LMS e-Learning Implementation Podcast Transcript #35 *i3 Research Rater Training – 21 CFR Part 11 and FDA Training Requirements for a Contract Research Organization Serving Regulated Industries (Transcript)*

[music]

Announcer: SyberWorks podcast. Learn any time, any place.

Mary Kay Lofurno: Welcome to the next edition of the SyberWorks LMS e-Learning Implementation Podcast Series, where we look at actual learning management system implementations and e-learning program roll-outs. My name is Mary Kay Lofurno. I'm the Marketing Director here at SyberWorks, and your host today.

SyberWorks specializes in custom e-learning solutions and learning management systems for corporations, governments, and non-profits. In this edition, we're talking with Alex Panait, Technology Specialist for i3 Research about their use of the SyberWorks learning management system to track and manage training for clinical research.

[music]

Mary Kay: And now let's meet Alex Panait, Technology Specialist for i3 Research. Good afternoon, Alex. Thanks for coming to talk with us today.

Alex Panait: Hello Mary Kay, it's a pleasure to be here.

Mary Kay: All right, great. Alex, tell me about yourself and what you do for i3 Research.

Alex: Within i3 Research, I work for a specialized group that provides radio training and monitoring services for our clients. i3 Research is known for its expertise in radio training. This is a service in which we manage the equipment of investigators for clinical trials and train them in the usage of specific medical scales and processes and point of the trial.

My personal responsibilities are pretty much the full range of tasks related to IT tools specific to my group, from administration and support to design and development.

Mary Kay: OK, great. Now I understand that i3 Research does research for the pharmaceutical industry, and you spoke about it a little more, but can you tell us just a little bit more about the company and the service you provide?

Alex: Absolutely. i3 Research is a full-service, therapeutically-specialized CRO. It's a Contract Research Organization.

Mary Kay: OK

Alex: We serve the life sciences community, including pharmaceutical, biotechnology, and medical device companies. The therapeutic areas of i3 and i3 Research are integrated throughout our product teams to achieve the highest level of quality.

We have five therapeutic areas: Cardiology, central nervous system, endocrinology and metabolic disease, oncology, and respiratory and infectious disease. My group in particular focuses on radio training and monitoring and in clinical trials in the central nervous system therapeutic area.

SYBERWORKS
Learn Anytime, Any Place

411 Waverley Oaks Road
Building 3, Suite 319
Waltham, MA 02452
www.syberworks.com
1-888-642-7078

Actually, the genesis of i3 was in our CNS work. That's an area i3 Research stood out in since its inception. Radio training, what my group does, is especially important in CNS trials because its not like taking someone's blood pressure, where you have easily measurable responses.

In order to measure changes in a subject's symptoms in a standardized way, we use a series of medical scales where the questions are soft.

Mary Kay: All right, well that sounds good. So, Alex, can you give me some of the business reasons that drove your organization to seek out and purchase a learning management system?

Alex: I3 in general is known for innovation. We do a fair amount of developing technology systems of our own. I'm sure you've heard of our i3 Cube. It's the first fully-integrated end-to-end clinical trial and data management software.

It made sense for us to start from the ground up on that because of our expertise. i3 Research also has a strong reputation in radio training, and we needed a partner that provides a top of the line solution to help us maintain our high standards of quality.

We have to provide training to the investigators involved in each study. And while some of this training can be provided in group or one-on-one sessions, an online, instructor-free approach is much more efficient, because we work with sites all over the world.

Mary Kay: All right. Now I know your industry is regulated by the Food and Drug Administration, and also the companies that you do research for are. Can you explain how this impacts your business requirements in regards to the LMS?

Alex: Right. Well, like you said, our LMS solution must comply with the requirements of 21 CFR Part 11, which is the set of criteria under which electronic records and signatures are considered equivalent to paper records.

We decided it would be more cost effective for us to use an outside compliant vendor, than develop our own solution for online training. And SyberWorks has the same high standards for quality that i3 Research prides itself on. Your platform provides the necessary features to be compliant.

Now, of course, compliance is still dependent on our processes. i3 Research has a solid reputation in innovative processes that enable us to maintain that compliance.

Mary Kay: All right. Can you give me a brief overview of who is using the system at your organization, Alex?

Alex: Well, my group currently uses SyberWorks LMS to deliver training to the raters involved in our clinical studies. We also have a number of i3 Research administrators for each study that monitor the progress of the users and offer assistance as it's needed.

Mary Kay: OK, great. I understand you have your own separate database for computer validation considerations, but other than 21 CFR Part 11 Compliance, which we touched on a little bit, what were some of the key business and system requirements that were important for your company's online training program?

Alex: Well, in order to meet our goals, we have to be able to prepare training materials for online delivery within a short time frame. And we also have to be able to deal promptly with any changes that come up, even while our training modules are live.

So it's important to i3 Research that the system is easy to use, but we also need to have flexibility in how we structure the training curriculum to meet all of our users' needs. For example, a module might have another as a prerequisite,

![SYBERWORKS - Learn Anytime, Any Place]

411 Waverley Oaks Road
Building 3, Suite 319
Waltham, MA 02452
www.syberworks.com
1-888-642-7078

or might require that the lessons are traversed in a specific order. Finally, all of this data that we collect would be far less useful if we weren't able to run a wide variety of reports against it.

Mary Kay: OK, that sounds good. Now let's talk about 21 CFR Part 11 Compliance and how you were able to configure the SyberWorks LMS for that.

Alex: As you mentioned, we have our own database, and we also have a separate instance of the SyberWorks program, so that i3 Research can control the upgrade process and ensure that services we provide maintain the highest level of quality. Many Part 11 requirements are addressed by the design of the SyberWorks LMS. For example, things like unique users, records of failed login attempts, things of that nature.

In addition, we've enabled the audit trail functionality provided by the LMS. And we require our students to use e-signatures to confirm they have reviewed the course materials. We also enforce that passwords are periodically changed. These are the type of measures that we have put in place to achieve compliance.

Mary Kay: OK, great. All right, can you tell us just a little bit more about the online courses you provide through the LMS?

Alex: For the most part, each of our courses focuses on one, or a few, medical scales, which vary depending on the study. We generally include an overall presentation of the topic. Occasionally, that's in video format. And in certain courses we have exercises we use to certify that the users have been trained.

Mary Kay: OK, sounds great. So what about some of the instructional design and planning processes that you use at your organization to develop this online training? Can you tell us a little bit about that process?

Alex: We consistently get very high ratings for our courses because of the quality standards and the innovation mindset at i3 Research. And, as I mentioned, the goal of the courses delivered online is to train raters in specific medical scales that will be used in a study. Similar materials to achieve this goal are provided by our clients, and the rest are created by i3 Research based on our previous training experiences.

Mary Kay: OK. All right. That sounds good. Just specifically, so people out there know, I always like to ask this question so they understand what tools your are using to develop, to literally develop, the courses. Can you tell us a little bit about the tools you're using to develop your online courses?

Alex: Sure. Currently, we are using common office software, such as Microsoft Word, PowerPoint, and Adobe Acrobat. We use these to prepare the materials and we build the course structure using the SyberWorks web interface.

Mary Kay: OK.

Alex: In the near future, however, we'd like to begin taking advantage of forms of delivery, such as SCORM, that allow more interaction with the user. And we'll probably begin using Captivate at that time.

Mary Kay: OK, that sounds great. So, Alex, is there anything more you would like to share about SyberWorks, before we close out?

Alex: My company, i3 Research, is recognized for quality and innovation. And SyberWorks is a great partner for us, because they focus on these values as well. So my team is very happy with the results we've had using the SyberWorks solution, and with the assistance we've received from the SyberWorks support team, even when some of our requirements were non-standard.

Mary Kay: All right. Well, that sounds great. Thanks for joining us today. We really appreciate you being able to spend time with us.

Alex: Thanks for having me.

Mary Kay: Thank you for joining us, with our interview with Alex Panait from i3Research, on the SyberWorks LMS e-Learning Implementation Podcast Series. Have a great week.

Announcer: SyberWorks Podcast. Learn any time, any place.

[music]