LABMINDS

Case Study

# AUTOMATED PREPARATION OF REAGENT SOLUTIONS FOR GMP LABS

## AT A GLANCE

LabMinds collaborated with a Top 20 Global Pharmaceutical company and made enhancements to Revo that evolved the research product into a GMP compliant solution.


C. Schwartz, Project Manager

## ABOUT OUR CUSTOMER

A top 20 global pharmaceutical company with headquarters in Europe, has been in operation for a century. With a mission of developing medicines and treatments for endocrine diseases, this company helps people live better every day. In order to speed the development of medicines and treatments to market, it has adopted a culture of innovation where implementing cutting edge technology is encouraged, embraced and expected. It was this innovation culture that spurred the concept of moving a research automation system into the GMP environment and improve the efficiency of laboratory personnel and operations there.

## THE CHALLENGE

To ensure the future success of late-stage product development processes, it continuously strengthens its capabilities, and seeks to maximize the time it spends on the science through investment in emerging and state-of-the-art technologies that can reduce otherwise trivial manual labor. This mindset drove the product development team's search for an automated solutions preparation system that is compliant with regulatory requirements in a GMP setting. For example, for the measuring devices in the system the team needed to follow the requirements stated in pharmacopeias (USP and Ph.Eur.). They recognized that the balances, pH probes, conductivity probes, temperature sensors and volumetric glassware must meet the stringent requirements set by these pharmacopeias. In addition, it was also essential to comply with data integrity requirements set by the FDA's 21 CFR Part 11 and EU's Annex 11. The selected system needed to capture and log critical aspects of record keeping such as audit trails, reports, recipe composition, user permissions and dosing records.

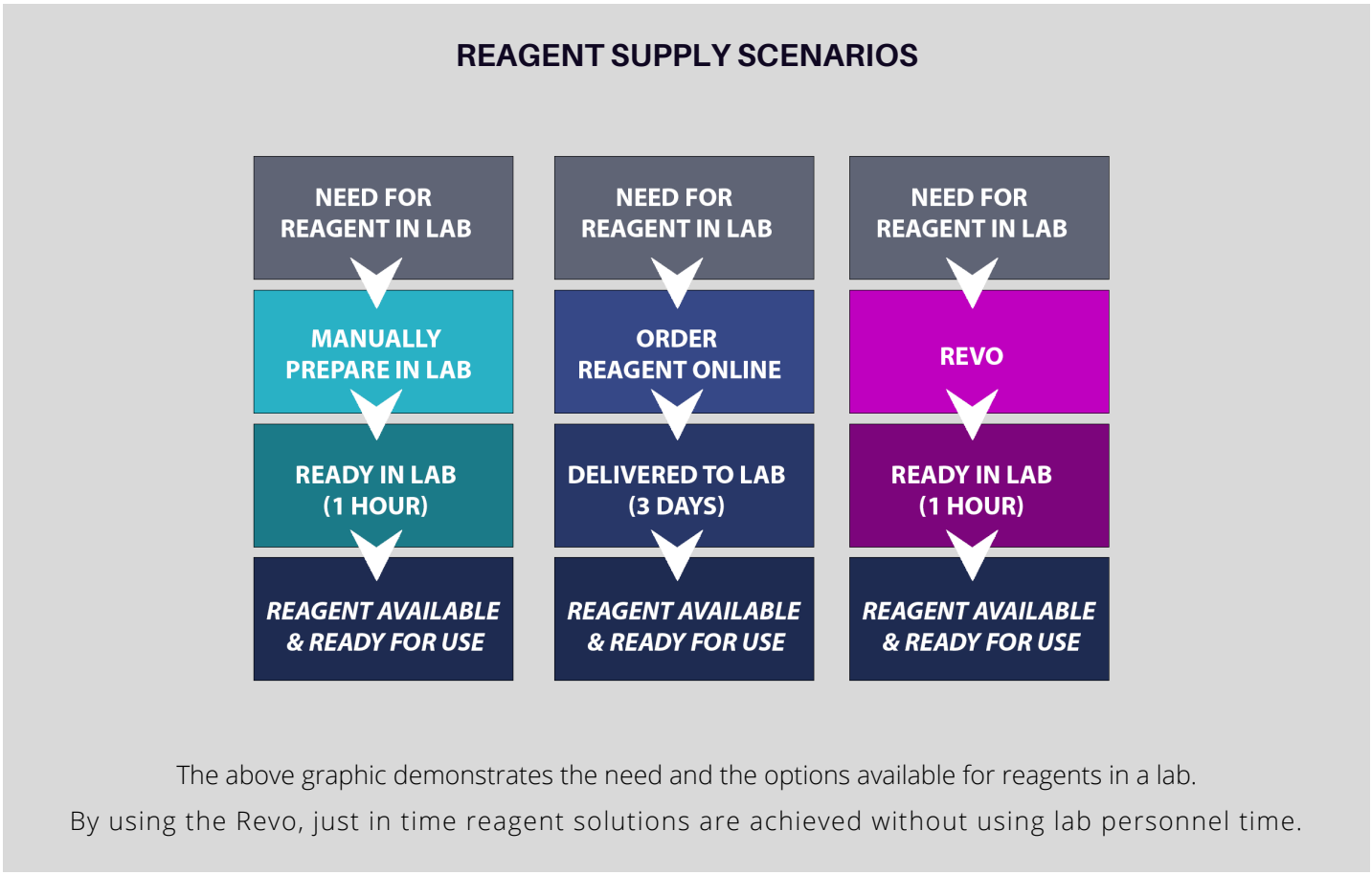
*"The flexibility the solution has provided for just-in-time preparation is a major benefit."*

**C. Schwartz**
Project Manager

## THE SOLUTION

After an extensive review of available solutions, they selected LabMinds® Revo®, the benchtop automated solution preparation system that enables companies to automate the reagent preparation process. LabMinds, upon the customer's request, decided to collaborate and make enhancements to Revo that would evolve the research product into a GMP compliant solution.

The project was launched in May of 2019 and they set out to find a dedicated and innovative technical Project Manager to drive this project. Schwartz was assigned as Project Manager. Schwartz is a specialist in laboratory automation and has a strong track record of leading teams and driving transformation. He accepted the challenge in a large part due to the fact that he had previous exposure to the Revo system from the 2016 SLAS conference when Revo won the innovation award. He recognized the potential to transform Revo into a GMP compliant system and accepted the challenge.




The above graphic demonstrates the need and the options available for reagents in a lab.
By using the Revo, just in time reagent solutions are achieved without using lab personnel time.

## FORMING A TEAM

Schwartz formed a dedicated team comprised of subject matter experts including a chemistry specialist and cross functional experts from other departments. This team combined forces with LabMinds and worked to deliver an automated solution preparation system that complied with GMP requirements. They knew that it needed to deliver a solution that provided the consistent quality, traceability and documentation required in the regulated pharmaceutical industry. The team also sought to solve three main challenges: reducing the time lab technicians spent on preparing reagents to allow them to focus on the science; limiting solution overproduction; and eliminating risk associated with manual documentation processes.

## SYSTEM APPROVAL

After 18 months of intense dedication, the team achieved a huge milestone and Revo was approved internally for use in its GMP laboratory. The system approval was earned through a series of rigorous data integrity process reviews and hardware upgrades. They were then able to tackle the challenges they set out to solve. Just a few months after the launch, the team on-boarded many of its recipes and is already seeing positive impact.

"I appreciate the opportunity to work for a company that is willing to implement cutting edge technology. We will reap many benefits moving forward," commented Schwartz, the Project Manager. "The flexibility the solution has provided for just-in-time preparation is a major benefit. We have already reduced solution overproduction costs and leveraged the Revo system to reallocate our reagent prep team from redundant tasks to work that helps increase the speed of product development."

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> Project Manager

C. Schwartz and the Revo system

## POSITIVE RESULTS

Prior to the implementation of GMP Revo, three laboratory technicians spent an entire day preparing reagents for the week. Upon review of recipes required, many were found to have an organic component. To overcome a current system limitation, LabMinds developed a workflow process where the Revo produces the aqueous portion of the solution with instructions for the organic component addition printed on the label. Even though organic components are still added manually it was decided that the newfound flexibility of automating the manual weighing, pH verification and data registration made the process worthwhile. The system now allows the team to order the reagents via the Web or mobile interface, and reduces the FTE time needed to fulfill monotonous, procedural laboratory tasks by 66%. This allows these key team members to focus on the data analysis and scientific work needed to produce results from sample analysis.

This lab technician team also used to ensure that they did not run out of reagents during the week by creating an extra supply. At expiry, extra solutions were thrown away. Now the team has implemented just-in-time inventory best practices and produce the exact quantities of the solutions they need. They know that they have increased flexibility, and if they need more solutions they do not have to stop analysis to create them. They can simply reorder via the easy Web interface, and the solution will be ready within an hour. This flexibility allows the team to reduce the amount of inventory needed each week.

Prior to the implementation, the team manually tracked preparation data on paper to ensure they could obtain the necessary information for upcoming audits. Now, the team utilizes a QR code printed on the bottle label that contains all information describing the preparation and scans this data directly into the LIMS system where a record is created for each bottle.

| CHALLENGES | BENEFITS |
| --- | --- |
| Reduce FTE time spent on preparing reagents | Reagent prep FTE time decreased by 66% |
| Limit solution waste | Just-in-time inventory best practices reduced solution overproduction costs |
| Eliminate risk with manual documentation processes | Documentation completed with full transparency and regulatory compliance provides peace of mind |

Scanning of QR code imports solutions data into LIMS

All samples, solutions and controls are registered in the LIMS, and this data aligns with existing records to populate the documentation of the analysis and ensures audit readiness. This process not only reduces the chance of human error, but also frees up time for the lab technicians to focus on other tasks. Our customer now has peace of mind knowing that documentation is completed with full transparency and regulatory compliance.

"After 6 months in operation I get continued feedback from the users on how happy they are to be relieved from the tight planning of manual preparation they used to have. Even though organic components are still added manually it is by far overshadowed by the newfound flexibility in the fact that all manual weighing, pH verification and data registration are completely removed from the process."

**C. Schwartz**
Project Manager



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