

LIMS: AN INSIDE PERSPECTIVE

Karl Yorgi works with the GPCD in the pre-clinical organization for Johnson & Johnson, supporting all of the GLP applications within pre-clinical. Thermo Electron Corporation's Laboratory Information Management System (LIMS), Watson, is one such application.

NGP. What labs is Watson deployed in?

KY. We're using it in bio-analytical labs and three J&J corporations that have sites across the world. The actual implementation is in Raritan, New Jersey. The company sites worldwide access the server at that one site.

NGP. What is Watson's primary function and how many samples are tested per year?

KY. We are primarily using Watson to assay bio-analytical samples. We are analyzing around 100,000 samples in-house per year. This doesn't include samples brought in from CRO labs – probably another 100,000 samples.

NGP. Prior to the Watson implementation, what business challenges were you facing? How did Watson address some of these issues?

KY. We had a LIMS before Watson, but the vendor was taking it off support. In addition, it was not a drug metabolism and pharmacokinetics (DMPK) focused tool. It was a build-your-own type of LIMS.

We were looking for a tool that was DMPK focused. There are a lot of generic LIMS out there, but we had already worked with a generic LIMS and realized some of the difficulties of forcing that to work in a DMPK lab.

Watson was a product that had gone through many evolutions. It had reached the point where it was becoming a more widely used tool by many of the CRO labs that we dealt with, so it was really the first choice for us to look at when we needed to consider migrating to another LIMS.

“The reaction of the users is really positive. It has been a real benefit to them, having been accustomed to our previous LIMS”

NGP. Watson is marketed as an out-of-the-box solution with minimal customization required. Based on your experience, what are the benefits of deploying a commercial off-the-shelf (COTS) solution?

KY. A COTS solution is beneficial in many ways. J&J has taken a position that if we can buy an off-the-shelf solution, we will.

Our previous solution was build-your-own and we experienced some problems with the development – you need to have developers with the capability, the training and the know-how to use whatever development languages are provided by the vendor. Once you develop it and validate it then you have to consider ongoing upgrades.

You need to have a core of developers in-house to sustain a LIMS that requires some type of customization. That's an overhead we did not want to maintain.

NGP. In order to implement Watson, did you have to change some of the processes within your labs to conform to the software?

KY. Yes, we did have to change some processes. For example: how are we going to do labeling now that Watson provides the application capability? We had an outside process for labeling that was completely different, so we needed to define parameters around that. We also needed to define parameters around security: how are we going to do security? How are we going to do the re-assay decision tree? How are we going to manage issues around electronic signature and audit trailing?

Watson provided the configuration capability to deal with these things and, even though it was off-the-shelf, gave us a certain measure of flexibility that we could adapt to our particular requirements.

NGP. How many Watson users are there, and what has been their reaction?

KY. We currently have about 100 Watson users who are using it across the various sites. The reaction of the users is really positive. It has been a real benefit to them, having been accustomed to our previous LIMS.

NGP. How has Watson improved laboratory productivity?

KY. The improvement in productivity mostly comes through the automated decision-making that Watson provides, especially in their regression analysis. It provides the ability to do a re-assay tree that chooses various concentrations automatically, depending upon certain criteria that you establish. It identifies standards that are outside a particular range and identifies them, and it identifies that same type of criteria with QCs.

NGP. How do you measure the success of the implementation?

KY. The implementation of this tool and its wide and positive acceptance by the user community is the best measure of its success.

NGP. Have you realized any other improvements?

KY. Consolidation of results is another big one for us. We are able to use the DMPK LIMS as a final repository of all our bio-analytical data worldwide. And we are able to maintain controlled availability of that data to our customers.

NGP. How will Watson enable you to move forward over the next 12-18 months?

KY. Thermo continues to add capability to the system as it goes from revision to revision. We are currently running revision 7.1. At revision 7.2 they have added some capability that will allow us to lock samples on a per sample basis as opposed to a per study basis, which we have now. For us that is a real gain – we can make sub-groups of data available to our customers before the entire study is locked. That's why we are implementing Watson 7.2 in 2006.

As long as the vendor continues to listen to the customers, and continues to add functionality into their product, it will continue to be useful to us. ■