WHITE PAPER

# TRENDS AND EMERGING PATTERNS IN REALIZING LABORATORY 4.0

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## Introduction

In the Digital Manufacturing era, the Laboratory of the Future or Laboratory 4.0 concept is fast emerging with the Internet of Things (IoT), Artificial Intelligence (AI) and Machine Learning (ML) technologies playing significant roles in defining a connected laboratory ecosystem. R&D is critical for new product launches in industries like Oil and Gas, Life sciences and Mining. Due to the high regulatory environment, these industries spend significant effort in the R&D stage. They have an extensive network of labs with considerable investments in infrastructure, and quality control (QC) is a critical process. The success of the QC and R&D process will determine the launch of the new products and the quality of the technology transfer to manufacturing/production. Laboratories like the QC Analytical Labs worldwide, R&D Labs, Bio-banking labs and niche functional Labs are the focus of Laboratory 4.0. Accelerating innovation and time to market being prime requirements, there is ample scope to digitize lab operations at multiple levels, enabling collaboration by sharing relevant information between labs with great speed and accuracy.

Recent advancements in technology, viz. IoT helps automate the laboratory process by connecting instruments, systems, applications and people. By enabling lab devices to communicate with each other and integrating information systems like Laboratory Information Management Systems (LIMS), Electronic Laboratory Notebook (ELN), and Chromatographic Data systems (CDS) under connected laboratory concepts, industries can transform their laboratory ecosystem and gain competitive advantage. High throughput screening systems and the adoption of AI increase speed and efficiency and enable informed decision-making.

This paper describes ways IoT can be utilized to transform brownfield and greenfield labs for digitizing and automating lab operations. It also provides a roadmap for the Lab of the Future across industries.

## The Laboratory 4.0 Imperative

It is well known that a new drug discovery launch takes about seven to ten years with complex processes employed in R&D. Significant data is generated in R&D, from experimental design, drug discovery, pre-clinical to clinical trials and beyond. There is an imperative to structure the lab operations, process and data collection, digitizing operations to remove manual errors and improve predictability, repeatability and traceability of process for compliance requirements.

Several activities and decisions during target design, identification, validation, lead optimization and trials require careful analysis of associated research data to converge and accelerate discovery. In the process, multiple stakeholders are involved, ranging from scientists, SMEs, lab assistants, technicians and external partners. As a result, there is a need for collaboration and ensuring all stakeholders have the same understanding to improve the innovation cycle by employing data-driven insights.

With much automated equipment in R&D labs, equipment integration has become vital to capture instrument data. The number of equipment and the proliferation of technology will increase in the coming years. Digitizing the operations by

connecting equipment, systems and processes is highly critical. By employing AI/ML predictive techniques, research iterations can be shortened, target screening and drug safety issues can be more elegantly tackled, and the time to market drugs can be significantly reduced. In this context, a Laboratory of the Future wherein R&D processes, systems and people become interconnected is an imperative for every enterprise.

Laboratories need to work in tandem with manufacturing to ensure proper technology transfer, compliance and quality checks at different stages of production. Quality Analysis and QC have many manual steps and involve multiple steps in sample preparations , data entry and collection of results from different instruments/devices. The samples, analyses, methods and results need to be traceable. Manufacturing brings in the challenge of data gathering and processing at scale and in real-time. Automating the collection and sharing of key data during this process will significantly improve laboratory efficiencies. It further reduces laboratory TCO by lowering costs for sample analysis, consumables required, and collaboration between people while increasing the innovation quotient and fostering effective decision-making in the organization.

## Realizing Lab of the Future

It's time for all laboratories, be it clinical, R&D or Quality Testing, to be transformed digitally end-to-end. A Digital lab journey will ensure an accelerated journey towards paperless labs through automation, integration and interconnection of different lab processes to drive efficiencies and scale.

The core of digitization is central data management with a system of records for different types of information and data workflows to automate inventory and decision-making.  It centralizes oversight and uses data and analytics to improve turnaround time.

**Basic Digital Lab/ Paperless Labs:**

All the Labs applications/systems like LIMS, ELN, CDS are integrated, and data flow is happening electronically between systems

**Advanced Digital Lab:**

Next step post Labs achieve Paperless goal, where robots and some extent of automation are in place to avoid manual interruption

**Autonomous Lab:**

These are basically self driving laboratories using AI/ML doing prediction of work based on historical events. Machine learning and modeling methods are used for predicting experiments, assay results etc.

*Figure 1: Roadmap for Lab of the Future*

## 1. Steps to Create a Lab of the Future

We recommend, based on numerous engagements with clients, developing the Laboratory of the Future in phases with incremental technology deployment:

### 1.1. Develop Integrated Ecosystems

Connected laboratory systems usher in huge benefits by transforming the working of the lab. It transforms the data exchange in the early stage of the product or process development to validating and launching them to the market. For example, it connects data across the drug lifecycle from drug discovery, clinical trials, process development, manufacturing, regulatory processes, automating data capture, and integrating different internal and external systems. This will facilitate various critical use cases like seamless tech transfer, safe data sharing with third-party labs and reuse of resources.

Global LIMS implementation is the first step towards integrated ecosystems in this journey. Fig 2. shows the conceptual schematic of a Futuristic Connected Laboratory ecosystem.

Automating and integrating legacy and modern laboratory instruments ensures data integrity and quick verification and release of results. Data integration with PLM systems for manufacturing specifications, bill of processes, and method protocols helps speed up innovation and lessen the time to market for newer products. The data from process control systems can provide the manufacturing context for the analyzed results. ERP integration provides stringent quality control, checks on inventory management and cost control. The AI/ML engine provides means to create meaningful advanced analytics and actionable insights into the laboratory process, utilizing the vast data and the capabilities of the analytics platform.

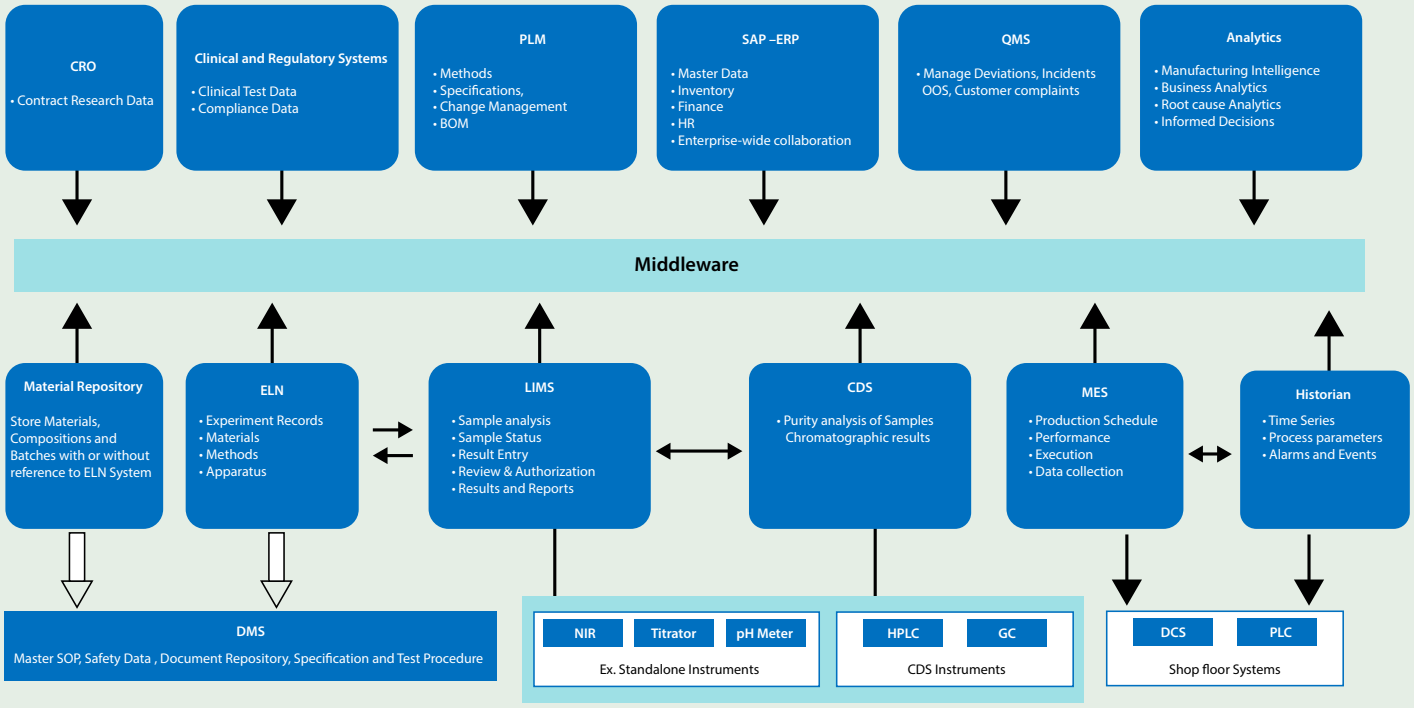



*Figure 2 : Connected Laboratory Ecosystem for Realizing Lab of the Future*

To summarize, the connected Laboratory ecosystem enables people and processes to transfer the Information/knowledge readily available at the fingertips.

### 1.2. Enabling People and Processes

Digital transformation in Laboratory 4.0 involves change management. The use of new technology, tools and automation of operations are changes in the current way of operations. Resources at work over the years need to be trained and enabled on these new tools, technology and processes. This should be a key focus for the transformation without disrupting operations.

In a connected lab, scientists/analysts will spend less time on execution and more time on research, as with better data and information sharing, many of the manual processes would be eliminated, thereby reducing lab cycle time. Connected Laboratories eliminate local repositories/excel files, organize data and information, and make knowledge sharing more transparent. Laboratories and research centers are storehouses of knowledge and call for robust knowledge management practices that are easily accessible, secure and scale per the organization's needs. It is expected that most companies derive more value from historical data by generating deeper insights into lab processes and improving them while eliminating redundant steps.

Connected Laboratory enables remote operations and data, controlling data anytime, anywhere, facilitating collaboration with expert teams and mobile operations, and reducing time for many R&D activities. It helps to stay connected and take actions, such as approvals, to keep the lab operating even while you are not physically present.

The key initiatives of Laboratory 4.0 and its potential benefits are discussed in section 2. New initiatives devised based on Industry 4.0 help improve the way of working for the Lab personnel (Fig 2). The way of work is influenced only when technological enablement brings relevant data with context to the right stakeholders at the right time. This affects laboratory processes and further brings a cultural change in the working methods, hugely impacting efficiency and outcomes. Simulation-based training allows Lab personnel to practice their skills and build expertise. These trainings are safe and free of consequences and help the Labs to adopt change by creating replicas of their operation with the equipment/instrument they use. This enables them to be part of the Lab of the Future journey.

### 1.3. Right Infrastructure in place

For the state of art laboratory ecosystems, infrastructure plays a key role. Decisions like hosting lab applications on physical servers in a local data center or cloud, along with mobility-based solutions, help teams to share data anywhere, anytime.

With the increase in digital, connected laboratory and cloud architecture, there is an increase in threat and vulnerability. Secure by design principles are adopted to ensure data security, data access and data governance like PII handling and GDPR. Security, a critical aspect, must be considered suitable from the design phase.

## 2. Trends and Emerging Patterns in Digital Lab

While creating a Lab of the Future with the right mix of technology, processes and people, the different trends shaping up in the industry must be considered.

These trends are in the three areas of Operations Processes, Technology and Integrated Planning Ecosystem. The lab processes must be re-engineered to facilitate transparency, collaboration and automation. Special attention to automation, including IoT devices, Robotics, and AI/ML, provides the much-needed tools for ensuring data-driven operations with high visibility and objective decision-making. These processes, be it experiment design, sample management, test planning, or overall lab operations, can be designed to work in synergy. Planning is an important area that ensures efficient utilization of resources. Integrated planning with contextual information from other business systems helps to focus not only on production planning but also on planning for quality analysis. It also supports enforcing the timely adoption of the right competencies by the scientific staff.

Some of the critical trends in these areas are outlined below:

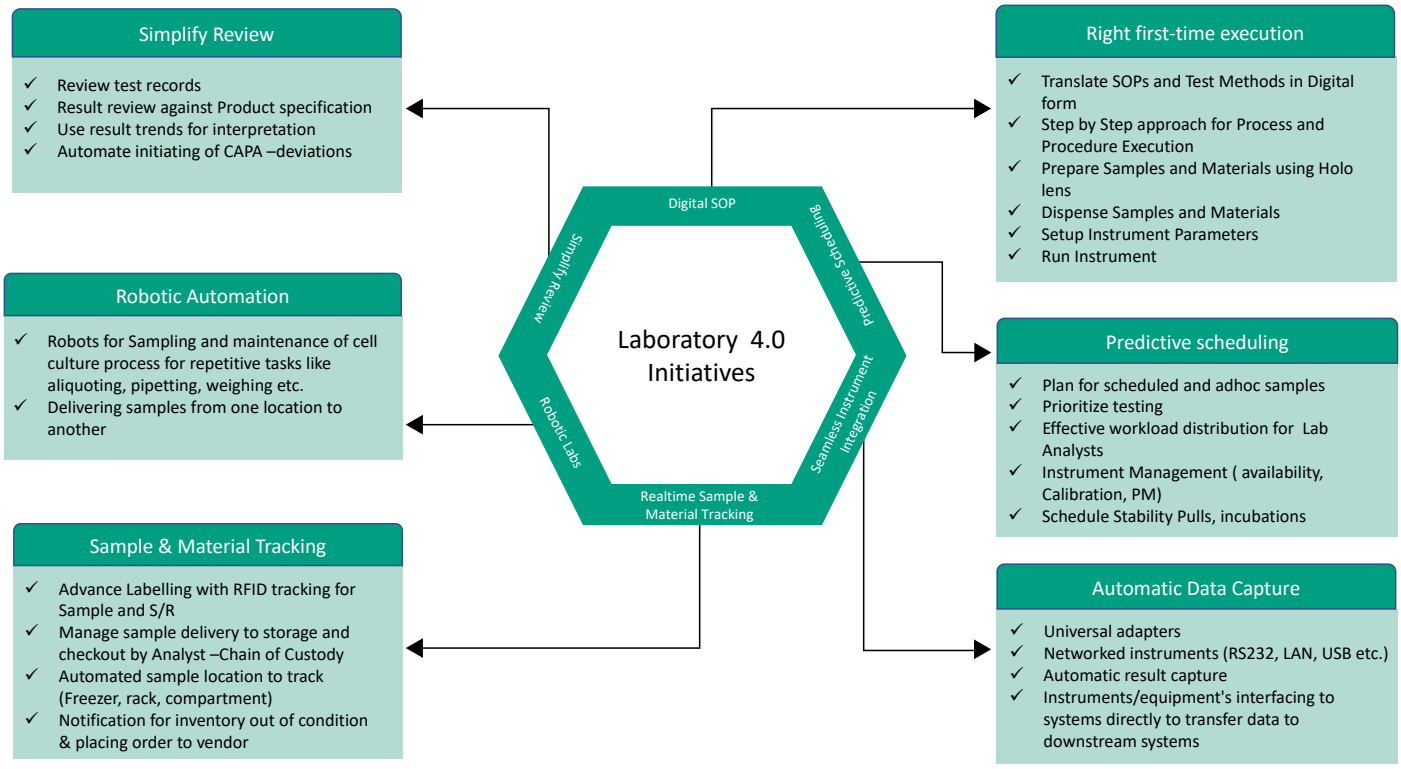



*Figure 3: Typical Laboratory 4.0 initiatives to transform operations*

### 2.1. Simplify Review using Data Analytics

Good manufacturing practices require production records to be reviewed by the quality team to detect deviations early before releasing the product to a specified market. Each record and its attribute need to be manually reviewed, which is cumbersome. A review by exception simplifies this audit in highlighting all attributes of a record that are not within market defined specifications and immensely benefits the quality assurance team [2].

Understanding and harnessing the power of lab data is another significant trend in Lab Informatics. By making lab data "Analytics ready" with manufacturing data lakes, lab data lakes etc., many analytical use cases can be realized, such as accelerated OOS investigations, reduced/risk-based testing, legacy data-based quality improvements, statistical quality control charts to check quality results deviations, reduced R&D iterations and accelerated stability tests.

With an increase in equipment, processes and automation, there is another challenge of more data. It is difficult to filter the volumes of data generated or even choose useful data for processing and analytics. Identifying the correct data set for data modeling, standardization, and harmonization will be challenging, as brownfields will have disparate and non-standard data. Laboratory data analytics will help reduce errors by providing ways to monitor QC results and by identifying the trends of lab analyzer results [3].

### 2.2. Right First-time Execution

Lab Execution systems can help digitize the paper-based SOPs and test method documents and improve lab quality and compliance. Basic errors in executing the test steps will be reduced and redundant steps eliminated, helping to enhance the total turnaround time or reducing overall lab cycle time for execution. It is essential to ascertain whether the analyst/ scientist has relevant qualifications to handle the test. Further, there needs to be a check on the instrument availability for test execution.

There are many commercial off-the-shelf (COTS) solutions like Thermo Scientific LES Solution [4], iLAB from Perkin Elmer [5], StarLIMS LES [6], and Biovia Compose [7] available in the market to address these requirements, capture samples, test data and digitize operations of the laboratory.

### 2.3. Eliminate Transcription errors with seamless Instrument Integration

Manual operations have led to errors and traceability challenges. To avoid transcriptional errors, it is essential to integrate all instruments (any make model and version) with LIMS or ELN in the Laboratory. Many LIMS packages can integrate instruments using their inbuilt modules like LabStation (LabWare), Instrument CI drivers by LabVantage and Integration Manager by Thermo Fisher. However, one will end up with writing parsers based on the different output formats of each instrument.

With real-time assessment of instrument performance, labs can immediately recognize any instrument problem and error in reporting results that are not in line with other analyzers. The ability to identify reporting differences between instruments over time allows the laboratory to monitor the quality of their lab results through the analytic testing phase for robust quality control [3].

## 2.4. Effective Sample and Material/Inventory Tracking

The chain of custody is a traceable record system that provides unbroken control over samples and their associated documents, raw measurement data and test results. It applies to samples from initial collection to final disposal. With smart labeling systems and RFID, it is easy to track the custodian and overall sample status in its lifecycle while automating the processes.

With the advancement of lab management systems and RFID technologies, it has become easy to locate samples, standards and reagents, including room/freezer/shelf/compartment. It can further eliminate manual processes by enabling automatic processes like placing an order in systems like Ariba to replenish materials based on the threshold limit or expiry date defined in the system.

### 2.4.1. Blockchain for Traceability

It is well known that the traceability of experiments, sample handling, testing, and changes to R&D methods, processes and inventory must be tracked. This involves both internal and external stakeholders of the enterprise. Contract labs and manufacturing organizations are also standard. In this context, blockchain technology, which is immutable, scalable and secure, can be harnessed.

## 2.5. Employing Advanced Robotics in the Lab

With a fast growing market for biopharmaceuticals, biotech companies must comply with strongly regulated production processes, which often require effort intensive tasks to control and adjust the growth parameters of recombinant cell lines. To overcome this enormous human effort, an autonomous mobile robot platform is helping to complete effort-intensive repetitive tasks.

Sample management is an inevitable and time-consuming part of the development and production of biopharmaceuticals to keep track of growth parameters and adjust them as required. Sampling and maintenance of cell culture processes are labor intensive, especially continuous perfusion operations that require 24/7 monitoring. Robots can be used at sample stations for pipetting or aliquoting. For instance, Bayer HealthCare, a USA biopharmaceutical major, has installed and successfully tested the use of robots in a pilot plant, saving valuable time and improving compliance and accuracy of operations [8].

## 2.6. Focus on Lab Scheduling and Planning

Labs must match their operations to meet the demand and supply requirements, considering the volume and complexity of tests. As a result, QC Laboratories have become a critical part of the supply chain. Digital Lab Planning and Scheduling will help accelerate the overall process. Benefits include on-demand test methods, improved availability of lab personnel, competency mapping for tests across roles, increased capacity and progress tracking [9].

Consolidating demands, e.g., lot release, product stability testing, deviation and out-of-spec investigations etc., can be done by integrating with existing business systems such as ERP or LIMS. These applications allow the automatic capture of a large part of the lab demand (lot release and stability testing)

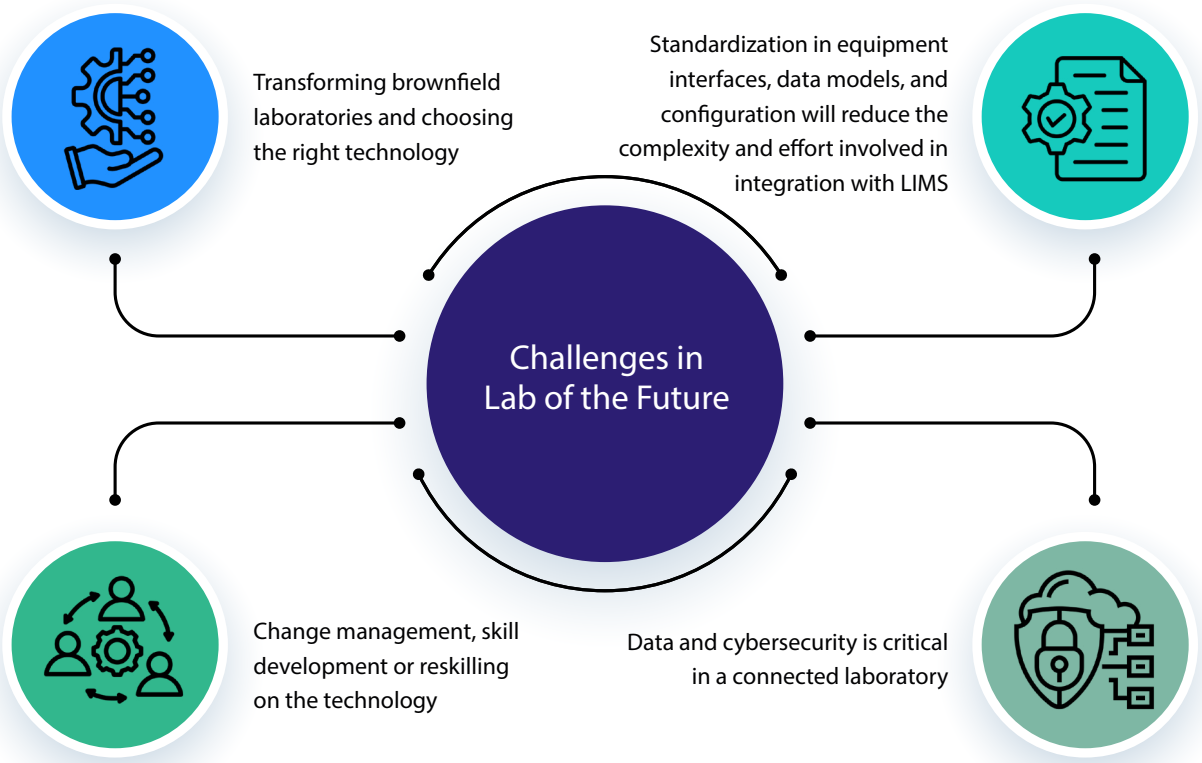
By defining team competency and qualification for the tests, tracking instrument availability and individual workloads, laboratory tests can be better scheduled, and better synchronizing plans and resources can improve team availability and lab effectiveness.

Providing a lab performance dashboard and driving lab processes based on Smart KPIs will improve adherence to plan and throughput.

## Conclusion

R&D organizations and industries face stiff competition and must introduce new products much faster. It is necessary to be more proactive and agile and collaborate with multiple labs, partners and stakeholders for radical innovation while protecting their intellectual properties.

There are challenges in the lab of the future -




Regulations are getting more stringent, but there is a need for a flexible decision system to discover more products and launch them successfully. This requires holistic, contextual information and an ecosystem with a well-connected automated laboratory and end-to-end digitalization of processes.

Data-driven decision-making with user-centric work processes helps drive effectiveness in the labs. Trends in the industry indicate the adoption of novel concepts like IIoT, integrated data management, robotics, analytics and cloud technologies to derive rich benefits. Implementing this architecture requires careful assessment, and a stagewise approach is preferable.

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