Q&A

Kham Nguyen

on Pharma 4.0, LIMS Integration, and System Validation

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SUMMARY

As pharmaceutical manufacturers accelerate digitalization, QC microbiologists now see lab connectivity as an exciting opportunity to automate their data collection and analysis. Learn about Rapid Micro Biosystems' expert perspective on the digitalization landscape and LIMS integration.

INTRODUCTION

Kham Nguyen, Director of Validations at Rapid Micro Biosystems, has helped many of the world's leading pharmaceutical manufacturers validate the Growth Direct® System in their QC microbiology labs during the past decade. In this question-and-answer session, Nguyen discusses digitalization and laboratory information management systems (LIMS) integration.

As someone who's been helping customers automate since 2010, do you see any major changes in attitude toward Pharma 4.0™?

I think the community's mindset has continued to evolve. The pharmaceutical industry has historically been very slow to adopt new approaches. In the past, we've seen a lot of reluctance to take the perceived risk associated with taking things to the cloud or incorporating an internet of things (IoT) into a site to facilitate Pharma 4.0. Many larger organizations have already taken the plunge. As these larger organizations continue to push boundaries, others see that auditors and inspectors don't have issues with these changes. In turn, this drives that next level of organizations to take that risk as well.

The US FDA has also been a clear catalyst for Pharma 4.0. They're now encouraging investments in technology, especially as it helps to automate and streamline how organizations manage data. They recognize that it is the better way.

What sticking points remain?

It's still a complex calculation for many organizations. How do you implement automation in a controlled and compliant manner? In this case, you're not just talking about FDA compliance but how does that impact your organization for SOX compliance, data integrity, cyber vulnerability, and beyond.

In your view, what are the key advantages of automation and LIMS integration in QC microbiology labs? How does microbial enumeration LIMS integration improve bioburden, personnel, and environmental monitoring?

A lot of companies invest in LIMS to go effectively paperless. By going paperless, you improve your data integrity. To capture the maximum return, you need to entirely eliminate manual and paper steps. As a

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key example, without automated data transfer from an instrument to your LIMS, someone still has to write the final result on a piece of paper and then enter it into a LIMS. If you're paperless for 99% of the process but someone could accidentally or purposely enter the wrong number during that last critical step, where does that leave you? Integrating your LIMS with technologies like the Growth Direct® System for microbial enumeration does not allow the end user to intercept or manipulate that data. Whatever the result is, it automatically goes to your LIMS, and it really closes and secures that whole data cycle.

What do the returns look like?

In our experience, the great majority of samples will show no contamination. A Growth Direct® System will send those clean results to a LIMS and those records are automatically closed, without any double counts or paper documentation. So, the Growth Direct® System is effectively eliminating a great deal of the backend labor. For the small percentage of plates that do have counts, the system sends an email notification to the QC lab. The microbiologists can then pick up those plates and focus in on those contamination events, so that they can ID them and quickly start their investigation.

THE INTEGRATION PROCESS

Tell us what a successful integration project typically looks like – the people who have to be engaged, the processes or operations that should be covered, the investment in time or effort required of company leadership.

There are nuances between LIMS systems, so there are going to be different integration maps. But generally, it starts with a customer who purchases our LIMS license and services for the Growth Direct® System. Then we bring in our customer success managers for implementations (CSMI). They're effectively highly skilled project managers, providing critical oversight for the entire project. Once they recognize and receive a PO, they'll go through, see the LIMS that's been purchased, and they'll confirm with the customer that they've engaged with LIMS system to establish a statement of work.

It's a collaborative effort between Rapid Micro Biosystems, our customers, and the LIMS provider. We'll all engage and then we start discussing what's required for this integration. A lot of times the LIMS system is already at the customer site. So, we just need their master data. Then, we create our configuration files for the Growth Direct® System. We execute those configurations onto the system, and we hand it back over to the LIMS team, and they'll do their statement of work. So, they'll have the Installation Qualification (IQ) and the Operational Qualification (OQ) for the LIMS system. From there, we hand it back to the customer and they'll do their final end-to-end test. At the end of all that, we've got a documented package that says, Growth Direct® System LIMS integration is complete and validated.

The timeline of this varies. Our familiarity and preexisting partnerships with LIMS platforms play a big role here. For example, we've had a working relationship with MODA™ for over three years now. So, we can turn MODA™ integration projects in around in two weeks. It doesn't take much time because we've already pre-created the integration, and now it's all about configuration. For something completely brand new that we haven't interacted with, it does take a couple of months. For most major systems, including SAP or LabWare®, we're in between. It really depends on the level of engagement we can get with the customer and their IT and LIMS teams.

FINDING A BETTER WAY

What are some common integration challenges?

There are two challenges that are most common.

1. Terminology and alignment around the different terminology. There's a lot of different platforms out there and everybody wants to brand. So, the terminology can vary. For example, what we call a sample ID, SAP might call something different, since it uses more manufacturing terminology. To solve this, we have kickoff meetings to establish alignment. Thankfully, these technology companies understand that you have to integrate with other equipment, platforms, and systems. So, there are methods of communication, whether web-based, API, or even Flatfile, which are universal and are employed no matter the platform to allow you to connect. It really just boils down to understanding the terminology and knowing how to align.
2. Another challenge discussed earlier is navigating customer IT and LIMS engagement. This is where our CSMI come in. They can help stakeholders understand upfront what the actual effort is going to be and that makes it a much smoother process for all involved. It's really managing everyone’s expectations.

Let’s say you’re a pharma manufacturer considering QC micro automation as a springboard for integration. Based on your real-world experience, what characteristics are at the top of your list when selecting a system?

For me, it comes down to one statement, “there's got to be a better way.” Before you start integrating, everything starts off in an Excel spreadsheet. You have to collect that data, populate that spreadsheet, then find the time to do the analysis in between taking next day samples. There's got to be a way to be more efficient and accurate.

I think that QC lab data collection, correlation, and analysis is not being done quick enough. So, as you look at your process, it starts with finding systems that really open your bottlenecks to provide greater speed without sacrificing quality. In an industry that moves so fast, you need to be able to make data-based decisions very quickly. Cell therapies are a great example. In those cases, someone's life is directly at stake. There's no time to be digging through spreadsheets; you have to automate.

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How is the Growth Direct® System evolving to keep up?

Well, we've have added the ability to synchronize multiple Growth Direct® System units and also connect them to a client's active directory. This streamlines things like password account management and gives IT better control. That's a feature I think all our customers love to see. We are also close to launching a system feature to automatically determine whether a contaminant is a mold. Early detection of mold helps users more quickly adopt the right resolution strategy, so this is a really exciting development.

Are there any noteworthy or new LIMS or MES that have not yet been connected to a Growth Direct® System?

I'm super interested in integrating with newer, smaller LIMS. Larger systems tend to be less agile. Smaller companies get to be more innovative with how they build their user interfaces and how they access and read data from other systems. For example, a system like STARLIMS hasn't seen much widespread adoption within pharma, but it's a system that's innovated a lot around how it captures and visualizes data. As another example, MODA™ is one platform that's got great traction, but they're still able to be nimbler and more aggressive with the innovation.

What attributes of the Growth Direct® System enable integration with a new LIMS or MES?

I would say it's not so much about the Growth Direct® System, it's about having strong internal software development and business development teams. Together, they can foster strong partnerships with LIMS vendors upfront that in turn allow our software to have pre-defined integration plans. Plus, the system was designed for universal communication with other systems. Thanks to our teams and that foundation, I can actually say, I've never come across a LIMS system that we couldn't integrate with.

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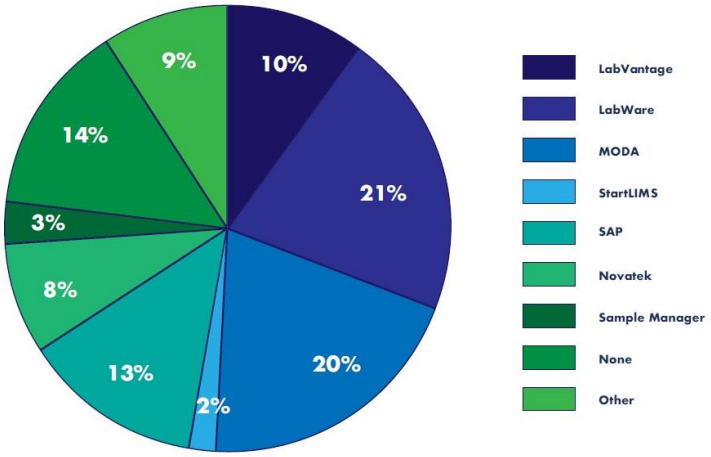


What do you think the future holds with respect to Pharma 4.0 and QC microbiology?

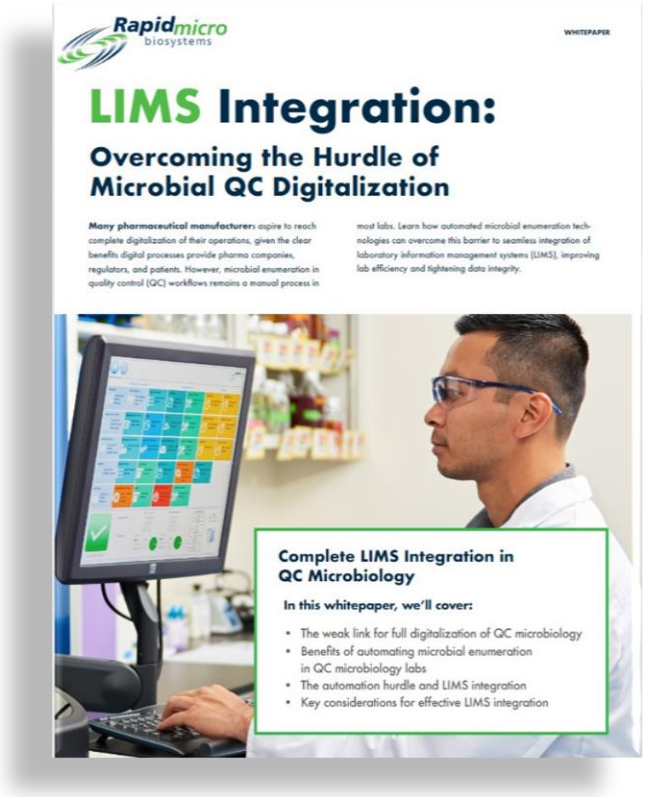
I think we're starting to see the tip of the iceberg as far as big data analysis. I see customers collecting big data, but I don't see many that have figured out what you do with it all. Machine learning and AI are the key to unlocking all that. Computing powers is getting to a point where we're not talking about little bits of data – we're talking about churning and processing massive amounts of data. Investment in the technology, AI, and machine learning is now providing meaningful solutions.

However, the community is not quite there yet as it relates to an internet of things within the facility. I think the focus has been on more outside of the facility, like collecting patient data to track trends in health. In the near future, more organizations will work to collect and analyze more internal data on how to improve their process.

In closing, what advice do you have for manufacturers looking to digitalize their QC lab operations using automation and LIMS integration?

With these types of investments within a facility, you can't just think, "I want to buy it tomorrow, implement it, and have it be effective." You need to have cross-functional collaboration. You need to have it well planned. These types of integrations and systems touch almost every aspect of your organization. To think that you can do this in a vacuum on your own without consulting others or without a plan is not going to lead to a high success rate. So, as clients and colleagues embark on this journey, I would say, plan it out ahead of time so that you can execute properly.

This planning stage can be as quick as one week or as long as one month. A lot of that is dictated by availability of the broader team. We're talking about a cross-functional team with multiple stakeholders. So, getting everybody together in one meeting is not always feasible, but that's where a team like ours that has the expertise and that's done it in the past comes in. We can engage with these different groups and put that integration picture together for them, making it all much more streamlined.



Want to Learn More?

For additional information about LIMS integration and automation in the QC microbiology lab with the Growth Direct® System, read our free whitepaper.

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