$548 each, with cumulative costs over a 3-month period adding up to a speculated \$20,430. Separately, mislabeling costs per specimen averaged out at \$712.

These costs can accumulate quickly and put pressure on lab revenue if the underlying causes persist.

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3.2 Difficulties in Sample Tracking



3.2.a Managing Storage Units



One of the principal logistical issues in tracking samples is retaining oversight of specimens in different types of storage units. For example, some types of specimens may need to be stored in freezers at -20 degrees Celsius, -80 degrees Celsius, and even in liquid nitrogen.

Others may be stored in refrigerators at +4 degrees Celsius. It is likely that these storage facilities will not be co-located, requiring manual work to transport samples, as well as creating data sprawl in recording the status and movement of individual specimens.

This difficulty is compounded when having to manage and track samples across their placement in shelves, racks, and boxes. Furthermore, samples may be spread over several distinct freezers, consuming space and using up valuable time in tracking, storing, and retrieving.

It is crucial that sample movements be recorded, however, this process can be laborious and time-consuming.

3.2.b Navigating Labeling Systems



Several complications can arise in sample management from illegible labels or inadequate labeling conventions. Many labs do not follow best practices for sample tracking, and it is common to see handwritten specimen labels - which introduces a costly human error component into the tracking process.

Firstly, manually entering data onto labels presents an opportunity for

transcription errors which can make it difficult to ensure that the correct sample has been retrieved. Labels may also be stuck poorly onto containers which often results in those labels falling off in freezers.

Additionally, different individuals in the lab may have used different labeling conventions, or writing could be illegible or fade over time. As a result, samples may sit unused in storage



due to uncertainty about their contents. These avoidable errors work to create <u>"[bottlenecks] in your laboratory".</u>

On a similar note, unclear labeling systems can lead to miscommunications about samples or test results. In a story all too familiar in the COVID-19 landscape, The American Association for Clinical Chemistry reports on a mix-up resulting from the differences between two organizations in their labeling conventions, leading to a miscommunication of COVID test results.

Four patients returning to the US from China were mistakenly assigned negative test results and were wrongly excused from quarantining. Subsequently, the report identifies a higher rate of incidence in mislabeling events during the pre-analytic phase.

3.2.c Managing Audit Trails

Maintaining a thorough audit trail across the entire sample lifespan is important for protecting the validity of data, and in staying compliant.

then becomes outdated quickly, and spotting anomalies can be difficult.

Many labs, however, continue to use legacy systems to track the movements of samples – commonly, these are paper-based systems or spreadsheets. The first issue with legacy systems concerns ensuring that all information is entered into records in the same format and using the same terminology.

Having to consult a key or index to this end and manually transcribe or input data increases the incidence of recording errors. Additionally, capturing the level of information needed on spreadsheets or paper records is difficult when considering the need to record sample contents, type of container, storage location, expiry or retention dates, sample movements between stores, etc.

This leads to a need to continually take notes when moving around the lab, which is not only laborious but again increases the frequency of recording errors – information also



Many labs, continue to use legacy systems to track the movements of samples

3.3 Incorporating Practices Into Your Sample Tracking

Maintaining oversight of samples across their entire lifespan can be laborious – but you can look to implement systems that streamline the maintenance of audit trails and make the best use of your storage facilities.

Firstly, it is important to monitor and track free storage space. In labs with high throughput, storage space will be held at a premium. 2D barcoded tubes such as those produced by Matrix, Micronic, or using TubeWriter's labeler to make unique 2D barcodes can save substantial amounts of space.

One downside of 2D barcoded tubes is the lack of human readable information that may be important in sample processing in the case that a scanner is unavailable.



3.3.a Mapping Out Storage

Clearly mapping out available space simplifies the storage of new inventory and helps planning efforts. When auditing your space tracking, it may be worthwhile to consider whether sample management software could create some efficiencies and reduce time-consuming tracking tasks. Freezerworks and Titian are a couple of leaders in this space.

This software provides an easy-to-update alternative to manually drawn diagrams of storage space and can be used to <u>audit store use</u> and identify redundant items. The maintenance of freezers and refrigerators is costly, so storing samples represents a possible opportunity cost – keeping unused or redundant samples stored due to poor space management, for example, can be expensive.

On a similar note, keeping back-up freezers and storage facilities in the case of a store breakdown is prudent to minimize any disruption during a technical fault.

Additionally, it can be helpful to map out labware usage and take stock of how many of each type of container



are in use. This process can present opportunities for standardizing equipment, which in turn brings bulk purchase savings.

As well as saving on equipment costs, standardization simplifies the movement of consumables between labs and aids the consistent use of protocols, as well as integrating with racks, storage compartments, and automation.

3.3.b Inter-Lab Communication

A report issued in the Journal of Applied Laboratory Medicine listed improved collaboration and communication between labs as the top recommendation to reduce the frequency of specimen identification errors.

Human error is a persistent issue in specimen labeling and tracking, which can be combated by streamlining cooperation in hand-offs. Other best practices to reduce the impact of human error in sample tracking include the use of <u>labeling automation</u>, the implementation of bar-coding, and the use of tracking software.

To this effect, the creation of consistent naming conventions and vocabulary is crucial in minimizing specimen mix-ups. Bar-coding is an increasingly popular solution to ambiguously or inconsistently labeled specimens.

In a similar way to how hospital staff scan both the barcode on the patient wristband and medication being administered, implementing barcode identification and applying the same principles in the lab can prevent costly mistakes.



3.4 Modernizing Your Sample Tracking

Thorough tracking through the entire lifespan of each sample is crucial – records need to be kept not only of sample locations, but also of storage conditions at all times in each facility.

Time spent in and out of storage units, time spent in analysis, and how many times a sample has been thawed, all needs to be recorded. Many labs could improve the accuracy of their audit trails through the use of LIMS, or lab information management systems.

These systems boast many advantages and efficiencies over the manual recording of data in spreadsheets or paper documents, housing all relevant data centrally in an easy-to-update interface.

Furthermore, labs may wish to consider the consolidation of standard operating procedures in a central document library or interface that can be updated when changes occur – this ensures continued compliance with regulations as well as efficiency.

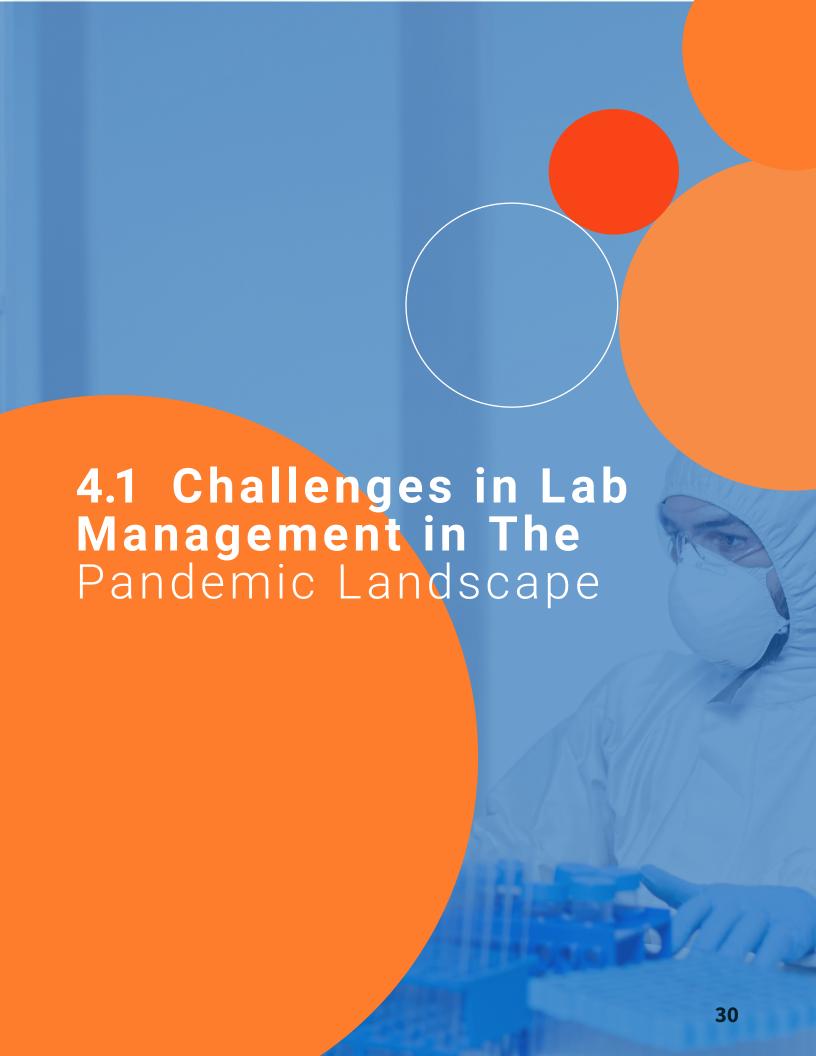


4.0 Lab Operations in a Post-COVID-19 Landscape

The pandemic has seen unprecedented staff shortages plague every industry, as well as forcing businesses to adapt their practices to comply with social distancing regulations while attempting to maintain day-to-day operations.

The sciences have previously resisted shifts towards hybrid work models, with many tasks requiring in-person attendance at the lab. However, the pandemic has accelerated the digitization of many lab operations and spurred increased buy-in of automation, marking a substantial change in attitudes towards lab operations post-COVID, and significant innovations in facilitating remote work.





4.1.a Managing Remote Staff

Lab managers have had to overcome a number of challenges in maintaining the 'new normal' in lab operations in the face of staff shortages, stringent social distancing measures, and unrelenting workloads.

Lab Manager notes some of the speed-bumps in adjusting to the pandemic, notably supporting staff with the challenges in remote work and leading teams virtually, adequately staffing labs while remaining compliant with social distancing as well as remediating staff COVID absences and having to shelve projects to keep up with increased workloads.

Managers have had to learn to use and standardize digital tools to communicate and coordinate with staff working remotely, while incorporating flexibility into a previously non-hybrid industry.

An increase in remote working has been associated with negative impacts on the mental health of staff – with less distinction between when the workday starts and ends, staff are less able to distance themselves from work, even once logged off.



4.1.b Staffing Shortages

Staffing shortages have been another significant hurdle for lab managers to navigate, and show little sign of letting up. The Great Resignation, as well as COVID factors, have led to significant staff shortages across the industry – and with a globally aging population, the volume of sample processing is continuing to increase while the qualified workforce shrinks.

There is a difficulty in recruiting graduates quickly enough to fill roles — and scientists that do fill roles may ultimately be employed in carrying out monotonous and unfulfilling tasks that can become costly in terms of opportunity cost and do little to advance wider lab outcomes.

It is important to consider the effects of this work on new hires, given that "adequately valuing the education level of lab employees and delegating the appropriate kinds of work to automation technologies effectively helps labs do more with less while keeping staff satisfied and engaged in their work too."



4.2 How COVID-19 Has Changed Lab Operations

4.2.a Reduced In-Lab Attendance

Lab managers have had to rethink how to conduct lab operations in the face of COVID-19 and social distancing restrictions, given that "the amount of time staff spend physically present in the laboratory has significantly reduced over the past 12 months" (2021).

The day-to-day running of labs has changed — more space is needed between equipment stations, adequate heating and ventilation is crucial, and extensive sanitization and deep cleaning protocols are now in place.

Projects, work tasks, operational prep, and instrument use, are all assigned and managed to keep in-lab personnel to a minimum at all times. These measures have seen increased use of scheduling software to regulate the use of lab space, as well as the digitization of brainstorming and meetings to maintain necessary collaboration across distances.

Social distancing and lab cleanliness measures, such as unidirectional people flow in-lab, are likely to stay



in some form for the foreseeable future as the international community continues to step down from the pandemic.

In terms of workload, projects need to be managed much more actively in order to ensure that output is maintained with fewer personnel in the lab at any given time. Staff that need to do bench work may set up rotation schedules, effectively booking out time to be in-lab. Similarly, on-site personnel capacities will be set.

To this effect, automation gives a much-needed boost to bandwidth, allowing high volume tasks to be completed more quickly, and without using up valuable staff time on-site.

The restrictions on lab operations entailed by the COVID-19 pandemic have given rise to advances in tech-enabled workflows, notably in life sciences.

IBM notes a couple of cases here, such as investigators extracting data from patient wearables for clinical trials, and providers connecting remotely to patients and investigators.



4.2.b How Automation and Process Innovation Are Changing Lab Operations

Social distancing restrictions and work from home mandates have accelerated the uptake of cloud computing in labs, with a need to transfer and store large quantities of data and enable remote access. The automation of data analysis tasks helps to organize and rationalize large volumes of information while reducing the need for staff to attend the lab to perform analytics.

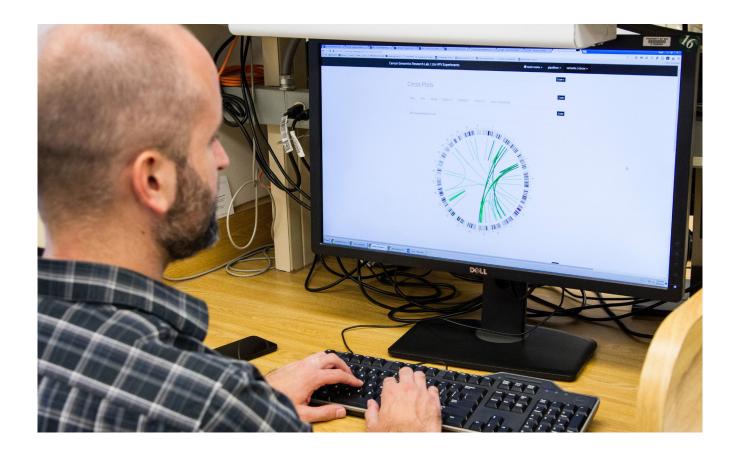
One COVID-related innovation case study is <u>Clear Labs' genome</u> <u>sequencing instrument</u>, which combines sequencing, robotics, and cloud-based analytics. Having been developed initially for food safety tasks, it was redirected during the pandemic. Automating the sequencing process with machinery saves between two and three days for preparatory work, and anywhere between four and ten days for analysis.

Other innovations include remote pH and temperature-sensing stir-bars, and remote centrifuge control. To facilitate remote instrument operation, labs may turn to management software platforms that provide a central secure



interface for remote monitoring and control of lab processes. With the changes mentioned in lab operations in a post-COVID landscape, demand has increased for smaller, simpler, and cheaper lab automation.

Formally, lab automation worked as a more niche solution for large-scale labs dealing with high throughput. However, with labs of all sizes now having to deal with reductions to on-site capacity, staffing shortages, and stringent cleaning and distancing regulations, more accessible types of automation are seeing greater rates of adoption.



Small and medium labs also stand to benefit substantially from automation, but cost acts as a barrier to entry. As such, smaller and less flexible but more affordable bench-top automation systems are becoming more popular - such as the Opentrons liquid handler system.

Smaller and less expensive systems are designed to automate a specific task, in contrast to fully automated systems that are more costly, but deal with higher throughputs and are more flexible.

4.2.c Lab Digitization Post-COVID-19

The pandemic has seen considerable acceleration of the digitization processes in labs, as companies have had to adapt to in-person restrictions and aim to be better prepared for any future disruptions.

Simon Meffan-Main, VP of product at Tetra Partner Network, relates a conversation with executives from a top ten pharmaceutical company, who previously "had a plan for digital transformation that was going to ride over the next five years. [They] are now compressing that plan into the next 18 months." He identifies the present wave of digital transformation and automation as the post-pandemic focus for biotech and pharma companies, as the industry seeks to foster resilience and institute robust systems for better handling of any future pandemics.

A key offshoot of this digitization is improvements in data liquidity in order to accommodate easier and more effective collaboration between companies in the future. While the pandemic saw heightened collaboration across the industry, efforts may have been hampered by difficulties in sharing data. Data that is kept in



different formats can be indecipherable without use of the correct technology, and this may even slow data sharing between different departments of the same company – with this difficulty compounded in sharing data between companies.

Thus, a greater focus on digitization moving onwards will increase the ease of collaboration and data sharing. A poll conducted at a conference by the <u>Pistoia Alliance</u>, a global not-for-profit advocating for greater collaboration in life sciences, reports that 72% of



attendees believe the lab of the future will be at least 50% virtual by 2030. This reflects changing attitudes in the industry towards the importance of digitization, and a recognition of its increasingly important role in building operational resilience and creating efficiencies.

While the pandemic has presented labs with no shortage of challenges, hardship has given rise to innovation in lab processes, changing conceptions about what can be achieved through remote working and how automation can create efficiencies as we move into a post-COVID norm.

One of the principal benefits of the restrictions imposed on lab workers has been an enhanced atmosphere of collaboration across the sciences, with innovations in lab digitization set to ease data sharing and cooperation into the future.

Conclusion

Laboratory processes and standards have undergone significant changes in recent years, adapting to the challenges of the COVID-19 pandemic.

A need arose for labs to accelerate their adoption of automation technologies and to quickly increase their levels of digital maturity.

Subsequently, the lab of the future may be here sooner rather than later, with an emphasis on automating time-consuming manual processes, enhanced collaboration, and prioritizing the digitization of processes and data.





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