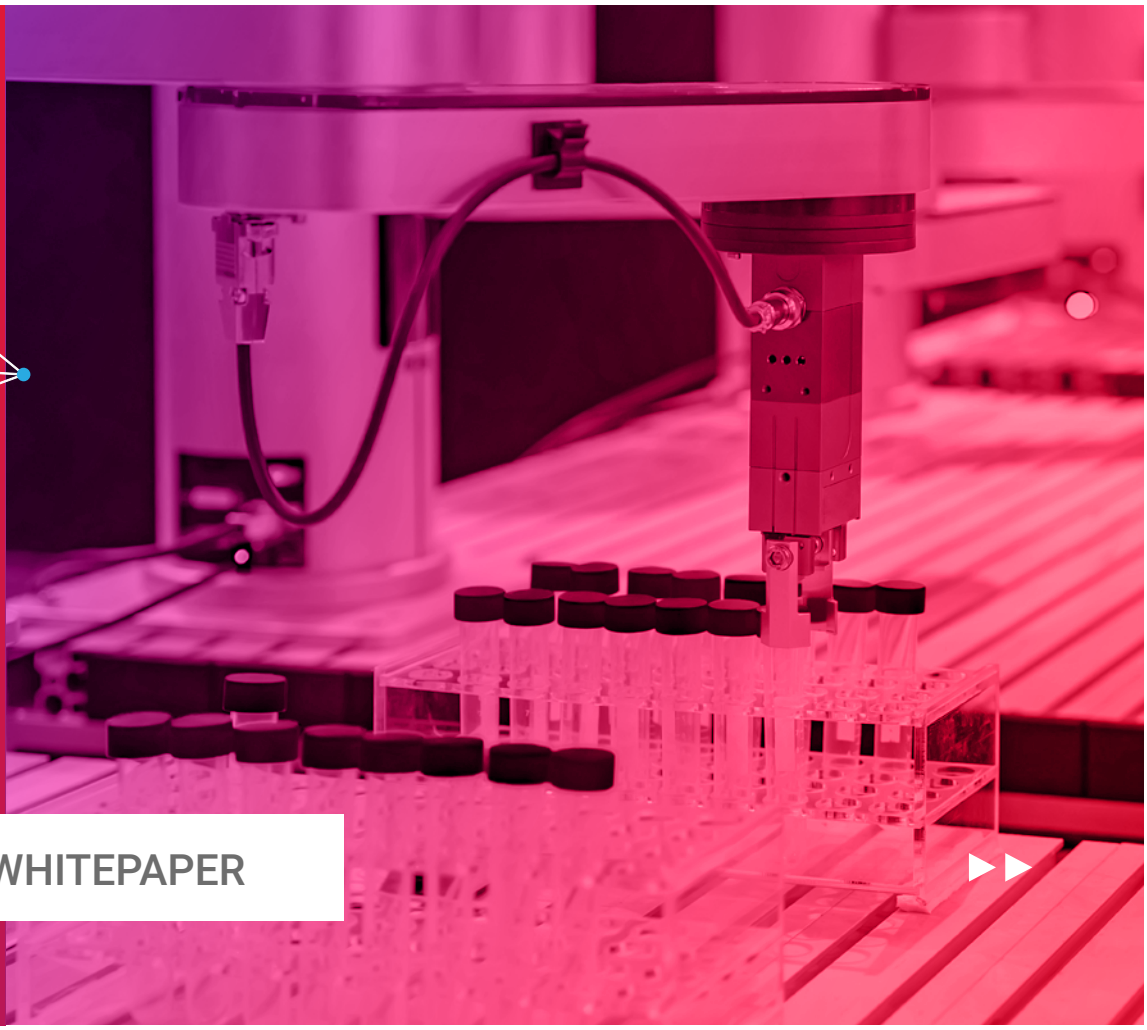
Tech Mahindra

The NXT Gen Smart Lab:

TRANSFORMING THE LIFE SCIENCES INDUSTRY



WHITEPAPER

Connected World.
Connected Experiences.

Abstract

Life science industry has been transforming over the years. The goal has always been to have innovative medication within a short span of time and the recent pandemic has been a true testimony for that.

Being a part of a highly regulated industry, life science industries face enormous challenges of meeting and complying with rules and regulations across the value chain. With fewer new chemical entity (NCE) / new molecular entity (NME) pipelines, the industry is pushed to innovate and develop novel compounds and vaccines at a faster pace. The question remains how to realize this in a short period.

Moreover, the pandemic demands right level of automation, artificial intelligence, advanced analytics, and digitization not only for the routine activities across the life science value chain but also in research and quality control laboratory for developing robust products and molecules in a smarter way.

Key Takeaways

The key areas covered in this whitepaper are as follows:

Introduction

Our vision for Smart Lab is a better, faster, and smarter version of the existing laboratory ecosystem. End-to-end connected systems, platforms, instruments would help in better operational efficiencies in the lab. When automated workflows and processes have been integrated within the connected network, it will speed up analytical operations, ensure data integrity and compliance by removing manual interventions and variability. Lastly, with the adoption of advanced analytics and adoption of new age technologies, real time operational visibility and business insights can be drawn more easily and help in following the logical next best actions.

Challenges

There are still challenges that lab scientists/ analysts/ chemists/ leaders face today. It is undeniable that the lab operations can be more effectively managed through the adoption and acceleration of digital technologies.

These challenges include:

Analysis or test execution yet to be fully automated.

Some of the lab instruments are not digitally connected and digital enablement is yet to be fully realized across the lab ecosystem.

Operational inefficiencies in research and quality control (QC) labs.

Scientists/ analysts use multiple non-integrated systems or applications with poor user-interfaces.

End-to-end workflows have not been digitally enabled, resulting in repetitive tasks and increases human errors across experiments, analysis, documentation, and data management.

Increased non-conformances cause increased batch rejection and delay in batch release.

Governance around data management is yet to be established completely. Thereby making business decisions using advanced analytics complex gradually.

With the adoption of digital tools, technologies and applications enable operational efficiencies and increase productivity in every area of research and quality control labs. When every iota of data is digitized and moved to secured cloud, it becomes more accessible for collaboration.

More so, use of advanced analytics and machine learning algorithms foster predictive maintenance and actual forecasting. It helps researchers for conducting virtual experiments to reduce the number of in-person experiments in a smarter laboratory ecosystem. Similarly, analysts can also conduct virtual testing to reduce the number of in person analysis.

The NXT Gen Smart Lab: A New Perspective

Figure 1: Smart Lab

[Fig-1] The imagination of labs of the future could be much smarter with the help of digital technologies and applications through end to end connected, automated workflows, and advanced analytics.

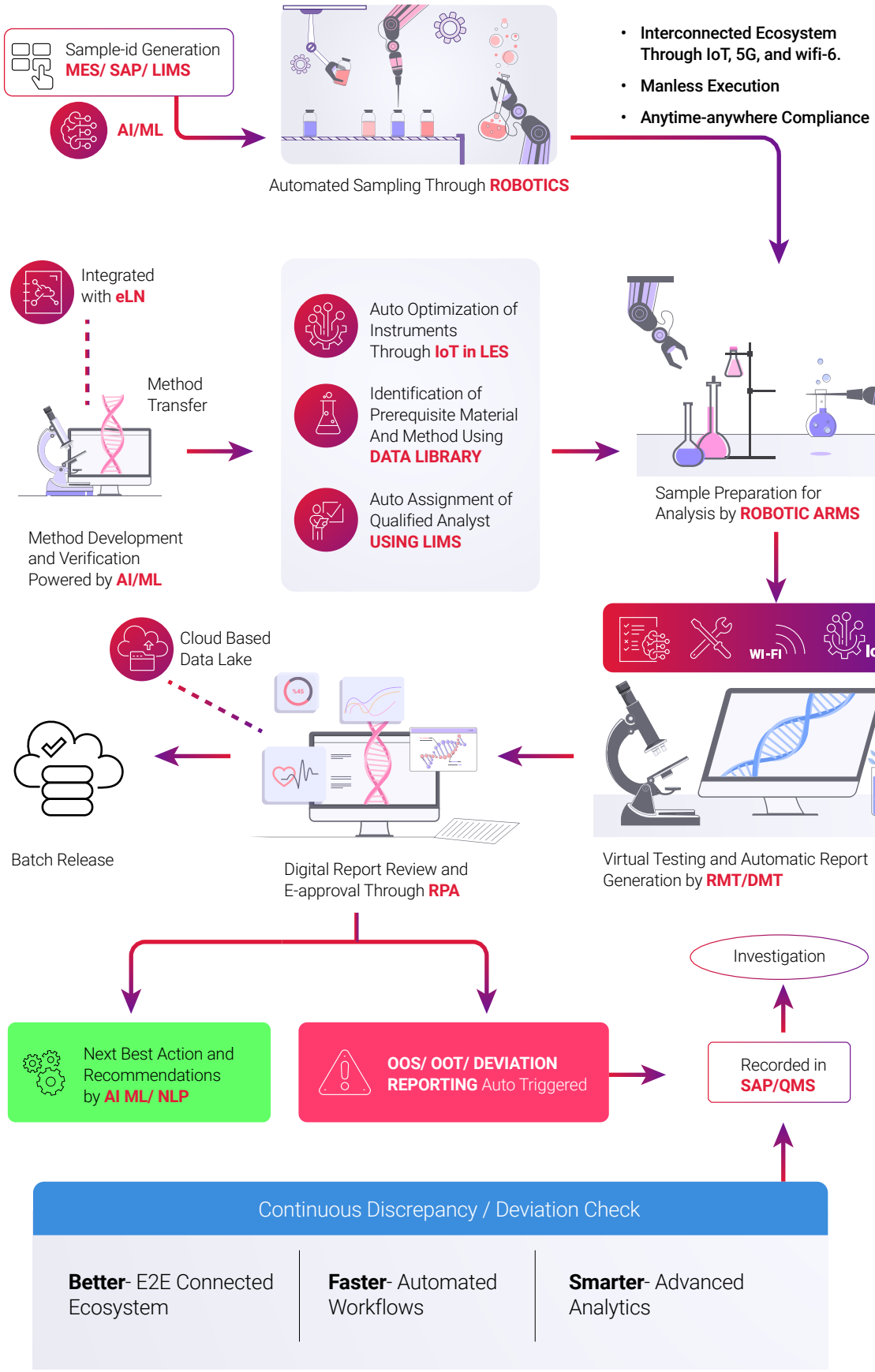


Figure 2: Concept for NXT Gen Smart Lab

[Fig-2] When end to end ecosystem being connected, automated and advanced, then performance will be 'better', 'faster' and 'smarter' in the lab.

Refer to the detailed narrative below:

BETTER Connected Ecosystem:

Laboratory functions and elements can be connected end to end digitally for all aspects of man, material, method, and machine. Along with platforms such as laboratory execution system (LES), manufacturing execution system (MES), system application and products in data processing (SAP), document management system (DMS), quality management systems (QMS), report management tool (RMT), data management tool (DMT).

Electronic method development, verification, and transfer from research lab to quality control lab will not only expedite the process but also create an efficient framework in place. With the creation and implementation of a digital method library to connect and integrate with relevant standard operating procedure (SOP), methods, reagents, and reference standards. This would enable seamless performance of lab activities.

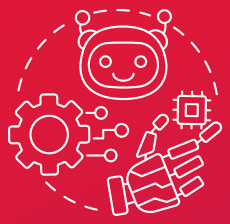
Connecting electronic lab notebook (ELN) with laboratory execution system enables real time visibility of experimental data.

Cleaning, usage, preventive maintenance, qualification, calibration status of instruments needs to be augmented with digital platforms. With the connected platforms in place, the system can auto select the qualified instrument to run an analysis. While preventive maintenance can be scheduled and performed as per annual schedule, unscheduled maintenance can be proactively predicted, and instrument performance can be improved through remote diagnostics or maintenance.

There must be a provision for creating a connected infrastructure for 'sample management'. Once the sample is being collected, sample details can be directly reflected in ELN/ MES/ SAP which may be connected to LES. Sample analysis can be prioritized through AI/ML based on the market need and batch release can be excelled over the traditional approach FIFO (First in First Out) and FEFO (First Expiry, First Out).

In the LES platform, it will auto-populate qualified analyst, calibrated and qualified instrument, validate method and respective sample for analysis. Upon completion of analysis, test reports can be generated automatically through report management tool (RMT)/ data management tool (DMT), for further electronic review and approval. Any discrepancy shall be auto populated in the quality management system (QMS) for appropriate action.

Individual test records or certificate of analysis (COA) can be maintained in cloud/data lake for tracking and visibility anytime, anywhere.



FASTER Automated Workflow

End to end workflow can be automated and managed digitally, such as auto-sampling, digital receipt and storage of samples, robotic sample preparation, robotic arm for sample injection, digital testing, e-review, and e-reporting of results. Complete master data can be archived and accessed through a data lake.

Through automated workflow, analysis and testing can be thoroughly monitored for any abnormalities. Such as during analysis, auto triggered alert will pop up in case of any malfunctioning or discrepancies, followed by real time impact assessment, AI/ML powered next best action to instruct Robots, Robotic arms for on time auto-rectification and continuation of sequence. It brings real world evidence and virtual realities into actual practice with the help of advanced technology like Metaverse (digital interface). This will help to find all necessary reasons or root cause to fix appropriate corrective action and preventive action (CAPA) and more importantly on time release of batch without lag time.

Advanced real-time data analytics for ongoing process verification, to track trend, and prevent deviations, outdated specifications, and trends, and for optimizing scheduling and capacity management. A digital twin can help to predict impact before making physical changes inside the lab.

A real time data collection, execution and monitoring will allow lab leaders to analyze laboratory systems more precisely. Using this automated workflow, proper sequence of lab activities can be identified and improved, helping reduce batch release time, reduce investigation time for discrepancies and human errors to smoothen lab operations.

SMARTER Advanced Analytics:

Robust methods can be developed through advanced analytics or AI/ML in research lab by referring previously developed methods. Thereby, significant reductions in method development turnaround time can be achieved.

Quality systems and processes can be reimagined with an innovative design enhanced with advanced analytics, artificial intelligence, and automation-built f day-to-day work in the lab.

Predictive analytics for risk-based decisions and proactive interventions to prevent quality issues through real time data and insights from self-visualization portal.

Establishing a paperless lab to avoid human error and have uninterrupted access to data through 5G networks. 5G networks would be able to transfer data from the lab instruments directly to the cloud, eliminating issues due to low performance network.

Robotic audit and corrective and preventive action (CAPA) management based on deep learning algorithms ensuring convenient audit readiness. Auditors can directly access the data in the cloud, assess the state of compliance and share their observations without even prior intimating the Organizations.

What Lies Ahead

The transformational journey from phygital to robotics lab would be the next big move and the adoption might take 2-5years. It gives confidence to lab leaders to adapt Man less execution for end-to-end lab operations which will enhance the agility, productivity, risk reduction, risk mitigation, real-time decisions and reduce batch time with complete attention to patient safety and product quality.

Successful adoption and deployment of digital solutions would significantly reduce the cost of poor quality (COPQ), cost of poor execution (COPE) and the cost of inaction in this competitive world.

Lab leaders must take a strategic approach in investing and adopting 5G, IoT, AI/ML based technologies, to calibrate expectation vs return on investment (ROI) and prepare for the future.

With the disruption of digital technologies converging at scale, recent evolution of Metaverse would reimagine the digital transformation landscape. It helps in realizing a unified and immersive experience by direct-to-avatar (DTA) product releases. Thereby creating a metalab in an augmented reality (AR)/ virtual reality (VR) world of seamless interaction between human and machine. Metaverse brings the growth in next level of digital technology by eliminating barrier between digital and tangible in the lab. Thereby, it excels real time release with virtual world in NXT Gen Smart Lab.

The roadmap designed must be “just right”, which would deliver high ROI and help the enterprise to benefit. This technology promises to be the first in market with zero compliance issue.

References

BioPhorum (2021, Dec) test executions across the lab is not fully automated **https://www.biophorum.com/download/deliverable-upload-lab-of-the-future-manifesto-digital-technology-based-capabilities-for-the-quality-control-qc-lab-of-the-future/**

Authors

Dr. Anjana Paty

Project Manager- Life Sciences Domain, Tech Mahindra

Anjana has over 13 years of Professional experience in the Pharmaceutical Industry as a Lead Auditor GxP, Lead Quality Assurance and Quality Management System. She is a Doctorate in Management Studies (TQM) from Indian School of Business Management (ISBM).

Dusmanta Kumar Sahoo

Domain Consultant- Healthcare & Life sciences, Tech Mahindra

Dusmanta has around 15 years of Professional exposure in Pharmaceutical Industry leading generic product development, product lifecycle management, new product launch. Advanced Management in Manufacturing Operation and Supply Chain from Indian School of Business (ISB)

Sampat Kumar Yandrapu Geetbala

Client Partner - Healthcare & Life sciences, Tech Mahindra

Sampat has two decades of IT experience in Life Science Industries and is instrumental for developing digital solutions using next gen technologies in the Manufacturing, Quality and Supply Chain. He is MCA, Certified Project Management Professional, Six Sigma Black Belt (CSSBB) and Pursuing Executive Master's in leadership from BAYES university (formerly CASS).