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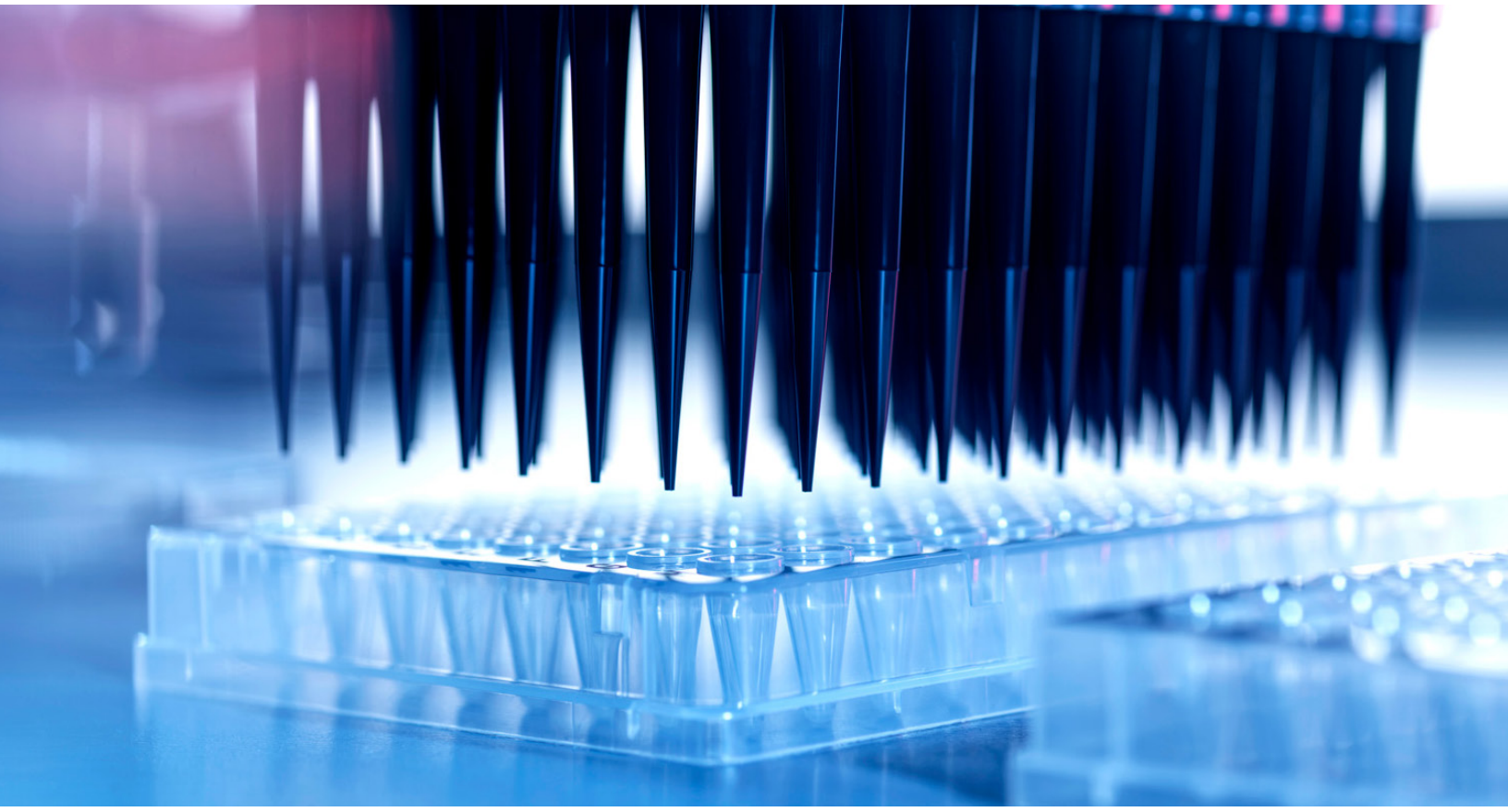
Life Sciences Practice

From bench to bedside: Transforming R&D labs through automation

Laboratory technology has been a steady runner in the world of pharmaceuticals, rather than a racing star—until now. A series of innovations points toward exponential gains in R&D productivity.

This article is a collaborative effort by Rita Cardoso, Kristian Kinscher, Tobias Ruof, Ahsan Saeed, Ulf Schrader, and Julius Seitter, representing views from McKinsey's Life Sciences Practice.



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For centuries, scientists have toiled in laboratories while surrounded by an ever-evolving set of instruments. In the 1990s, the introduction of benchtop automation devices led to a burst of productivity and discovery, enhanced by the computerized networking made possible in the 2000s and 2010s. For most pharmaceutical companies, that's where the R&D lab remains today—stunningly outfitted with the centrifuges and liquid-handling stations that have contributed to vital discoveries for the advancement of health. But most labs remain short of the advanced automation, miniaturization, and integration that can enable scientists to reach the bounds of what's possible.

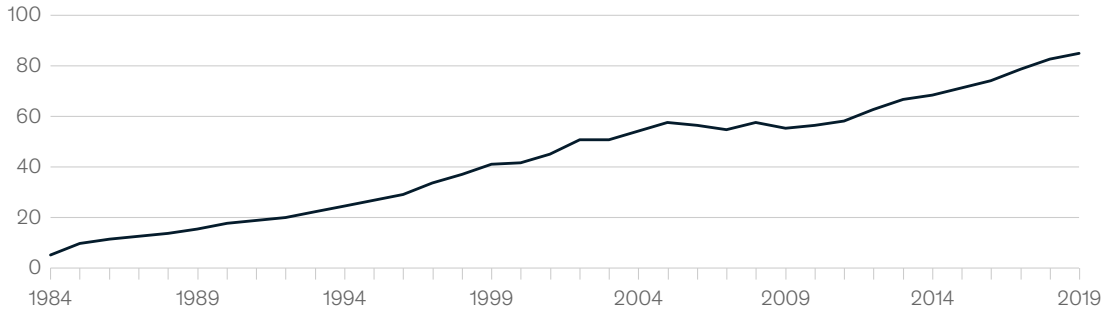
Pharmaceutical industry executives may be asking, "Where are all those research dollars going?" Sharp increases in R&D spending have secured only middling gains: in the United States, R&D spending doubled to $80 billion in 2019, from $40 billion in 2001, but the number of new drugs developed over the same time increased only marginally (Exhibit 1).

Paradoxically, a substantial proportion of increased R&D budgets has been absorbed into rising labor costs while skills shortages have constrained overall capacity.

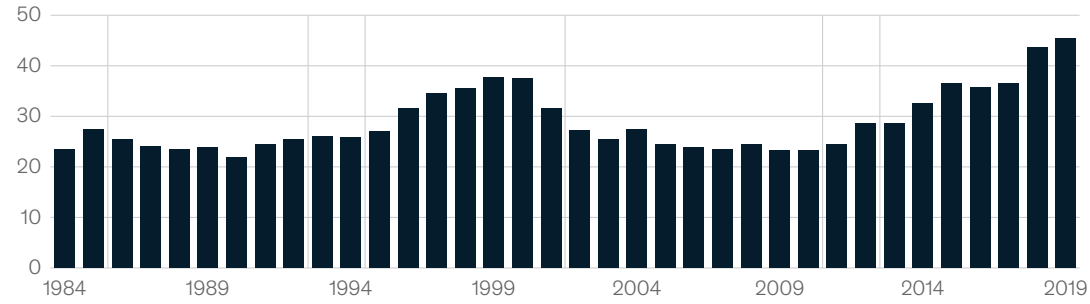
Exhibit 1

US R&D spending more than doubled from 2001 to 2019, but the number of newly developed drugs has increased only marginally.

Annual R&D spending by PhRMA[1] member firms, $ billion



Approvals of new drugs (5-year moving average),[2] number of NME[3] approvals



[1]Pharmaceutical Research and Manufacturers of America.
[2]A 5-year moving average replaces the value for each year in an annual data series with an average over 5 consecutive years. (Here the arithmetic mean of each annual value and the preceding 4 is used.) A moving average is smoother than the underlying data series and is useful for reducing year-to-year changes unrelated to overall trends in the data.
[3]New molecular entity.
Source: "Research and development in the pharmaceutical industry," Congressional Budget Office, April 2021

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Reducing the time from laboratory bench to bedside holds significant promise. In our experience, pharmaceutical companies have the potential to bring medicines to market more than 500 days faster and reduce costs of development by 25 percent by implementing a comprehensive set of levers, including—crucially—automation. Critical breakthroughs in laboratory orchestration, robotics, and liquid-handling technologies are now offering a trajectory out of these conflicting pressures, presenting laboratory automation as a strategic priority, and spawning a flurry of industry partnerships, accelerated investments, and advances.

Automation and the future of pharmaceutical R&D

Automation is not a silver bullet or a one-size-fits-all fix, but full automation can bring numerous benefits to R&D labs (see sidebar "The difference between a manual R&D lab and a fully automated one"). Specifically, it has significant potential to contribute to improvements across all primary laboratory KPIs, including the following:

— *Shorter cycle times.* Each screening process can easily include up to 10,000 compounds. As long as the industry continues to rely on manual tasks completed through a combination of isolated benchtop devices, cycle times are likely to remain lengthy.

— *Higher throughput.* Drug discovery also still relies to a large extent on manual steps and capacity constraints. A physical limit on lab space and not enough highly skilled scientists make it impossible to achieve high-throughput screening.

— *Better reproducibility.* Low reproducibility is one of the major impediments to successful drug discovery. Manual steps and paper-based documentation make precise, reproducible work under lab conditions unduly difficult.

— *More predictability.* Many pharmaceutical companies are early in building their capabilities to predict the bioactivity of chemical, biological, or medical substances. Most need to overcome a lack of available data and limited integration of IT and operational technology into the drug development process.

Today, a confluence of technical breakthroughs, increasing integration and compatibility of technologies, and advancements in supporting digital systems have made exploring automation options both more accessible and more urgent. Given that automation can only be successful if it is adopted and integrated into scientific processes, the experience and needs of the scientists involved should guide decision making. The balance of this article overviews four priorities for rolling out successful automation in pharmaceutical R&D, all of which contribute to laboratory KPIs.

Miniaturization and high-throughput screening

R&D processes have progressively moved away from using single vials to high-throughput microtiter plates that allow scientists to conduct 96, 384, or even 1,536 experiments in parallel. As well as increasing throughput by up to 100 times, these plates can reduce the volume of sample material and reagents needed by up to 90 percent, expanding the number of experiments that are possible from limited patient samples. They also enable more precise handling of materials, which increases the speed of biological processes and makes it possible to reproduce the same results elsewhere.

The maximum of 384 wells, which was based on the physical limits of tip-based liquid-handling technology, has also now been surpassed. Recent breakthroughs in acoustic liquid handling presage completely new formats, such as droplet microarrays, which are slides of glass with individual droplets instead of wells. These allow tens of thousands of reactions to happen in parallel. Additional groundbreaking technologies, such as droplet microfluidics as part of a lab-on-a-chip, are further clearing the way to high-speed, sequential experiments.

The difference between a manual R&D lab and a fully automated one

A few critical qualities distinguish manual R&D labs from automated ones.

The processes common in status quo laboratories that remain the norm in pharmaceutical R&D are inefficient and leave much room for improvement:

- low-throughput formats, such as vials
- isolated benchtop devices for single-step processes, which require staff to move samples manually from device to device
- manual, paper-based record keeping, with data recorded separately from each device
- manually analyzed assays that use spreadsheets

On the other hand, the future, automated vision of leading R&D operations employs much more efficient processes:

- miniaturized and high-throughput equipment that can test hundreds and potentially thousands of samples simultaneously
- all modular devices connected in a single automated workflow
- automatically documented digital results and testing parameters
- automatically analyzed data using advanced analytics, applying machine learning to process efficiency and pattern recognition

Digitization of records

The physically visible part of lab automation would not be possible without corresponding digitization and automation of records. Digital record-keeping systems, such as laboratory information management systems (LIMS) or electronic lab notebooks (ELN), equipped with user-friendly workflow generators, are now an indispensable part of modern laboratory infrastructure. They save time in preparing test records and writing up test results on paper, as well as in the checking of handwritten records by peers to ensure there are no errors. Digital record-keeping systems have also enabled better management of workflows, creating structures for research that are adaptable and flexible, which is a core requirement as research evolves based on its findings.

Interconnected laboratory suites

Typical pharma R&D setups consist of dozens of different devices, often from different vendors. This has meant research staff have had to bridge device interfaces manually—for instance, by moving plates between devices or by entering measurement results obtained from one device into another. As well as putting substantial time in monitoring and setting up devices, this process has required daily schedules to be planned around device runtimes. With research staff shortages limiting throughput, resolving this manual bridging has been a core focus in the world of laboratory technology. Most significantly, reducing the workload for scientists within the equipment loop creates the possibility of 24-hour, lights-out automation without overnight staffing. Such around-the-clock use of the same equipment could potentially triple throughput.

Therefore, this integration of data standards and device communication is now emerging as a game changer in laboratory technology as leading software providers offer laboratory orchestration or device scheduling software platforms. The new software provides drivers for a variety of laboratory hardware together with consulting or engineering services to connect hardware in a vendor-agnostic way, thus offering a holistic automation solution.

With data connected to central dashboards, the new, automated systems link every device to shared analytical systems, which, together with new capabilities in advanced analytics and machine learning, can accelerate outcomes. Gains can include the optimizing of scientific processes—for instance, in deciding which reagent in step A led to certain results in step D, or insights about operational efficiency, such as why the use of a

specific device is below average at certain times. Such monitoring, correction, and identification of patterns is enabling the whole process of discovery to be optimized and extended (Exhibit 2).

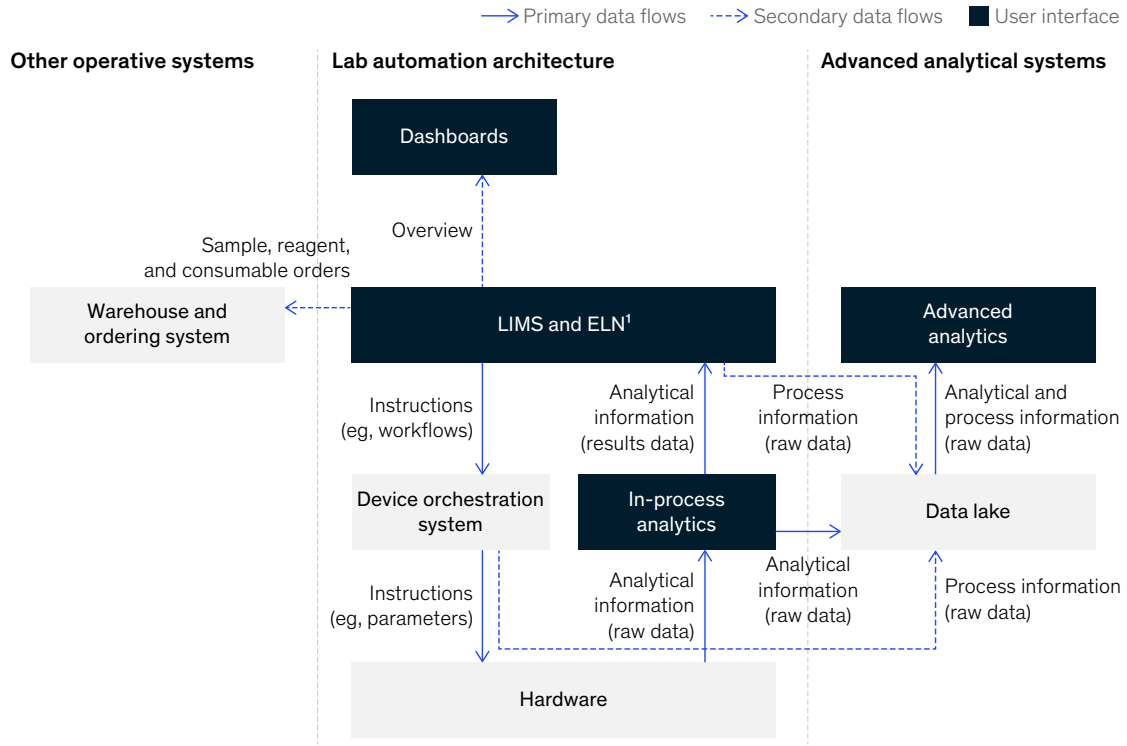
Dynamic vendor landscape and vendor partnerships

The number of hardware vendors—which have been central to pushing progress in lab technology—has more than doubled, to 206 from 93, over the past 15 years, fueled by demand and relatively low industry barriers to entry.[1] The vastly enhanced potential of laboratory technologies now emerging has triggered expanded investments and attention, including novel partnerships between pharma companies and vendors to accelerate new applications (see sidebar "Approaching successful lab automation transformations"). The past two years alone have seen more than a dozen announcements of partnerships between pharma companies and start-ups launching projects on automation solutions.[2]

As laboratory technology emerges as a high-return strategic lever, pharmaceutical companies' research scientists are increasingly directly involved

Exhibit 2

Software capabilities can be integrated into a holistic lab software architecture.



[1]Laboratory information management systems and electronic lab notebooks.
Source: McKinsey analysis

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[1] McKinsey analysis of laboratory automation on Crunchbase, October 2021–March 2022.
[2] McKinsey analysis of media reports. For examples, see "Codex DNA signs early access collaboration and licensing agreement with Pfizer to further develop CodexDNA's novel enzymatic DNA synthesis technology for Pfizer's use in its research and development of mRNA-based vaccines and biotherapies," GlobeNewswire, January 10, 2022; and "Eli Lilly and Company in collaboration with Strateos, Inc. launch remote-controlled robotic cloud lab," Eli Lilly and Company, January 9, 2020.

Approaching successful lab automation transformations

As several players explore the potential to transform their R&D lab processes through automation, we see a five-step approach to achieve state-of-the-art lab automation.

1. Define the North Star vision, with clearly articulated targets for entire R&D lab processes (for example, throughput, robustness, and cycle time).
2. Develop a three- to five-year strategic road map to achieve the vision, consisting of key milestones (including capability building) critical for overall success.
3. Implement a pilot use case while working together with a preferred vendor.
4. Develop long-term partnerships with vendors to prepare for upscaling.
5. Scale up automation solutions across the entire R&D function.

in identifying and specifying priority laboratory innovations. This involvement is further accelerating the applicability, relevance, and timeliness of technology gains.

Breakthroughs in acoustic liquid handling and laboratory orchestration have moved laboratory automation to the forefront in delivering greater R&D success in far shorter cycle times. At the same time, the readiness of new technology platforms, such as the mRNA and viral-vector platforms used in the high-speed development of vaccines for COVID-19, are further accelerating the pharmaceutical industry's innovation capabilities. These developments are helping to fuel the laboratory technology industry's imperative to automate.

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