



PODCAST

To listen to the entire interview,
log on to www.FuturePharmaUS.com



BREAKING NEW GROUND

Future Pharmaceuticals interviews **NORBERT BITTNER**, Managing Director at Up to Data professional services, about breaking new ground in bioanalytical submissions and specifically the iStudyReporter Bioanalytics, the first purpose-built automated solution for regulatory reporting of Watson LIMS data

Future Pharmaceuticals What is the impact of using iStudyReporter in a bioanalytical lab?

NORBERT BITTNER If you look at today's bioanalytical lab and the process of creating a submission document, you will find that most of these reports are created manually. This means that scientists are creating Word documents by copying and pasting data from the LIMS systems and sometimes manually adding information from other software, like lab notebooks, and after that the report is reformatted to meet the internal corporate guidelines. As a result, changing the document to add new data becomes a fairly complex, error-prone process. From our experience, the amount of time spent to create such a report varies from a few hours to many days depending on the complexity. If you think about the requirements for automating this process, you find that there are two major points: First a commercial tool must be very flexible since every pharmaceutical company has its own special set up for bioanalytical experiments to match the product. The second point is that the tool must ensure a valid and automated data transfer to the report because you don't want the scientists to spend their valuable time on revalidating the document by scanning through it and comparing it to the LIMS data.

Our product, the iStudyReporter Bioanalytics, is a purpose-built solution to create regulatory submission documents. It's optimized for bioanalytical study reports in a way that it is delivering configurable data tables to match the requirements of the diverse bioanalytical experiments. You can specify which study information should

be part of the document and iStudyReporter assembles these tables and protects them within a Word document. While this data is protected, other sections of this document are unprotected for the scientists to be able to add their scientific discussions. Since these documents are based on normal Word templates, the vast amount of standard information can be added to the template prior to the creation process, so it's possible to virtually create a complete study report by the push of a button. By using iStudyReporter Bioanalytics, you ensure that resources are used efficiently for their respective qualifications, since, in our opinion, a purpose-built tool for submission reporting should be used to best support a purpose-built LIMS.

FP Why is it the right time to change the report generation process?

NB It's simply because we have the better solution with iStudyReporter Bioanalytics. Today we have a competitive environment that requires pharmaceutical companies to increase the efficacy of R&D processes. Analytical labs are seeing more drug candidates than ever before, within the same timeframe and without any increase in staffing, so there's a lot of pressure on these labs today. But on the other hand, the American Association for Pharmaceutical Scientists (AAPS) and the European Bioanalysis Forum have spent a significant amount of time discussing harmonized approaches in this area. The industry has now achieved a certain state of harmonization and we put the technology in place to create a mapping of these harmonized approaches to a standardized data representation in a tool that

creates the submission documents.

This is possible because iStudyReporter Bioanalytics is a part of a product family that is purpose-built for the creation of submission documents of protocol-driven studies. The main features are the highly optimized presentation of experimental data either as tabular data or graphs of the data. This includes the capability of protecting the data in a Word document to prevent unintentional changes and the ability to have a template-based creation of Word documents that allows for a very simple adoption of corporate guidelines. The free text sections can be enriched by iStudyReporter with detailed LIMS information. iStudyReporter also has document management features which monitor the complete change control of this Word document and allow you to use a pre-configured workflow that enables a 21 CFR Part 11 compliant systems.

FP For a customer, what steps are necessary to implement iStudyReporter Bioanalytics?

NB When implementing iStudyReporter, there are four areas that should be considered during the implementation process: First, the implementation itself; with iStudyReporter Bioanalytics we deliver a preconfigured system that covers toxicokinetic and validation experiments for the Thermo Watson LIMS. If the representation of the experiments does not match your desired form, then we will have to do some configuration work to meet these requirements, but this is rarely done. The validation effort can be minimized, since the current GAMP 5 guidelines allow for reducing the overall effort by using a risk-based



approach. So you can for example, re-use our validation documentation and do some business process tests internally to confirm your requirements. The key benefit of the configuration capabilities is to help reduce your validation work and costs. Thirdly, security is a major issue. iStudyReporter delivers a default security setup that gives you a good starting point, but of course it has to match your internal organization. For instance, the approval workflow has to be configured to match your organization's policies.

Lastly, iStudyReporter gives high-level access to data so it's not necessary to have LIMS knowledge to create a document. The users have to have the knowledge of what is necessary to create the document and which information the document shall contain. They have to be aware of the designated content of the submission document, but only on a very high level. Therefore, only minimal end user training is required and the training we provide covers more of the system management aspects and the configuration since we want our customers to be able to do the required configuration themselves.

FP How do you address the respective issues and needs of big pharma companies, smaller pharma companies and clinical research organizations (CRO)?

NB That comes down to the different requirements these three groups have. When we work with big pharma companies, most of them have requirements that come from the many separate IT systems they have in place — such as different sites using one centralized system or, with a global company, multiple languages within a single system. Also, if you're submitting to different countries, you have to fulfill the different requirements of the authorities in these countries. All these requirements and issues can be addressed by iStudyReporter. For example in the case of multiple languages, iStudyReporter is capable of configuring them, as well as configuring your own internal language.

With the CRO, the main driver is that they have a lot of customers with many ways of setting up experiments, and of course, having contracts that require them to report the data from these experiments in a way that match the customers'

policies. With iStudyReporter, templates can be set up for each customer's corporate identity which gives them a high level of consistency throughout the documentation.

For the small pharma companies, iStudyReporter can assist in setting up experiments, since the software can be used out of the box and covers most of the pharmaceutical bioanalytical experiments. Additionally, we feature a help system delivering typical workflows and procedures of pharma companies, which helps speed up the implementation process in a smaller company.

But if you look at the competitive situation that all these companies are facing throughout the industry, it becomes clear that the pressure to increase efficacy is the key driver behind the requirements of all these companies.

FP Not all data for a submission is stored in a single system. How do you address the problem of separate, but related, data sources?

NB There are two points here: a technical aspect and a user aspect. From a technical point of view, which is the easiest part for us, we have put in some technology in our product that enables us to access information from any source — whether it's a database, a Web service or an Excel file. We can extract this information and put it in a report.

It's more complex when it comes to the user aspect, because what normally happens when you have separate systems is that you must be trained to use all systems to compile the information for a report.

For example, the batch you're investigating by the experiment might be documented in a different system. This means when you create a submission document, you must be trained in both systems. For example; you must be trained in SAP and LIMS to extract the batch information and the results for the report.

If you put iStudyReporter in place, the impact for the user will be that iStudyReporter is configured to extract the information from the SAP system and the LIMS. The user will be presented with just the data — which means that this process is totally transparent to the user.

Separated systems are not only systems with different information content, but sometimes

there are multiple company sites. When two companies merge, this might result in different ways of doing processes and creating reports. Putting iStudyReporter in place, even on different systems holding the same kind of data like bioanalytics, will result in report harmonization. You don't necessarily have to harmonize on a LIMS level, but you can harmonize on a reporting level.

But iStudyReporter is not just a system that absorbs information from other data sources; it also generates information necessary for the submission processes. We are interfacing with the common eCDT systems so we can transfer our created documents in the background to the correct place in the eCDT system, currently it's PDF documents and with upcoming initiatives, we will be submitting XML documents.

FP Can you give us a brief outlook on what the future will look like in this arena?

NB iStudyReporter Bioanalytics is not a single product, but part of a family of products. We have iStudyReporter Stability in place, a solution that covers the requirements for reporting stability-related information to the agencies. From early development to production, you can generate stability tables or more complex trending reports. iStudyReporter Stability can also create parts of the annual product review.

But this is just a single point of reporting — though, even if iStudyReporter Bioanalytics and Stability are in place, there are separate reports created from these systems. The current "trend" in the industry is to have a high level view on the information you have in place. You can have a detailed look at the relation of information from different systems. This initiative is known as quality by design. There are many discussions going on around this and with iStudyReporter and the technology we have in place, we are on the way to set up what we call the Product Quality Warehouse that gives you access to quality-related information in a more interrelated way than it is possible currently.

With the iStudyReporter family, we will continue to deliver purpose-built solutions to increase the efficiency of the submission process in the R&D environment. **FP**



NORBERT BITTNER is Managing Director and Co-founder of Up to Data Professional Services. He is responsible for the overall product strategy and the development of the iStudyReporter product family. His expertise of over 15 years of implementation projects within pharmaceutical research and development in national and international companies is the background to make the products practical and advantageous for the customers.

Are you still creating study reports this way ...



Watson is a registered trademark of Thermo Scientific.

Regulatory compliant bioanalytical study reports for your WATSON™-LIMS.

Pharmaceutical research is a race against time.

Increase the efficiency of your R&D process by adding **reliable and automated regulatory reports** to your Thermo Watson™-LIMS.

Whether you are a pharmaceutical company or a CRO - add more value to your investment by speeding up the submission with a safe, simple and cost effective tool.

Can you afford to be late?

Visit <http://www.uptodata.com/isrbioanalytics.html>