Unlocking Productivity: How Advanced Technologies are Transforming Microbial Quality Control in Pharma

By Stephanie Kremser and Nathalie Renema, MilliporeSigma

Pharmaceutical manufacturers are facing a perfect storm of challenges. Aging populations in advanced economies are shrinking the pool of qualified laboratory personnel, while the volume and complexity of Quality Control (QC) testing is growing—especially with the rise of biologics and advanced therapies. At the same time, global competition is exerting relentless pressure to optimize costs without compromising safety or compliance. Against this backdrop, automation and robotics, in combination with digitalization, are emerging not merely as helpful tools, but as strategic enablers of productivity gains, greater throughput flexibility and facilitated compliance.

From repetitive routines to higher-value activities

The vaccine bottleneck during the COVID pandemic has led many pharmaceutical companies to rethink manufacturing capacities. Being able to scale up at short notice is an important capability not only in manufacturing itself but also in QC because they go hand in hand. Facilities that offer the flexibility to operate seven days a week and for long hours, or even 24/7, have the competitive edge in a faster moving market where demand fluctuates. With staff availability being a general challenge in the industry—and a very particular one at weekends—robotic systems and automated workstations offer a way to cope with the growing volume of microbial QC samples anticipated for the coming years. Designed to drastically reduce repetitive, time-consuming tasks, these systems speed up throughput and free up personnel hours. This allows experienced microbiologists to focus on higher-value activities like data interpretation, method development and root-cause investigations.

Typical examples of tasks that robots can perform are media preparation and sample handling, but also automated colony counting on environmental monitoring plates. To complement Rapid Micro Biosystems' Growth Direct® kinetic colony counter that we already distribute, which features faster results, integrated incubation and dedicated consumables, we are now developing a benchtop counter for higher throughput. It is designed to automatically process a carousel holding up to 100 settle or contact plates each hour and is compatible with the plates and incubators of most manufacturers. As an end point system, it performs plate reading once at the end of the incubation period by an analysis software that distinguishes between microbial colonies and non-colony artifacts. Reducing personnel hours on such routine tasks allows QC labs to make more efficient use of their skilled employees, which in turn results in a more engaged workforce.

Error prevention increases the robustness and reliability of QC testing

A further benefit is risk reduction. In the manufacturing of biologics, the value of production batches has risen in recent years. As an inevitable consequence, the cost of error has increased. Automated robotic QC systems vastly reduce human error because they perform standardized motions tirelessly and accurately, and they vastly decrease the risk of contamination because there is no direct human intervention. This translates into fewer false positives, lower investigation costs and shorter downtimes. In essence, they enhance the robustness and reliability of QC testing, safeguarding both product quality and production continuity.

Adoption of laboratory automation, however, must be economically feasible: for example, the payback period and total cost of ownership must be right. Standardizing platforms can reduce integration complexity and lifecycle costs. This includes the required consumables, which must usually be modified to enable robotic handling.

A good example is our gamma irradiated IsoBag® rapid transfer bags for easy transportation of ready-to-use environmental monitoring plates into and out of isolators via the 190 mm alpha port. The adapted, robot-compatible IsoBag® Auto bags for fill & finish processes in gloveless isolators are based on a similar concept but contain a rack with media plates and barcodes for automated scanning, which enables state-of-the-art traceability. A robotic arm in the isolator can unload the rack and reload it after sampling, and the plates remain safely in the rack throughout incubation. As this workflow involves no manual handling of the plates until reading, it reduces the risk of handling errors and contamination.

Productivity gains and facilitated compliance

The productivity benefits multiply when robotics and automation, as is usually the case, are paired with digitalization. The captured real-time data provide actionable insights: trends can be monitored, deviations flagged earlier, and investigations into out-of-specification results accelerated. Scheduling is streamlined, documentation burdens reduced, and overall operational efficiency enhanced. Beyond the resulting productivity gains, digitalization also supports regulatory compliance. Automated data recording throughout the testing workflow—from sampling to incubation and final evaluation—helps to ensure complete traceability and data integrity.

It is important to note that not every task lends itself to automation, in particular not low-volume tests. Manual capabilities will also remain essential for system maintenance, validations and new sample types. The future of QC is not a binary choice between humans and machines, but a harmonized partnership where automated systems and skilled personnel both have their place.

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With more than 14 years of marketing and sales experience, Stephanie has honed her expertise at one of Europe's largest agrochemical contract research organizations. She joined the organization in 2021 as a digital sales specialist focused on German pharmaceutical clients before transitioning to her current role in 2024.

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01/2026