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A Frost & Sullivan Virtual Think Tank Executive Summary

# The Pharmaceutical Research and Development (R&D) Laboratory of the Future

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Frost & Sullivan, the Growth Pipeline Company™ for almost 60 years, hosted a virtual think tank entitled *The Pharmaceutical Research and Development Laboratory of the Future*. The purpose of the think tank was to discuss important issues encountered in the past year, explore various needs and changes in the way pharmaceutical R&D is conducted in the laboratory, and deliberate what could be in store for the future.

This summary document highlights important insights, perspectives, and takeaways from the session.


***Moderator:***

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  Frost & Sullivan

***Thought Leaders:***

- **BEATE HANSON, MD**
  *Head, Global Clinical Research*
  Baxter International
- **ANDREAS HUHMER**
  *Senior Director, Global Vertical Marketing*
  Thermo Fisher Scientific
- **PRIYA MANNAN**
  *Vice President and Director of Compliance, Data Privacy and Associate General Counsel*
  Novartis
- **INGUVA SIVARAM**
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  Novartis
- **CHRISTOPHER WU**
  *Director, Quality Control*
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The COVID-19 pandemic forced pharmaceutical research laboratories to do more with less, despite relentless demand for new therapeutic agents. Now, life science researchers and vendors are contemplating how to best guarantee safety and quality as some of these changes become permanent and accelerate transformational initiatives.

As with many organizations, labs big and small have been impacted by the current coronavirus pandemic. With some states slowly lifting the social distancing measures necessary to slow the spread of the virus, some lab are now putting together plans to return to work in a very different environment than the one staff left.[1]

The pandemic affected laboratory output regarding staffing and supply chains. With fewer workers physically on-site and the persistent threat of consumables and equipment shortages, decision-makers have considered adopting system automation, effective cross-training, and remote collaboration.

The immediate of the crisis (Covid-19) has been a major disruption to work practices. Travel bans and shelter-in-place orders are widely in effect and many corporations have shifted to work from home policies. Some big companies such as BMS and Eli Lilly have announced suspension or delay of some of their clinical development programs in order to keep their people safe.[2]

> **An audience poll indicated that the greatest impact of COVID-19 on their labs was the speed of receiving test results (44%), followed by inadequate staff to run tests, a lack of cross-training on equipment (33%), and concerns about the quality of results due to staff training and time constraints (22%).**

Reflecting on these results, the panel discussed their own challenges with obtaining critical data in a timely fashion, especially those related to staff being quarantined and requirements for social distancing. Several panelists expressed how favorable it would have been to run experiments from home.

Even prior to the pandemic, the research community had been contemplating “the lab of the future” as scientists, vendors, and others explored how improvements to productivity, efficiency, innovation, economics, and other desired parameters could be achieved. Drivers for this continue to include the desire to increase effective collaboration, the number of new candidates entering the pipeline, flexibility of staffing assignments, and overall digitization by the industry. Related to this, Industry 4.0 is supplying new potential for transparency, quality, and safety, and more intelligent approaches to pharmaceutical development and manufacturing.[3]

# Strategies for Preparing R&D Labs for the Future

Geographically dispersed teams will have access to data never seen before and must be able to process and retrieve it on demand to collaborate effectively. The importance of storage, along with legal and regulatory requirements, will highlight new, lab-related issues in the future.

Frost & Sullivan's, "Data Science Impacting the Pharmaceutical Industry", discovered that data science tools are promising technologies transforming drug discovery speed, cost, and efficiency. When combined with other emerging tech areas, artificial intelligence (AI) technologies move to the next phase of progress. Therefore, they are expected to witness adoption by biotech and pharma companies in the next four to five years. Further, with COVID-19 pandemic, AI and machine learning (ML) can be utilized for clinical trials and drug research against the coronavirus to screen large databases and perform docking studies to identify existing potential drugs or design new drugs using advanced learning algorithms.[4]

Andreas Huhmer, the senior director of global vertical marketing at Thermo Fisher Scientific, stated that customers want scientific research solutions that provide faster results and facilitate deeper insights on the samples they analyze. As an example, he shared a demand for tests that not only identifies the primary binding site for a potential new agent but also potential toxicities and side effects at binding sites for that same agent so researchers can more quickly

 

and accurately determine which agents warrant further investigation. Today, cellular thermal shift assays driven by modern Orbitrap-based, high-resolution mass spectrometry workflows, complimentary advanced mass spectrometry data analysis solutions, and multiplexing allow efficient monitoring of protein–complex dynamics and protein-drug interactions on a proteome-wide basis, providing insights at a scale simply impossible with traditional binding assays.

According to Frost & Sullivan research, bringing therapeutics and medical devices to market rapidly and efficiently is paramount to improving patient outcomes and contributing to a company's bottom line. Without well organized, easily accessible, thoroughly documented data, the value of a drug or device may not be fully realized. The challenge with every new partnership or outsourcing opportunity lies in how quickly and efficiently a pharmaceutical company can analyze the data coming from different sources to make business decisions.[5]

## Should Quality Be Sacrificed for Speed and Cost?

The pharmaceutical R&D lab of the future is a massive undertaking that must never sacrifice quality while accepting the realities of time and budgetary pressures.

> During the session, the audience was polled as to which they considered most important: speed, quality, or cost; the leading response was quality.

The panel agreed with the audience that quality should never be sacrificed over cost and/or speed. This perspective was also in-line with a customer study commissioned in January 2021 by Thermo Fisher that surveyed 200 global participants highly involved in R&D strategy and decision making across a variety of industries; in this study, quality of results was viewed as the most important to partners and customers. Most respondents (59%) agreed that their lack of strategic partnerships with suppliers prevented them from maximizing the value of aligned development roadmaps.

Huhmer pointed out that artificial intelligence (AI) is now able to derive high-quality results quickly and cost-effectively from both large and fragmented data sets, allowing companies to obtain greater insights in shorter periods of time, thus reducing the costs involved in running multiple tests. "As a supplier," he said, "[Thermo Fisher is] looking at the role AI can play in enabling better, smarter-connected scientific instruments for the user community to close the skilled personnel gap. We see flexible integration capabilities as the foundation of enabling the connected laboratory. Building a laboratory ecosystem that connects people, instruments like chromatography and mass spectrometry, corresponding consumables, and software will require the right capabilities and tools. Transforming the labs of our customers means enabling

 

their scientists to manage their analytical data and workflows, perform analysis on data from multiple instruments within a single system, while maintaining data integrity and maximizing productivity."

Thermo Fisher Scientific currently offer a complete suite of digital solutions enabling customers to connect everything from lab automation, data management and digital partners giving companies complete control and oversight of their labs.[6]

## Transformation Initiatives

The use of digital technology is no longer a competitive advantage – it is the price of admission for doing business. Yet, for many life sciences firms looking for large-scale digital transformation, the volume, velocity, and variety of data being generated by scientists is overwhelming the systems currently in place to support it. Up to 70% of research is not reproducible, often due to the inability to find the original research data or because the experiments conditions are inconsistently or inadequately catalogued. There is also the aspect of trust, where without access to raw data scientist are often inclined to repeat the experiments.

> **Pharmaceutical transformation influencers include better ways to address extended research timelines, R&D costs, value-based care shifts, increased standardization, and the need to incorporate cutting-edge technology advancements[7].**

Christopher Yu, the director of Genentech's Quality Control Division, spoke of the "if it isn't broken, don't fix it" attitude that persists in labs and reduces the desire to explore new technologies. It is not that scientists are afraid of new technologies, but rather that they are either too busy or do not see the need. Inguva Sivaram, the global lead of business technologies and ARD at Novartis, noted that a learning curve must be factored into any new process, and all stakeholders should be involved to guarantee a smooth transition The entire panel agreed that any transformation depends on a company's vision of the future and its willingness to evolve.

R. Muenz (2020) states "In this age of the Internet of Things (IoT), sharing protocols electronically can eliminate many sources of error and enhance reproducibility. This approach also facilitates improved method transfer for intra- and inter-laboratory comparison trials (ring trials). Coupling electronic protocols to semi- or fully-automated laboratory technologies can further reduce variability and human error."

Beate Hanson, the head of clinical research at Baxter Pharmaceuticals, emphasized that any technology which allows studies to be run in parallel saves time and money, and in addition, when coupled with AI to examine various hypotheses in parallel, better products will result. Huhmer added that when more quality data is extracted from each sample, fewer samples are needed to achieve the same results, thus reducing the possibility of handling errors.

> **Data security, especially patient data, is a top concern for all stakeholders. A common question surrounding the security of moving data to the cloud is if it will be less secure than maintaining data in a company's own data center.**

In addition to concern for data security executives also want to know if a newly implement digital ecosystem will meet the rigor that regulatory bodies require for electronic data systems.

Priya Mannan, the vice president and director of compliance and data privacy and associate general counsel at Novartis, stated that it is not regulations which are holding back transformational initiatives, but rather identifying laboratories from within all Novartis labs worldwide or outside vendors, such as contract services providers. She stated that this identification should be done early in the process so that transmission compatibilities are identified and data integrity meets regulatory and legal standards.

This need for global studies in new areas of therapeutics has put pressure on company legal requirements for data security and integrity and on the number of chief risk officers (CROs) who have the technical and personnel resources to conduct such studies. Companies that do not plan far enough ahead may find themselves waiting in line for a qualified CRO to accommodate their studies.

Hanson identified the necessity of connecting with CROs early in the development process as many other companies are seeking contracts with the same CROs and outside researchers in particular therapeutic areas; therefore, not establishing contracts with these organizations may lead to delays in clinical trials. She also pled for the industry to continue development of new specialists as therapeutic targets are evolving.

Participants agreed that while no company has unlimited resources, the effective use of existing resources and the willingness to embrace new technologies will determine success.

 

# Improving Staff Experiences and Engagement

Technology solutions and services innovations in the life sciences are transforming the laboratory regarding how work is performed for both companies and individuals. By allowing scientists to concentrate more on their missions, discoveries will be positively impacted. Connected laboratories have increased access to global scientific experts and highlight the need for pharmaceutical companies to reskill or upskill their own workforces to maximize the value of each resource.

The webinar audience was polled regarding the major restraints in achieving their 5-year goals. Among their most pressing challenges was staff recruitment and retention, but panelists pointed out that connected labs will streamline many of today's labor-intensive processes and be more flexible to accommodate individual client needs. Cross-training (and anytime, anywhere access to training modules) will also take on added importance.

Sivaram explained that Novartis has a pilot laboratory in which employees test and determine the value of new technologies. For example, Novartis found that sample management with robotics frees researchers to concentrate on other important tasks, and that AI and the Internet of Things (IoT) have reduced documentation times from weeks to hours.

 

# Looking Toward the Laboratory of the Future

The lab of the future involves innovation and collaboration. Innovation means developing data flow-driven systems to improve efficiency and effectiveness. Collaboration means working with global laboratories to speed therapeutic development from hypothesis to final-stage clinical studies via digital connections.

The use of digital technology is no longer a competitive advantage – it is the price of admission for doing business, Yet, for many life sciences firms looking for large-scale digital transformation, the volume, velocity and variety of data being generated by scientists is overwhelming the systems currently in place to support it.[8]

Working with the right external partner in the journey towards the lab of the future can be the difference between success—including being seen as an organization on the edge of industry innovation—and being left behind.

The key to implementing a digital strategy is determining where efficiencies can be made with the business and where technologies can provide a competitive edge. New technologies are critical to digital transformation, but prioritizing, selecting, customizing, implementing integrating, and optimizing them is just as critical. Labs need the right partner to help guide them through the transformation journey and choosing a partner that does not set them up for success can negate the benefits of digital transformation and threaten productivity, performance, and adoption at every step.

> The rising demand for smart instruments and digital tools within diagnostic, academic, and commercial research labs will powerfully drive the smart lab market.
>
> – Frost & Sullivan

# Endnotes


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