Galatek

Case Study | March 2026

Automated Mobile Phase Preparation Transforms QC Laboratory Operations

Top 20 Pharma Quality Control Laboratory |
Galatek Automated Mobile Phase Preparation System

THE CHALLENGE

The QC laboratory plays a critical role in ensuring the quality and safety of pharmaceutical products before they reach patients. Within the lab, HPLC and LC-MS instruments are relied upon daily for release testing, stability studies, and in-process controls. Each of these analytical methods requires precisely prepared mobile phases — a process that, in most QC labs, I performed entirely by hand.

At a Top 20 Pharma company, manual mobile phase preparation introduced several persistent challenges. Analysts spent significant time weighing solid reagents, measuring liquid solvents, adjusting pH, filtering, degassing, and labeling each bottle. Human variability in these steps led to inconsistencies in mobile phase composition, which occasionally contributed to out-of-specification (OOS) results and costly retesting cycles.

> *"We were spending hours each day on mobile phase prep alone. Any small deviation in pH or concentration could cascade into a failed test and trigger an investigation."*
>
> **— QC Lab Manager**

From a compliance perspective, documenting every step of the manual process to satisfy GMP and FDA 21 CFR Part 11 requirements was labor-intensive and error-prone. As testing volumes continued to grow, the QC team recognized that manual preparation was becoming the bottleneck that limited overall laboratory throughput.

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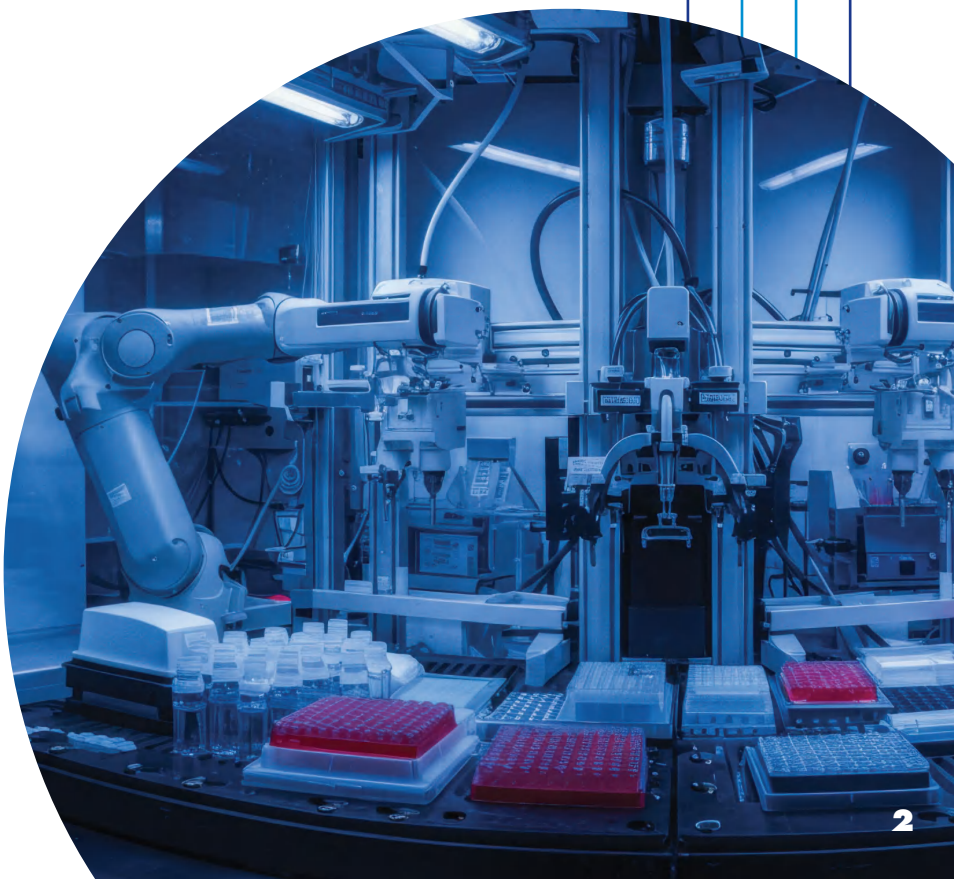
DEFINING THE PATH FORWARD

The QC team set out to find an automated solution that could address all three pain points simultaneously: consistency, compliance, and capacity. After an internal assessment, the team defined four core goals for any new system.

QC Lab Automation Goals

1. Eliminate manual variability in mobile phase preparation to reduce OOS events
2. Ensure full GMP and FDA 21 CFR Part 11 compliance with automated documentation
3. 24/7 operation for supporting mobile phase usage increase to keep pace with rising testing demands
4. Minimize lab footprint while maintaining flexibility for diverse HPLC and LC-MS methods



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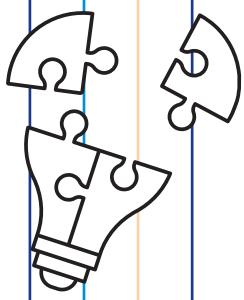
A FIRST-OF-ITS-KIND SOLUTION

When the QC team at this Top 20 Pharma company began searching for an automated mobile phase preparation solution, they quickly discovered that no comparable system existed on the market. Conventional laboratory automation addressed individual steps — dispensing, mixing, or pH adjustment — but nothing integrated the entire mobile phase workflow from raw materials to finished, labeled bottles in a single, unattended process. The Galatek Automated Mobile Phase Preparation System was the first platform to deliver true comprehensive automation of mobile phase preparation for HPLC and LC-MS applications:



The system seamlessly executes every stage of the process: solid reagent dosing, liquid reagent dispensing, mixing for dissolution, precise pH adjustment, filtration, dispensing into mobile phase bottles, ultrasonic degassing, and automated labeling and tagging. Every step is performed with analytical-grade precision — powder dispensing accuracy within ±1% of feeding volume, reagent dispensing precision of ±0.1%, and pH testing resolution of 0.01 pH units — a level of consistency that manual preparation simply cannot match.

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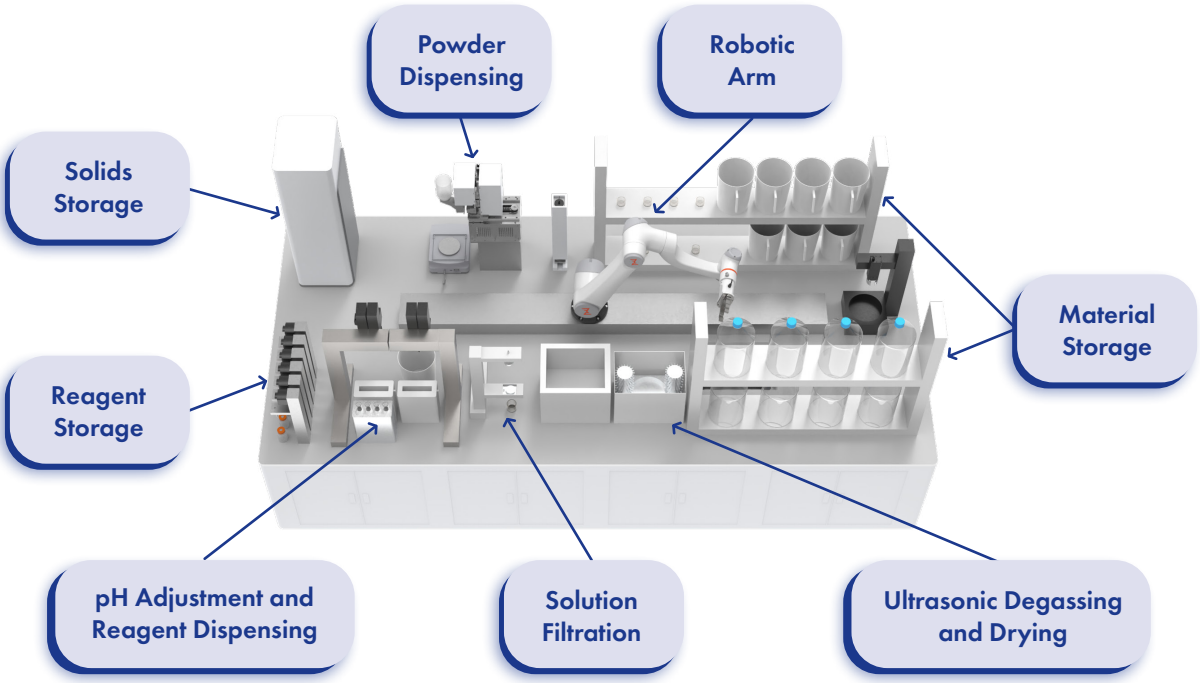
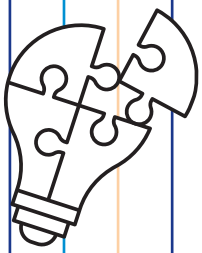
Built to Adapt to Any QC Laboratory

Beyond its unique end-to-end capability, the Galatek system was designed from the ground up to be configurable to any laboratory's individual analytical needs. Its modular architecture allows each customer to select and combine functional modules based on their own method portfolio, choose preparation volumes of 0.5L, 1L, 2L, or 5L per batch to match specific method requirements, and scale daily throughput of up to 100 L/day. No two QC laboratories run the same mix of methods, and the Galatek platform is built to address that reality.

For this pharma company, this meant deploying the full configuration with all seven functional modules, including automated pH meter calibration and automated balance calibration. The system accommodated the full range of buffer systems, organic solvent blends, and pH-sensitive mobile phases required by the lab's diverse testing portfolio — from routine release testing to complex stability-indicating methods. With capacity for 17 types of liquid reagents and 11 types of raw powders in inventory, the platform matched the lab's complete formulation library from day one.





> *"Nothing else on the market could do what Galatek offered. And the fact that the system adapts to our specific methods and mobile phase recipes — rather than forcing us to redesign our workflows to fit the equipment — made the decision straightforward."*
>
> **— Senior QC Analyst**

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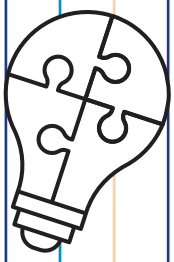
THE IMPACT ON QC OPERATIONS

Since deploying the Automated Mobile Phase Preparation System, this QC laboratory has experienced measurable improvements across every area targeted by the original project goals.

Area	Outcome
Consistency	Near-elimination of mobile phase variability; significant reduction in OOS events related to mobile phase preparation
Compliance	Automated audit trail and electronic records fully aligned with GMP and FDA 21 CFR Part 11; documentation effort dramatically reduced
Throughput	Up to 100 L/day preparation capacity, freeing analysts to focus on higher-value analytical work
Footprint	Compact 4m × 2m × 2.1m system consolidates seven process steps into a single integrated unit
Labor	66% reduction in manual labor needs dedicated to mobile phase production



The Galatek system's automated low-inventory alarm function has also streamlined reagent management, alerting staff before supplies run low and preventing workflow interruptions. Because the platform is designed to accommodate each laboratory's existing reagent inventory and formulation library, the team transitioned from manual to automated preparation seamlessly, and analysts continued using their validated methods with no reformulation required.

> *"The system has fundamentally changed how our analysts spend their day. Instead of preparing buffers for hours, they're now focused on data analysis and method development — the work that actually moves our products forward."*
>
> **— QC Director**

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LOOKING AHEAD

With the Galatek Automated Mobile Phase Preparation System now fully integrated into daily operations, this company's QC team is exploring opportunities to expand its use. The platform's modular architecture means that as new analytical methods are validated, or testing demands grow, additional modules, formulations, and throughput configurations can be added without replacing the core system — the same flexibility that Galatek offers every customer it works with.

The success of this initiative has also sparked broader conversations within this company about extending automation to other precision-critical QC workflows. For the laboratory team, the Galatek system has demonstrated something that was previously unavailable in the market: a fully automated, end-to-end mobile phase preparation platform that adapts to any laboratory's methods rather than the other way around. The result is not just improved efficiency — it is a measurable elevation in the quality and reliability of every analytical result that leaves the lab.

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