Digitization, automation, and online testing: The future of pharma quality control

Emerging technologies can make quality control (QC) faster and more efficient. What do pharma companies need to do to become QC leaders?

Yan Han, Evgeniya Makarova, Matthias Ringel, and Vanya Telpis

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The emerging technologies that characterize Industry 4.0—from connectivity to advanced analytics, robotics and automation—have the potential to revolutionize every element of pharma-manufacturing labs within the next five to ten years. The first real-life use cases have delivered 30 to 40 percent increases in productivity within already mature and efficient lab environments, and a full range of improvements could lead to reductions of more than 50 percent in overall quality-control costs. Digitization and automation will also ensure better quality and compliance by reducing manual errors and variability, as well as allowing faster and effective resolution of problems. Use cases have demonstrated more than 65 percent reduction in deviations and over 90 percent faster closure times. Prevention of major compliance issues can in itself be worth millions in cost savings. Furthermore, improved agility and shorter testing time can reduce QC-lab lead times by 60 to 70 percent and eventually lead to real-time releases.

While most of the advanced technologies already exist today, few pharmaceutical companies have seen any significant benefits yet. On one side, quality leaders often struggle to define a clear business case for the technological changes, which makes it difficult for them to convince senior management that lab digitization or automation can deliver significant impact. On the other side, companies rarely develop a clear long-term lab-evolution strategy and blueprint, which can lead to some costly investments with unclear benefits. For example, many companies have already taken steps to become paperless by first simplifying paper records to minimize the number of entries and then digitizing lab testing records. Now those moves are being superseded by new advances in equipment connectivity that enable direct transcription of thousands of data points without any manual data transcription and without any reviews.

To capture opportunities offered by existing and emerging technological advances, companies should set clear goals, define robust business cases for any level of investment, and engage in rapid piloting of the new technologies followed by fast scale-up of pilots that deliver promising results. To succeed in the future, pharma companies need both the *foresight* to make long-term strategic investments, including those in R&D for developing and filing new test methods, and the *agility* to adapt those plans as technologies rapidly evolve.

Three horizons of lab evolution

Multiple digital and automation technologies have created opportunities for change in pharmaceutical laboratories. Most pharma labs have not yet achieved digital transformation, but labs can aim for one of the three future horizons of technological evolution (Exhibit 1).

Digitally enabled labs achieve at least 80 percent paperless operations. These labs transition from manual data transcription and second-person verification to automatic data transcription between equipment and the general laboratory information-management system (GLIMS).

Digitally enabled labs use advanced real-time data analytics and ongoing process verification to track trends, prevent deviations or out-of-specifications, and optimize scheduling. They employ digital tools like smart glasses to translate standard operating procedures into step-by-step visual guidance on how execute a process. They create a digital twin of a lab to predict impacts before making physical changes. All these are currently available technologies, with time to impact as short as three months for each case.

An average chemical QC lab can reduce costs by 25 to 45 percent by reaching the digitally enabled lab horizon. Potential savings at an average

Exhibit 1 As pharmaceutical labs incorporate new technologies, they will evolve to become more digitized, automated, and distributed in nature.

Pharmaceutical lab evolution

	Digitally enabled labs	Automated labs	Distributed quality control
Location of quality-control test execution	• 90%+ of testing in labs • Some limited testing done online	• 60–80% of testing in labs • 20–40% of testing on shop floor	• 0–20% of testing in labs (eg, specialty) • 80–100% online real-time testing, review by exception
Use of data and advanced technologies	• Automated data transcription between equipment and systems • Advanced data analytics for real-time data insights and optimized schedules • 80% paperless lab	• Full automation of testing and nontesting lab processes	• Automated transcription of testing and product-quality-relevant process data • Artificial-intelligence-enabled equipment and robots • Parametric release • 100% paperless
New capabilities	• Data engineers and data scientists • Advanced IT systems to support data capturing and analytics	• Lab supertechnicians with knowledge of advanced technologies • Advanced automation/robotics engineers	• Engineers to maintain and enhance automated systems • Lab skills on shop floor
Availability today	• 100% available	• 70–80% available (not all investments may be cost-effective yet)	• 50–60% available (may differ by type—eg, more options for biologic sites)

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microbiology lab would be in the 15 to 35 percent range. Productivity improvements come from two main sources:

1. the elimination of up to 80 percent of manual documentation work

2. the automation, and especially optimization, of planning and scheduling to improve personnel, equipment, and materials utilization

With fewer manual errors and data-enabled analyses of root causes, labs can reduce investigation workloads by as much as 90 percent.

Digitally enabled labs also reap compliance-improvement benefits from reduced errors and variability, as well as seamless data retrieval and analysis. The increased productivity and scheduling agility can also reduce lab lead time[1] by 10 to 20 percent.

One large global pharma company transitioned to a digitally enabled lab within its Italian digital lighthouse plant. Lab productivity at the site jumped by more than 30 percent after the company implemented advanced schedule optimization by harnessing a modular and scalable digital-twin platform adapted to the lab-specific scheduling constraints. The site also used advanced analytics to reduce deviations by 80 percent, eliminating reoccurring deviations altogether and accelerating deviation closure by 90 percent.

Pharma companies have many options when it comes to choosing and customizing technological

solutions to create digitally enabled labs. In addition to custom digital-twin and advanced-analytics platforms, other solutions include real-time insights from IoT platforms such as ThingWorx, lab scheduling software such as Bookitlab or Smart-QC, and digital assistants with visual operating procedures from providers such as Tulip.

Automated labs use robots, cobots, or more specific advanced automation technologies to perform all repeatable tasks like sample delivery and preparation. At the automated-lab stage, some high-volume testing (for example, microbial detection and water for sterility) is performed online instead of in physical labs. Automated labs can also use predictive-maintenance technologies to plan for infrequent tasks, such as for large-equipment maintenance, which can be performed by lab analysts with remote expert support.

While full implementation of digital enablement is not a prerequisite, automated labs can build upon digitization to deliver greater value and higher cost savings. Automated microlabs can enable additional cost reduction of 10 to 25 percent inside the lab, while also capturing a similar amount of savings outside the lab. The same improvements at chemical labs have the potential to produce 10 to 20 percent savings beyond that achieved by digitally enabled labs. The productivity improvements come from automation of up to 80 percent of sample-taking and sample-delivery tasks and of up to 50 percent of sample-preparation tasks, as well as from the reduction of equipment-maintenance cost through remote monitoring and failure prevention. Automation also reduces sampling and related logistics tasks performed by operations outside the lab, which produces the equivalent of up to 25 percent lab-cost savings[2] for microlabs and up to 8 percent equivalent lab-cost savings for chemical labs.

Pharmaceutical companies can also achieve additional benefits beyond efficiency. Remote-monitoring and predictive-maintenance capabilities built into the equipment will decrease downtime and ultimately enable companies to reduce their use of expensive devices, such as chromatography, near-infrared spectrometers, and isolators. By shifting to instantaneous microbial detection for environmental monitoring, companies may also reduce their overall lab lead time by 40 to 75 percent.

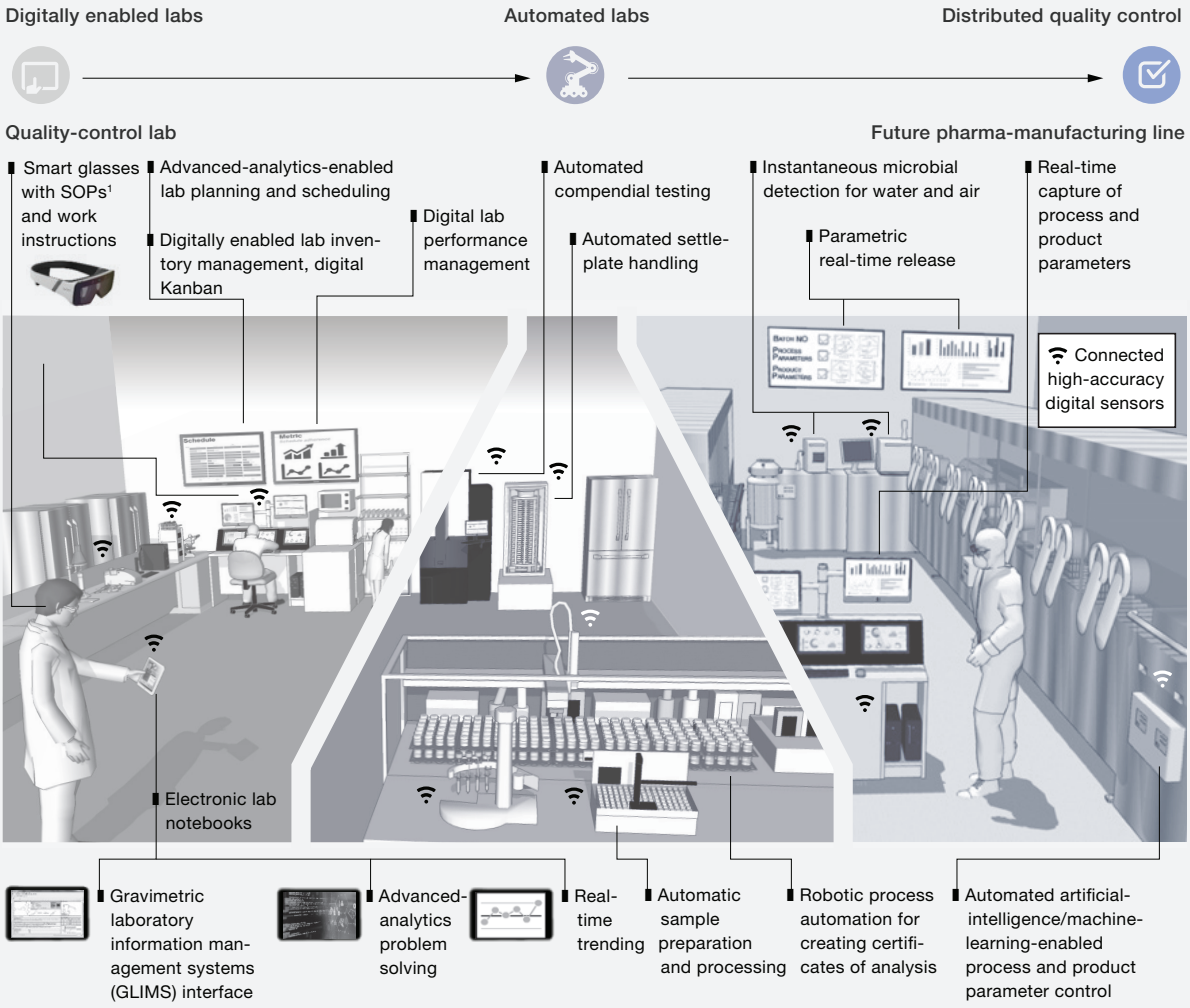
Technologies already exist—in healthcare and research labs or in manufacturing operations—that can be adapted to pharma-manufacturing labs in a relatively straightforward way to reach the automated-lab horizon. Vendors offering solutions include Aethon and MICROMO (sample distribution systems), BioVigilant, Colifast (online microbial-testing systems), Metrohm and Sotax (automated sample prep), Milliflex, Light Guide Systems (work-flow optimization with visual guidance), and Scope (assisted maintenance).

Distributed quality control represents a true disruption to traditional ways of providing quality control. At these sites, nearly all routine product testing would take place on the production line, enabling real-time release testing (RTRT). Equipment and robots at distributed QC facilities have artificial-intelligence capabilities. In the distributed QC scenario, labs continue to perform specialty and stability testing. This testing can take place off-site in a centralized location. Adoption of process analytical technology (PAT) and RTRT has been relatively slow because of regulatory filing and approval requirements. To be able to make a smooth shift to online testing in the future, operations need to start collaborating with R&D now to develop an optimal quality-control and filing strategy, especially for new products and manufacturing sites.

Distributed QC facilities primarily add value by significantly reducing the footprint and costs of a traditional lab. Because of significant R&D-investment requirements, as well as the need for

equipment and operational changes, existing sites with stable or declining volumes are unlikely to make a compelling business case for distributed QC in the short and even medium term. At the same time, sites that have been rapidly growing or under construction may be able to capture significant value from reducing capital-expenditure investment for building or expanding traditional QC labs if they can move a significant share of routine testing online. Distributed QC and real-time release would also enable true continuous-manufacturing processes (Exhibit 2).

Exhibit 2 Digitization and automation will transform quality-control work in the lab and on the shop floor by introducing new ways of working.



[1]Standard operating procedures.

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On the path to the future: How one company is exploring and adopting new quality-control technologies

To better understand how companies approach leading trends in the quality-control (QC) lab space, the authors spoke with Natasha Zuyev, vice president and chief quality officer at Johnson & Johnson Family of Companies. Through an enterprise-wide manufacturing-for-the-future (MFF) initiative, Johnson & Johnson companies have been exploring new QC technologies through a series of test-and-learn exercises. Individual companies already have paperless labs in place, with most instruments directly interfacing with a laboratory information-management system.

McKinsey: Which technologies or innovations do you believe are most critical for the evolution of the QC function over the next five to ten years?

Natasha Zuyev: I believe that the evolution will take more than five to ten years, but we will see acceleration in the adoption of modern technologies over the next years. In the past few years we've made significant progress toward electronic batch records. In the future, artificial intelligence (AI) and machine learning have huge potential to automate many transactional processes within the QC function. Process analytical technology (PAT) and real-time release testing (RTRT) will also play a critical role in our continuous-improvement journey. While it's been a long time coming, I am confident that the path forward lies with in-line PAT and RTRT augmented with online process controls.

McKinsey: What are the biggest barriers to this evolution?

Natasha Zuyev: There are certainly challenges. The biggest in my mind is a clear business case. It takes significant investment and time to develop and validate new testing methods and to obtain regulatory approvals. Accordingly, there is not always a clear ROI [return on investment] and a clear business case for PAT projects. Another challenge is data infrastructure and availability of an IoT platform. Finally, organizational capabilities and skills are critical for successful transformation to the lab of the future.

McKinsey: What is your approach to implementing advanced technologies?

Natasha Zuyev: Our approach within the J&J MFF program is a three-step process: source, test, scale. We have advanced-technology teams closely connected and colocated with tech companies, academia, and suppliers to maximize their access to new disruptive technologies. They scan and evaluate technologies, then bring them to a proof-of-concept stage to confirm it works in a lab setting. We then test these technologies in the real world in specific, practical test-and-learn (T&L) sprints. We seek to prove that the technology is feasible, quantify its value and impact, and get a better understanding of which capabilities and skills (people, process, and systems) will be needed to make the technology operational and scale it across our organization. Once we come out of a T&L successfully, we deploy and scale the technology where it brings the most value for the business. We do that through our Johnson & Johnson enterprise-wide operating system and standard methodology (J&J Production System [JJPS]), which includes diagnostic, implementation, and long-term capability-building and sustainability stages.

McKinsey: How does new technology in the QC lab change the talent strategy?

Natasha Zuyev: This is a very important question. New technologies require new capabilities, and we are working on developing the required skill sets. The industry needs more expertise in areas such as data analytics, PAT, RTRT, and AI. We are developing training courses and certification programs that will prepare our talent for new digital opportunities.

For example, Biogen plans to use this distributed QC method of real-time release and review by exception in its new manufacturing facility near Solothurn, Switzerland. When production starts up in 2019, the Solothurn facility will achieve raw-material control through screening and genealogy, with minimal testing using rapid identification and electronic data exchange. Bioreactor processes controlled through in-line instruments will eliminate the need for process control sampling. The new facility will have adaptive process control levers, lab execution by recipe, and automated data transcription from all equipment, all based on a deep understanding of raw materials, processes, and product characteristics. The integrated control system allows employees to see data and react in real time.[3]

As pharma companies start exploring ways to build distributed QC facilities, they may be able to pull in relevant technologies from adjacent spaces. For example, the PharmaMV platform from Perceptive Engineering and the Sipat platform from Siemens could provide the advanced process control necessary to enable parametric release. Meanwhile, AI systems from companies such as Arago and IBM could allow pharma companies to automate tasks that historically have been performed by highly trained expert employees. (For a view on one company's efforts, see sidebar, "On the path to the future: How one company is exploring and adopting new quality-control technologies.")

Typical implementation pitfalls hampering successful transformation and value capture

As pharma labs evolve, they face significant costs associated with implementing IT and automation solutions. Even expensive solutions can deliver a strong positive return on investment (ROI), but many companies, unfortunately, struggle to capture value from these digital upgrades. These companies typically encounter one or more of the following pitfalls:

1. *Not having a clear vision of what evolution horizon is the right target for a specific lab.* While most labs can make a solid business case for the digitally enabled horizon, not all labs have sufficient volumes and operational setup to justify automation and distributed QC. For example, it could be hard to justify an investment in automating a smaller lab where the potential cost savings might be less than $200,000 a year, whereas the same investment could quickly generate positive ROI for a large sterile facility with significant environmental-monitoring volumes.

2. *Not having a compelling business case for the transformation.* Many companies start implementation of costly IT systems without a clear understanding of the full benefits such solutions can generate. This often results in delays in implementation and the rollout of partial solutions. For instance, labs might move to paperless systems on individual modules but still need significant manual efforts to move data from one system to another. This can lead to situations where analysts must record test results into a paper log before manually entering the data into a laboratory information-management system (LIMS). This manual-entry step prevents them from capturing the full savings they should get from automating documentation.

3. *Targeting a fully tested end-to-end future-state prototype rather than testing and rapidly scaling up high-value solutions to capture quick wins.* For example, schedule automation and optimization can be implemented quickly and start generating significant value even if a lab is not yet mostly paperless and fully digitized.

4. *Lacking proper planning or management for rollout of new systems and technologies.*

In extreme cases, it can take pharma companies several years and more than $100 million to implement a LIMS. Given such a lengthy time frame and the fast pace of technological change, some of the LIMS capabilities are liable to become obsolete before they get rolled out across the entire network. Pharma companies need skilled resources to accelerate the rollout and should avoid the temptation to engage in excessive customization at each site. A poor rollout can cost five to ten times more and take three to five times longer than a properly planned investment executed with good long-term planning.

5. *Not having a full understanding of the capabilities of the systems they acquire.* Pharma companies may purchase a system such as LIMS to comply with data-integrity regulations without truly understanding or considering the system's potential to generate improvements in productivity.

6. *Pursuing automation rather than optimization.* Scheduling automation can deliver 2 to 3 percent of the QC cost savings, but automation *plus* dynamic scheduling optimization can yield three to four times more value.

7. *Self-imposed constraints from a perceived need to validate all systems and technologies.* Many of the high-impact changes, such as optimized scheduling and data-enabled deviation analysis, do not require validation and refiling.

8. *Missing the skill set to extract full value from their data.* Most typical pharma labs do not have the advanced analytical capabilities needed to get the maximum value from data sources. As a result, the labs collect data, but the data does not get used properly to generate insights that could prevent problems or reduce testing volumes.

9. *Spending too little time and effort on developing a robust change-management program.* Digital transformation requires radical changes in mind-set and has major implications for the organization and individual employees who must develop new skills and competencies. To succeed, companies must make up-front investments in changing the culture, winning buy-in across the business, and forging strong links between business and IT functions.

How to get started?

The good news is that most of the technologies needed to attain any of the three horizons of Industry 4.0 QC labs already exist today. Many of the technologies mentioned are already being deployed in pharma environments, with some successful pilot projects already completed and others in the approval stage.

To successfully implement Industry 4.0 technologies, pharma companies need to set the right aspirations and move quickly. Here are five things they can do to get started today:

1. Test several use cases and technologies quickly to find the best ones for each lab type.

2. Create lighthouse QC labs to showcase the potential benefits of amalgamating these innovative technologies.

3. Find out which innovative tools can have the greatest immediate impact, then roll them out quickly across multiple sites. Don't get bogged down trying to set up a fully functioning lab with every possible desirable technology. Many use cases, such as scheduling optimization, can be implemented before other elements (for example, paperless labs) are in place.

4. Establish a clear target state and business case for each lab early on. Track the value capture along

the way, and reinvest the savings toward the next technological upgrades. It is important to make an assessment separately for chemical labs and microlabs, because the baseline cost and the impact of improvements may differ significantly.

5. Aim for the highest-value horizon justified by the business case when planning and building new labs to preempt the need for digital-transformation upgrades right after the lab opens its doors.

6. Start building the needed talent base and skills early on. Clearly understand future capability needs, invest in training high-potential employees, and invest in hiring employees with the new required skill sets (for instance, advanced data analytics) during early stages to enable faster scale-up.

Modern technologies can make QC faster, more agile and reliable, more compliant, and more efficient. By setting appropriate goals, choosing the right technologies, and scaling up quickly, pharma companies can become QC leaders and reap the rewards in the form of speed, compliance, cost savings, and productivity improvements.

[1] Turnaround time from receiving the sample in the lab to releasing the lab testing results.

[2] Cost savings estimated on the lab baseline.

[3] Biogen presentation, EMEA Users Conference, OSIsoft, October 2017, London, United Kingdom.

Yan Han is an analyst in McKinsey's North America Knowledge Center, **Evgeniya Makarova** is a partner in the Chicago office, **Matthias Ringel** is a senior expert in the Lyon office, and **Vanya Telpis** is a senior expert in the New Jersey office.

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