Bioscience Solutions

# MODA™ Solution

## The Gap Between LIMS Capabilities and QC Microbiology Needs


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**LIMS requires a high degree of customization to meet QC Microbiology requirements. This means that LIMS implementations often lock users into a functionality set that can't accommodate technology advancements and regulatory changes; at least not without considerable time, effort and money.**

## Introduction

QC Microbiology challenges are immense due to sample volumes that often exceed 100,000 samples per year, with some biopharma operations reaching one million samples annually. Effectively managing that workload coupled with accommodating the complexities of microbiology methods requires a data management solution designed to specifically meet those challenges. All too often, the platform choice to solve these challenges is decided by an organization's IT department; with little understanding of the deficiencies that traditional LIMS platforms present to the QC Microbiology operations. This paper explores the shortcomings of LIMS to manage a compliant and economical solution to the microbiology processes in an aseptic manufacturing environment.

### Understanding the True Cost of Ownership

Organizations often over-estimate the ability of LIMS (Laboratory Information Management Systems) to efficiently manage the complexities and sample volumes for a QC Microbiology operation. IT departments are constantly looking for ways to leverage existing infrastructure investments with an expectation that it is a cost-saving decision to use what is already available. What is often overlooked are the realities of how the QC Microbiology operation will be constrained by the inefficiencies of the LIMS architecture and workflow. In reality, LIMS deployments to manage environmental monitoring fall short of providing a paperless end-to-end solution. Organizations choose to either live with less functionality, i.e. less compliance or spend significant time and money to customize the LIMS to provide some workable solution.

QC Microbiology tests are location-based. All data associated with a sample collection trace back to the location at which it is taken. LIMS, by design, are product-based, that is, all operational relate to the product sample. This design criteria is a significant challenge to a comprehensive paperless QC Microbiology solution. The ability to associate all relevant data to a location, e.g. product lot number, personnel in the room, media

lot information, organism identification, etc. does not exist in LIMS. As such, a LIMS project for QC Microbiology requires costly customization work to meet the basic needs of the microbiology staff.

With customization comes an increased cost for validation. LIMS, unlike the MODA-EM™ Solution, is not a configurable out-of-the-box solution (COTS). Each LIMS customization carries a unique and expensive validation effort and is very specific to that version of the application. Upward compatibility to future releases of the LIMS is very difficult without heavy re-validation time and effort. This drives up long-term cost of ownership.

Change management is another important consideration for overall system costs. In the QC Microbiology space, changes to the sampling routines are common. Frequencies for sample collection, new methods, and updated specifications for detection limits are all dependent on a system administrator to input those changes. LIMS are inherently complicated and require highly trained, expensive resources to implement changes. Compare the time, effort and cost of implementing routine changes into a LIMS with a purpose-built COTS where business users make changes through simple configuration updates. Routine LIMS changes for QC Microbiology are expensive and in this domain change is inevitable.

Finally, there is a significant cost component to a LIMS project for QC Microbiology articulated by the adage, "time is money". LIMS project delivery times for QC Microbiology are often greater than one year due to the customizations required. And, time is money. When compared to a typical project time line of 6 months for the MODA-EM™ Solution, those extra months of work impact overall project costs.

## Enforcing Data Integrity

Careful review of FDA warning letters to pharmaceutical manufacturers over the past 24 months reveal that regulators are citing deficiencies in managing microbiology data at a higher rate than any time in the past. The reasons for these increases are multifold, but at the core, the complexities of the EM process (schedule, sample, incubate, results entry, review and approve) require a system that can efficiently manage that process and meet the data integrity standards that are part of the regulatory audit process. The data integrity challenge for environmental monitoring is the ability to collect data in a contemporaneous manner. Due to design shortcomings for LIMS, it is impossible to meet this standard.

Contemporaneous data collection in an aseptic manufacturing environment is a challenge for LIMS because they lack an offline functionality. LIMS require real-time access between the client and the application. Aseptic manufacturing environments are not conducive to a strong, uninterrupted Wi-Fi connection. Lacking offline data collection functionality, LIMS require data collection by hand, generally on paper, and transcribed well after the time of sample collection. This process does not meet the contemporaneous standard.

Contemporaneous data collection also requires real-time electronic data collection and electronic data transfer to the data management solution. LIMS do not provide system or device interfaces as an out-of-the-box capability. Interfaces to common devices, such as non-viable particle counters, air viable systems, endotoxin detection systems and organism ID systems require additional customization. LIMS implementations often deliver a workflow that requires data to be transcribed rather than collected in an electronic format.

## Using Data to Make Decisions

Ask any microbiologist, what is the most time consuming and challenging part of the environmental monitoring process, and the answer will consistently be – trend report generation. That is, unless that scientist is using the MODA™ Solution. In that case, the time frame for generating any trend analysis is measured in seconds versus hours or even days. Trend reports represent the most meaningful way to both monitor and analyze the extent to which an organization is in control of its aseptic manufacturing environment. In an optimized scenario, with real-time access to data, trend analysis can provide a proactive approach to intervention if data is observed with a negative trend. Having the ability to spot these trends and take corrective action are the true benefit of a completely paperless system. All variables must be captured in a single system so that root cause determinations can be efficiently carried out and proactive notifications of potential excursions can be generated automatically. Finally, whenever a regulatory auditor walks in the door, you can be sure that they will be asking for trend analysis data. The ability to provide this data quickly and efficiently is a staple of a paperless system.

LIMS do not provide a comprehensive, paperless approach to managing and representing EM data. Generally, a LIMS is nothing more than a repository for EM results with limited, if any, trend analysis capabilities. Trend reports are inflexible and narrow in their scope. Decision making is limited due to the fact that LIMS cannot represent all data within a single view or report because of the disjointed way LIMS stores data. Associating a sample with personnel present at the time of sample collection along with an organism identification of the action limit requires searching for those data in separate sections of the LIMS application. It is a limitation of a system based on a sample or product centric design.

## Integrated Automated Laboratory

Pharmaceutical manufacturers are constantly challenged to increase profitability by improving operational efficiencies and reducing overhead costs while maintaining the highest levels of quality assurance. As such, many IT organizations are seeking ways to achieve increased levels of automation between dependent systems (CAPA, ERP, LIMS) as well as testing devices (viable air, non-viable particle counters, etc.) From its inception, the MODA™ Solution was designed to provide a total paperless approach to QC Microbiology including the direct electronic data capture from testing devices. Over time, the library of out-of-the-box interfaces has grown to stay current with the industry and customer requirements. In contrast, LIMS interfaces are typically a one-off, custom project relying on extensive time and effort to build, test, deploy and validate. With LIMS, there are no guarantees that future versions of the software will be compatible with existing interfaces. As new microbiology technologies and methods are introduced, LIMS vendors do not take a proactive approach to building interfaces to their systems. To a LIMS vendor, QC Microbiology is just another user group. To us, it is a community in which

we continuously invest to drive a completely paperless process and up-to-date electronic data interfaces are at the core of that commitment.

## Building a Justification

Whether or not an organization chooses to invest in the MODA™ Solution or chooses to "make due" with LIMS depends on the recognition and understanding of the true value differences between the two choices. When the value of the MODA™ Solution is fully understood by QC Microbiology, there is a recognition that the system provides a better user experience, a significant advantage in maintaining compliance to SOPs and data integrity standards and a robust solution that addresses the key challenges of applying an electronic solution to managing the immense volume of EM, utility and personnel samples. The reality is that despite these advantages, quality control departments are often influenced to accept LIMS, because the IT organization or senior management doesn't fully understand the value advantages and the real costs, both short-term and more importantly, long-term.

It cannot be overstated that the value of the MODA™ Solution begins with the people with whom our customers interact; the project team. Our technical field personnel bring years of direct MODA™ Solution experience to customer projects. They understand the domain and its unique requirements because they have lived that experience directly. As such, project timelines are accelerated because of that knowledge. Typical project timelines for implementing and validating the MODA™ Solution range between 5 to 8 months, depending on the scope of the project. This is a fraction of the time it takes to implement LIMS for QC Microbiology. The speed of deployment for the MODA™ Solution is a direct result of the configurable design of the application. In addition, the configurable design provides significant flexibility advantages to accommodate emerging technologies and regulatory requirements. The unfortunate truth is that LIMS implementations ultimately take longer to implement and validate. Because of the high degree of customization LIMS implementations often lock users into a functionality set that can't accommodate technology advancements and regulatory changes; at least not without considerable time, effort and money. In the end, a critical analysis of a MODA™ Solution investment versus a LIMS investment for QC Microbiology shows that the MODA™ Solution has a significantly lower cost of ownership over the lifetime of the investment and is much more flexible with respect to adding new functionality than a LIMS, be it test methods, instrument interfaces or workflows.

## Summary

The QC Microbiology domain is changing faster than ever before with the emergence of new methodologies designed to accelerate the process of detecting microbial contamination events. Coupled with that is an ever increasing sample workload as organizations move to more aseptic manufacturing. The MODA™ Paperless QC Microbiology Solution continues to outperform LIMS in speed to deployment, scalability across an enterprise and lower overall cost of ownership. A LIMS expansion to accommodate the QC Microbiology organization may seem to be a prudent solution, but closer evaluation of the gaps that exist between those systems and the MODA™ Solution shows that LIMS will incur significantly more cost and more risk with regulatory auditors.

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