SPEAKER SPOTLIGHT:
LIMS in the Smart Lab

As large pharmaceutical companies attempt to transition towards smarter labs, replacing and upgrading LIMS systems is becoming increasingly important, and is vital in moving towards a paperless lab. However, many of these systems are decades old, and there are several obstacles in the way of transitioning towards more modern systems. Cindy Novak from Takeda observes the changes in the area of informatics tools and technologies, and describes the challenges and opportunities of bringing LIMS systems into the 21st century.

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Cindy has been working in the Biotech and Pharmaceutical industries for over 20 years. During her career, Cindy has participated in numerous LIMS projects in roles ranging from subject matter expert to technical specialist as well as participating in various projects for Empower, OpenLab, ELNs and lab instruments. She has worked at multiple companies as they navigate through the M&A process, both as the acquiring company and the acquired company. Cindy is currently an IT Manager at Takeda working to deploy an integrated Laboratory Systems Solution for a new manufacturing facility in Ireland as well supporting the legacy Baxalta and Shire lab systems and working toward a unified Lab Systems solution.

Please describe your role within the Takeda, and what your current work entails.

I am an IT Manager within Takeda, based in North America. I am currently working as a project manager to implement multiple lab systems at our new manufacturing site in Ireland. The goal of the site has been to be paperless from day one. We have successfully implemented MODA and we are expecting to deploy LIMS by June of this year. Our LIMS will be fully integrated with Empower, Maximo and ERP in the first release (due in April) with integrations with all lab instruments, and MODA in the second release (due in June). This will allow a fully digital experience for our users for our engineering runs and beyond.

You have worked with LIMS systems. What do you think the future holds for these systems, and how can they meet the standards of a Smart Lab?

I have been fortunate to work with most of the major LIMS systems. One of the common elements across most LIMS used in QC is that they are several years behind in functionality, flexibility and user experience. This stems from the Quality side being very regimented and until recently, resistant to the standards of a Smart Lab. In order to meet the standards of a Smart Lab, the push will have to come from the customers similar to other major industry changes over the years (e.g. CFR 21 Part 11). Until the consumer pushes for these changes, there is nothing driving the vendors to change their products to meet these standards.

When you look at LIMS used in R&D, you see that they are far more flexible and aligned with the Smart Lab standards and vision. This is because the drive toward Smart Lab and the associated standards are coming from the R&D space. Vendors respond to customer demand and the resulting products are reflective of this.

There is a need to bring the traditional LIMS systems into the 21st Century, as many labs use systems that are decades old. How might this be addressed?

This is a significant challenge within the industry. Upgrading or replacing a LIMS is a lengthy, expensive undertaking that most companies avoid unless they have no other choice. Since computer systems are often seen as overhead and not something with a significant ROI, the funding is difficult to justify. "If it's not broken, don't fix it." Until there is a major driving force such as regulatory change or software becomes obsolete, companies will be slow to change. Unfortunately, this means that companies may opt to continue using a LIMS that works well (usually heavily customized) even if it is no longer supported by the vendor. It will take a major shift in regulations or an equally influential driving force before a large number of companies will change. If enough companies band together to make Smart Labs the new industry standard, everyone will ultimately have to upgrade or replace their existing LIMS to meet the new standards and stay competitive.

Takeda is looking to expand into SmartLabs. What are the key steps Takeda has taken in this area?

This is difficult to answer as Takeda traditionally has been a rather siloed organization. From a top down perspective, the message is clear that we need to expand into SmartLabs. However, in the time that I have been at Takeda, there has been very little obvious movement in this direction in the Quality and Manufacturing areas. Similar to many organizations, the expansion into SmartLabs is starting in R&D. Although it is slowly gaining traction the necessary resources are not yet in place. There is a concerted effort to change this in 2020. I look forward to our movement in this area.

In your opinion, what have been the most important developments in the area of SmartLabs & Laboratory Informatics over the last 12 months?

The single most important development I have personally witnessed in the last 12 months is knowledge. The technology developments have been in process much longer than the past year. However, it has only been in the past year that the conversation has really expanded across the industry and more importantly, across functions. In the R&D space, Smart Lab and Laboratory Informatics is not a new concept. Companies have been working toward Smart Lab for many years and Lab Informatics is well established.

In the Quality and Manufacturing spaces, this is a relatively new conversation. We have only recently begun to understand the concept of the Smart Lab and the benefits it can bring to our space and our companies. While Laboratory Informatics has been used in the space for many years, we are in our infancy when it comes to making the data useful. It is no longer enough to collect and store data. We are learning how to collect meaningful data and more important, we are learning how to use that data.

In a laboratory environment, which technologies which are currently in the development stage do you think would have a significant impact?

There are several major technologies that are in development of early adoption that I think will have major impact in the lab environment. The one I think has the most potential to change how we work in the labs is the use of virtual reality (VR). While the technology in general is not new, the use within the lab and integrated with lab systems is an intriguing development. I don't necessarily see benefits (yet) to integrating VR with a LIMS or ELN, the broader use within labs for support and troubleshooting could prove to be a cost and time saver. I can easily see this technology allowing for rapid, real-time assessment and resolution of issues with an assay or an instrument from any location around the world.

Additionally, technologies being offered by several companies that promote and support adoption and implementation of standards in the lab environment will be vital for faster time to market and better adherence to regulations. While this is not new technology in the pharm environment, it is still in early adoption in the R&D space and just starting to expand into Quality and Manufacturing. It is exciting see watch this develop and I look forward to seeing these technology solutions being expanded across entire organizations in the next 5 – 10 years.

What are the biggest challenges that you are aiming to overcome?

I think my biggest challenge at the moment is managing a site implementation knowing that we will be starting a global project in the near future. On the surface, this may not seem to be a challenge. The site is running on the currently release of the platform we will use globally and has built the system with the goal of being fully digital. The initial challenge has been building a local system with a global mindset. The site is intent on building for their specific requirements and have paid little attention to future global deployment of the same platform. As project manager and a member of the global implementation team, I continuously challenge decisions that may be in conflict with the global strategy.

The other side of this same challenge is the input I'm providing to the global project. There is a heavy dependency on external resources for the project. While this isn't a problem by itself, it does present a challenge when ensuring that the best interests of the users and the company are represented. Feedback I provide is based on both the current project for the single site as well as many years of experience with global projects. The internal resources for the global project are limited, so it's vital that these resources are strategically deployed so the project is successful.